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PhD Thesis

Quality Management in Healthcare:

Challenging Healthcare-Associated Infections

Dissertation submitted in total fulfilment of the requirements of the degree of Doctor of Philosophy in the subject of Public Health, expertise in Policy, Management and Administration in Health

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Acknowledgements

To God.

To Pedro that stood there again, and again, and again …

To my family,

To my friends, especially to Carlos Vasconcelos and Daniela, that gave me strength and believed that I was capable to do this… Thank you for everything!

To my supervisor Professor Paulo, for helping me to do this work,

To all Infection Control teams and Quality Management teams that opened their door to show me how important is their work… thank you for your time, attention and knowledge!

To Life.

To Health.

Abstract

Healthcare-associated infections (HAI) are a worldwide problem with devastating effects, with both economic and public health impacts in the medium and long term, and its high prevalence and incidence rates contributing strongly for mortality and morbidity rates.

A study was performed with the main objective to analyse HAI prevention and control systems, to identify what are the barriers for Structures, Processes and Results at hospital level and to determine how quality management models and tools can help to improve of these systems.

An exhaustive literature review related with HAI prevention and control issues and quality management in healthcare issues was accomplished and, from this, several international projects to promote HAI prevention and control systems were identified, as well as a set of barriers at international level.

A multi-case study was also performed, aiming to analyse HAI prevention and control systems from three hospitals with different quality management models. From this study barriers were identified, as well as management tools used to promote HAI prevention and control system, best practices and improvement suggestions.

As the main result a HAI prevention and control management system model was developed, based on ISO 9001 model and supported in the process-approach model, incorporating all the suggestions obtained from the literature review and from the multi-case study.

This study also provides an extensive analysis on HAI prevention and control management issues and on quality management issues, at national and international level. The result is innovative and highlights several possibilities of improvement as well as valuable information to health authorities.

Keywords: Healthcare-associated infections, prevention, control, quality, management, tools, models, systems

Resumo

As infeções associadas aos cuidados de Saúde (IACS) são considerados atualmente um problema mundial com efeitos devastadores, quer ao nível económico quer ao nível da saúde pública a curto e a longo prazo, cujas taxas de prevalência e incidência estão a dar um forte contributo nas taxas de mortalidade em morbilidade.

Foi realizado um estudo com o objectivo de analisar os sistemas de prevenção e controlo das IACS, quais as barreiras identificadas para as Estruturas, Processos e Resultados, ao nível hospitalar e como os modelos e ferramentas de gestão da qualidade poderão promover a melhoria destes sistemas.

Foi efetuada uma revisão exaustiva da literatura sobre os sistemas de gestão de IACS e sobre os modelos de gestão da qualidade aplicados à saúde e foram identificados diversos projetos internacionais assim como diversas barreiras identificadas a nível internacional.

No sentido de melhor entender a realidade nacional foi efetuado um estudo multi-caso para analisar os sistemas de gestão da prevenção e controlo das IACS de três hospitais com modelos de gestão da qualidade diferentes. Com este estudo conseguiu-se identificar as barreiras, as ferramentas de gestão da qualidade e as melhores práticas utilizadas para promover a efetividade dos sistemas prevenção e controlo de IACS assim como sugestões de melhoria.

Como resultado foi desenvolvido um modelo de gestão da prevenção e controlo das IACS, suportado no modelo da ISO 9001 e no modelo de abordagem por processos, onde foram incorporadas as sugestões, as melhores práticas identificadas na literatura e no estudo multi-caso.

Este estudo proporciona também uma análise exaustiva de questões relacionadas com a gestão dos sistemas de prevenção e controlo da infeção e questões relacionadas com a gestão da qualidade na saúde, ao nível nacional e internacional. O resultado, que poderá ser analisado como uma plataforma para futuros trabalhos nesta área, é inovador e assinala possibilidades de melhoria assim como informação de relevo para as autoridades de saúde.

Palavras-Chave: Infeções associadas aos cuidados de saúde, prevenção, controlo, qualidade, gestão, ferramentas, modelos, sistemas.

Resumen

Las infecciones relacionadas con la asistencia sanitaria (IRAS) se consideran actualmente un problema mundial con efectos devastadores, tanto en términos económicos como en términos de la salud pública en el corto y largo plazo, con una prevalencia y una incidencia con muy fuerte contribución para las tasas de mortalidad y la morbilidad.

Se realizó un estudio con los objetivos de analizar los sistemas de prevención y control de IRAS, cuáles son las barreras identificadas para las estructuras, procesos y resultados a nivel del hospital y cómo los modelos y herramientas de gestión de calidad pueden mejorar estos sistemas.

Se realizó una revisión exhaustiva de la literatura sobre los sistemas de gestión de la prevención y control de IRAS y sobre los modelos de gestión de calidad aplicada a las organizaciones sanitarias e fueran identificados algunos proyectos internacionales con el fin de aumentar la eficacia de estos sistemas, así como varias barreras identificadas internacionalmente.

Con la finalidad de mejor comprender la situación nacional se realizó un estudio de casos múltiples para examinar los sistemas de gestión de la prevención y control de IRAS de tres hospitales con modelos de gestión de calidad diferentes. Con este estudio fue posible identificar las barreras, las herramientas de gestión de calidad y las mejores prácticas utilizadas para aumentar la eficacia de estos sistemas así como sugerencias de mejora.

Como resultado ha sido desarrollado un modelo de gestión de la prevención y el control de IRAS, con el suporte del modelo de la ISO 9001 y del modelo de enfoque en procesos, donde se incorporaron sugerencias y las mejores prácticas identificadas en el estudio de casos múltiples y en la literatura.

Este estudio también ofrece un análisis exhaustivo de las cuestiones relacionadas con la gestión de los sistemas de prevención y control de la infección y las cuestiones relacionadas con la gestión de la calidad en materia de sanitaria a nivel nacional e internacional. El resultado, que puede ser analizado como una plataforma para el trabajo futuro en esta área, es innovador e indica las posibilidades de mejora, así como información de interés para las autoridades sanitarias.

Palabras-clave: infecciones relacionadas con la asistencia sanitaria, prevención, control, calidad, gestión, herramientas, modelos, sistemas.

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Abbreviations

AB – Accreditation Body

ACSA – *Agencia de Calidad Sanitaria de Andalucía*

AMR – Antimicrobial Resistance

AHRQ – Agency for Healthcare Research and Quality

APIC – Association for Professionals in Infection Control and Epidemiology

ASTHO – Association of State and territorial Health Officials

BURDEN – Burden of Resistance and Disease in European Nations

BSC – Balanced Scorecard

CAF – Common Assessment Framework

CAHS – Central Administration of Health System

CAI – Community-Associated Infection

CAUTI – Catheter-Associated Urinary Tract Infection

CB – Certification Body

CDC – Center for Disease Prevention and Control

CDI – *Clostridium difficile* Infection

CHKS – Comparative Health Knowledge System

CLABSI – Central Line-Associated Bloodstream Infection

COS – Clinical Orientation Standards

CPS – Centre for Performance Sciences

CQC – Care Quality Commission

CQI – Continuous Quality Improvement

CSF – Community Support Framework

DEBUGIT – Detecting and Eliminating Bacteria Using Information Technologies

DHSS - Department of Health and Social Security (UK)

DH – Department of Health

DGH – Directorate-General of Health

DUQuE – Deepening Understanding our Quality Improvement in Europe

EARS-Net – European Antimicrobial Resistance Surveillance Network

EARSS – European Antimicrobial Resistance Surveillance System

ECDC – European Centre for Disease Prevention and Control

ECDIS – European *Clostridium difficile* Infection Survey

ECDIS-Net – European *Clostridium difficile* Infection Survey Network

ECSI – European User Satisfaction Index

EFQM – European Foundation for Quality Management

ENQual – European research Network on Quality management in health care

EPIS – Epidemic Intelligence Information System

ES – Epidemiologic Surveillance

ESAC-Net – European Surveillance of Antimicrobial Consumption Network

EU – European Union

EUCAST – European Committee on Antimicrobial Susceptibility Testing

EXPERT – External Peer Review Techniques

FMEA – Failure and Mode Effects Analysis (risk management methodology)

HACCP – Hazards Analysis and Critical Control Points

HAI – Healthcare-associated Infection

HAI-Net – Healthcare-Associated Infections Network

HAP – Hospital-Acquired Pneumonia

HCAI - Healthcare-ACquired Infection

HELICS – Hospitals in Europe Link for Infection Control through Surveillance

HFMEA – Healthcare Failure and Mode Effects Analysis (risk management methodology apply to healthcare)

HICPAC – Healthcare Infection Control Practices Advisory Committee

HPA - Health Protection Agency

HQI – Health Quality Institute

HR – Human Resources

IC – Infection Control

ICC – Infection Control Committee (executive, technical am advisory teams)

ICT – Infection Control Team (executive team)

ICU – Intensive Care Unit

IGHA – Inspectorate-General for Health Activities

IoM – Institute of Medicine

IMPLEMENT – Implementing Strategic Bundles for Infection Prevention & Management

INICC – International Nosocomial Infection Control Consortium

IPC – Infection Prevention and Control

IPSE – Improving Patient Safety in Europe

IPSEC – International Patient Safety Event Classification

ISO – International Organisation for Standardisation

ISQua – International Society for Quality in Health Care

IQIP – International Quality Indicator Project

IT – Information Technology

JCAHO – Joint Commission on Accreditation of healthcare Organisations

JCI – Joint Commission International

KF-CHKS – King's Fund model, actually managed by CHKS, accreditation organisation from UK

KF-HQS – King's Fund model managed by Healthcare Quality Service (responsible for Healthcare accreditation in UK in the past)

MARQuIS – Methods of Assessing Response to Quality Improvement Strategies

MDR – Multi-Drug Resistance

MeSH – Medical Subject Headings

MONIQuOR – *Monitorização da Qualidade Organizacional dos Centros de Saúde*

MOSAR – Mastering Hospital Antimicrobial Resistance and its spread into the community

MRSA – Methicillin-Resistant *Staphylococcus aureus*

MSSA – Methicillin sensitive *Staphylococcus aureus*

NAC – National Accreditation Council

NAO - National Audit Office

NCHQ – National Council for Health Quality

NEQAS – National External Quality Assessment Service

NHP – National Health Plan

NHQS – National Healthcare Quality System

NHS – National Health Service

NHSN – National Healthcare Safety Network

NICE – National Institute for Health and Care Excellence

NINSS – Nosocomial Infection National Surveillance Scheme

NNIS – National Nosocomial Infection Surveillance

NP – Norma Portuguesa (Portuguese Standard)

NPIPC – National Programme for Infection Prevention and Control And antimicrobial Resistance

NSQAH - National System for Quality Assessment in Healthcare

OECD – Organisation for Economic Co-operation and Development

ORCAD – Improving quality and safety in the hospital: the link between organisational culture, burnout, and quality of care

PATH – Performance Assessment Tool for Quality Improvement in Hospitals

PDCA – Plan – Do - Check – Act (Management methodology)

PHCC – Primary Healthcare Clusters Centres

PILGRIM – Preventing Community and Nosocomial Spread and Infection with MRSA ST 398

PROHIBIT – Prevention Of Hospital Infections By Intervention and Training

PRP – Pre-Requisite Programme

QFD – Quality Function Deployment

QIP – Quality Indicator Project

QUALIGEST – *Qualidade da Gestão*

QUASER – Quality and Safety in European Union Hospitals

RAH - Regulatory Authority of Health

RCA – Root-Cause Analysis

SARS – Severe Acute Respiratory Syndrome

SENIC – Study of the Efficacy of Nosocomial Infection Control

SFIA – Skills Framework for the Information Age

SHEA – Society for Healthcare Epidemiology of America

SIMPATIE –Safety and Improvement for Patients in Europe

SINAS – *Sistema Nacional de Avaliação em Saúde* (National Healthcare Evaluation System)

SMART – Specific, Measurable, Achievable, Realistic and Time scaled

SPI – Standard and Performance Indicator

SSI – Surgical Site Infection

TB – *Tableau du Bord*

TC – Technical Committee

TESSy –The European Surveillance System

TQM – Total Quality Management

TRICE – Training Infection Control in Europe

TROCAR – Translational Research on Combating Antimicrobial Resistance

UK – United Kingdom

UNE – *Una Norma Española* (Spanish Standard)

USA – United States of America

VAP – Ventilator-Associated Pneumonia

WHA – World Health Assembly

WHO – World Health Organisation

CHAPTER I - Introduction

Motivation

Healthcare-associated infections (HAI) are, nowadays, a worldwide problem with devastating effects, with both economic and public health impacts, in the medium and long term. This problem made the headlines as media and general public became aware of several cases associated with this type of infection, especially those caused by agents for which the existing treatment no long works effectively, such as in the case of infections caused by multi-resistant microorganisms, and on alerts that some line of action in therapeutic terms may be exhausted. This means that, at the present time and all over the world, rates of high prevalence and incidence of HAI are new contributions for mortality and morbidity rates.

In 1959 a report published by the Central Health Services from United Kingdom (UK), referred to hospital infections caused by *Staphylococcus* as a major concern. Since then, this type of HAI, and others generated by other microorganisms, continues to occur, despite the increase of knowledge and understanding of the necessary measures necessary for their an effective control.

The scenario does not get any better when we analyse the problem from a cost perspective. At this point, it is known that there is direct impact in the hospitalisation costs, as well as in the diagnostics (tests, examinations, etc.) and in the treatments (antibiotics, surgery and others) expenditures. A 1992 study, developed by Center of Disease Prevention and Control (CDC) from United States of America (USA), estimated that the cost of infection control programmes was approximately 6% of total costs of infections (1-5). In a 2003 report published by the Department of Health (DH) from UK, entitled "Winning Ways: Working Together to Reduce HAI in England", it was estimated that the annual cost associated with HAI per patient bed for a year was identical to the cost of an infection control programme applied to a hospital with 250 beds (6).

When it comes to quality management systems, costs with HAI may be comprised as non-quality healthcare costs. According to an estimate from the Juran Institute, non-quality costs are approximately one-third of direct healthcare costs, and according to Nordgren *et al.* (2) inflation of these costs is, in part, due to the increased of length of stay and with the provision of additional implicit care.

HAI prevention and control also became an emerging health management issue due to its negative impact on the performance of healthcare organisations, especially in performance dimensions such as effectiveness, clinical safety, and patient safety (7-9).

Patient safety awareness as an important management issue increased when, in 2000, the Institute of Medicine (IoM) from United States of America (USA) published a report entitled "To Err is Human: building a safer health system" with some shocking numbers of harm associated with medical errors and adverse events arising from related clinical practice and inpatient stay in healthcare organisations due to lack of safety and quality of care. This report also pointed out that the error rate in healthcare is higher than in other sectors, and that a similar situation was noticed regarding the delay on the development and implementation of risk management systems in healthcare when compared with other high-risk sectors (10).

As presented, HAI is an important issue for patient safety management systems and for the quality of care. For better reasoning, three definitions of "quality of care" should be considered. The first, presented by IoM, states that quality of care is the "degree to which healthcare services for individuals and populations increase the likelihood of desired heath outcomes and consistent with current professional knowledge" (11, p.21). To the World Health Organisation (WHO), in its report published in 2000, "quality of care" was presented as an integrated set and planned activities based on the definition of explicit goals and performance evaluation, covering all levels of care, with the objectives of continuous quality improvement of care (12). The third definition was presented by DH from UK, in 1997, defining quality of care as "doing the right things at the first time to the right people at the right time, in the right place at the lowest cost" (13, p.23). These definitions highlight that healthcare systems role is to ensure excellent results of care through appropriate structures and processes and the promotion of the satisfaction of interested parties.

This is basic common sense for healthcare sector as it is for all other sectors. Industry, for example, due several factors including ensuring competitiveness and sustainability over time, developed quality assurance models that promote quality improvement of the organisation, products or services. The recognition of these models impact in the industry led to the development and improvement of several models applicable to healthcare organisations, such the King's Fund model (currently known as CHKS[1] model), and Joint Commission on Accreditation for Health Care Organisations (JCAHO) (currently known as Joint Commission). There were other models developed for general usage, such ISO 9001 (International Organisation for Standardisation) and EFQM (European Foundation for Quality Management) that currently are also used by healthcare organisations to develop and

[1] Comparative Health Knowledge System (CHKS) is an accreditation body from UK.

implement quality management systems and to support continuous quality improvement efforts.

However, although there was some systematic evidence of the use of these models for promoting quality improvement in healthcare in countries such as UK and USA, in other countries, and until recently, the promotion of quality in healthcare was simply ensure by basic training and education, as well as through professional requirements impose by health professional groups and according to the existing legal framework.

Several years after the acknowledgement of its importance for industry related sectors, quality management models recognition by healthcare organizations is finally emerging and gaining a new "momentum" through its association with patient safety.

The worldwide interest and public pressure around the concepts of "patient safety" and "quality" and its linkage with HAI are, at the present moment, some of the motivations that drive an increasing number of healthcare organisations to develop and propose recommendations to improve the quality of care based on quality management systems and tools.

But, there is important to question: Can quality management systems contribute to enhance patient safety through the promotion of HAI prevention and control systems? And, if this is true, how can it be done?

The "quality in healthcare" concept, although strongly related with the concepts of "results" and "outcomes", cannot be limited to this perspective. As argued by Donabedian (14), quality in healthcare must also be analysed from two more perspectives, structures and processes, and the quality evaluation must encompass all three simultaneously. These three perspectives approach must be considered, not only in relation with the evaluation process, but also for the entire healthcare delivery process, including design, planning, and production/delivery of product/service. In addition, and according to the actual requirements from healthcare organisations, it is expected that the PDCA[2] cycle is adapted to ensure continuous quality improvement.

Several studies published at international level arguing that quality outcomes in healthcare can only be achieved with a proper and dedicated management of structures, processes, and results. When it comes to HAI prevention and control, there are scientific and historic facts that demonstrate that quality management tools, considering all these perspectives, can in fact

[2] PDCA cycle is a four-step management method: Plan – Do – Check – Act. Shewhart originally described it in the 20's but it was made popular by Eduards Deming. It is known as Deming Cycle or Shewhart Cycle. Later, Deming modified PDCA cycle for to Plan-Do-Study-Act (PDSA) because the relationship between the concept "check" and the concept "inspection". Regardless of this possible relationship the management method most used today is the PDCA, without emphasizing the possible relationship between the concepts "check" and "inspection".

promote effective improvement in these systems. Some of these facts were presented through the work of Florence Nightingale, becoming clear that organisational factors related with quality management (systematisation, analysis of processes and their optimisation, statistical process control, among others) were conditions for the improvement of infection control in military hospitals (15).

In a more recent work published by CDC about the efficacy/effectiveness and benefits of the implementation of infection control programmes, it is mentioned, as an example, how JCAHO introduced in 1976 a surveillance programme and infection control in their hospital accreditation programme to promote the quality management and continuous quality improvement (16).

Liyanage and Egdu (17-19), in their study about the appropriateness of facilities management in HAI prevention and control systems, suggested that for healthcare professionals in general, HAI is a purely clinical problem, not giving much importance to other factors such as facilities/knowledge/performance management covering all organisational areas. According to these authors the quality management systems could function as an integrator of different organisational factors in HAI prevention and control systems.

The Council of Europe, in its Recommendation Rec (2006) 7 on Patient Safety, highlighted the importance of implementing a management system approach in the design and development of safe structures and processes to ensure the appropriateness of patient management in terms of safety and prevention of adverse effects in the provision of healthcare services (20).

In a systematic literature review conducted by Stone, Pogorzelski, *et al.* (21) on the relationship between HAI and variables related from "nursing professionals" to "structures", no evidence was found assigning the decrease HAI risk to the nurse itself, but managed to assemble the following: i) to identify a relationship between the use of permanent full-time nurses *vs.* the use of rotating nurses in an increased risk of HAI and ii) to verify the importance of interdisciplinary teamwork, communication channels established to ensure effective communication and training in risk associated with HAI.

In another study by Griffiths, Renz *et al.* (22) carried out to determine the impact of organisational factors and management (such as clinical management, leadership, human resources policy and clinical governance, among others) in HAI control, a set of risks to the success of programmes were identified and highlighted such as poor leadership, lack of clear definitions of management, lack of defined responsibilities and appropriate measures for infection control.

In another study by Makai and Klazinga (23) about quality management models implemented in Hungarian hospitals and their effect on patient safety, conclusions demonstrated that there was a statistically significant relationship between the level of development of quality management systems in hospitals and the number of activities for patient safety. The authors emphasised that, according to the data presented, the strategies for quality management systems developed in the past did not ensure the high level performance expected for patient safety, requiring the implementation of additional measures in the existing management models.

Spencer and Walshe (24) in their study about the policies and strategies developed for quality improvement in European health systems (supported by MARQuIS project - Methods of Assessing Response to Quality Improvement Strategies), found that the main objectives and values identified by respondents were related to standards and guidelines development, promotion and integration of patient safety, promotion of systems for measuring/assessing and improving information systems and registration. One of the factors identified as responsible for the biggest impact in promoting quality improvement in health systems was the development and implementation of accreditation and certification systems.

The study carried out by Shaw, Kutryba *et al.* (25) about quality and safety systems and their support structures (Based on MARQuIS project) concluded that the organisation and professional management were the determinant key factors of quality systems in hospitals. The authors suggested the need for better definition of organisational services.

European Council Recommendation on Patient Safety, including the Prevention and Control of Healthcare Associated Infections, defined lines of action towards the promotion of patient safety and control of HAI that included the use of indicators of structures, processes and results as well as the implementation of accreditation/certification systems (26). In 2010, and following this recommendation, the European Centre for Disease Prevention and Control (ECDC) presented a report, written by experts on HAI prevention and control, that suggested the five most effective in HAI prevention and control core components of existing programmes, identified as: i) development of organisational structures to include management support, prevention, objectives, action plans and multidisciplinary committees (quality, safety, infection control); ii) monitoring methods, detection of outbreaks and its management, goals achievement; iii) training and education programmes for professionals; iv) behavioural change and quality of interventions and v) the local policies and provision of resources for the introduction of standard precautions and others. They also concluded that it would be more appropriate to adapt and improve programmes and practices, taking into account the recommendations presented, than to elaborate new ones. For this propose the report also referred the importance that the European Union (EU) project “Prevention of Hospital

Infections by Intervention and Training (PROHIBIT)", starting in 2010, could have on the recommendations of best practices to adapt for the prevention and infection control programmes (27).

In the work done by Groene, Klasinga *et al.* (28) based on the MARQuIS project, developed in European hospitals between 2005 and 2007, aiming to evaluate different strategies to improve quality and its impact on healthcare in terms of effectiveness and safety, it was found that the highest levels of patient safety in hospitals were associated with accreditation/certification systems, with significant differences from hospitals that had not present these systems (29).

Finally in another work Groene, Klasing *et al.* (30) presented a descriptive study about the DUQuE project (Deepening our Understanding of Quality Improvement in Europe), taking place from 2009-2013 and exploring how the improvement of quality organisational systems, culture, involvement of professionals and empowerment of patients are related to the quality of hospital care, measured in clinical effectiveness, safety and patient-centred dimensions. In this project, and in order to answer questions such as "What is the most effective quality tool?" several key objectives were identified for project development: i) research about associations between the maturity of the quality improvement systems and clinical effectiveness and safety/patient involvement and ii) identify factors that enhance the activities of quality improvement in hospitals, as well as external pressure imposed by accreditation, certification and any external programme evaluation.

As presented, Acknowledging and understanding the trilogy: Quality Management– Patient Safety – HAI Prevention and Control[3], is considered fundamental to better identify barriers and interventions that can improve HAI prevention and control systems.

Objectives

The main objective of this work is to analyse the trends of HAI prevention and control systems and how quality management tools can improve these systems.

The following research questions need to be attended:

How to characterize the healthcare-associated infections prevention and control systems evolution?

[3] HAI prevention and control system includes also Antimicrobial resistance (AMR) issues.

What was done worldwide to promote healthcare-associated infections prevention and control systems?

How HAI prevention and control is linked with quality management tools?

How quality management tools can promote the prevention and control of healthcare-associated infections?

How accreditation and certification models can promote healthcare-associated infections prevention and control systems?

What are the most significant barriers to the effectiveness of these systems?

Related with Structure?

Related with Process?

Related with Results?

What are the perceptions of Portuguese healthcare professionals, about healthcare-associated infection prevention and control systems in their organisations?

What are the main barriers?

How can these systems be improved?

Thesis Synopsis

The work presented in this thesis is organised in chapters, as follows:

Chapter II provides an insight on the research methodology used in the development of all the subsequent chapters of this thesis.

Chapter III focus on the state of the art, providing the definition of healthcare-associated infections (HAI) and an analysis on the international and national evolution of HAI prevention and control management systems. The national framework for HAI prevention and control systems is also analysed in detail.

Chapter IV provides some definitions and evolution related with quality management systems and tools and analyses some healthcare quality management models and how they promote HAI prevention and control systems.

Chapter V provides the results from fieldwork, based on a multi-case study.

Chapter VI provides a discussion and the presentation of a management model for HAI prevention and control systems based on ISO 9001 and process-approach models. Global conclusions, and some perspectives for future research work are also presented.

Annexes Chapter is presented at the end.

CHAPTER II – Methodology

Introduction

This chapter describes the methodology used to support the work. A qualitative strategy was performed, supported by an exploratory methodology in an early stage, followed by descriptive and explanatory methodologies. The first stage (exploratory) aimed to clarify and understand the problem, to collect data and to establish and frame research questions that globally support the work done. With this purpose, an exhaustive literature review and documentation analysis were performed, as well as informal meetings with healthcare professionals, congress and scientific meetings, and some informal discussions with healthcare professionals associated with HAI prevention and control systems were conducted. In the second stage (descriptive and explanatory) the multi-case study methodology was implemented, supported by qualitative analysis (analysis of documents, and interviews) in order to provide a more comprehensive analysis of research questions (31-38).

In the Chapters III, IV and in the work published in 2011 in the article "Challenging healthcare-associated infections: a review of healthcare quality management issues" (see Annexes Chapter - Annexe I) an exploratory methodology was applied. In the work published in 2012 in the article "Healthcare-associated infections: on developing effective control systems under a renewed healthcare management debate" (See Annexes Chapter - Annexe II) both descriptive and explanatory methodologies were applied. In Chapter V (Multi-case study analysis), a descriptive methodology was used. In the Chapter VI (Discussion and Conclusions), was applied a descriptive methodology supported by a conceptual model. These methodologies will be described in more detail.

Methodology CHAPTER III – Evolution of Healthcare-Associated Infection Prevention and Control Systems

For this chapter, the exploratory methodology was supported in a selective literature review using a set of MeSH[4] terms (Table 1), free terms (Table 2) and the combination of both, in several scientific databases, such as Pubmed, Biomed Central, Emerald and B-on, and other information sources such as sites from relevant entities (Table 3), books and legal documents, at national and international level. After the identification and analysis of articles and other

[4] Medical Subject Headings (MeSH).

texts using this method the snowball method was applied to improve the research. In this analysis some inclusion and exclusion criteria for articles selection (Table 4) were established to limit the research.

Table 1 - MeSH terms (tree structure) used in the literature review of Chapter III.

MeSH terms - tree structure		
Environment and public health	Public Health	Communicable Disease Control
		Disease Notification
		Hand Hygiene
		Infection Control
		Cross infection
		Catheter-related infection
Bacterial Infections and Mycoses	Infection	Cross infection
		Ventilator-associated pneumonia

Table 2– Free terms used in the literature review of Chapter III.

Free Terms	
Healthcare-associated infections	Antimicrobial resistance
Health care-associated infections	Surveillance
Healthcare-acquired infections	Hospitals
Nosocomial infection	Patient safety
Hospital infection	Barriers
Prevention	Constraints
Control	Programmes/tools
Best practices	Standards

Table 3 - Sites from relevant entities related with HAI prevention and control systems issues - national and international level.

National Sites	
General-Directorate of Health	*http://www.dgs.pt/*
Portuguese Government	*http://www.portugal.gov.pt/pt.aspx*
Central Administration for Healthcare Systems	*http://www.acss.min-saude.pt/*
General Inspection of Healthcare Activities	*http://www.igas.min-saude.pt/*
Health Portal	*http://www.portaldasaude.pt/portal*
Regulatory Authority of Health	*https://www.ers.pt/*
HAI prevention and control & AMR Microsite	*http://www.dgs.pt/ms/3/default.aspx?pl=&id=5514&acess*
Regional Health Administration – North	*http://www.arsnorte.min-*
Health Plan 2012-2016	*http://pns.dgs.pt/?cpp=1*
Legix	*http://www.legix.pt/*
Portuguese Observatory for health systems	*http://www.observaport.org/*
International Sites	
Agency for Healthcare Research and Quality (AHRQ)	*http://www.ahrq.gov/*
Center for Disease Prevention and Control (CDC)	*http://www.cdc.gov/*
Comparative Health Knowledge System (CHKS)	*http://www.chks.co.uk/*
Department of Health, UK (DH)	*https://www.gov.uk/government/organisations/department-of-health*
European Centre for Disease Prevention and Control	*http://www.ecdc.europa.eu/en/Pages/home.aspx*
European Union (EU)	*http://europa.eu/*
Health Protection Agency (HPA)	*http://www.hpa.org.uk/HPAwebHome/*
Healthcare Infection Control Practices Advisory	http://www.cdc.gov/hicpac/
Joint Commission (JC)	*http://www.jointcommission.org/*
National Audit Office (NAO)	*http://www.nao.org.uk/*
National Healthcare Safety Network (NHSN)	*http://www.cdc.gov/nhsn/*
National Healthcare Service, UK (NHS)	*http://www.nhs.uk/Pages/HomePage.aspx*
Organisation for Economic Co-operation and	*http://www.oecd.org/*
Society for Healthcare Epidemiology of America (SHEA)	*http://www.shea-online.org/*
The Australian Council on Healthcare Standards	*http://www.achs.org.au/*
World Health Organisation (WHO)	*http://www.who.int/en/*

Table 4 - Inclusion and exclusion criteria for articles selection of Chapter III.

Inclusion criteria	Exclusion Criteria

Articles should:
- Be published and available in a journal in public domain;
- Address an issue related to HAI Prevention and Control Systems;
- Only apply to healthcare entities (hospitals);
- Discuss HAI prevention and control systems and relevant results;
- Discuss tools/processes/programmes related to HAI prevention and control systems;
- Contain a description of HAI prevention and control system implementation process;
- Contain information about:
  - Management models used, tools developed/used, indicators developed/used;
  - Setting characterisation (including dimension, structure, resource used, planning issues, processes),
  - Communication issues (tools channels, processes, and results).
	Articles should not be applied to:
	- Other healthcare entities than general hospitals;
	- Specifically care processes analysis without link to quality management tools;
	- Non-industrialized countries, undeveloped countries and developing countries;
	- Projects with main purpose of financial improvement and/or changes that only concern to financial issues;
	- Change in software and/or hardware and information technology (IT) only;
	- No discussion of healthcare issues.

Methodology CHAPTER IV – Evolution of Quality Management in Healthcare

In this chapter the previously described methodology was also used. In the following tables MeSH terms and free terms (Table 5), and relevant sites (Table 6) are presented.

Table 5 – MeSH terms (tree structure) and free terms used in the literature review of Chapter IV.

MeSH terms - tree structure			Free Terms

Healthcare Quality, Access, and Evaluation or Health Services Administration	Quality Assurance (or Assessment, Quality)	Benchmarking
		Clinical Audit
		Credentialing
		  Accreditation
		  Certification
		  Licensure
		Facility Regulation and Guidelines as Topic
		  Best Practices
		Professional Review
		  Peer Review
		Total Quality Management, Total
		  Continuous Quality
			Quality
			Process management
			Quality programmes
			Quality standards
			Management
			Innovation
			Quality control
			Feedback
			Reporting
			Systematisation
			Control
			Hospital
			Audit
			ISO

	Quality of Health Care	Health Care Evaluation Peer Review, Health Standards of Care Quality Improvement Quality Indicators, Health Care	**Quality tools** RCA (Root Cause Analysis) FMEA (Failure Mode and Effects Analysis) HACCP (Hazard Analysis and Critical Control Points) Checklist Monitoring BSC (Balanced Scorecard) EFQM (European Foundation for Quality Management)

Environment and public health	Public Health	Management, Safety
		Communicable Disease
		  Hand hygiene
		  Infection control
		Population Surveillance
		  Public Health Surveillance
			Healthcare policies
			Health systems
			Strategies

Table 6 – Sites from relevant entities for Healthcare Quality issues, at national and international level.

Entity	Site
National	
General-Directorate of Health	*http://www.dgs.pt/*
Portuguese Government	*http://www.portugal.gov.pt/pt.aspx*
Health Portal	*http://www.portaldasaude.pt/portal*
Central Administration for Healthcare	*http://www.acss.min-saude.pt/*
General Inspection of Healthcare Activities	*http://www.igas.min-saude.pt/*
Regional Health Administration – North	*http://www.arsnorte.min-saude.pt/*
Regulatory Authority of Health	*https://www.ers.pt/*
Health Plan 2004-2010	*http://www.dgsaude.min-saude.pt/pns/capa.html*
Health Plan 2012-2016	*http://pns.dgs.pt/?cpp=1*
Legix	*http://www.legix.pt/*
Microsite Quality in Health	*http://www.dgs.pt/ms/8/default.aspx?pl=&id=5521&acess=0*
Portuguese Accreditation Institute	*http://www.ipac.pt/*
Portuguese Association for Hospital	*http://www.apdh.pt/*
Portuguese Observatory for health systems	*http://www.observaport.org/*
International	
Accreditation in Canada	*http://www.accreditation.ca/*
Agencia de Calidad Sanitaria de Andalucía	*http://www.juntadeandalucia.es/agenciadecalidadsanitaria/*
Agency for Healthcare Research and	*http://www.ahrq.gov/*
American Society for Quality (ASQ)	*http://asq.org/index.aspx*
Australian Commission on Safety and	*http://www.safetyandquality.gov.au/*
Comparative Health Knowledge System	*http://www.chks.co.uk/*
Department of Health, UK (DH)	*https://www.gov.uk/government/organisations/*
European Foundation for Quality	*http://www.efqm.org/*
European Union (EU)	*http://europa.eu/*
Institute for Healthcare Improvement, USA	*http://www.ihi.org/Pages/default.aspx*
International Organisation for	*http://www.iso.org/iso/home.html*
International Society for Quality in Health	*http://www.isqua.org/*
Joint Commission (JC)	*http://www.jointcommission.org/*
National Audit Office (NAO)	*http://www.nao.org.uk/*
National Healthcare Service, UK (NHS)	*http://www.nhs.uk/Pages/HomePage.aspx*
National Institute for Health and Care	*http://www.nice.org.uk/*
Organisation for Economic Co-operation	*http://www.oecd.org/*
The Australian Council on Healthcare	*http://www.achs.org.au/*
World Health Organisation (WHO)	*http://www.who.int/en/*

For this chapter, some inclusion and exclusion criteria for the first selection of articles from scientific databases were also defined, as presented in Table 7.

Table 7 – Inclusion and exclusion criteria for articles selection of Chapter IV.

Inclusion criteria	Exclusion Criteria

Articles should:
- Be published and available in public domain;
- Address an issue related to quality management issues, certification and accreditation and other quality issues;
- Discuss health policies and strategies;
- Patient flow and/or process design with the purpose of improving patient care in terms of Quality Management topics;
- Contain description of the healthcare quality management implementation process;
- Contain information about:
  - Models used, tools developed/used;
  - Setting characterisation (including dimension, structure, resource allocation, planning issues, processes);
  - Healthcare quality dimensions presented by different authors;
  - Communication tools (channels, processes, and results).
	Articles should not be applied to:
	- Other healthcare entities than general hospitals;
	- Specifically care processes analysis without link to quality management tools;
	- To undeveloped countries and developing countries;
	- Projects with main purpose of financial improvement and/or changes that only concern to financial issues;
	- Change in software and/or hardware and IT (only);
	- No discussion of healthcare issues.

An Excel standard form for data extraction and content analysis (Table 8) was created. The Endnote software (version X6) was used to manage bibliographies, citations and references. The software and standard form were used in all chapters where literature review was performed.

Table 8 – Labels and content description of standard form created for data collection, extraction and analysis.

Labels	Content description
Country or region	Identification of country/region (developed country only)
Publication year	Identification of research and publication period
Area	Area identification: Quality (Q), Healthcare-associated infection (HAI), Patient Safety (PS)
Methodology	Type of studies
Study Setting	Identification and characterisation of setting (general hospitals, teaching hospitals military hospitals, wards hospitals, Intensive unit care – hospitals)
Study objective	Identification of study main objectives
Key points	Keywords and relevant terms
Summary	Article summary, data and discussion analysis and principal conclusions

To analyse how quality management models could promote HAI prevention and control systems, a selective literature research using MeSH terms and free terms used in the methodology of Chapter IV (Table 5) was initially performed and crossed with MeSH terms and free terms used in the methodology of Chapter III (Table 1 and Table 2), using the same scientific databases mentioned previously. After this research was concluded, several articles were identified and analysed taking into account inclusion and exclusion criteria established for the two separated researches (Table 7 and Table 4). The snowball method was subsequently applied to improve the research and to find other relevant articles. The work was supported by the same information sources identified in the mentioned chapters (see Table 6 and Table 3).

Methodology CHAPTER V –Multi-Case Study Analysis

According to the type of objectives defined for this work, the research strategy adopted was a cross-sectional multi-case study with an explanatory and descriptive research methodology.

As the main objectives were to identify how quality accreditation models (JCI[5] and KF-CHKS[6]) and quality management certification model (ISO 9001[7]) could improve HAI prevention and control, and to analyse in detail each HAI prevention and control system from hospitals with these three models, a multi-case study in three hospitals (31, 38) was performed.

[5] Joint Commission International (This model will be analysed in following chapters).
[6] King's Fund model. This is an accreditation model managed by an UK entity. This model is accredited by CHKS.
[7] ISO 9001 is a international standard used for quality management systems ceritfication. This standard will be analysed in following chapters.

The applied explanatory and descriptive research methodology was considered relevant because it was fundamental to find answers to questions such as "Why quality management tools help to promote HAI prevention and control systems?" and "How quality and management tools can help to promote HAI prevention and control systems?" (Explanatory methodology), and "What quality and management tools can do to promote HAI prevention and control systems?" (Descriptive methodology) (36, 39).

Information Sources

Several information sources were used, such as internal and external documents (among which legal / regulatory documents), records, national and international best practices, pictures, informal meetings, interviews, and field notes; All these was done by direct observation (39). Information triangulation was also promoted, in order to corroborate data from different sources.

Selection/Case Sampling

As mentioned previously, a multi-case study was performed, mainly due to the main objectives of this work: to identify how quality accreditation models (JCI and KF-CHKS) and quality management certification model (ISO 9001) could improve HAI prevention an control; and analysed in detail each HAI prevention and control system from three hospitals with these three models. For this, it was decided to use a convenience sample consisting on three hospitals, each one with a different quality management model.

The universe of public hospitals with accreditation models and certification models was identified and the sample selection was done following some inclusion/exclusion criteria (Table 9).

Table 9 – Inclusion and exclusion criteria for hospitals sampling selection.

Inclusion criteria	Exclusion Criteria

- Public Hospitals;
- General hospitals: central and regional (district) (must include a mix of general medicine and general surgical services, admitting both emergency and planned cases);
- Hospitals involved in early process for healthcare accreditation in Portugal:
  - KF-CHKS - since 2000-2001
  - JCI - since 2004-2005
- Accreditation/certification model applied to all hospital;
- Hospitals with quality Department/Service/Structure;
- Hospitals with HAI prevention and control Committee.
	- Specific specialised hospitals;
	- Hospitals with ISO certification obtained by KF-CHKS accreditation model.

After the inclusion and exclusion criteria application, three public hospitals were chosen, located in the north region of Portugal. All selected organisations are public corporate entities (one of the hospitals is from a local health unit and two hospitals are from hospital centres).

Due to confidentiality constrains, these three hospitals will be identified by the following fictitious names: "KF-CHKS Hospital", "JCI Hospital" and "ISO Hospital". Although National Strategy for Healthcare Quality refers to another accreditation model for healthcare providers – the model from *Agencia de Calidad Sanitaria de Andalucía* (ACSA) - no hospital was selected considering this model since a global implementation of the model to a hospital entire organization could not be identified (only some partial hospital departments/services implementation was noticed in some cases).

After hospital selection an authorisation request for the study (by registered letter and email), was sent to Administration Board of each hospital (Table 10). Upon obtaining the appropriate authorisation the Quality Director and the HAI prevention and control system Coordinator of each hospital were contacted (by email).

Table 10 – Study request issues and content.

Study request issues	Content
- Interviewer identification	- Name and filiation
- Research main objectives	- Objectives for fieldwork and general objectives of work performed
- Research methodology	- Semi-structure interview
- Tools and instruments for interview	- Interview guidelines and audio record system
- Interviewees characterisation	- Key-informers: Quality management director, HAI prevention and control committee (executive and advisory members)
- Ethical issues	- Confidential issues, data protection methodology
- Documentation to validate study propose	- Articles about these matter published previously, Curriculum Vitae
- Other documentation	- Interview guidelines

Interview Process

In each hospital key-informers from quality management department and from the HAI prevention and control committee (executive team and advisory team) were interviewed. In each hospital, and based on the criteria established by the National Programme for Infection Prevention and Control (NPIPC), the key-informers from HAI prevention and control were chosen by the HAI prevention and control Coordinator. During the first meeting with HAI prevention and control Coordinator the importance to interview healthcare professionals from different careers (physicians, nurses, engineers, and other careers such as pharmacists, microbiologists, and others) was stressed. Unfortunately, and since the interviewees selection was performed by the HAI prevention and control Coordinator, it was not possible to

interview elements from the same career and from the same intervention area at hospital level at the three different hospitals.

Data collection – Documents and Documentation Analysis

A comprehensive set of documents were analysed before and during fieldwork: External documents, such as: legal/regulation documents at national and international level (see Chapters III and IV), informative documents from international organisations (such as best practices recommendations from HAI prevention and control systems and quality in healthcare), quality standard models and HAI prevention and control standards at national and international level, reports at national level and international level were used for the work preparation and planning. All these documents were obtained from reliable sources (recognised national and international organisations) to ensure information reliability. During the research field work, more specifically during the interviews and meetings, several internal documents, such as: HAI prevention and control manuals, software to collect data, quality plans, quality procedures, certification and accreditation certificate (scope), posters related with HAI prevention and control, internal services organisation charts were analysed.

The documentation analysis was conducted through content analysis methodology, supported by a standardized form, organised by categories: quality management systems (Q), HAI prevention and control systems (HAI), and both (Q-HAI). Within each category sub-categories were identified, such as: legal/regulation, recommendation, standards, tools and best practices (40).

Data Collection – Interviews

During the interview process several interview methodologies were used (structure, semi-structure and informal) because, although there was a set of well-defined questions and in a sequence (structure interview characteristics), a set of not previously identified questions emerged from the interview process (informal interview characteristics). Nevertheless, the most used was the semi-structure interview methodology due to the defined set of questions or topics to be explored without exact phrases or predetermined order. This interview methodology has several advantages, namely regarding the possibility of accessing very important and relevant information through interviewees words that reflect their perception about issues addressed; of interviewers to clarify some relevant aspects during the interview process; and to generate at initial study stage some points of view, guidelines and assumptions for further research (39, 41). For this, and as mentioned previously, an interview guideline was developed based on previous informal meetings with some key-informers, and

supported by the interviewer knowledge about Quality in healthcare and HAI prevention and control systems issues. The interview guidelines were developed to better understand the interviewees perceptions for: quality management tools and implementation process in each hospital, HAI prevention and control systems and processes implemented in each hospital; the role of quality management tools in the HAI prevention and control in each hospital; the impact of each quality management model in the HAI prevention and control systems defined by national law, regulations and best practices.

The interview guideline was structured in two parts: one part centred in quality management issues for quality management healthcare professionals (general questions for all models and specific questions for each model) and other focused in HAI prevention and control systems issues for healthcare professionals (see Annexes Chapter - Annexe IV).

To test interview guidelines a pre-test (pilot test) was conducted by interviewing participants with identical characteristics of future study interviewees. These participants were also asked to identify interpretation difficulties and suggestions to improve the interview process. Supported by this information a question reformulation was carried out, including some terminology changes (terms less clear or too technical), question separation (too general into more focused questions), introduction of new questions and order review.

All interviews were performed at the same time frame (February 2013- July 2013) at the three selected hospitals.

The interview and content analysis were performed in three stages: interview audio record; transcription of the recording contents; and content analysis (40). The first stage was performed with the support of audio record iPhone application, after the interviewee authorisation for audio recording. The second stage was performed with the support of Word software where full transcription was recorded and revised for better understand respondents speeches. The last stage was performed with the support of NVivo 10 - QSR International Software, where transcriptions were coded within predefined categories and nodes.

Methodology for Article "Challenging healthcare-associated infections: a review of healthcare quality management issues"

The methodology applied in this article (see Annexes Chapter – Annexe I) was a selective literature review carried out in the same databases of previous chapters, using the keywords presented in Table 11. These keywords were focused in three different issues, Patient Safety, Quality and HAI, with the main objective to analyse how these three important issues were linked. After the identification and analysis of several articles and texts the snowball method

was applied to improve the research. As previously stated, some inclusion and exclusion criteria were also established (Table 12).

Table 11 – Keywords used in the literature review, related with international projects developed for patient safety, quality in healthcare and HAI.

Keywords for		
Patient Safety	**Quality**	**And HAI**
Patient Safety	Quality in Healthcare	Infection control
Safety Management	Hospital Performance	Hospital
	Improvement	Prevention
	Quality Management	Antimicrobial Resistance
		Surveillance
Standards Programmes Projects Indicators Tools Measurement		

Table 12 – Inclusion and exclusion criteria used to identify international projects related with patient safety, quality in healthcare and HAI.

Inclusion criteria	**Exclusion criteria**

- International Projects
- Projects developed by international organisations
- Projects related with:
  - Patient Safety
  - Quality in Healthcare
  - HAI Prevention and Control
	- Projects exclusively for non-developed countries/developing countries
	- Projects applied only in a specific country
	- Projects focused only in financial issues or other issues not related with:
	  - Patient Safety
	  - Quality in Healthcare
	  - HAI Prevention and Control

To validate the results a comparative analysis was done, between articles information and each project website and other relevant websites (Table 13).

Table 13 – Projects and other relevant websites for article "Challenging healthcare-associated infections: a review of healthcare quality management issues".

Projects	**Website**
BURBEN	*http://www.eu-burden.info/*
Core Components for Infection	*http://www.who.int/csr/resources/publications/WHO_HSE_EPR_2009.../en/*
DEBUGIT	*http://www.debugit.eu/*
DUQuE	*http://www.duque.eu/*
EARS-Net	*http://www.ecdc.europa.eu/en/activities/surveillance/EARS-Net/Pages/index.aspx*
EUInfoPas	*http://ec.europa.eu/health/patient_safety/policy/index_en.htm*
EUNetPas	*http://www.eu-patient.eu/Initatives-Policy/Projects/Non-EPF-led-EU-projects-*
Europe4Patients	*http://ec.europa.eu/health-eu/europe_for_patients/index_en.htm*
Clean Care is safer Care	*http://www.who.int/gpsc/en/*
HAI-Net	*http://www.ecdc.europa.eu/en/activities/surveillance/hai/pages/default.aspx*
HCQI	*http://www.oecd.org/health/health-systems/healthcarequalityindicators.htm*
HELICS	*http://www.ecdc.europa.eu/search/Pages/results.aspx?k=ALL%28helics%29*
IPSE	*http://ipse.univ-lyon1.fr/*
IQIP	*http://www.internationalqip.com/*
MARQuIS	http://ec.europa.eu/research/fp6/ssp/marquis_en.htm
MOSAR	http://www.mosar-sic.org/mosar/en-gb/index
ORCAB	*http://orcab.web.auth.gr/*
PATH	*http://www.pathqualityproject.eu/*
PILGRIM	http://http://cordis.europa.eu/projects/rcn/88867_en.html
PROHIBIT	*https://plone.unige.ch/prohibit/*
PSI	*http://www.qualityindicators.ahrq.gov/modules/psi_overview.aspx*
QUASER	*http://www.kcl.ac.uk/nursing/research/nnru/research-*
Safe Surgery Saves Lives	*http://www.who.int/patientsafety/safesurgery/*
TESSy	*http://ecdc.europa.eu/en/activities/surveillance/TESSy/Pages/TESSy.aspx*
TRICE	http://trice.uniud.it/node/7
TROCAR	*http://www.trocarproject.eu/*

Methodology for Article "Healthcare-associated infections - on developing effective control systems under a renewed healthcare management debate"

The methodology applied in this article was a systematic literature review (42-44) carried out in the same databases of previous chapters, using MeSH terms from Table 1 and free terms presented in Table 2. To improve the selection some inclusion and exclusion criteria were applied (see Table14). The standardized form with the structure presented in Table 8 was also used.

Table 14 – Inclusion and exclusion criteria for article "Healthcare-associated infections - on developing effective control systems under a renewed healthcare management debate".

Inclusion criteria	Exclusion criteria
Articles should: - Contain abstract; - Be published and available in a journal in public domain; - Address an issue related to HAI Prevention and Control Systems in hospitals; - Contain a description about HAI issue study; - Contain a description of the barriers or constraints to prevention and control of HAI; - Discuss HAI control systems relevant results about structures (resources, environmental conditions, organisational culture/values), process (clinical processes – best practices, therapy process, and management processes) and results (data, data quality, report); - Contain quantitative data about at least one dimension of Healthcare-associated infection: Patient safety, infection type, hospital characterization (including dimension, structure, resource utilization, planning issues), management issues (programs/methodologies to control infection), communication issues (tools channels, processes, data available) and others; - Have been published between January 2006 and September 2011.	**Articles should not be applied to:** - Articles not related with healthcare issues - Articles analysing care processes - Non Developed or Developing Countries - Projects with main purpose of financial improvement - Articles analysing change in software and/or hardware and IT; - Articles with description of methods, models and theories without empirical data.

The detailed methodology is presented in the article published (See Annexes Chapter - Annexe II).

CHAPTER III – Evolution of Healthcare-Associated Infection Prevention and Control Systems

This chapter details some concepts and evolution, at national and international level, of healthcare-associated infection prevention and control systems. It will start with the presentation of main concepts and definitions, followed by an analysis of the international framework, taking into account the most relevant factors. Finally, the national framework will also be subjected to an analysis.

General Concepts

The term "healthcare-associated infection" is very recent. In fact, in the early stage of the problem analysis, this type of infection was named "nosocomial infection" because its identification and analysis was limited to hospitals. According to CDC and National Nosocomial Infection Surveillance (NNIS) a "nosocomial infection" is a localized or systemic condition 1) that results from adverse reaction to the presence of an infectious agent(s) or its toxin(s) and 2) that was not present or incubating at the time of admission to the hospital. Two other special situations in which an infection is considered nosocomial must be considered: (a) infection that is acquired in the hospital but does not become evident until after hospital discharge and (b) infection in a neonate that results from passage through the birth canal (45, p.1). Nevertheless, the term "nosocomial infection" was considered obsolete in 2008 given the existence of these infections in other healthcare providers rather than hospitals. The term was replaced by "healthcare-associated infection" (HAI) (46). Other terms can be identified for this type of infection, such as "hospital infection" or "healthcare-acquired infection" (HCAI), but the most used is HAI.

The magnitude of HAI problem can be measured by incidence[8] studies or prevalence[9] studies. Although both are important measures for HAI problem, the prevalence measures are considered inferior to incidence measures because prevalence rates are dependent from the casual factors and also by the infection duration. On the other hand, incidence studies are more difficult to promote (more expensive, more time).

[8] The incidence of a disease is the number of new cases in a certain period of time. The incidence rate is the number of new cases per specified unit of population and time.

[9] The prevalence of a disease is the frequency of the disease, measured at a designated point in time. The prevalence rate is the proportion of the population with the disease in the numerator and the total population (affected and unaffected) in the denominator.

The most common types of HAI include surgical site infections (SSI), central line-associated bloodstream infections (CLABSI), the catheter-associated urinary tract infections (CAUTI), and ventilator-associated pneumonia (VAP)[10].

The problem

Healthcare-associated infection is a major patient safety[11] issue, affecting the quality of care of hundreds of millions of patients every year in both developed and developing countries. Given that HAI is linked to the behaviour of healthcare professionals and, in some cases, to healthcare system gaps (e.g. lack of adequate equipment, inadequate methods and processes), this burden translates into a frustration and loss of trust in the healthcare system and healthcare professionals all over the world.

The concern about infection control at hospital level is not an actual issue. Data relating with Florence Nightingale work shows that in the Century XIX some efforts were developed to control hospital infections due to military hospital stay. During the XX century, infection has been identified as a leading cause of death in hospitals but the lack of knowledge regarding the mechanisms of transmission proved to be a major difficulty, for which a solution was not to be found until the end the century. Since this important discovery, it was possible to introduce basic hygiene methods, which in conjunction with the use of antiseptics during surgery, led to a significant improvement in infection control. Although the general knowledge about this issue and the efforts to reduce it have increase considerably, the problem persists and it is actually a major issue for health systems all over the world.

Several factors can difficult the reduction/elimination of the HAI: biological and technical issues (such as seriously ill patients, more susceptible to infections, conditions that impair the immune system - such as chemotherapy and transplants, use of invasive procedures which increases the likelihood of infection, mixed populations of patients inside the hospital that promotes crossover and transmission, increased microbial resistance), and organisational issues (such as lack of adequate hygiene and cleanliness methodologies, lack on top management commitment with the hospital infections problem, and others).

The spread of antimicrobial resistance (AMR) among many microorganisms has rendered formerly easily treatable infections more difficult to manage. This problem introduces a

[10] These infections are the most common, but in some settings it is possible to find puerperal endometritis and gastrointestinal infections and others.

[11] Patient safety was defined by the European Council as "*freedom for a patient from unnecessary harm or potential harm associated with health care"*, and as a key dimension of Healthcare Quality (Source: European Council. Recommendation (2009/C 151/01) of 9/06/2009 on Patient Safety, including the Prevention and Control of Healthcare Associated Infections C 151.Official Journal of the European Council).

significant impact in the community and in healthcare facilities, especially in hospitals, where the susceptibility of the population may act as reservoir of resistance in the absence of effective infection control programmes.

The antibiotics and other antimicrobial drugs have revolutionised the infections treatment since the discovery of Sulfamide drugs in 1935. When penicillin was introduced in 1946, 5% were resistant *Staphylococcus aureus* infections and in 1952 this resistance was already nearly 85%. During 30 years, the pharmaceutical industry has developed a broad range of new drugs to combat infections, including methicillin and vancomycin, to substitute the penicillin for the resistant cases. In 1992 The National Academy of Sciences reported a dangerous new phenomenon: the emergence of new and virulent diseases that are resistant to antibiotics. In 1999 the first cases of vancomycin resistance were reported in Japan and USA, at that moment, the last drug line for infections. Currently, it has become common the existence of Methicillin Resistant *Staphylococcus aureus* (MRSA). The importance of MRSA in comparison with Methicillin sensitive strains (MSSA) relies in the resistance to all beta-lactamase and other important antimicrobials agents. Although the pathogenicity is similar for both, the major threat is that MRSA strains have endemic potential and can increase drastically the number of infections in hospitals, higher mortality, and additional costs that also contribute to the burden of human suffering. These strains has been identified in the 60s but only in the 90s, due to a strain identified in an UK hospital, was acknowledged as a serious problem. In the report of the National Surveillance of Nosocomial Infections from the UK (including the period from 1997 to 1999, which covered 96 English hospitals), 46% of the organisms that caused infection in surgical wounds were *Staphylococcus*, of which 81% were *aureus* and 61% of these were MRSA. In some European countries, such UK, Portugal, Greece and Italy, more than 40% of MRSA in *Staphylococcus aureus* population can be noticed. However, MRSA is not a problem in Scandinavia and The Netherlands (only 1% of the *Staphylococcus aureus* population is MRSA) due to the actions developed since 1995, under the "Search and Destroy" policy (47-50).

The appearance of infections such as viral haemorrhagic fevers, avian and pandemic influenza, and severe acute respiratory syndrome (SARS)[12], highlighted the need of effective infection-control practices in healthcare settings. It is known that a considerable proportion of the burden of disease attributable to HAI is preventable, and many interventions, at lower cost, can bee effective.

[12] The severe acute respiratory syndrome is a viral respiratory disease in humans, which is caused by the SARS coronavirus. It was first reported in Asia. In 2003 and WHO and CDC provided guidance for surveillance, clinical and laboratory evaluation, and reporting.

In 2010 the International Nosocomial Infection Control Consortium (INICC)[13] published the results of a surveillance study related with device-associated HAI used in Intensive Care Units (ICU) (from January 2003 through December 2008 applied in 173 consortium hospitals in 36 countries from Latin America, Asia, Africa, and Europe). The study had several conclusions: crude excess mortality in adult patients was 18,5% for CAUTI, 23,6% for CLASBI and 29,3% for VAP (Despite the fact that the use of devices in developing countries hospitals ICU was similar to that reported by CDC National Healthcare Safety Network (NHSN) related to USA hospitals, rates of device-associated infections were higher in the ICU of INICC hospitals). Other conclusions included that the AMR rates found in INICC hospitals for MRSA isolates (NHSN – 56,8% and INICC – 84,4%), *Enterobacteria* resistant to Ceftazidime (NHSN – 27,1% and INICC – 76,3 %), and *Pseudomonas aeruginosa* resistant to Fluoroquinolones (NHSN – 30,5% and INICC – 42,1%), were significantly higher than those reported in NHSN hospitals, and the increased length of stay associated with HAI varied between 5 and 29,5 days (51).

In 2011 the World Health Organisation (WHO) published the endemic burden report of the most frequent types of HAI and the epidemiological assessment differences among countries according to income levels. This report presented relevant available evidence from the scientific literature published from 1995 to 2010 on the endemic burden of the most frequent types of HAI, identified the major obstacles and gaps to assess the magnitude of HAI burden worldwide and determined solutions and future perspectives for improvement. One of the major problems encountered was related to the reliability of HAI data from other healthcare organisations than hospitals, due to the fact that the culture of infection prevention and control and the surveillance systems are inexistent or poorly developed in these settings. This report showed that in the high-income countries, several national surveillance systems and international networks regularly provided information at national level, but in the low- and middle-income countries there were very few national studies available and the majority had no HAI reporting system implemented. Some data from annual epidemiological report on communicable diseases in Europe was also referred, published in 2010 by the European Centre for Disease Prevention and Control (ECDC), namely that 13 in 28 European high-income countries (46.4%) had national surveillance systems in place in 2008 to monitor ICU-acquired infections, SSI, or both, and were regularly reported to the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) network. According to these studies, the proportion of infected patients in ICU could be approximately 50% and most of these were HAI. It is also pertinent to refer the report that, in high-income countries, approximately 30%

[13] International Nosocomial Infection Control Consortium (INICC) is an international network, created in 2002 by Dr. Victor D. Rosenthal from Argentina and now 46 countries of Africa, Asia, Europe and Latin America participate in this network.

of ICU patients are affected by, at least, one episode of HAI with considerable associated morbidity and mortality (52, 53).

In the USA and Europe, urinary tract infection was the most frequent type of infection hospital-wide (36% and 27%, respectively). In the USA, this type of HAI was followed by SSI (20%), CLABSI, and HAP[14] (both with 11%). In Europe, the second most frequent was VAP (24%), followed by SSI (17%), and CLABSI (10.5%) (53).

European estimations indicated that HAI was the cause of an annual16 million extra-days of hospital stay and 37000 attributable deaths, and that, additionally, contributed to additional 110 000 deaths. Several studies can be identified related with HAI costs, which highlight the fact that the cost associated with a hospital bed with an infected patient during one year would be identical to the cost of infection control programme implemented in a hospital with 250 beds. The key finding is that the burden of HAI worldwide is very high in terms of morbidity, mortality, extra-costs, and other outcome indicators (6, 53).

It is important to mention information from ICU, that participated in the surveillance and infection control programmes coordinated by INICC, about the decrease of CABSI and CAUTI over recent years due the adoption of best practices such as hand hygiene promotion strategies, the implementation of standard and isolation precautions, environmental cleaning, water and sanitation in healthcare settings, sterilization and disinfection procedures, and infectious waste and sharp disposal, including other specific measures for injection safety (51). Some recommendations were made, related with the importance of quality improvement tools and the need to promote their implementation, the importance of reporting systems in data quality, the promotion of learning mechanisms related with HAI prevention and control systems, the promotion of the visibility and commitment of decision-makers and healthcare top managers, the increase of individual accountability among healthcare professionals and patient involvement (53).

International Framework

In1983-1984 the WHO developed a prevalence survey in 55 hospitals of 14 countries representing four WHO Regions (Europe, Eastern Mediterranean, South-East Asia and Western Pacific) to determine the magnitude of the problem and to prepare the development of surveillance systems for HAI and AMR (one of the components of the WHO Global Medium Term Programme for 1984-1989). This survey showed that 8,7% of hospital patients had HAI and, at that time, more than 1,4 million people worldwide suffered complications

[14] HAP – Hospital-Acquired Pneumonia.

associated with HAI (54). Upon these conclusions, WHO published several guidelines and recommendations related with HAI control systems and other related areas, such as AMR, waste management, facilities management, to promote the effectiveness of infection prevention and control systems.

Healthcare-Associated Infections and Patient Safety

WHO published in 2002 the Practical Guide for HAI Prevention and Control. This guide established a set of core components for the prevention and control infection programmes to be implemented for all countries. The core components presented were related with: i) epidemiologic surveillance (definitions, type of infections, criteria for disease classification, reservoirs and transmission), ii) infection control programmes (different levels, ICC, infection control professionals, responsibilities/roles of different members, guidelines), iii) hospital infection surveillance (strategies, network, prevalence/incidence studies, data collection and analysis, education and training), iv) how to deal with outbreaks (identification, planning and research), v) prevention of hospital infection (risk stratification/risk assessment, reducing transmission - some procedures related with equipment, infrastructures, materials, protective equipment, environment cleaning and disinfection, sterilization and reprocessing of medical devices), vi) prevention of common endemic hospital infections (specific policies and practices related with equipment, infrastructures, and clinical best practices), vii) infection control precautions in patient care (standard precautions, AMR), viii) environment precautions (buildings, planning construction and renovation, traffic flow, materials, air, water, food, waste), xix) antimicrobial usage and AMR (therapy, antibiotic control policy, monitoring antimicrobial use), x) preventing infections on staff (monitoring exposure of some bacteria) (55).

The acknowledge of the importance of these guidelines for infection control systems and the awareness of its implementation difficulties, promoted the development (started in 2008) of a new set of recommendations about the infection prevention and control systems at national level and at local healthcare facilities. In 2009 the WHO published the “Core components for Infection Prevention and Control Programmes (IPC)” as the result of an exhaustive research about the different programmes, best practices, and scientific studies developed and implemented all over the world. The core components were established by category, as presented in Table 15 (4).

Table 15 - Summary of core components of infection prevention and control programmes suggested by WHO (Source: WHO (4)).

Category	Components
Organisation of IPC programmes	A structure responsible for policies, goals, strategies, legal, technical framework and monitoring. Existence of qualified dedicated technical staff with defined responsibilities, scope and functions. A budget adequate to meet programmed activities.
Technical guidelines	Development, dissemination and implementation of technical evidence-based guidelines for prevention of the relevant risks and/or infections, adapted to local conditions.
Human resources	Training for all healthcare professionals in IPC and specialised training of infection-control professionals. Adequate staff responsible for IPC activities. Address biological risks and implement preventive measures.
Surveillance of infections and assessment of compliance with IPC practices	Established priorities for surveillance of infections and pathogens, standardised case definitions and active methods of surveillance. Systematic assessment of compliance with IPC practices. Detection of outbreaks and prompt response. Documentation HAI issues and IPC practices.
Microbiology laboratory	Standardisation of microbiology laboratory techniques. Promotion of the interaction between IPC activities and the microbiology laboratory. Use microbiology data for surveillance and IPC activities. Establish laboratory biosafety standards.
Environment	Minimum requirements for IPC: clean water, ventilation, hand-washing facilities, patient placement and isolation facilities, storage of sterile supply, conditions for building and/or renovation.
Monitoring and evaluation of programmes	Regular monitoring, evaluation and reporting of IPC outcomes, processes and strategies at national level and in healthcare facilities. Promotion of evaluation in a non-punitive culture.
Links with public health or other services	Links between public health services and the facilities for events of mandatory reporting. Permanent coordination with activities related to waste management and sanitation, biosafety, antimicrobial pharmacy, occupational health, patients and consumers and quality of healthcare.

Key issues for further developments were also identified: skills and curricula for training of infection-control professionals (description and assessment methods for training strategies and skills necessary for infection control professionals); workload ratio of infection-control professionals; strategies for implementation (organisational structure, culture of safety, evidence-based interventions vs. surveillance findings); applicability of core components (identification of the components that are associated with success). A set of new issues was also presented, to be incorporate in the HAI prevention and control systems such as: national programmes for all healthcare providers and not only for hospitals; establishment of links with other programmes and healthcare organisations (such as scientific associations); guidelines for dealing with epidemiologic outbreaks and the importance of an International Health Regulator creation.

The recognition of HAI importance on patient safety and quality of care, and the fact that one of the major causes of transmission was related with hand hygiene issues, launched in 2004 a set of programmes to promote the global awareness about these issues. The World Alliance for Patient Safety was one of the first movements to promote the union of politicians, health agencies, healthcare professionals, users and patients around the motto “First, Do No Harm”

(56, 57). Several initiatives have been undertaken to raise global awareness and to obtain country commitment to support actions on this issue. One of first initiatives was the International Patient Safety Event Classification (IPSEC), developed to harmonise the classification and terminology for Patient Safety. This work is supported in JCAHO work (Patient Safety Taxonomy) and was completed in 2008 (58).

HAI was identified as a fundamental priority and selected as the main issue of the First Global Patient Safety Challenge launched by World Alliance for Patient Safety. This challenge was developed under the banner "Clean Care is Safer Care", and aimed to implement several actions to reduce HAI worldwide, regardless the level of development of healthcare systems and the availability of resources. The implementation strategies to promote hand hygiene in healthcare, as the cornerstone of HAI prevention and control systems, included the integration of several interventions in the areas of blood safety, injection safety, clinical procedure safety, and water/sanitation/waste management (3).

In 2004 WHO launched two important set of recommendations and guidelines for the environment management and for hand hygiene promotion. The first set of recommendations was related with environment issues, covering areas such as: waste disposal, cleaning and laundry, disinfection and sterilization. There was also a set of recommendations at policy/strategy level and for resources allocation and monitoring systems. These recommendations came to operate the previously identified about this subject in the Practical Guide of Infection Control, published in 2002 (55, 59-61).

The development of technical guidelines for the promotion of hand hygiene started in 2004 and in April 2006 an advanced draft was available. The final document was published in 2009, after the scientific-evidence review and the implementation of several pilot tests to evaluate feasibility, acceptability and sustainability, with the goal to provide technical information to support training materials and help to plan implementation strategies. This document was complemented with other WHO publication related with tools to improve hand hygiene strategies: "My Five Moments for Hand Hygiene"[15], hand hygiene self-assessment framework, "SAVE LIVES: Clean your hands" programme[16], Multimodal Hand Hygiene Improvement Strategy[17] (56, 62-67). After the First World Challenge, the WHO launched, in 2007, the Second Global Patient Safety Challenge, this time focused on complications of surgical care, one of the major causes of death and disability worldwide. One of the most

[15] The "my Five Moments for Hand hygiene" is a user-friendly, innovative way to understand, monitor and practice hand hygiene action at point of patient care.
[16] This is an annual global campaign, launched in 2009 and it is an extension of WHO First Global Patient Safety Challenge: "Clean Care is Safer Care".
[17] The Multimodal Improvement Strategy is based on the recommendations. They were field tested in a wide range of different healthcare settings for feasibility, adaptability and success. This is complemented with a guide for the application and a package of 32 implementation tools including posters, templates, and instructions.

common causes of serious surgical complications is the surgical site infection, and evidence indicated that existing safety practices do not appear to be used reliably in any country. The goal of this new Patient Safety Challenge, launched by WHO, was to improve safety in surgical care by defining a set of safety standards for four topic areas: teamwork, anaesthesia, prevention of surgical site infection and measurement of surgical services. To support the implementation of these standards there a set of documentation was developed, comprising with guidelines, manuals, and checklists (68-70).

Antimicrobial Resistance

In 2001, the WHO published its first set of recommendations for the containment of AMR. These set of recommendations, strongly related with HAI issue, provided a framework of interventions to slow the emergence and reduce the spread of antimicrobial-resistant microorganisms. The governments were called to develop an effective action plan supported in the introduction and enforcement of appropriate regulations and allocation of appropriate resources for education/training and surveillance. These recommendations included: education for patients/general community, and prescribers and dispensers; implementation of management systems and guidelines to promote HAI prevention and control programmes and effective AMR; promotion the access of diagnostic laboratories and a better interaction with the pharmaceutical industry; control the use of antimicrobials in food producing-animals; introduction of regulations, policies and guidelines associated with HAI and AMR; promotion of education and training for healthcare professionals; promotion of antimicrobial usage and AMR and HAI surveillance systems (71).

In 2012, more than 10 years after the publication of AMR prevention and control recommendations, the WHO published a report with AMR analysis and implementation "effects". A set of remaining gaps was identified, such as: lack of common definitions for surveillance (there were no globally accepted definitions for multi-drug resistance - MDR), lack of geographically representative data (the resulting lack of data from several areas in the world minimizes the benefits of a AMR surveillance), gaps on laboratory capacity and diagnostic testing (there were no competent laboratories for diagnostic testing in many countries), gaps in data management and networking capabilities and methodological obstacles for AMR surveillance systems. This document also analysed the importance of AMR in HAI prevention and control and concluded that interactions with other structures (as the engineering experts responsible for healthcare infrastructures, devices and equipment) have resulted in some improvements, such as better antimicrobial delivery systems, new approaches to wound dressing, isolation cubicles which can be assembled within a room, cleansing/decontamination methods and procedures. In relation with HAI prevention and

control, a set gaps was also identified: inadequate infrastructure and human resources (inadequate buildings, understaffing), lack of sufficient trained HAI prevention and control professionals, inadequate data on AMR infections (also associated with the lack of standardized methods for measuring HAI), and lack of information on costs and cost-effectiveness (there was insufficient information about HAI costs and societal costs of interventions) (72, 73).

United States of America

In the USA, HAI prevention and control systems are directly related with the Centres for Diseases Prevention and Control. CDC was created in 1946, as "Communicable Disease Centre", and is one of the major operating components of the Department of Health and Human Services.

During the 60s, the concern about HAI increased and some important approaches to deal with this problem were made by Sir Robert E. O. Williams in his book "Hospital Infection" published, in 1960, and by Alexander Langmuir, in 1963, with his basic framework for the new approach to nosocomial infection surveillance at CDC and Hospital Epidemiology. A general conclusion stated that "Good surveillance does not necessarily ensure making the right decisions, but it reduces the chances of wrong ones" (74, 75). This initial efforts were followed by the work of the CDC, namely with the development and implementation of several strategies and surveillance programmes for USA hospitals. One of the most known was the training video produced in 1961 by the USA Public Health Service with a hand washing demonstration with hand washing techniques recommended for the use of healthcare professionals (76).

CDC launched the first National Surveillance Programme in 1955 (Polio surveillance) and in 1970 sponsored the 1st International Conference on Nosocomial Infections, where the "design" of National Nosocomial Infection Surveillance System was first presented. NNIS was in place from 1970 till 2004, when National Healthcare Safety Network (NHSN) replaced it[18]. National Centre for Infectious Diseases managed this network, from the Division of Healthcare Quality Promotion, in the Coordinating Centre for Infectious Diseases in CDC.

The NNIS objectives were kept but some simplifications were introduced through protocols, data capture and reporting system with electronic support. The introduction of HAI outcomes in Patient Safety Component and modules of HAI based on a new strategy that collects, separately, HAI data related with procedures, devices and medication, is also noticed. In

[18] NHSN was created in 2005 and is the most widely used HAI tracking system in the USA. It integrates and supersedes 3 legacy surveillance systems at the CDC: the NNIS system, the Dialysis Surveillance Network (DSN), and the National Surveillance System for Healthcare Workers (NaSH).

accordance, a trained Infection Control Professional or a Hospital Epidemiologist must coordinate data collection and all members participating in this new system must include an annual survey of the facility.

Developments

There is a long tradition in evidence-based HAI prevention and control methodologies, most of them supported by HAI surveillance and control programmes promoted by CDC, the American Hospital Association, and JCAHO[19]. Some unanswered questions were identified, such as: What is important in infection control? How a surveillance and control programme can be effective? To answer these questions CDC initiated in 1974 the SENIC project (Study of the Efficacy of Nosocomial Infection Control) aiming to examine the effectiveness of surveillance and control programmes implemented by hospitals. The main goals of this study were: 1) to measure the extent of adoption and implementation degree of surveillance programmes in USA hospitals, and 2) to determine if an infection rate reduction associated with the implementation of these programmes could be identified (programme effectiveness). This study included also the analysis of specific characteristics of the implemented programmes. The results of this study allowed to conclude that the implementation of infection control surveillance activities in hospitals reduced the HAI rates by approximately 32%, if the surveillance programme include four critical components: 1) appropriate surveillance activities and vigorous control efforts, 2) one full-time infection control professional per 250 beds (at least), 3) a trained hospital epidemiologist and 4) feedback for surgeons about surgical wound infections rates. In 1983 another survey of infection surveillance and control programmes was conducted in a random sample of USA hospitals. The main conclusion was that hospitals had actually increased the intensity of their surveillance and control activities, but the failure to implement these critical components limited the potential for improvement in prevention (at that time, these programmes were capable of preventing an estimated 9% of infections) (77, 78).

In a report published in 1992 by CDC, to present the state of the art knowledge about the effectiveness of HAI surveillance, prevention and control, and their cost-benefits obtained by SENIC project, an estimation of more than two million of patients annually with HAI was presented and associated costs were referred to be more than 4,5 billion dollars. The report also stated that the surveillance programmes costs were about 60 000 dollars *per* 250 beds (total of 243 million dollars in all USA hospitals). This data allowed verifying the decrease of

[19] Looking to the importance of these measures in the quality of the healthcare services, in 1976 JCAHO added to its set of accreditation standards a surveillance programme for infection control. Actually, in its accreditation programme for hospitals a specific standard to promote the best practices in the prevention and control of infection was included. This will be analysed in next chapters.

general costs associated with HAI if surveillance programmes for HAI prevention and control were implemented. The cost of surveillance programmes for infection control was about 6% of the infections costs and if the hospital, with an infection control programme, reduced more than 6% of the infections rate, it could mean clear benefits (both economic and to public health) in its implementation. This study also highlighted the importance of the healthcare professionals training on infection control and the need of NNIS methodologies review, such as the infection control record (use of risk adjustment in HAI record) and information feedback to healthcare professionals. As a consequence, JCAHO adopted the NNIS methods and started gathering information on a wide range of infection control clinical indicators (16).

Subsequently to this study, several other studies were conducted about HAI estimated costs and business case analysis from a hospital perspective. In latest later study a summary of the economic aspects to evaluate and costing interventions was presented, aiming to support board-decision in funding HAI prevention and control programmes (79). Several important steps can be highlighted:

PART I:

- To frame the problem and develop a Hypothesis about potential solutions;
- To meet with key administrators (to ensure commitment and support from leadership, to identify critical individuals and departments who may be affect by the proposal);
- To identify critical costs that may be include in the analysis, including administrative data);
- To determine the annual cost;
- To determine which costs can be avoided through reduced infections rates (they may be supported with evidence-based on information/data and literature review);
- To determine the costs associated with the infection of interest at the hospital;
- To calculate the financial impact;
- To include the additional financial or health benefits;
- To make the case for the hospital business case (meet again with key stakeholders individually to present and discuss your findings, develop a implementation plan and find support);
- To, prospectively, collect cost and outcome data once the programme is in effect;

PART II:

- To define the economic analyses type (cost-effectiveness – costs for number of lives saved or infections prevented, cost-utility – costs by adjusted benefits, such as health preferences scores or utility weighted, and cost-benefit – costs money by benefits money);

- To state monetary values in constant unit terms;
- To measure the attributable cost of nosocomial infections;
- To measure the economic impact of interventions to reduce nosocomial infections (define the type of study to support the measurement).

It should be noted that, regardless the time gap with SENIC study, some of the measures presented are still accepted today as international standards. For example, the ratio of trained infection control nurses *per* number of beds, which has been proved to be adequate in that context, didn't suffer any change. The question is if these measures are still appropriate nowadays, given the changes suffered by healthcare systems at all levels (increased bacterial resistance, shorter stays, outpatient procedures, etc.).

Other studies, developed to evaluate the implementation and compliance with recommendations and guidelines, were referenced. One of them, related with hand hygiene, was developed between 2001-2003 and applied to 40 USA hospitals—members of the NNIS, to compare HAI rates before and after implementation of guidelines recommendations (one year before and one year after). It was verified that wide dissemination was not sufficient to change practice, and only some hospitals had initiated multidisciplinary programmes to promote the practice change. Related with the HAI rates, no impact was determined (80).

In 2008 a representative from the Committee to Reduce Infection Deaths, speaking in the 16th Congressional Hearing on Hospital Infections (and reported by Reuters) about the hospitals cleanliness, concluded on a lack of testing surfaces in hospitals when comparing with catering service/industry where HACCP (Hazards Analysis and Critical Control Points) methodology is mandatory.

Nevertheless, some initiatives were implemented with success as the development of workshops for ideas to improve patient safety, development of care bundle approach, and others, – that have reduced HAI rates (CLABSI and VAP) considerably (80).

Data

In 2007, the CDC reported that deaths due to MRSA were greater than those caused by AIDS. At this time MRSA infection was rapidly becoming one of the most prevalent and threatening diseases of our time. Since then, approaches to promote governance and compliance with this issue are noticed: mandatory regulation about HAI prevention and control systems were implemented in some States (most of them for MRSA prevention and control) (81), accreditation systems and reimbursement rules employed by insurance companies and

government agencies, with emphasis not only in HAI prevention and control but also penalising who do not achieve improvements in rates as mentioned before (82).

In 2009, CDC reported that nearly 1,8 million people have acquired HAI resulting in 100.000 related deaths (82).

In 2010 the National Healthcare-Associated Infections Standardised Infection Ratio Report, (using data reported to the NHSN) published the statistics for CLABSI and SSI for two 6 months time periods in 2009. The results demonstrated that for CLABSI, there was no measurable improvement in the level of prevention between sequential reporting periods, and for SSI prevention there was a slightly improvement between sequential time periods.

The main objective of these serial comparisons was to provide an improve means for monitoring the impact of interventions and to indicate the successes of State-based and national HAI reduction efforts (83).

In 2012 it was reported that 1 in 20 patients in USA hospitals were affected by HAI and that the costs were more than 33 billion of dollars in excess medical costs for hospitals every year (84).

Governance

At national level HAI governance is done via State regulation and the standards for hospital operating within each State (based on the regulation) are produced by the Department of Health and Human Services from CDC. The HAI problem on patient safety issues, particularly a series of high-profile outbreaks due to breaches in infection control procedures, led to regulatory and other policies actions in several States, specially related with prevention and control programmes, rates publication, addition screening and control programmes for MRSA, prevention procedures, isolation procedures, personnel preventive equipment and reporting system. Related with the latest, there is mandatory reporting data in 28 States (27 mandatory reporting data to State and State reports publicly; one mandatory reporting data to State (by rule) and voluntary public reporting by State. In 23 of these States it is required to use the NHSN to report to State), One State has voluntary reporting to State and two have voluntary reporting data to State and mandatory public reporting by State (81, 82, 85-87).

As stated, State health agencies are responsible for patient protection across the healthcare system, serving as a bridge between healthcare and the community, and they have an important role to play in definition of HAI prevention and control policies. Actually several initiatives were developed, at State level, to promote the implementation of HAI prevention and control programmes, including efforts to ensure that valid data are reported.

In 2010 CDC and the Association of State and Territorial Health Officials (ASTHO) established collaboration to advance State-level HAI prevention efforts. From this collaboration emerged a project, named "Eliminating Healthcare-Associated Infections" that, till now, has developed actions in two stages.

The first one released in 2011 a toolkit, named "Eliminating Healthcare-Associated Infections: State Policy Options", to provide to senior policy-makers a guidance to use legal and policy interventions to implement a comprehensive HAI prevention and control programmes (87).

It was identified a framework with four fundamental baselines to promote HAI prevention and control systems, well supported by an adequate financial resources, as it can see in the Figure 1.

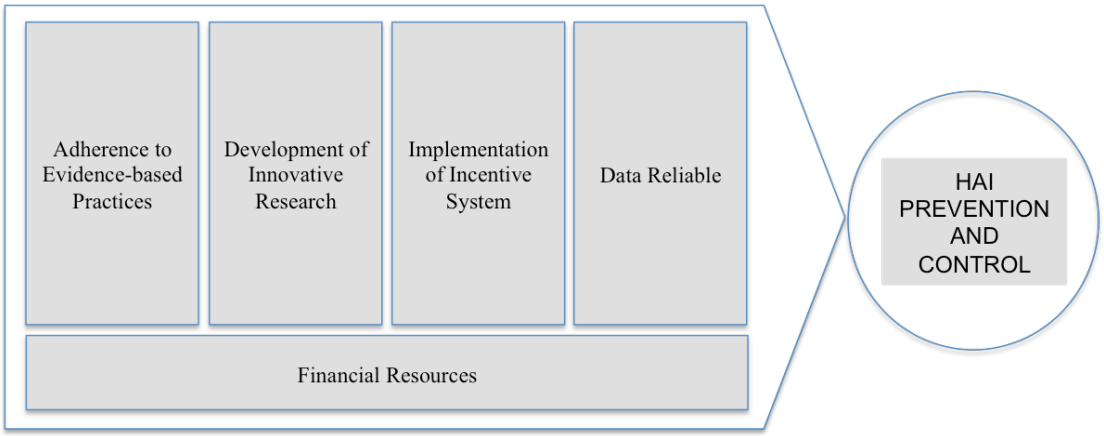

Figure 1 – Framework for the promotion of HAI prevention and control systems (source: ASTHO and CDC (87)).

The main objective of this tool was to implement a public health model, based on a set of recommendations, which promotes adherence to evidence-based practices and uses valid data to respond to emerging threats related with HAI. This toolkit describes several policies[20],

[20] Reporting systems - Definition of reporting system main scope (facility safety and quality improvement, public health and epidemiologic use, or public reporting); definition, at level State (if the reporting system is mandatory); definition of data collection system to be implemented and strategy for data validation; definition of formats, frequency and timelines.
Financial support – Establishment of financial support; identification of funding implications for HAI reporting and prevention;
Financial Incentives – Establishment of financial incentives for facility reporting costs, increased reimbursement, and quality improvement payments; improvement promotion; to target poor performances for HAI prevention assistance and to foster improvement.
Financial Disincentives - Establishment of statutory disincentives; definition of penalty for not compliance (e.g. not reporting valid data, not meeting a certain benchmark).
Advisory councils – Assignment to health agency to appoint experts, consumers, and key stakeholders.
Licensure – To expand licensing authority as appropriate to require HAI reporting and prevention; definition of prevention promotion requirements; promotion of HAI prevention through staff licensure (e.g., infection control training).
Training - Set as main goal to have all healthcare professionals trained in HAI prevention and patient training; Use of existing mechanisms to require HAI training (e.g., medical and nursing schools, CME, licensure requirements);

including, advisory councils, financial incentives and disincentives, licensure and training requirements and public reporting options, and can help decision-makers to organise HAI prevention and control systems.

This first stage gave special attention to: HAI identification through validate data and prioritise actions for infections that represent either the gravest threat to health or the clearest opportunities for progress; clarification of HAI definitions to implement consistent data surveillance; identification of sustainable/creative streams of financial support for data collection and validation; training promotion, on a regular basis, for State health officials, facility staff, and practitioners; coordination of collaboration between health departments and facilities (by aligning State and federal reporting requirements and improving communication).

The second stage was initiated in 2012, with the publication of the report "Policies for Eliminating Healthcare-Associated Infections: Lessons from State Stakeholder Engagement", built on the toolkit, which summarizes the outcomes of stakeholder meetings and phone consultations (84). The goals for this stage were: to provide an inventory of promising policy interventions; to catalogue indicators of effectiveness (e.g., process measures); to identify a list of indicators that may help to track the progress of specific policies and any interaction among policies; to identify, if possible, specific policies or a suite of policies that show early promise in reducing HAI and promote benchmarking; recommend next steps or future questions that might be explored to further reduce HAI.

It was verified that most of the States HAI policies are relatively new (most of then since 2006) and, as so, limited information was published about the effect of HAI-related policies on infection rates, mostly supported by data generated by mandatory public reporting (86).

At hospital level HAI governance is associated with legislation, accreditation system and reimbursement rules employed by insurance companies and government agencies, meaning that the USA HAI prevention and control systems has moved on from trying to control rates to more direct actions to penalise who do not achieve rates improvement. This is clearly presented in the new strategy associated with HAI prevention and control, when the payment (by the Centres for Medicare and Medicaid Services) of cases who acquire certain infections were to be denied and it was considered illegal to charge patients by the providers. As the cost difference between an infected and uninfected case is high, the providers considered this a severe penalty (since 2008 this strategy was applied to CAUTI, CLABSI, VAP, SSI, MRSA sepsis and HAI caused by *C. difficile)*. Nevertheless, with this strategy, governance and accountability of the system has increased (88, 89).

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ensure trainers have the capacity and expertise necessary on reporting and prevention; maximise existing expertise; consider innovative and sustainable funding mechanisms for training.

The concern with governance and leadership issues at hospital level led to development of some guidelines to support their implementation in healthcare organisations. For example, in 2008 the Institute for Healthcare Improvement (IHI) (with its campaign associated with patient safety – 5 Million Lives Campaign), launched a strategic quality improvement framework as a roadmap for leaders based on five core components: "Mission/vision – Foundations – Will – Ideas – Execution". This framework helps leaders to develop the organisational will, generate or find strong ideas for improvement and then execute them. All this is supported by an execution framework with seven leadership leverage points to help leaders to answer "but how…" questions: establishment of specific system-level aims (90, 91).

Another organisation, the National Association for Healthcare Quality (NAHQ), also developed a guide with recommended actions to help leaders of healthcare organisations to implement protective structures that promote accountability for integrity in quality and safety evaluation, data collection, and reporting to internal and external bodies (92).

USA has a long tradition in producing HAI guidelines and recommendations. CDC and other USA organisations, such as Society for Healthcare Epidemiology of America (SHEA)[21], Healthcare Infection Control Practices Advisory Committee (HICPAC)[22], published a set of recommendations and guidelines for infection control such as: definitions, terminology and vocabulary for HAI (since 1969) (45, 46, 93-95), environmental control (since 1982) (96-98), sterilisation and disinfection (since 2008)) (99), infrastructures (since 1998) (97), hand hygiene (since 1981) (100), isolation precautions (since 1996) (101, 102), antimicrobial resistance (since 1997) (103), healthcare professionals, (since 1983) (104), medical waste (since 1992) (105), public reporting of HAI (since 2005) (86), surveillance methodologies (since 1969) (106).

For clinical processes, several guidelines and recommendations were published at national level since 1991, associated with different type of infections, mostly related with the four more common HAI (CAUTI, VAP, CLABSI and SSI) (16, 107-116).

The education and training programmes are well supported by CDC and other organisations, such as professional organisations (Association for Professionals in Infection Control and Epidemiology - APIC) and healthcare quality organisations (e.g. Agency for Healthcare

[21] SHEA was founded in 1980 and is mission is to prevent and control HAI and promote research in the field of healthcare epidemiology.

[22] The HICPAC is a Federal advisory committee assembled to provide advice and guidance to Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of infection control and strategies for HAI surveillance/prevention and control, antimicrobial resistance and related events in USA healthcare settings. The principal activity of HICPAC is to provide advice on periodic updating of existing CDC guidelines and development of new CDC guidelines.

Research and Quality - AHRQ). Actually some States use certification in infection control or other methods to enforce training requirements (117-119).

European Evolution

Since the 70's, the EU has demonstrated its concern about HAI impact in health systems of its countries Members. The concern about this issue is presented, in 1972, by the resolution (72) 31– *sur l'hygiene Hospitalière* published from the Council of Europe. This was the first official set of recommendations presented at European level to Member States. After the publication of this document each Member State had to disseminate it at national, regional and organisational levels.

Emphasis was given on the promotion of: 1) surveillance and knowledge about HAI treatment (ICC implementation, antibiotic surveillance); 2) transmission prevention between persons and equipment/material (procedures definition and implementation); 3) hospital cleanliness (air decontamination, infrastructures, isolation and other procedures); 4) education and training (infection control programmes in the Curricula of medicine and nurse courses, specialists graduation in Infection Control); 5) medical professional surveillance (healthcare professional surveillance); 6) hygiene promotion in hospitals (infection control plans at national, regional and local level) (120).

In 1984, the European Council launched another important recommendation for the prevention of hospital infections. This document aimed to alert the governments of Member States to the importance in pursuing their efforts to give full effect to Resolution (72) 31, to promote by all means the application of the strategy described and work together within the Council of Europe to give support to Member State request, including the organisation of periodical courses in hospital hygiene for all relevant categories of staff. The major recommendations were about: definitions (terminology, nomenclature and codes to be used for medical and surgical reports of septic complications); surveillance, awareness and prevention of infections acquired in hospitals; monitoring, control committees, rational use of antimicrobial agents; prevention of transmission of microorganisms; hospital environment cleanliness improvement; identification, handling and transport of hospital waste; pest control; training and education of staff and of non-patients; medical surveillance of staff; medical report (121).

Given the lack of knowledge about the control of hospital infection carried out in different countries of Europe, the European Council developed a multicentre pilot study in order to identify the main differences between HAI prevention and control systems, attended by 10

hospitals selected randomly. This study concluded that there were significant differences between the existing HAI prevention and control systems in those hospitals, emphasising the shortage of properly trained professionals to implement the policies and strategies for infection control, and especially the absence of practices standardization. It was also referred that healthcare sector was a decade or more behind other industries on risk management issues essential to ensure basic safety for the patients. Due to this, the creation of standards for infection control at European level was suggested (122).

Later, based on Article No. 152 of the European Treaty, the European Parliament and the Council presented the Decision 2119/98/EC in 1998, a network for epidemiological surveillance and control of communicable diseases in the European Community was set up. This Decision was published to establish the regulation for "Hospital in Europe Link for Infection Control through Surveillance - HELICS" project[23] (after 2005 this project became a work package of IPSE – Improving Patient Safety in Europe project). The aim of the European Parliament Decision was to set up a network, at European level, to promote cooperation and coordination between the Member States with a view to improving the prevention and control, in the Community. This network had the responsibility to collect relevant data, to develop and monitor procedures aiming to ensure the systematic activity of the Member States at surveillance level (123, 124). In 2000, to define what communicable diseases and special health issues would be covered by epidemiologic surveillance, another decision was published, Decision nº 2000/96/EC, where HAI was addressed (124-127).

The work done by CDC in this area (behind the USA borders), the need to improve the coverage and effectiveness of existing dedicated networks between Member States for surveillance of communicable diseases (as established by the Decision Nº 2119/98/EC) and the need to foster cooperation with third countries and international organisations competent in public health field (in particular to pursue closer collaboration with WHO), led to the creation of the European Centre for Disease Prevention and Control (ECDC) in 2004 by the European Parliament. ECDC, an independent agency, should serve as a community source of independent scientific advice, assistance and expertise from trained medical, scientific and epidemiological staff from its own resources or from those of recognised competent bodies acting on behalf of Member States authorities responsible for human health. The ECDC has

[23] The project "Hospital in Europe Link for Infection Control through Surveillance" was created in 2000 to standardise the European methodology for SSI surveillance and of HAI in ICU. Since 2003, HELICS project is responsible for data collection from national surveillance networks of HAI according to the standardised method and developed a protocol for a point prevalence survey of HAI, however without much adherence in Member States in subsequent years. The HELICS-SSI and HELICS-ICU protocols formed the basis for the current ECDC HAI-SSI and HAI-ICU protocols. (HELICS) had two phases: the first phase (1997) aimed to lay the practical foundations for a European Network on hospital associated infections and the second phase aimed to create a robust and validated surveillance system and establish reference data sets. The HELICS 2 implementation report was presented in 2005, and the surveillance network continued to operate through the "Improving Patient Safety in Europe" (IPSE) network till 2008, when it was transferred to the ECDC coordination.

as mission to identify, assess and communicate current and emerging threats to human health from communicable diseases, and ensure the integrated operation of dedicated surveillance networks of authorities and structures designated under Decision Nº 2119/98/EC, where necessary, with the assistance of one or more surveillance networks (128).

Antimicrobial Resistance

In 1999, the European Council, based on recommendations and decisions about infection control published at that time, emphasised AMR as an important issue in HAI prevention and control, through the June 1999 Resolution "Strategy against the microbial threat" and the Recommendation 2002/77/EC from November 2002, on the prudent use of antimicrobial agents in human medicine. These European documents aimed to present the strategy against microbial threat, based on some compromises, such as: control and preventive action related with surveillance of antibiotic resistance in humans, control usage and promotion of prudent use, infection control in healthcare, researching effects of preventive measures, best use, spread mechanism and development of antibiotic resistance. The Member States were called to establish multi-disciplinary and cross-sectorial policies, monitoring of supply and use of antibiotics, to promote adherence to principles of infection control in hospitals and non-hospital care, to promote optimal prescribing and use of antibiotics, to promote actions to raise healthcare professionals awareness, to include the priority for surveillance of antibiotic resistance, and to ensure the reporting system (129, 130).

To ensure the application of this strategy presented there were done some recommendations to Member States about the prudent use of antimicrobial agents in human medicine based on data quality and collection of data in appropriated level. The surveillance systems should be sustainable with: clear regulation of data access and ownership; implementation of preventive measures to support the prudent use of antimicrobial agents; development of evidence-based principles and guidelines; implementation of hygiene and infection control standards in organisations and in community and access their impact in the prevention of community diseases; promotion of education and training of healthcare professionals about antimicrobial resistance (undergraduate and postgraduate level), training on immunisation programmes and hand hygiene. It was also asked to Member States to cooperate with the commission for development and evaluation of indicators to monitoring prescribing practices of antimicrobial agents, information and communication.

Patient Safety

The World Alliance Strategy for Patient Safety, launched in 2004 by WHO, and the Luxembourg declaration on Patient Safety, launched in 2005, recognised that the access to high quality healthcare is a key human right to be valued by the European Union, and led to the publication in 2006, by the Council of Ministers of Europe, of a set of recommendations to Member States governments to ensure the patient safety importance in health policy, especially in quality improvement policies. The need to establish a patient safety policy (which promotes a culture of safety at all healthcare levels), and the adoption of a prospective approach and preventive patient safety (which highlight the importance of learning from incidents that have already occurred, and which will pursuit the absence of harm to the patient) were defined as main priorities. These two priorities must be accomplished with a set of supporting systems, such as: a system for incidents reporting and recording (not punitive, independent of other regulatory processes, designed to encourage the record process); the development of education and training system; an indicators system to monitoring and evaluate patient safety (able to identify safety problems, evaluate the effectiveness of interventions and facilitate international comparisons); a benchmarking platform to promote the international cooperation and exchanging experiences (at all levels, from the design of systems, standard processes, record and reporting, indicators development); patient safety research and innovation systems.

Additionally, some prerequisites were to be met: patient safety should be recognised as the foundation of the healthcare quality; a systematic approach should be implemented to ensure the design of structures and processes to obtain the expected results; language standardisation related with patient safety should be promoted; quality and risk management should be included in the contents of healthcare professional education and training courses; among other issues (e.g. human behaviour knowledge to promote effective risk management; system-based approach to improving patient safety, assuming quality management and risk management integration; establishment of quality indicators to promote assessment and evaluation; and the establishment of research and legal framework) (20).

Following these recommendations, the European Commission published in 2007 the Health Strategy White Paper, where patient safety was considered a priority area for action. One of the actions set out in the second programme for community action in the field of health (2008-2013) aimed to improve citizens health security through the promotion of measures to improve patient safety related with high quality and safe healthcare, including relation to AMR and HAI. After these developments, patient safety, including HAI prevention and control were considered strategic issues for European Commission at legal level and included in 2008 work programme (131).

In 2008, to promote the Patient Safety legal framework development, the European Council held a public consultation and an assessment to identify the most adequate strategy in terms of its possible social, economic an environmental impact. It was decided the development of a Communication and a Council Recommendation on patient safety including the HAI prevention and control (the general objective of the recommendation was to prevent and reduce human illness and diseases and to obviate sources of danger to human health - article 152 of the Treaty). In a general perspective, this initiative aimed to stimulate Patient Safety Policy development and future action in and between Member States. Objectives (and indicators) to be developed at European level and Member State level, in accordance with other international and European organisations (such as ECDC, OECD[24], WHO) were also identified (132-134):

- To develop case definitions for HAI in accordance with Decision 2119/98/EC (Indicator: Commission decision covering HAI case definitions, source: ECDC, external expertise);
- To foster with ECDC the establishment of surveillance methods and indicators to allow evaluation of implementation and effectiveness of measures for HAI prevention and control, guidance on best practices and minimum infrastructure requirements, as well as training curricula for healthcare professionals (Indicator: Availability of surveillance methods, indicators, guidance on best practices, curricula for healthcare professionals agreed at EU level);
- To monitor the implementation and effectiveness of the recommendations on HAI prevention and control (Indicators: Process - standard operating procedures and hand hygiene, and structure - number of infection control professionals, indicators to developed by ECDC, building on the work of Improving Patient Safety in Europe project - IPSE);
- To promote the HAI level decrease in Member States (indicator: HAI prevalence and incidence in Member States);
- To develop and promote the research agenda on patient safety, based on Information and Communication Technologies, new tools for HAI treatment and prophylaxis and cost effectiveness (Indicator: number of accepted applications on patient safety).

In 2009 the results of IPSE project were published and the general conclusion was that a remarkable consensus was achieved with the proposed standards and performance indicators (SPIs) that could be used at a national and international level to stimulate and review improvement in HAI prevention and control systems, and antimicrobial stewardship activities (13 international indicators and 13 national indicators were defined). These indicators covered

[24] Organisation for Economic Co-operation and Development.

different categories, from Resources, Organisation for Prevention and Control Policies and Surveillance Policies to Education (135).

Also supported in IPSE results some important barriers for HAI prevention and control were identified, such as (82, 136):

- Organisational culture and values do not regard HAI as an important risk factor;
- Lack on the professional involvement at all levels;
- The inadequacy of the hospital infrastructures and trained personnel;
- Shortage of trained epidemiologists;
- Education and training especially among undergraduates;
- Neglect infections acquired in community may redound on hospital infections;
- Lack of information about the long term burden of disease may distort investment decisions;
- Lack of costing data at all levels and absence of economic evaluative studies;
- Low apparent appreciation of infection control system needs to be taken into account in contracts with multiplicity of healthcare providers;
- Absence of public health professional involvement or infection control procedures in the contract process.

Finally, after the consultation and assessment process and also based on information from all the European projects concluded till then, the European Recommendation on Patient Safety, including HAI Prevention and Control, was published in 2009, complementing the work done by WHO through the "World Alliance for Patient Safety", OECD and Council of Europe (26).

The principal recommendations on patient safety issues at Member State level were:

- Develop national policies and programmes on patient safety;
- Inform and empower patient in safety policies;
- Set-up and improve blame-free reporting and learning systems;
- Education and training of healthcare professionals about patient safety and infection control and prevention;
- Implement prevention and control at all level of healthcare institutions, establish or strengthen active surveillance systems;
- Improve the information given to patients and support research.

At European level it was important to:

- Develop common definitions and terminology, working with ECDC and WHO;
- Promote the sharing of information between Members States;
- Promoting the development and implementation of European programmes.

A set of recommendations, related specifically with HAI prevention and control, were also presented:

- Implementation of HAI prevention and control measures at national and regional level (standards and risk-based infection prevention and control measures, communication of control measures between healthcare providers; development and implementation of guidelines and recommendations at national level; use of structure and process indicators, as well the results of accreditation or certification processes in place);
- Enhance HAI prevention an control at institutional level (HAI programmes must consider organisational and structural arrangements, antimicrobial stewardship, resource requirements, surveillance objectives, training and information to patients, organisational governance for elaboration and monitoring HAI programmes, arrangements for qualified personnel to implement HAI programmes);
- Establish or strengthen active surveillance systems at national and regional level (prevalence surveys at regular intervals, accompanied with structure and process indicators, report data) and at institutional level (high quality of microbiological documentation and patients records, surveillance of incidence of target infections types and indicators of process and structure to evaluate the implementation of infection control measures; considering the use of surveillance of particular infection types and/or particular strains of healthcare-associated pathogens for timely detection of alert healthcare associated organism or clusters of healthcare associated infections).

A set of actions was established to promote these recommendations implementation:

- Designating the competent authority responsible for patient safety;
- Embedding patient safety as a priority issue in health policies;
- Development of safer and user-friendly systems, processes and tools;
- Regularly reviewing and updating safety standards and/or best practice;
- Encouraging health professional organisations to have an active role in patient safety;
- Promoting safe practices to prevent the most commonly occurring adverse events;
- Involving patient organisations in the development of patient safety policies;
- Disseminating information to patients on patient safety standards, risk, safety measures, complaint procedures and available redress;
- Establishment of reporting and learning systems;
- Encouraging patient safety education and training for all staff in healthcare settings;
- Embedding patient safety in the education or training of health professionals;
- Developing core competences, knowledge, attitudes and skills for all healthcare staff.

Table 16 presents a summary of recommendations defined for HAI prevention and control and the related implementation plan at national/regional level, and institutional level (hospitals).

Table 16 – Recommendations published by European Union in 2009 for Patient Safety, including the Healthcare-Associated Infections and actions developed by the Member States (Source: European Commission (137)).

Level	Recommendation	Actions developed
Institution (Hospital)	Enhance HAI prevention and control at healthcare institutions level	With ICC and ICT[25] legal requirements, legal requirements for HAI prevention and control issues, and a dedicated budget
	Improvement of the information provided to patients by healthcare institutions	Implementation of mechanisms to encourage healthcare institutions to provide information to patients about HAI, such as, binding regulation, professional guidelines, accreditation or certification systems
National/ Regional	Adoption and implementation of a strategy for HAI prevention and control	Definition and implementation of a national strategy for HAI prevention and control
	Implementation of prevention and control measures at national or regional level to support the containment of HAI	Implementation of national HAI prevention and control programmes, Hand Hygiene Campaigns and guidelines for hand hygiene
	Establishment or strengthen active surveillance systems	Implementation of HAI surveillance from some specific HAI (SSI, ICU, CLASBI, Multidrug-resistant bacteria), and implementation of HAI prevalence surveys
	Foster education and training of healthcare workers	Implementation of common core of competences (curriculum) for specialised training and/or education programmes for infection control staff at national level, regular training for all healthcare workers at institutional level
	Support research	Implementation of a inter-sectorial mechanism to define priorities for research in the field of infection prevention and control
	Establishment of an inter-sectorial mechanism or equivalent system	Implementation of a mechanism to coordinate the strategy for HAI prevention and control, that can be the same that coordinate the prudent use of antimicrobial agents and be linked

It was established by these recommendations that all Member States should report the Commission on the progress of the implementation by June 2011 to promote the follow-up at community level. As so, in April 2011, Member States were asked to report to the Commission on their progress in implementing the Recommendation.

In 2012 the European Commission published the report with this study conclusions (137), such as: all countries developed national policies and programmes; 25 Member States had established a competent authority responsible for patient safety at national or regional level; 15 Members States update regularly patient safety standards guidelines and accreditations procedures; adverse events information systems were totally operational in 15 Member States and partly implemented in 11 other; actions performed by greatest number of countries were "designate a competent authority responsible for patient safety" and "encourage training on

[25] ICT – Infection Control Team (executive team).

patient safety"; action performed in lowest number of countries were "embedding patient safety in the education and training of health professionals" and "dissemination of core knowledge on patient safety".

The main conclusions specifically related to HAI prevention and control were: 18 Member States consider that this strategy should be implemented at national or federal level; most of the strategies for HAI prevention and control were linked to strategies for the prudent use of antimicrobial agents; guidelines for hand hygiene are available in 22 countries and hand hygiene campaigns have been carried out in 18 countries; guidelines for HAI prevention and control in hospitals are available in 23 countries; there were legal requirements and/or professional guidelines for hospital ICC in 22 countries; In 24 Member States there are five Member States had legal requirements for a dedicated budget at hospital level; only two Member States report that they have no requirements for governance arrangements in hospitals; 26 countries had, at least, one type of surveillance network for HAI; in 13 countries there were nationally agreed common core of competences (curriculum) for specialised training and/or education programmes for infection control professionals; regarding the education of healthcare professionals other than infection control staff, 13 countries have a nationally agreed common core of competences in basic principles of hygiene and infection prevention and control and 12 countries have mandatory induction training for all healthcare professionals in healthcare institutions (regular training for all healthcare professionals in healthcare institutions is mandatory in 14 countries.; three Member States have also training for managers of healthcare institutions).

In the beginning of 2013, based on the IPSE work about core competences for infection control professionals, ECDC proposed a set of core competences with the main goal of developing a basic training strategy at European level in this area. This technical document, named "Core competences for infection control and hospital hygiene professionals in the European Union", is the result of a multi-staged process of review and update of a previous list of core competences for infection control and hospital hygiene. In this document core competences are classified in areas and domains, and proposed for two levels of expertise: Introductory and Expert. This document was published with the intent of proposing a comprehensive list of core competences that should be adopted by infection control and hospital hygiene professionals across Europe. The areas and domains are presented in Table 17 (138).

Table 17 – Areas and domains of competency in infection control and hospital hygiene (source: ECDC (138))

Area	Domain
Area 1. Programme management	Elaborating and advocating an infection control programme Management of an infection control programme, work plan and projects
Area 2. Quality improvement	Contributing to quality management Contributing to risk management Performing audits of professional practices and evaluating performance Infection control training of employees Contributing to research
Area 3. HAI Surveillance and investigation	Designing a surveillance system Managing (implementation, follow up, evaluation) a surveillance system Identifying, investigating and managing outbreaks
Area 4. Infection control activities	Elaborating infection control interventions Implementing infection control healthcare procedures Contributing to reducing antimicrobial resistance Advising appropriate laboratory testing and use of laboratory data Decontamination and sterilisation of medical devices Controlling environmental sources of infections

HAI Prevention and Control Projects

As previously stated, the European Commission was already addressing HAI/AMR and patient safety by funding several projects under the latest Health Programmes. As already mentioned, the first one was the IPSE Project (Improving Patient Safety in Europe), created in 2005 to support the European HAI surveillance and control (it aggregates within the HELICS Project); the SIMPATIE project (Safety and Improvement for Patients in Europe) was launched in 2005 (and closed in 2007) to use Europe-wide networks of organisations, experts, professionals, and other stakeholders to establish a common European set of vocabulary, indicators, internal and external instruments for improvement of safety in healthcare; the BURDEN project (Burden of Resistance and Disease in European Nations) was created in 2010 to understand the dimensions of the economic and societal consequences of AMR; and the IMPLEMENT project (Implementing Strategic Bundles for Infection Prevention & Management), was created in 2011 to provide evidence on how to decrease HAI incidence and to improve antibiotic use under routine conditions.

Within the Sixth (2002-2006) and Seventh (2007-2013) Framework Programmes for Research and Technological Development, the European Commission funded several research projects in HAI/AMR area, patient safety area and quality improvement area. In strict relation to HAI/AMR, the MOSAR project (Mastering Hospital Antimicrobial Resistance and its Spread into the Community) was launched in 2007 to better understand the transmission dynamics of resistant pathogens and study the effectiveness of interventions to reduce HAI. The TROCAR project (Translational Research on Combating Antimicrobial Resistance) was launched in 2008 with main objective to investigate the fundamentals of the

epidemiology of new highly virulent multi-resistant strains. The DEBUGIT project (Detecting and Eliminating Bacteria Using Information Technologies), was created in 2008 and focused on risk assessment and patient safety, aimed to develop a Medical Knowledge Repository, drawing on information and temporal patterns of patient harm provided through a virtual Clinical Data Repository. The PILGRIM project (Preventing Community and Nosocomial Spread and Infection with MRSA ST 398), created in 2009, aimed to promote the identification and implementation of instruments to accelerate control and integrate risk management of AMR. The PROHIBIT project (Prevention of Hospital Infections by Intervention and Training), was created in 2010 to analyse existing guidelines and practices for preventing HAI in European hospitals, to identify factors that enable or reduce compliance with best practices, and to test the effectiveness of interventions of known efficacy. In relation to patient safety area and quality improvement area several other projects were created: the QUASER project (Quality and Safety in European Union Hospitals), since 2010 to 2013, to explore the relationships between the organisational and cultural characteristics of hospitals and how these impact upon clinical effectiveness, patient safety and patient experience in EU countries; the ORCAD Project (Improving quality and safety in the hospital: the link between organisational culture, burnout, and quality of care), created in 2010 to promote the benchmarking of organisational factors that impact on healthcare professionals well being, quality of hospital care and patient safety.

Since its creation in 2004, the ECDC is the coordinator of all European HAI network (HAI-Net): in 2008 the HAI surveillance was transferred from IPSE to ECDC and since then it is responsible for the HELICS surveillance[26]; in 2010 all the surveillance systems were integrated in the TESSy system (The European Surveillance System). Based on the ECDC Strategies for Disease Specific Programmes 2010-2013, this system is responsible for the coordination of the European Antimicrobial Resistance Surveillance Network (EARS-Net)[27] (139), the European Surveillance of Antimicrobial Consumption Network (ESAC-Net, formerly ESAC)[28], HAI-Net[29] and Epidemic Intelligence Information System (EPIS)[30]. In

[26] ECDC HAISSI protocol for the surveillance of SSIs
(See http://www.ecdc.europa.eu/en/activities/surveillance/HAI/about_HAI-Net/Pages/SSI.aspx), and ECDC HAI-ICU protocol for the surveillance of HAI in ICUs.
(See http://www.ecdc.europa.eu/en/activities/surveillance/HAI/about_HAI-Net/Pages/ICU.aspx).

[27] The European Antimicrobial Resistance Surveillance Network (EARS-Net) is responsible for the data collection and analysis on AMR from national surveillance systems. The aim is to contribute to greater public awareness and scientific understanding of AMR and its importance in public health.

[28] The European Surveillance of Antimicrobial Consumption Network (ESAC-Net, formerly ESAC) is responsible for the data collection and analysis on antimicrobial consumption from Member States, both in the community and in the hospital sector. The aim is to provide timely information on antimicrobial consumption and increase public awareness.

[29] The Healthcare-Associated Infections Network (HAI-Net) is responsible for data surveillance collection and analysis of surgical site infections and HAI in intensive care units. HAI-Net is also responsible for point prevalence surveys of HAI and antimicrobial use in European acute care hospitals and prevalence surveys of HAI and antimicrobial use in European long-term care facilities. HAI-Net is also responsible for support capacity building for surveillance of Clostridium difficile infections at European level.

addition, a technical document for national point prevalence surveys of HAI and antimicrobial use in acute care hospitals[31] was developed by experts from the Member States and ECDC in 2009-2010, and was implemented in the Member States in 2011-2012 (140). Furthermore, the ECDC is supporting a project for building capacity for the surveillance of *Clostridium difficile* infections (ECDIS-Net)[32] (141). In 2010, the ECDC carried out a study to identify infection control training needs in Member States and updated the IPSE core competences for infection control supported in the "Training Infection Control in Europe" project (TRICE)[33], launched in 2006 (142). Finally, ECDC is also sponsoring the development of guidance and indicators for HAI prevention[34].

This issue was presented in more detailed in the article "Challenging healthcare-associated infections: a review of healthcare quality management issues" (See Annexes Chapter – Annexe I).

United Kingdom

Concerns with the HAI problem are not a recent issue in the UK. During the XIX Century, as mentioned previously in this chapter, nurse Florence Nightingale started to develop initial efforts to control hospital infections due to military hospitals stay. Her "Notes on Nursing", published in 1863, had a profound impact on the design and management of hospitals. During

[30] The Epidemic Intelligence Information System (EPIS) is responsible for the real-time communication platform specifically designed for secure and rapid exchange of AMR and HAI information between Member States and ECDC. See http://www.ecdc.europa.eu/en/activities/diseaseprogrammes/ARHAI/Pages/about_programme.aspx?MasterPage=1

[31] Technical document "Point prevalence survey of healthcare-associated infections and antimicrobial use in Europe acute care hospitals" was created to establish some criteria for the development of a point prevalence survey of HAI and antimicrobial use in acute care hospitals. The main objectives of this document are: to enable the estimation of the total burden (prevalence) of HAI, and antimicrobial use in acute care hospitals in EU; to describe patients, invasive procedures, infections (sites, microorganisms, including matters of AMR) and antimicrobials prescribes (compounds and indication); to disseminate results to those who need to know at local, regional, national and EU level how to raise awareness, train and enforce surveillance structure and skills, to identify common EU problems and set priorities accordingly; to evaluate the effect of strategies and guide policies for the future at local/national/regional level; to provide a standardized tool for hospitals to identify targets for quality improvement. This document is very important to systematise and standardise the surveillance process.

[32] After the recognition in 2005 of a new hyper virulent Clostridium *difficile* strain (PCR ribotype 027) in Europe, the first pan-European surveillance study, the "European Clostridium Infection Survey (ECDIS)" was performed in 2008-2009. Based on the results of the ECDIS study, it was decided to provide support for further capacity building for surveillance of CDI across Europe. To develop a European enhanced CDI surveillance protocol with case-based epidemiological data and microbiological data for typing and susceptibility testing linked at the national level. See *http://www.ecdisnet.eu/*

[33] The "Training Infection Control in Europe" project (TRICE) is an IPSE project. The main objective was to harmonise consensual core training for infection control professionals through a core curriculum that include new components such as quality and risk management, community acquired infections activities, etc. This is more one activity to the European willingness for the recognition of qualifications, launched by the Bologna process (Directive 2005/36/EC). This core curriculum is organised into three main areas: programme management, quality improvement and infection control. Each part consists of different professional tasks (16) in which 15 are common to infection control doctors and nurses. For each task were identified necessary competences.

[34] The Structure and process Indicators (SPIs) project was built on IPSE activities but ECDC continues the work to the identification of Structure and Process indicators for the evaluation of HAI control and prevention programmes. Some SPIs were integrated in the point prevalence surveys of HAI and antimicrobial use for both acute care hospitals and long term care facilities, while other indicators are developed as a function of the development of guidance for the HAI prevention and control.

this century, infections have been identified as a leading cause of death in hospitals. In 1865 Joseph Lister followed her efforts to combat hospital infections and initiated a new period in the surgery field, with the introduction of preventive measures, such as the use of acid carbolic (phenol) as antiseptic, to combat the operative wound infections.

In the beginning of the XX Century Leonard Colebrook identified healthcare professional-patient transmission as one of the major problems in the infection control and started to promote the use of protective equipment. In 1955 he suggested that every hospital should had a physician as infection control officer and promoted the implementation of an annual evaluation of infections acquired in hospitals, including result publication.

In 1959 and in the beginning of the 60s an important emphasis in HAI was noticed, caused by *Staphylococcus* because of the prevalence increase, despite the greater understanding of the measures for their control (143).

The first and second national UK HAI prevalence surveys were conducted in 1980 and 1993/94, with the overall prevalence rate of 9,2% and 9,0% respectively, but different definitions of HAI were employed not allowing direct comparisons between the two studies results. In 1999 the estimated cost to National Health Service (NHS) hospitals for people that acquire a HAI was over £1 billion a year (144, 145).

The first government guideline related with HAI was published in 1988 by the Department of Health and Social Security (DHSS) entitled "Guidance of Infection Control Standards on the Control of Infection in Hospitals" followed by other important guidelines for implementing infection control systems and surveillance policies and practices (146, 147). In 1990 the Infection Nurses Association alerted to the fact that quality assurance programmes were developed for hospitals without incorporating infection control issues (it was explained that it would required a substantial quantity of resources and that it was difficult to quantify). The King's Fund Organisation included some issues related with infection control in its accreditation model and the Royal College of Pathologists were performing Laboratory Accreditation. In 1991 two important documents were published related with patient safety and healthcare system, "Patient's Charter" and "The Health of the Nation Green Paper", which emphasised the importance of hospital infections as a quality of care indicator. The Infection Control Standards Working Party was created, responsible for the coordination of interested parties in standards development. The first set of infection control standards was published in 1993 after a long process of review and validation performed by an extensive range of interested parties (148).

In 1996, the Nosocomial Infection National Surveillance Scheme (NINSS) was created under the Public Health Laboratory Service and Department of Health recommendations, to develop

a voluntary national reporting system to promote anonymous data comparison between hospitals. The NINSS model was based on NNIS managed by CDC, USA (48, 149).

But it was not until the establishment of HAI prevention and control strategy in the UK that the NHS adequately explored this area. In 2000 the National Audit Office (NAO) published a report with the results of an audit process done to HAI management and control systems in acute NHS trusts in England: the number of deaths resulted directly from HAI was estimated in 5000 per year (9%) and the costs to NHS hospitals associated with HAI were huge (over £1 billion a year). Although the difficulty of estimating HAI costs due to all variables needed, the possibility of the cost decrease was identified (between 15% and 30%) if hospitals develop and implement HAI prevention and control systems (150).

This report, especially focused on infection control teams and infection costs, pointed relevant number of problems: lack of detailed specification within service agreements and lack of compliance with them increased the difficulty of data assessment by health authorities; the prioritisation of resources for dealing with HAI is restricted due to the absence of basic and comparable information about HAI rates; inexistence or reduced direct chief executive involvement (only 11% formally approved the HAI programme); wide variations in the ratio of infection control nurses to beds; the budgets for HAI prevention and control systems vary widely and do not include all the elements suggested by government recommendations; there were no departmental HAI control guidelines for healthcare professionals; lack of IT support was a major constraint for the effectiveness of infection control systems.

As stated, the deficit of HAI prevention and control systems effectiveness was associated with a large variety of factors: human factors (human immunity), treatment processes (use of invasive devices/procedures), organisational management (excessive occupation of wards, beds to close together, patients movement, professionals allocation), behavioural (lack of compliance with hand hygiene and cleaning measures, lack in the protective equipment use), structural (number of infrastructure, number of single rooms, number of sinks, costs), environmental (contaminated air/ground/water/surfaces) and others beyond the organisation (misuse of antibiotics) (150, 151).

Recommendations were formulated to support a new HAI prevention and control approach which included top management commitment (at national and local level); mechanisms development to promote responsiveness in HAI presence (best practices guidelines and recommendations); development of HAI indicators as quality and patient safety indicators; surveillance system improvement (with feedback for healthcare professionals); education and training promotion for healthcare professionals; prudent use of antibiotics; audit guidelines for infection control systems and more specification of service requirements agreements;

research and development; quality information to stakeholders to ensure transparency in relation to risk (reporting system) (150).

At this moment in time, the NHS management framework for HAI prevention and control, from national level to institution level, was defined as presented in the Figure 2.

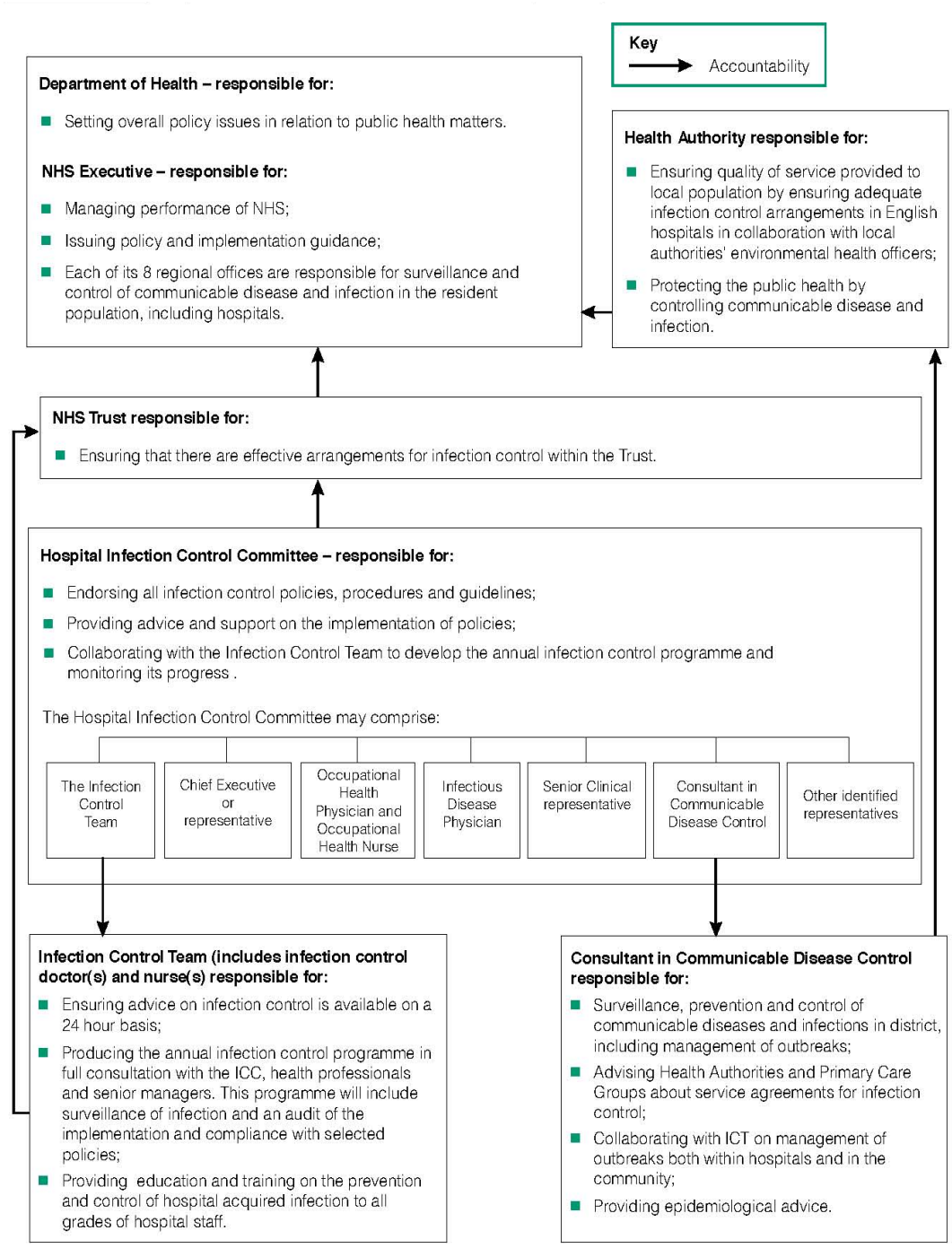

Figure 2 –NHS management framework for HAI prevention and control, UK (source: NAO (150)).

These recommendations promoted the establishment of several approaches to improve HAI prevention and control, such as: Infection control standards produced since 1999; Standards

for environmental cleanliness published since 2000; Antimicrobial resistance strategy launched in 2000; reporting systems mandatory for infections caused by *Staphylococcus aureus* (MRSA) since 2001 with plans to include other infections resistant to antibiotics; Standards for National Cleanliness, including the Hand Hygiene Project "cleanyourhands" designed to improve hand hygiene (since 2002); Guidelines for the prevention of HAI produced by National Institute for Health and Care Excellence (NICE) since 2003; Guidelines for effective decontamination of medical devices created in 2000 by DH and review and improved in 2003 by the Medicine and Healthcare Products Regulatory Agency; incorporation in 2003 of two hospital performance indicators related with HAI management in the system "Star Rating" for NHS hospitals; the introduction of the concept "Modern Matrons" at hospital wards to promote the application of high standards for infection control and cleaning / hygiene (since 2001). The patient involvement in HAI control was also promoted with the creation of Patient Environment Action Teams with patient representatives, responsible for assessing hospitals cleanliness from a patient perspective (152-158).

One of the most important approaches was established in 2002 when the DH published the infection control strategy for NHS, named "Getting Ahead of the Curve: A strategy for combating infectious diseases", supported by an action plan to create a modern system to prevent, study and control infection diseases. According to this document it was of importance to create a new national Infection Control and Health Protection Agency that could integrate health protection functions at national, regional and local level; a local health protection service (working with the national agency) and a national consult expert panel. At more operational level several other issues were considered: to strength and expand the infectious disease system surveillance; development of action plans to address infectious disease priorities; development of strategies to minimise the antimicrobials use; rationalisation of microbiology laboratories and introduction of standards; a microbiology inspection system; promotion of the public reporting; stronger professional education and training programmes, research and innovation programmes, and the revision of the law (159).

Independently of all these measures, it was found that the degree of improvement was small, and that in some hospitals the HAI rates increased (especially in surgical wound infections, associated with hip replacement). In 2003 the report from the Chief Medical Officer called "Winning Ways: Working Together to Reduce Healthcare Associated Infection in England" stressed the need to change at many different levels such as the importance of quality improvement activities to promote the right culture within local NHS organisations; ensuring the leadership; promoting HAI as an indicator of quality and patient safety; and assuring high quality of information. New "must do" actions were introduced to promote active surveillance

and research, reducing infection risk with invasive procedures and devices, reducing reservoirs of infections, promote high standards of hygiene in clinical practice, prudent use of antibiotics and organisation management.

Active surveillance and research was established: the mandatory surveillance system for HAI (including bloodstream infections with MRSA and other pathogens, surgical site infections, *Clostridium difficile* associated diseases, serious incidents associated with infections and infections after discharge from hospital); application, in each NHS organisation, of risk analysis tools such as "root cause analysis" (RCA) and "Hazard Analysis and Critical Control Point" (HACCP), in the HAI prevention and control, the coordination promotion between the new Inspector of Microbiology and the reference laboratories to ensure the useful information timely; available comparative data associated with HAI and AMR for clinical teams, public reporting of HAI rates for each country area in the web site of the Chief Medical Officer; a national audit to deaths associated with HAI to identify avoidable factors; reporting of serious outbreaks of infection to Health Protection Agency (HPA)so that it can advice and support for management and control of incident.

Related with invasive procedures and devices clinical recommendations and procedures were introduced for the decontamination and reprocess of instruments and other clinical devices. For reducing reservoirs of infections other measures were established, such as the appropriate provision of isolation facilities, better bed management, inclusion of infection control staff in advisory teams for rebuilding and refurbishing, cleaning and disinfecting programmes to ensure adequate hygiene and cleanliness, pest control and waste disposal and treatment.

Regarding the promotion of higher standards of hygiene in clinical practice, it was established the importance of demonstrating consistently high levels of compliance with hand washing and hand disinfection protocols and the adequate use of protective personal equipment.

For the prudent use of antibiotics, the use of narrow spectrum antibiotics instead of broad-spectrum groups was defined, including the recommendation that should only used for prevention of infection where benefit has been proven.

Within relation to organisation management, a report chain within the organisation was established, as well as the designation of an infection prevention and control coordinator with authority to change inappropriate clinical practices and antibiotic prescribing decisions, to be a integral member of the organisation clinical governance and patient safety teams, assess the impact of existing and new policies, produce and publish an annual report on the state of HAI.

All these recommendations were supported by technical guidelines, standards and other government documents, and got the support of public entities, such as strategic health authorities (the National Patient Safety Agency, Patient Advice and Liaison Services, Royal

Colleges and professional regulatory Bodies, Clinical Governance Support Team, the Modernisation Agency, the new Inspector of Microbiology, and the Health Protection Agency) (6).

In 2004, the DH confirmed that 300 000 cases of HAI per year was the best estimate number and a report published by NAO presented some conclusions about the measures implementation degree and their results. It concluded that some progress was achieved at trust level concerning with the implementation system/process and with the infection control teams strengthening but there were limited progress in the improvement of: isolation facilities or reduce bed occupancy rates, cleanliness and compliance with good hand hygiene, the quality in the acquisition of robust data on MRSA bloodstream infections (with mandatory surveillance since 2001), and of information about HAI extent and cost. This report also alerted to one of the major HAI control problems, the staff behaviour, data availability and quality, (limited) progress in the implementation of national mandatory surveillance programmes, (lack of) evidence of the impact of different interventions strategies in the HAI prevention and control (153).

Following this report, a target was introduced to reduce the MRSA bloodstream infections across all NHS hospitals by 50% by 2008. The approach proposed by DH to achieve this result was a combination of financial incentives, close performance management and support to institutions.

Several other programmes and documents were developed to support this commitment: establishment of a Programme Broad to provide leadership and direction to reduce HAI rates; publication of guidelines, such as the "Towards cleaner hospitals and lower rates infections", new legislation and inspection regulations (Health act 2006 - Code of Practice for the Prevention and Control of Healthcare Associated Infections) and new mandatory surveillance programmes (such as the *C. difficile*) (155-157, 160, 161).

At this time the NHS roles and responsibilities for HAI prevention and control, from national level to institution level, were defined as presented in the Figure 3.

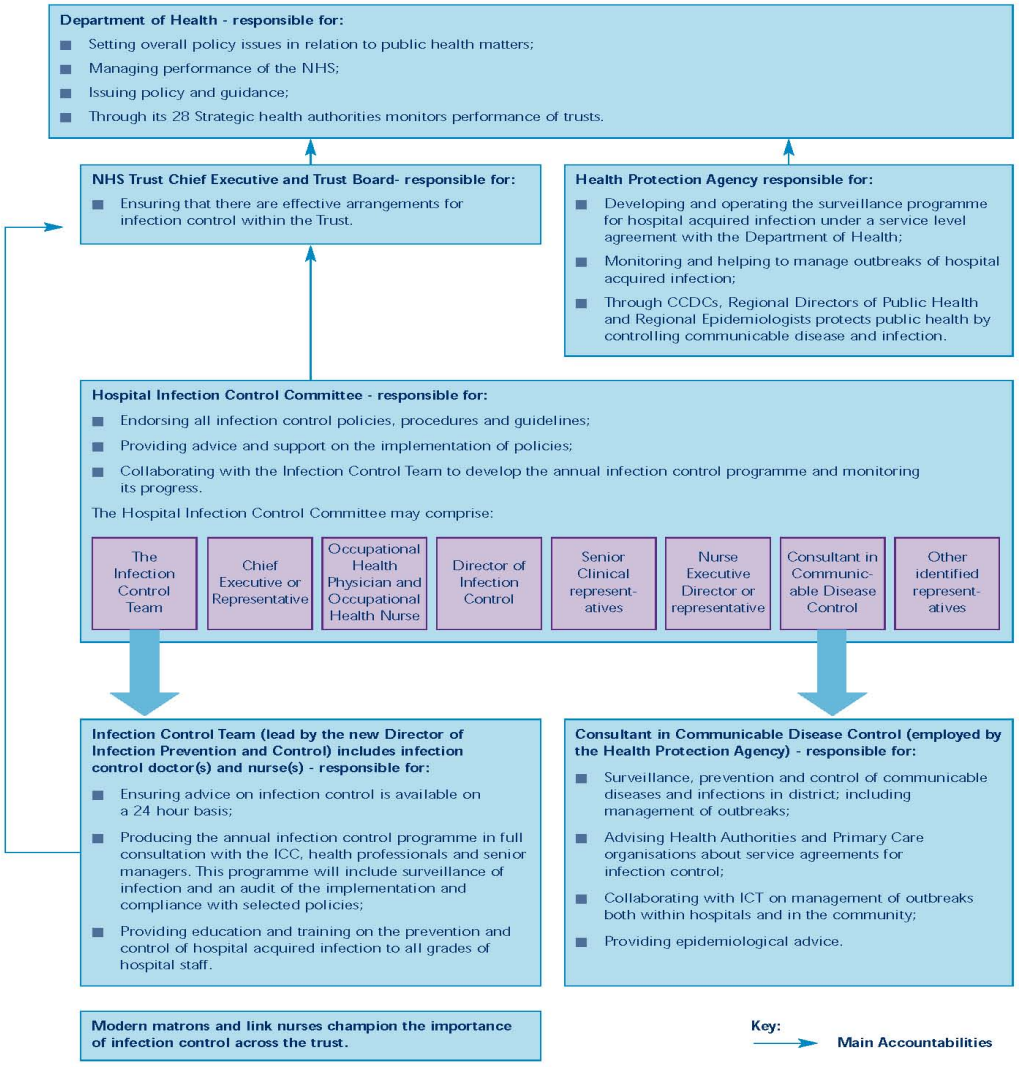

Figure 3 - NHS management framework for HAI prevention and control, from national level to institution level (Source: NAO (153)).

In 2006 the third HAI prevalence survey was carried out in the UK, including 190 acute hospitals. Results showed that the HAI prevalence in England was 8,2% compared with 7,6% for the UK and Ireland collectively (different definitions of HAI were employed not allowing direct comparisons between the three studies results). The most common types of infections were gastrointestinal system infections (22,0%), urinary tract infections (19,7%), pneumonia (13,9%), and surgical site infections (13,8%). MRSA prevalence was established as 1,28%, with MRSA being the causative organism in 15,5% of all HAI (145).

In 2008 the reduction in number of MRSA bloodstream infections reached 57% against the expected 50% and the reduction of *C.difficile* infections was 41% against the expected 30% in 2010-2011. An investment of £120 million promoted the reduction of treatment cost between £141 million and £263 million as well as a general reduction of the discomfort, disability and probable death caused by HAI (82).

Based on previous reports, one of the principal barriers for effective HAI prevention and control systems was identified as being the organisational culture. To minimise this barrier, in 2008 the HCAI and Cleanliness Service from DH developed a guide to help healthcare organisations to promote and embedding a culture of quality and safety, capable to promote the effectiveness of HAI prevention and control systems. As mentioned in that document: "sustainable change in the culture of the trust will occur only if its staff change their mindset" (162, p.7). This guide states that, to ensure board-to-ward culture, it is necessary to: establish a clear vision; provide effective leadership; ensure competence and measure compliance; communicate clear accountability (and escalation policies); implement an assurance framework; learn from others, both inside and outside the organisation.

In 2009 NAO published another report with the main objective to analyse and compare the UK HAI control systems strategy with others countries, and based on the initiatives set out by the NHS department: how the resources were invested, barriers to improving HAI prevention and control and data comparable on HAI extent. The results pointed that good governance is the central issue to infection control systems and antibiotic stewardship. Other conclusions were found to promote the infection control system effectiveness: audit at local and national levels should be used to ensured best practices; well designed and repeated prevalence studies to promote the HAI management effectiveness; the "Search and Destroy"[35] policy is probably best suit to countries that have low rates, as it requires a robust infection control facility; the importance to include root analysis and statistical control (and others methods) in the study of HAI prevention and control systems; to improve the surveillance programmes as an useful research resource; existence of new fast testing technologies to improve HAI prevention and control but not eliminating the need for HAI control programmes; the use of invasive procedures and devices are strongly linked to high infection rates; the monitoring of the antimicrobial stewardship should continue to be high priority and must be cross over the AMR surveillance and HAI rates; the contracts for cleaning must be specific to each area; training and employing epidemiologists and increase the infection control competences for the healthcare professionals; the importance of adjusting funds to infection prevention and control systems needs; development of costs studies and economic evaluations for HAI prevention and control interventions and to improve antimicrobial stewardship (82, 163).

In 2009, the roles and responsibilities of NHS different bodies for HAI prevention and control, from national level to institution level, were defined as presented in the Figure 4.

[35] The "Search and Destroy" strategy was developed by The Netherlands Government to promote the effectiveness of HAI prevention control systems in healthcare services. This strategy is supported by a robust screening to identify colonised or infected persons, isolation and eradication treatment.

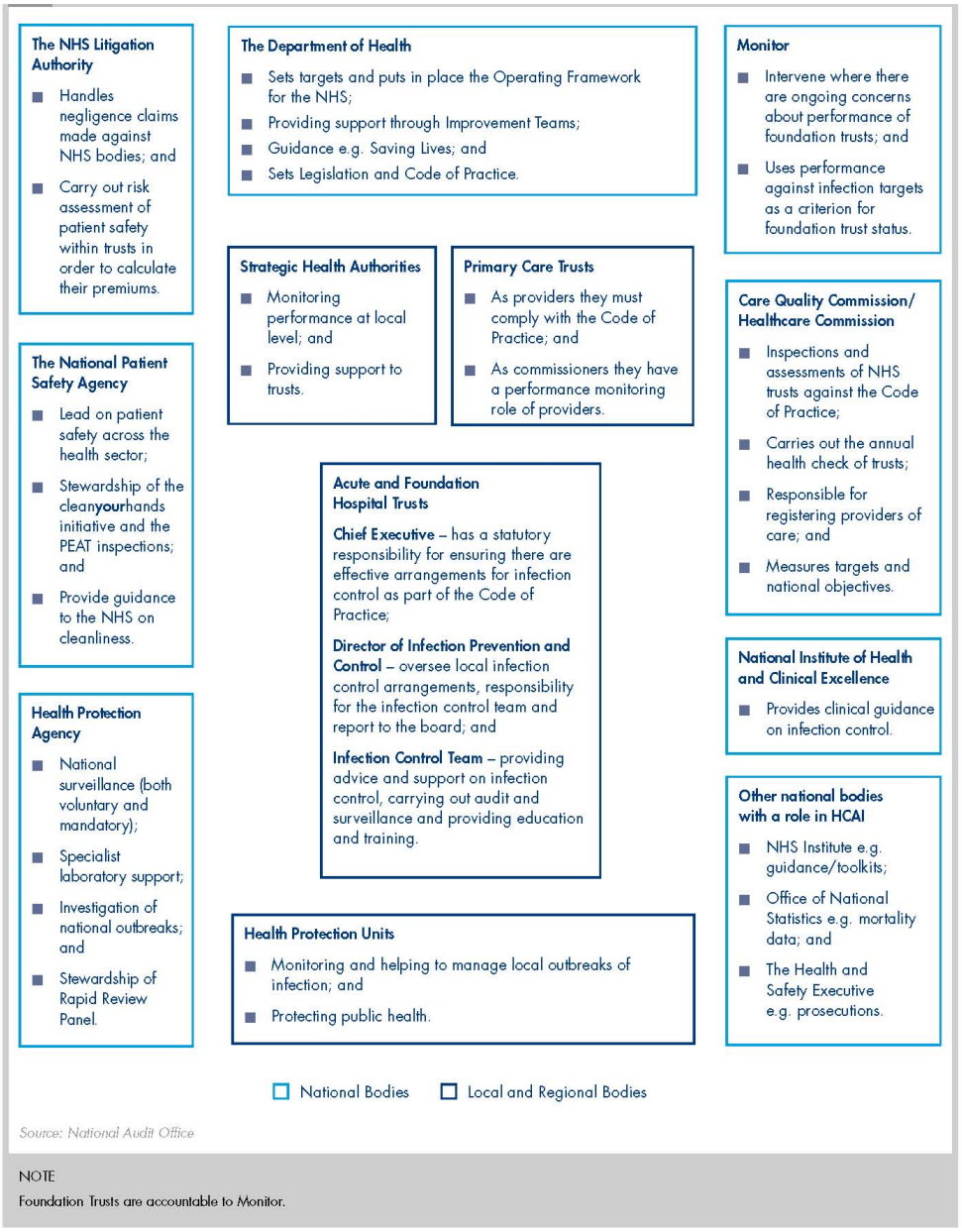

Figure 4 – NHS-UK entities roles and responsibilities related with HAI prevention and control, from national level to hospital level (Source: NAO (163)).

In 2010 the Health and Social Care Act 2008 was published, as a code of good practice on the prevention and control of infections and related guidance to help providers of healthcare and social care to implement their infection control systems. It included criteria from Care Quality Commission[36] (CQC), to take into account when assessing compliance with registration requirement on cleanliness and infection control. This was considered necessary to ensure that adequate management and organisational processes are implemented and, as a consequence, the highest standards of infection prevention and control could be set up and maintained (161).

[36] The Care Quality Commission is the independent regulator of health and adult social care services in England.

After 2009 NAO report, four issues, that needed to be tackled at all levels (national, regional and hospital level) to improve HAI prevention and control systems and reduce HAI rates, were identified: promote continuous improvement culture; promote a whole-system approach, with structures their roles and responsibilities well defined; ensure healthcare professionals compliance with HAI prevention and control best practices; and promote monitoring and record hospital prescriptions and the use of antibiotics.

As a consequence of this report and other national documents (82, 163), NICE and HPA developed a quality improvement guide, defining eleven quality improvement statements related with management issues necessary to promote better HAI prevention and control (164). The principal aim was to help top management to develop and implement a system that could promote HAI prevention and control practices evaluation, could assist the identification of areas for quality improvement, could monitor progress, and provide leadership and support for infection control teams and other healthcare professionals. These statements are presented in Table 18.

Table 18 – Statements from quality improvement guide developed by NICE and HPA (Source: NICE and HPA (164)).

Statement	Content
Quality improvement statement 1: Board-level leadership to prevent HAI	Trust boards demonstrate leadership in infection prevention and control to ensure a culture of continuous quality improvement and to minimise risk to patients.
Quality improvement statement 2: Be a learning organisation	Trusts use information from a range of sources to inform and drive continuous quality improvement to minimise risk from infection.
Quality improvement statement 3: HAI surveillance	Trusts have a surveillance system in place to routinely gather data and to carry out mandatory monitoring of HAI and other infections of local relevance to inform the local response to HAI.
Quality improvement statement 4: Workforce capacity and capability	Trusts prioritise the need for a skilled, knowledgeable and healthy workforce that delivers continuous quality improvement to minimise the risk from infections. This includes support staff, volunteers, agency/locum staff and those employed by contractors.
Quality improvement statement 5: Environmental cleanliness	Trusts ensure that standards of environmental cleanliness are maintained and improved beyond current national guidance.
Quality improvement statement 6: Multi-agency working to reduce HAI	Trusts work proactively in multi-agency collaborations with other local health and social care providers to reduce risk from infection.
Quality improvement statement 7: Communication	Trusts ensure there is clear communication with all staff, patients and carers throughout the care pathway about HAI, infection risks and how to prevent HAI, to reduce harm from infection.
Quality improvement statement 8: Admission, discharge and transfer	Trusts have a multi-agency patient admission, discharge and transfer policy, which gives clear, relevant guidance to local health, and social care providers on the critical steps to take to minimise harm from infection.
Quality improvement statement 9: Patient and public involvement	Trusts use input from local patient and public experience for continuous quality improvement to minimise harm from HAI.
Quality improvement statement 10: Trust estate management	Trusts consider infection prevention and control when procuring, commissioning, planning, designing and completing new and refurbished hospital services and facilities (and during subsequent routine maintenance).
Quality improvement statement 11: New technology and innovation	Trusts regularly review evidence-based assessments of new technology and other innovations to minimise harm from HAI and AMR.

Each statement was supported on information and examples that helped managers to better understand and to monitor related achievements. There was also some information about the type of evidence of achievement, interactions with legal/regulation framework and national indicators. The 1000 Lives Plus project also developed some guidelines to promote quality improvement in Healthcare (165, 166).

The Netherlands

In 1959, participants on the national symposium "Cross Infections in Hospitals" started to discuss the hospital infections caused by *Staphylococcus* with the hygiene and cleanliness problems. After this first approach to the problem and following several suggestions from university researchers, the government created the Committee of the National Health Council. The main task for this committee was to develop guidelines for HAI prevention and control. In 1976 the committee launched the first set of guidelines and recommendations named "Advice on revised guidelines for prevention and control of nosocomial infections".

In 1981, the Working Party on Infection Prevention (WIP) was founded to stimulate infection prevention and control in The Netherlands. The main aim of this national governmental body was to develop guidelines that cover a wide range of topics, including general personal hygiene, disinfection, sterilisation and prudent use of medical devices. These guidelines are still published in the Internet and are the basis of local guidelines developed by the Hospital Hygiene and Infection Prevention Department, at hospital level. There is also the Dutch Health Care Inspectorate at national level, which is responsible for auditing hospitals with respect to Hospital Hygiene and Infection Prevention organisation, reporting outcomes and publishing improvement recommendations at national level. At hospital level a Hospital Infection Prevention Committee was created, composed by infection control practitioner, medical microbiologist, medical staff from the ICU, nursing staff, hospital pharmacist, a consultant on endoscopy, a consultant on sterile aids and an occupational health specialist. A National Network for Prevention of Nosocomial Infections by Surveillance, was created with the collaboration between participating hospitals, the Dutch Institute for Healthcare Improvement and the National Institute for Public Health and Environment. Associated with HAI Prevention and Control system, the Working Party on Antibiotic Policy was created, being responsible for guidelines publication for prudent antibiotic stewardship (49).

The "Search and Destroy" strategy was developed by The Netherlands Government in 1988 to promote the effectiveness of HAI prevention control systems in healthcare services, especially to combat MRSA infections. This strategy is supported by a robust screening to identify colonised or infected persons, isolation and eradication treatment (49, 167, 168).

The importance of MRSA control and elimination is supported by the following set of reasons: once in an institution, MRSA is nearly impossible to eradicate; MRSA is at least as virulent as its Methicillin sensitive equivalent (MSSA); MRSA adds to the existing rate of *S. aureus* infections (more severe and expensive); the environmental contamination and survival promote endemic settlement; sick patient are vulnerable to persistent colonisation and infection.

The national strategy, developed and implemented in The Netherlands, has shown that it was possible to suppress and prevent MRSA to become endemic in the hospitals, and that this could also prevent the spread of other infections in the hospitals. The WIP published, since 1995, guidelines for the containment of MRSA that supported the "Search and Destroy" strategy, based on effective measures such as the implementation of isolation precautions methodologies, screening methodologies (patients and healthcare professionals), hygiene and cleaning methodologies and antimicrobial methodologies (47, 50).

Portugal

It seems that the first information about HAI was published in 1930 but no related documented information is available. Following the *Resolution (72) 31–sur l'hygiene Hospitalière,* published by the Council of Europe in 1972, Portugal published normative information from the General-Directorate of Hospitals in 1979. This document was sent to all hospitals and aimed to inform about the European Council Resolution and to get some information through a questionnaire about: 1) if the hospitals had Infection Control Committees (ICC); 2) studies in infection control area; 3) healthcare professionals awareness about infection control (169). Since this first European initiative and supported by the international evolution of related recommendations, as well as legal and statutory regulations from relevant international organisations, Portuguese healthcare organisations became more aware and sporadic related movements started at hospital level in relation to HAI prevention and control.

In 1986, the General Directorate of Hospitals published another recommendation from the European Council, Recommendation Nº R (84) 20 of the Committee of Ministers to Member States on the Prevention of Hospital Infections. At this time there was no legal regulation in Portugal about this subject (170).

Regardless of the importance of ICC development and implementation, as recommended by the 1972 Recommendation of the European Council, and communicated by normative information to all hospitals, it was not before 1993 that the Portuguese General Directorate of Hospitals decided to focus again on this issue, through another normative information to all

hospitals. This normative aimed to reinforce the previous European recommendations (prevention and control of HAI, education/training and ICC implementation) and to identify the Portuguese legislation/regulation that support those recommendations (General Regulation for hospitals – Decree - law nº 48358 from 27/04/1968 and Hospital Statute - Decree-law nº 48357 from 27/04/1968). Afterwards other recommendations for HAI prevention and control were created, such as the Directorate-General of Health (DGH) recommendation in 1996, which determined the development and implementation of ICC across all NHS hospitals, public and private, set ICC as top management advisor of technical issues, determined the resources provision and established the ICC composition, roles and responsibilities (171, 172).

The first comprehensive step to develop a national programme for HAI prevention and control was the creation of the Infection Control Project (initially under the State Administration Secretariat and subsequently under the Institute of Informatics and Financial Management of Health) in 1988. In 1999 this project was transformed in the National Programme for the Prevention and Control of HAI, through a legal document from DGH (in 2000 it was transferred to the National Health Institute, Dr. Ricardo Jorge and in 2006 it was transferred again to the DGH - Department of Clinical Quality Services). This document established the coordinator group and main objectives for programme implementation; develop a record network for Infection (as recommended by Decision nº2119/98/EC of 24/09/1998 from European Council); defined quality indicators for structures and processes, development of best practices, procedures and guidelines, education and training for healthcare professionals (173-175).

This programme, as a strategic document, was translated into practice in 2002 with the publication, in Portuguese language, of the WHO Practical Guide for HAI Prevention (176).

Since then, additional national recommendations were developed, mainly by adopting/adapting some CDC recommendations, such as: the prevention and control of surgical site infections, the prevention of ventilator-associated pneumonia infections, the central line-associated bloodstream infections prevention; isolation precautions; environment cleanliness and control; hand hygiene; surveillance systems; and reprocessing in endoscopy (177).

In 2005 Portugal started its Public Administration Reform and the programme coordination was transferred to the Division of Clinical Quality Services from the DGH. According to the strategic plan for health system (the National Health Plan (NHP) 2004-2010) it was clearly necessary to reformulate and readjust the existing programme for HAI prevention and control.

With this purpose, a working group was created to design the programme in accordance with lessons learned and work done by ICC till then (178, 179).

Between 2007 and 2008 the new National Programme for HAI Prevention and Control (NPIPC) was developed and approved by the Ministry of Health and, based on international orientations, the ICC coordinator group was created at regional level and the ICC at organisational level was restructured and implemented (180-187).

This programme considered four strategic action lines: the organisation management; the individual and organisational development; the HAI record and monitoring; and the communication and reporting. The aim of this national programme was to promote better knowledge about HAI in Portugal and a long-term incidence decrease, contributing to patient safety. It was also stipulated the creation of a HAI National Record System.

The Portuguese NHS roles and responsibilities for HAI prevention and control are presented in the following figures: at regional level (Figure 5) and national level (Figure 6).

REGIONAL LEVEL

Regional Health Administrations

Are responsible for:

- Promote the collaboration and institutional communication between Hospitals, Primary Care providers and Continuous Integrated Care providers in order to promote HAI prevention and control;
- Joint efforts, available resources and knowledge to meet needs and enforce policies to promote clinical safety and improve quality of care.

Coordinator Groups

Are responsible for:

- Collaborate in the implementation of actions proposed and its dissemination to healthcare organisations;
- Propose recommendations for HAI prevention and control and monitoring its application;
- Develop and propose epidemiological surveillance studies, and providing feedback appropriate and timely;
- Collaborate in the use of antibiotics policy, based on surveillance data;
- Collaborate in the definition of strategic policy for cleanliness, hygiene and sterilisation in healthcare organisations as a way to standardize procedures and improve the quality of care;
- Promote the establishment and implementation of reporting systems for HAI, within and between healthcare organisations in each region;
- Promote the outbreak research, conducting epidemiological surveys and results dissemination in healthcare organisations;
- Propose and implement training programmes with the NPIPC coordinator group;
- Implement an evaluation / monitoring system.

Figure 5 – Portuguese NHS management framework for HAI prevention and control, at regional level.

At hospital level, each hospital should develop an internal HAI prevention and control programme based on guidelines presented by National Infection Control Programme coordinator. This internal programme should be designed and implemented according to four fundamental dimensions: epidemiologic surveillance, standards and recommendations production, training and education and continuous audit programme (186).

NATIONAL LEVEL

Ministry of Health
Is responsible for set targets and design the Strategy and Policy for NHS and set legislation and regulation.

Regulatory Authority of Health (RAH)
is an independent organisation, subject to Ministry of Health supervision, responsible for the supervision and regulation of health sector in accordance with the law and status.

National Health Institute, Dr. Ricardo Jorge
Is an independent organisation, subject to Ministry of Health supervision, and responsible for:
- Collaborate wit DGH in Epidemiologic Surveillance Programmes (e.g. HAI and AMR programmes);
- Evaluate the execution and results of National Health Plan and National programmes promoted by DGH.

Directorate-General of Health (DGH) Through the Department of Quality in Health the DGH is responsible for:
- Coordinate at National level:
  - Health Programmes, such as, National Programme for Infection Prevention and Control, National Programme for Prevention of Antimicrobial Resistance and National Programme for Accreditation in Healthcare;
  - National HAI record network;
  - The Epidemiologic Surveillance System and ensure the national participation in the EARS-Net;
- Promote education and training programmes for ICC professionals;
- Develop HAI prevention and control guidelines;
- Production and dissemination of statistical information;
- Develop and execute the National Health Plan;
- Support healthcare services about HAI prevention and control and Patient Safety.

Central Administration of Health Systems
Is responsible for ensure, through the Shared Services of the Ministry of Health, the adequate information and communication technology systems to promote HAI prevention and control systems (e.g. Surgery saves lives toolkit).

Inspectorate- General of Health Activities (IGHA)
Is responsible for audit, inspection, supervision and development of disciplinary action to ensure compliance with law and high levels of technical performance in all healthcare activities (e.g. responsible for evaluate the hospital compliance with the National Programme for infection Prevention and Control).

Health Professional Associations and other Health Organisations
Are responsible for:
- Collaborate with DGH in the development of guidelines and recommendations for clinical practice, including medication prescription;
- Development of Curricula for healthcare professional courses (undergraduate and graduate);
- Promotion of Education and Training Programmes for healthcare professionals;
- Promotion of Research, Development and Innovation.

Figure 6 – Portuguese NHS roles and responsibilities for HAI prevention and control, at national level.

The national management framework for the Programme for HAI Prevention and Control is presented in the Figure 7.

Based on these recommendations, in 2007 a set of infection control objectives, targets and indicators was established (e.g. by Regional Health Administration – North) to be included in the hospital contracting process. These objectives were focused on process goals and materialised in four objectives associated with different dimensions (Table 19). Regardless of all the advantages that this measure could bring to HAI prevention and control system (financial incentives), it was eliminated from hospital contracting process in 2011.

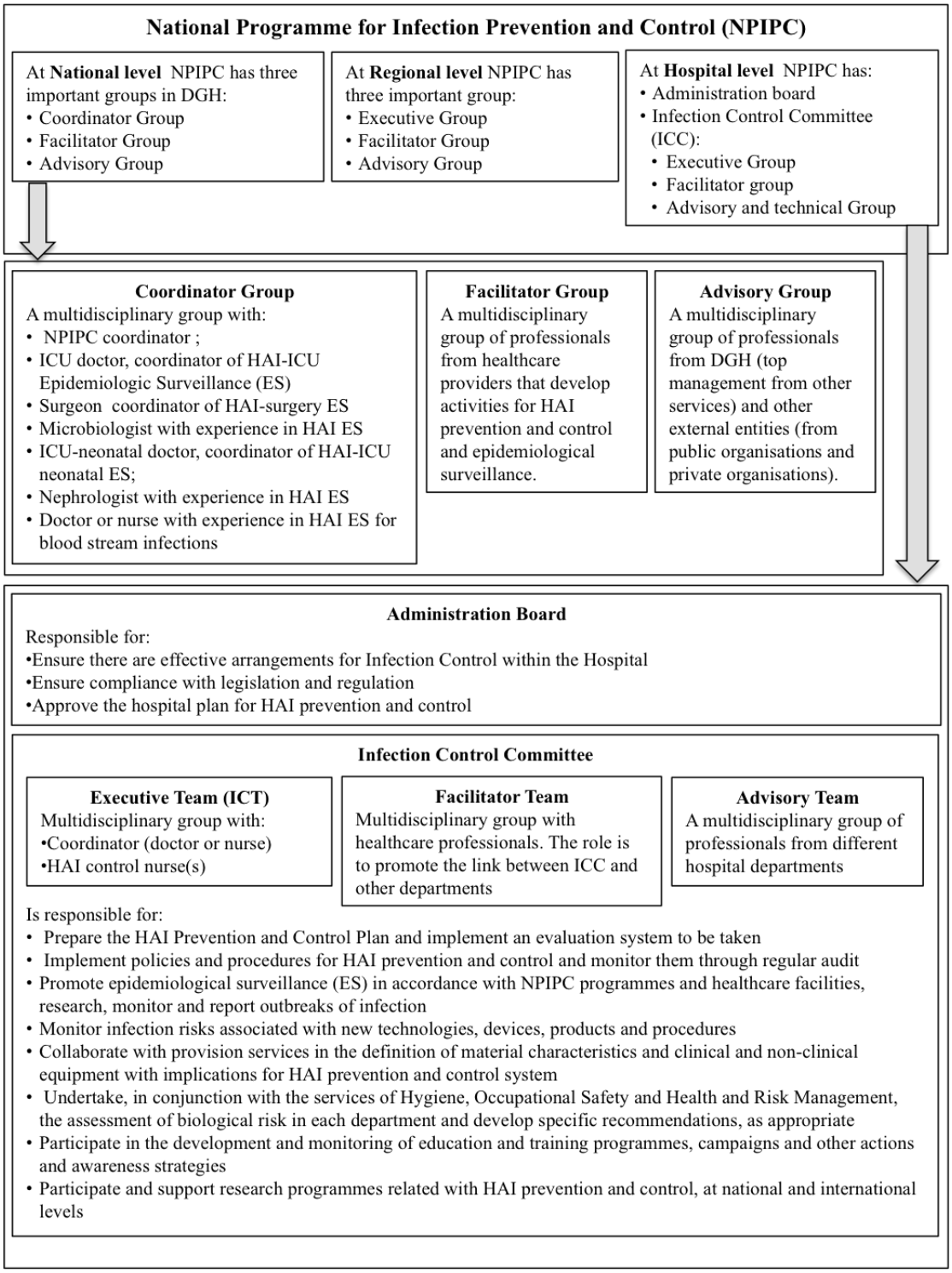

Figure 7 - Portuguese management framework for the National Programme for Infection Prevention and Control (NPIPC).

Table 19 – HAI prevention and control objectives established by Regional Health Administration – North for hospital contracting process (Source: Ministry of Health (188)).

Objective	Content	Indicator	Instrument
- Existence of any formal communication mechanism between the Microbiology services and ICC to report information about microorganisms problem	- Definition and detection of microorganisms problem (or multi-resistant nosocomial transmission) in microbiology laboratory; - Daily communication between the laboratory and ICC, about microorganisms problem; - Implementation of basic precautions or based on basic transmission (contact, droplet or particle) in colonised / infected patients with this type of microorganisms (this involves professionals training and physical structures).	- Binomial variable YES/NO	List of microorganisms that laboratory microbiology considers as "Microorganism Problem" and Ecology Hospital Report
- Adherence to at least one of the existing epidemiological surveillance programmes from NPIPC or other epidemiologic surveillance programme considered relevant to the institution	- National infection Control Surveillance programme provides: - HELICS Prevalence (2 surveys with at least 3 months difference); - HELICS Surgery; - HELICS ICU; - Surveillance of Nosocomial Bloodstream Infection; - Surveillance Neonatology; - Surveillance Dialysis; - Other surveillances: - Infection of the bloodstream associated with central venous catheter; - Ventilator-associated respiratory infection; - Urinary tract infection associated with indwelling catheters.	- Binomial variable YES/NO	Epidemiologic reports of periodic surveillance
- Conduct at least four annual meetings of the ICC and promote training	- Conduct at least four annual meetings of the ICC; - Conducting training with the following characteristics: - encompass the following professionals: doctors, nurses, medical assistants, health diagnosis technicians and treatment technicians; - covering at least 10% of professionals, with representativeness on professional groups; - with, among others, the following topics: Universal Precautions; Hand Hygiene; Surveillance process; Microorganisms Problem and Isolation Procedures.	- Binomial variable YES/NO - Fully realised / partially realised/ not performed	Meeting Report Training programmes
- Structure information system capable of measuring and following outcome indicators	- Consumption of alcohol solution for hands disinfection; - Re-hospitalization for HAI; - Prevalence and incidence of MRSA, *Acinetobacter baumannii* multiresistant and *Pseudomonas aeruginosa* multiresistant; - Consumption of vancomycin, linezolid and carbapenems.	- Number of litres per 1000 hospital days; - Number of rehospitalisation for HAI; - Denominators: for total isolates same species (per 1000 hospital days); - Denominators: for the total consumption of antibiotics, per 1000 hospital days.	Hospital Report

As recommended by international community, developments in prevention of antimicrobial resistance were also promoted, namely with the creation of the coordination group for the

prevention of AMR, responsible for the coordination of the National Programme for Prevention of Antimicrobial Resistance development, approved and published in 2009 (189, 190). This issue had a new development in 2011 when the government recommended, to Portuguese NHS providers, the implementation of antimicrobial committees for promotion of National Antimicrobial Resistance Programme and the adequate use of some antibiotics, such as Ampicillin, Amoxicillin and Amoxicillin/Clavulanic acid (191-193).

The national management framework for the National Programme for the Prevention of Antimicrobial Resistance is presented in the Figure 8. This framework was valid till February 2013. Since then, NPIPC and the National Programme for the Prevention of Antimicrobial Resistance have been merged.

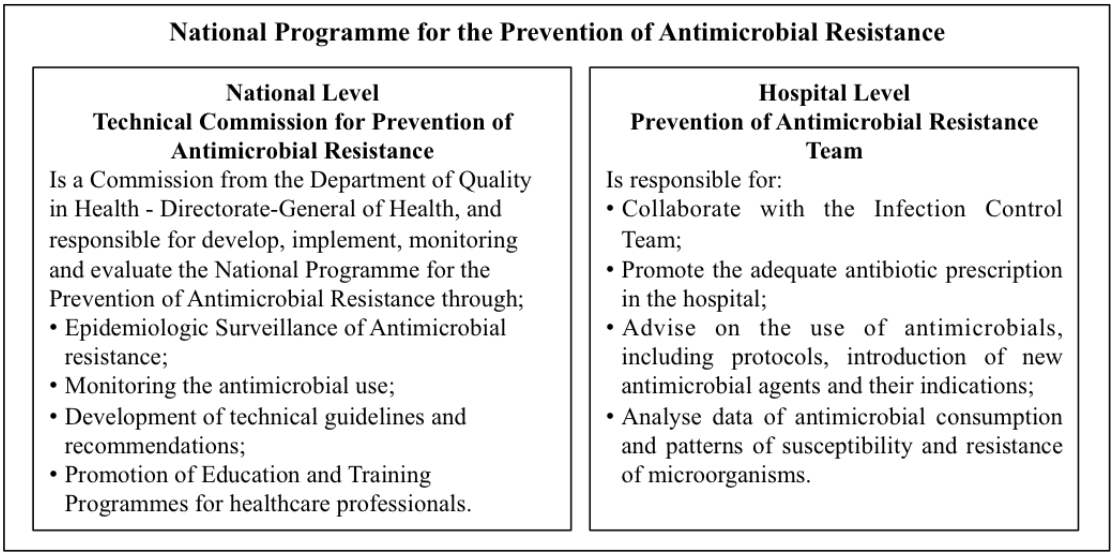

Figure 8 – Portuguese management framework for the National Programme for Prevention of Antimicrobial Resistance.

In 2013, additional government documentation was published, to promote the revitalisation of the Epidemiological Surveillance System for Antimicrobial Resistance and establishing the mandatory notification in two levels: "microorganisms alert" with immediate notification and "microorganisms' problem" on quarterly basis[37]. DGH and the National Health Institute - Dr. Ricardo Jorge, are the responsible entities for the coordination and evaluation of the established system (192, 194). More changes are expected due to new strategies at national level: the fusion of National Programme for Prevention of AMR with National Programme for HAI Prevention and Control (194); and the promotion of closer ties between the infection prevention and control system and quality system at hospital levels (inclusion of infection prevention and control into the National Strategy for Quality in Health) (195).

[37] The criteria used to define these microorganisms were based on the recommendations of EUCAST (European Committee on Antimicrobial Susceptibility Testing).

Projects developed in Portugal

In accordance to the international campaign for hand hygiene, supported by the First Challenge from World Alliance for Patient Safety "Clean Care is a Safer Care", Portugal joined this campaign by the end of 2008, through the national strategy for the improvement of hand hygiene. In 2009, 91 hospitals had registered a hand hygiene adherence rate over 50%. The report published in 2011 concluded that hand hygiene adherence rate increased from 46% (diagnosis rate, before the implementation of the campaign) to 65% (after the implementation of the campaign). A more detail analysis showed that this adherence rate increase was verified in all healthcare professionals between the two evaluations, but the medical personnel were among the healthcare professionals with lower adherence rate. Analysing the "five moments" programme introduced by the WHO, moments with higher adherence rate were those that protected healthcare professionals and the environment (after the risk of exposure to blood and body fluids and after contact with the patient) and the moments with less adherence were those more directly related with the patient safety ("before patient contact" and "before clean or aseptic procedures"). In accordance to these conclusions, it was proposed a national main target of 75% for adherence rate (the target proposed by WHO was 90% till 2013). In 2010, 78 hospitals participated in the campaign and the national adherence was 64%, lower than the 65% verified in 2009. It could be verified that all healthcare professionals had lower adherence rates when compared with the results from 2009 (but all above the 50%) and the medical personnel was, again, among the healthcare professionals with lower adherence. It was also important to verify that, according with the European Antimicrobial Resistance Surveillance System (EARSS), in 2009 Portugal decreased by 4% the MRSA rate (in 2008 Portugal was one of the two European countries with MRSA rates above 50%) (196-198).

The Second Challenge launched by World Alliance for Patient Safety, "Safe Surgery Saves Lives", had also repercussions in Portugal. In 2010 the DGH, published a set of normative/technical documentation based on WHO recommendations for the implementation of "Safe Surgery Saves Lives" project in all NHS operating rooms. This documentation included the "Checklist Surgical Safety" (available in hospital intranet), recommendation and guidelines. This normative was mandatory and time framed for implementation by September 2010 (199-204). Due to the reduced compliance rate verified in hospitals, DGH decided to promote its revitalisation in 2013 by a normative document that emphasises the importance to implement the project "Safe Surgery Saves Lives" according to the manual, "WHO Guidelines for Safe Surgery 2009". This document specifies the mandatory application of these recommendations in all NHS operating rooms and in all healthcare organisations contracted by the State. These recommendations are considered the minimum standard of

clinical quality. All surgical procedures should carry out the use of the "Surgical Safety Checklist" and the Surgical Apgar in hospital information systems, which have interface with Health Data Platform (HDP) (205).

Epidemiologic Surveillance

The results of the first HAI Prevalence National Survey carried out in 2003, supported by an investigation involving 67 hospitals (public and two private) were published in 2005. The national average for HAI prevalence rate was 9,7%. It was found that the most problematic departments were: general surgery (8,64%), medicine (13,45%), paediatrics (6,52%), gynaecology (1,2%), other services (3,13%) and ICU (34,33%). It was also found that the agents responsible for most dominant HAI were: *E. coli* (15,83%), *S. aureus* (18,45%), and *P. aeruginosa* (15,73%). The remaining identified microorganisms had rates below 8%. Other important conclusion obtained with this survey was the increased of HAI prevalence with exposure to devices / invasive procedures and with the increase of the hospital length of stay (after the 8th day prevalence in patients was higher than 10%, reaching scary values from 22 days - about 32% in prevalence rate) (206).

The second National HAI Prevalence Survey, coordinated by NPIPC, was carried out in 2009 to evaluate the HAI prevalence after the implementation of the Hand Hygiene National Campaign. This prevalence survey involved 114 hospitals (80% of public hospitals and 34% of private hospitals). For this, and to ensure the quality of data collected, DGH developed a protocol for conducting the survey, based on CDC/ECDC protocol for the epidemiologic survey. This report revealed a HAI prevalence rate of 11,03%. It was found that the most problematic departments were: UCI (45,7%), and Burn Unit (44%). The most predominant infections were the urinary tract infections (24%) and the respiratory infections (34,6%). The main risk factors were the presence of invasive devices/procedures and the surgery. The dominant microorganisms were *S. aureus* (MRSA) (15,8%), *P. aeruginosa* (14.5%) and *E. coli* (12,7%). To promote the improvement of these results it was suggested the importance of increase adherence to national surveillance systems supported by HELICS, for high-risk departments such as ICU (HELICS-ICU), surgery (HELICS- Surgery) and others (207, 208).

The third National HAI Prevalence Survey was carried out in 2010 and 97 hospitals participated (83 public and 14 private). The HAI prevalence rate was 11,7% (there was a prevalence rate increase in almost 2%, when compare with the HAI prevalence rate from 2003) and the departments with higher rates were the ICU (39,8%), surgical services (16,3%) and haematology/oncology (15,9%). The main risk factor was the presence of invasive devices/procedures. The *Staphylococcus spp.* (*aureus* and *epidermidis*), *E. coli* and *P.*

aeruginosa accounted for 66% of the microorganisms isolated and 48,9% of the patients were doing antibiotic treatment (209).

In 2012 the fourth National HAI Prevalence Survey was carried out. At this time, epidemiologic survey was complemented with antimicrobial use survey and was part of the ECDC European study, involving the participation of 30 countries. In this study 103 hospitals participated and it was mandatory for public hospitals (88 were public hospitals, 13 private hospitals and 2 were military hospitals). The prevalence rate was 10.6% (compared with 6,1% of European prevalence rate) and the departments with higher rates were the ICU (24,5%), rehabilitation services (18,90%), medical services (12,3%) and surgical services (10,3%). The most common HAI were the respiratory infection (29,3%), the urinary tract infection (21,1%) and the surgical site infections (18%). The antimicrobial use rate was 45,4% (compared with 35,8% of European antimicrobial use). This survey also allowed the identification of some other important issues related with the national infection control programme: the reduced number of infection control nurses and "almost" the total absence of IC doctors in the ICC (210).

As detailed before, there was an increase of HAI prevalence rate since 2003 till 2010 and a decrease was noticed in 2012. However, the presented data must be carefully compared due to the fact that different methods were used by the different HAI prevalence surveys.

In 2011 another national government body, the Inspectorate-General for Health Activities (IGHA), evaluated the national compliance degree with NPIPC implemented in healthcare organisations since 2007, based on national regulation and recommendations from DGH[38]. The evaluation target was the work developed by ICCs of 96 healthcare public providers and 31 healthcare private providers. The evaluation was supported by a questionnaire sent to all the providers to be completed and returned to IGHA for analysis. This report referred that it should be adopted a global programme for all healthcare organisations to promote efficacy and effectiveness, including fundamental criteria such as: adequate structures, adequate procedures, monitoring the results and identifying the problems, training of all professionals. It refers the importance of "adopt a safety culture" to promote the HAI prevention and control. The questionnaire aimed to analyse the compliance degree of the established goals by NPIPC according to four levels of intervention: epidemiologic surveillance, education and training, definition of best practices guidelines and consulting support for ICC. The questionnaire was developed in seven dimensions: ICC composition; epidemiologic

[38] For the evaluation it was taking into account the follow rules/regulations/recommendations: "*Despacho nº 18052/2007 de 14/08/2007 - Reestruturação das Comissões de Controlo de Infecção", "Circular Normativa nº 18/DSQC/DSC de 15/10/2007 - Constituição e operacionalização das Comissões de Controlo da infecção", "Higienização do Ambiente nas Unidades de Saúde - Recomendações de Boa Prática", "Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde: Manual de Operacionalização".*

surveillance programmes and practices audit; best practices and recommendations development; training; support and technical reports; structures and infrastructures for ICC; ICC perception evaluation of the support given by the NPIPC national coordinator team in the programme implementation. 71 public hospitals and 12 private hospitals answered the questionnaire (71,8% of public hospitals and 38,7% of private hospitals, covering a large national number of hospital beds, almost 22000, distributed throughout the country. The results from this evaluation are presented in Table 20.

Table 20 – Results from national compliance evaluation of NPIPC, reported by Inspectorate-General of Health Activities (Source: IGHA (211))

Dimension	Results
ICC composition	More than 80% of public hospitals and private hospitals had an internal ICC regulation based on the NPIPC manual. In 2010 only 76% of public hospitals and 58,3% of private hospitals had a plan for HAI prevention and control as defined in DGH normative nº 18/DSQC/DSC at 15/10/2007. In 27% of public hospitals and 50% of private hospitals the top management did not approved the plan (Administration Board, as defined in the NPIPC). Almost all the public hospitals that answered the questionnaire had a meeting place for ICC; the number of week/month working hours for ICC was not define in 24% of public and private hospitals; the meeting periodicity most frequent was weekly and monthly in public hospitals and weekly for private hospitals, but there were hospitals that only met 1/semester, 1/quarterly, some "when is necessary", "occasionally", All of the private hospitals and 93% of public hospitals had laboratorial support (microbiology) (the private hospitals had this kind of support done by certified laboratories rather than not certified laboratories). Most of the public and private hospitals had lab information supported by IT and 63% of public hospitals and 41% of private hospitals referred that ICC has direct access to lab information.
Epidemiologic surveillance programmes and practices audit	89% of public hospitals and 58% of private hospitals had participated in the National Prevalence Survey by in 2009 and 2010, but in other programmes for specific population the participation rate was very low (public hospitals had a weak participation and private rarely participated); the information source was basically the lab information (88,7% of public hospitals, and 58,3% of private hospitals), services connections (66,7% of public hospitals and 50% of private hospitals) and clinical patient record reviewed by nurses (66,7% of public hospitals and 58,3% of private hospitals). The notification system was only used in 22,5% of public hospitals and 25% of private hospitals; only 28% public hospitals and 16,7% private hospitals used IT tool for the epidemiologic surveillance (some of the hospitals didn't have the tool and other were in the implementation stage); The audit process conducted more frequently was the Infrastructures and environmental control (66,2% of public hospitals and 33,3% of private hospitals), followed by the infection control basic precautions (64,8% of public hospitals and 33,3% of private hospitals), decontamination of medical devices (28,1% of public hospitals and 25% of private hospitals) and reprocessing endoscopes (14% of public hospitals and 25% of private hospitals).
Best practices and recommendations development	90% of public hospitals and 75% of private hospitals answered that they had best practices manual but most of them, weren't approved by top management.
Training	More than 90% of public and private hospitals answered that they promoted basic training for the different professionals groups, but with special incidence in nurses and operational assistants.
Support and technical reports	The ICC were frequently asked for technical reports (60,6% of public hospitals and 58,3% of private hospitals) and for new material /equipment acquisition (67,6% for public hospitals and 58,3% of private hospitals), there were 91,5% of public hospitals and 75% of private hospitals that had AMR committee; The Occupational service existed in 87,3% of public hospitals and en 66,7% of private hospitals; in 91,5% of public hospitals and in 58,3% of private hospitals there were guidelines for "accidents involving needles and sharps material"; 84,5% of public hospitals and 58,3% of private hospitals ICC are articulated with the Occupational services.

(Cont.)

Dimension	Results
Structures and infrastructures for ICC	In more than 70% of public hospitals there were isolation rooms; in 7, 3% of public hospitals and in 100% of private hospitals there were Central Sterilisation services; In 21,2% of public hospitals and 8,3% of private hospitals the ICC were articulated with the IC regional coordinator group (only 9 public hospitals and 1 private hospitals considered important this articulation for the IC activities promotion); there were identified low rates of articulation with integrated care units and primary care units.
ICC perception evaluation of the support given by the HAI-PCP national coordinator team in the programme implementation	In more than 80% of public hospitals and nearly 33% of private hospitals asked for support from the National Coordinator Group but only 57,7% of public hospitals and 16,7% of private hospitals saw their questions solved (there was very difficult to contact, the IT platform wasn't working, there was no feedback from the national reports, there were no follow-up meetings for objectives discussion and operational programme achievement evaluation); There was a low involvement rate in Epidemiologic surveillance programmes, only 59,2% of ICC answered that the blood stream epidemiologic surveillance programme was very useful. About Hand Hygiene Campaign it was considered very useful for 74,6% of public hospitals and 58,3 of private hospitals; There was suggested that the Coordinator group had an IT support for all hospitals with the following areas: AMR surveillance, "epidemiologically" significant organisms surveillance, infection events in dialysis, benchmarking between organisations, feedback information on time, national report on time; other suggestions: advanced education and training for all healthcare professionals, management activities development for HAI prevention and control programmes; procedures and standards reviewed.

As stated, low compliance with regulation and normative published by DGH was noticed in general terms. Regarding ICC composition, main issues were: no roles and attributions; low participation in surveillance programmes and this was also done by healthcare professionals without ICC participation or data knowledge; low acceptance of ICC recommendations by healthcare professionals; no information about guidelines and best practices manuals or their implementation degree in the field. Some constrains were identified in relation with training and education: low participation by doctors in ICC education and training programmes and there was none impact (penalty) in the organisations/individuals that didn't participate. In relation to ICC structures and infrastructures it could be verified that ICC were working alone/isolated from other services at national, regional and organisation level and there was no articulation with regional coordinator. This was also verified between national organisations (such as DGH) and ICC. It was also pointed out that procedures/standards published by national organisation coordinator need to be reviewed. At organisation level there was low support from top management to ICC, although the normative framework approved in 2007 established, it was obvious that ICC as not aware of their priorities, their roles an attributions in the infection control programme.

After these conclusions were presented, some recommendations were identified: top management must recognise its responsibilities in NPIPC; epidemiologic surveillance must be mandatory; hospitals funding should also be allocated based on infection control indicators (211).

After this report, DGH decided to emphasise some issues (related with regulation and standards compliance) such as the importance to promote safe surgery best practices, based on WHO methodologies (199, 205, 212) and in best policies and practices for HAI and AMR prevention and control systems (192, 194, 213-216).

Discussion

The strategy for HAI prevention and control changed over these years in order to give answers to: international recommendations for HAI prevention and control, patient safety and quality in healthcare; national needs and socio-economic requirements, specifically from NHS; hospitals requirements and all interested parties; needs and rights of citizens.

Since 2007 a great effort has been made to place Portugal at international level, particularly at European level, with regard to this matter. An attempt to strengthen the relations between HAI prevention and control systems and quality in healthcare strategy at national level and at hospital level was noticed.

The national strategic approach for HAI prevention and control developed includes: structures at all levels (national/regional/hospital level); processes (programmes at national level, at hospital level and at unit level); and results at national and hospital level (prevalence reports at national and hospital level and evaluation reports).

Portugal has developed a legal/regulation framework for HAI prevention and control all over these years (see Annexes Chapter - Annexe III) to respond to national and international recommendations and identified needs. As showed significant changes were introduced since 2007, and reinforced since 2010.

Actually Portugal meets several recommendations proposed by EU, namely: a national strategy for HAI prevention and control and for AMR prevention and control and it is translated into a national HAI-AMR prevention and control programme; identification od organisations responsible for the development, implementation, coordination, monitoring/evaluation of this programme at national, regional and organisational level; a legal/regulation framework was developed to ensure the effectiveness of HAI-AMR prevention and control programme; structures and processes are developed at al levels to ensure the effectiveness of HAI-AMR prevention and control programmes. But, as detailed, several barriers were identified, most of them associated with management issues and cultural issues.

Portugal now finds itself in a difficult period with severe economic and social problems, caused by a deep and structural financial crisis. This situation is, in part, responsible for the

deficit in the motivation and involvement of professional and the lack of financial capacity to promote and improve HAI prevention and control system. Therefore it is necessary to analyse the situation from the perspective of "what was already done" in Portugal about best management practices that could energise and improve the current infection control programme.

CHAPTER IV – Evolution of Quality Management in Healthcare

Introduction

In this chapter the concepts and evolution, national and international, of quality management tools applied to healthcare organisations will be analysed. It will start with the presentation of the main concepts and definitions, followed by an analysis of the international framework taking into account the most relevant factors associated with the "trilogy" of Healthcare-Associated Infections: Healthcare Quality Management Systems and Patient Safety. The national framework will also be subjected to a detailed analysis.

Ti chapter also includes a description of projects developed since 1985 by international organisations such as WHO, CDC/ECDC, EU, OECD, AHRQ, and others, for the promotion of quality management systems, patient safety and HAI/AMR prevention and control. These projects, although focused on different health related issues, have a common goal: Quality of Care. To better identify and analyse these projects a literature review was carried out and the result was published in the article "Challenging healthcare-associated infections: a review of healthcare quality management issues". This work is focused only in projects related with organisational issues (see Annexes Chapter – Annexe I) (217).

General Concepts

"Quality" is not a modern concept. Since prehistoric time "Quality" is a determinant factor for the Human Specie: in the past as a survival factor for species, and currently as a competitiveness and survival factor for organisations. From Greek Empire, the philosopher Aristoteles, speaking about quality, referred that "We are what we repeatedly do. Excellence, then, is not a way to act, but a habit".

The quality movement, as we know in the Modern Era started during the industrial revolution, with the implementation, by Frederic Taylor, of some planning and control tools. With these tools important gains in productivity were achieved.

Quality concept evolution is clearly connected to survival factors: the risk of non-quality was considered fatal during the First World War, when involving the supply of military products out of specification. The emergence of this problem within the military industry promoted the definition of the first significant quality function - Inspection. Inspectors were responsible for separating the defective products from those who were not, although defects were not

investigated as a "cause-effect" problem. In many industries the inspector role was extended to metrology, including the design of some measuring devices and testing, involving equipment maintenance and calibration, and resulting in data analysis and, finally, prevention.

The 20's resulted in important developments to the quality concept, mainly due to the integration, by Walter Shewhart, of statistical disciplines, engineering, and economics in a simple, but highly effective, tool for quality control applicable to production: the control charts. To support this tool, a set of plans for sampling inspection and quality control was developed. This tool played an important role in quality control developments from 1940 through the present time, promoted by Shewhart work and others like Ishikawa (218-220).

Another war, the Second World War, highlighted other quality problems: deficiencies on design control (conception and development stage) leading to incomplete specifications; use of unproven technologies or materials; products production with specification very close to lower limits of specifications. The need to establish best practices for production and not to support the product quality only in inspection emerged from the analysis of these problems.

In the 60's, new developments in quality issues were evidenced with the introduction of quality assurance concept, where a set of activities could be systematically implemented, to ensure that product or service requirements were identified and fulfilled.

Although these quality concepts were initially developed in the USA its implementation were not so consistent and in the 80's the American industry became less competitive, especially when compare with the Japanese industry, highly efficient and strongly supported by quality concepts of American engineers, such as Juran and Deming, two important quality "gurus". Acknowledging its deficiencies, the USA organizations embarked on a massive effort to improve efficiency through new quality concepts and tools like Lean Manufacturing[39] and Total Quality Management (TQM)[40]. In the 90's the USA manufacturers had regained their presence as global competitors (218).

The institutionalisation of quality assurance started to be seen as a requirement for value chain activities and, later, as a management tool applicable to the entire organization. By then, a systematic approach to quality became necessary, through the definition and implementation of a quality management system comprising all relevant activities. This approach was revealed as an important step to the evolution of the concept from "quality by conformance", towards "quality by design" and "quality by management" (221).

[39] Lean Manufactoring is a management philosophy derived mostly from Toyota Production System and is a production practice that considers the expenditure of resources for any goal other than the creation of value for the end costumer to be wasteful, and thus a target for elimination.

[40] Total Quality Management (TQM) consists o organisation-wide efforts to install and make permanent a continuous improvement climate, ensuring that the organisation improves its ability to deliver high quality products and services to costumers.

Several words and terms are associated with concepts, theories or methodologies used to describe quality: quality assurance, quality management, quality improvement, clinical governance, and total quality management. There is no concerted international classification of these concepts and its understanding is different between countries, between stakeholders and over time. In health systems, the most used terminology is quality assurance, quality improvement and clinical governance. Independently of the word or term, actually all of them have evolved to the quality management concept.

Quality assurance, for several authors, tends to focus on correcting problems in patient care and rely essentially on standards or guidelines for structures and processes. In most of the organisations this was supported by a "quality assurance department" charged with the detention of after-the-fact individual errors and, often, with the punitive actions (222, 223). Thus, quality assurance can be defined as an effort to identified and overcome problems through the performance and behaviour of organisations and professionals towards more suitable results for health outcomes, expenditures or both. Once obtained there is no need to do anything more. This approach is seen as purely reactive (224).

Quality management can be defined as a set of coordinate activities developed in an organisation, to ensure not only the quality of a product/service, but also the quality of means to achieve it. It can be considered four main components for quality management: quality planning, quality control, quality assurance and quality improvement (225).

Quality improvement or continuous quality improvement are based on TQM theories, and combines a scientific methodology with a management philosophy to continuously improve the organisation processes. Some authors considered that quality improvement could be seen as a progressive step built upon the concepts and methods of quality assurance. This approach is proactive and emphasizes the use of the quality management PDCA cycle or other improvement method, to promote monitoring and evidence-based decisions (224, 226, 227).

Clinical governance is a concept that emerged in the UK NHS in the early 90s and is defined as "a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (228, p.1). This concept is totally focused in the delivery of care to patients and their carers, and includes four basic dimensions: professional performance (technical quality), resource use (efficiency), risk management (the risk of injury or illness associated with the service provided), and patient satisfaction. The introduction of clinical governance in the UK NHS aimed to improve quality of clinical care at all levels of healthcare service provision.

Other important concepts are accreditation and certification. Formal definitions for accreditation and certification presented by ISO are: Accreditation is "third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks"; Certification is "third party attestation related to products, processes, systems or persons." (229, p.14). The "third party" in accreditation process is an independent body, accreditation body (AB), which normally is a government agency. In certification process "third party" can be any independent organisation, a certification body (CB), recognised (accredited) by the AB for that propose.

Most national strategies for quality in healthcare are based on a mix of statutory and voluntaries activities. Although quality certification processes or accreditation processes are voluntary processes, some issues are concern with public health and safety (such as infection, hygiene and others) and are covered by legislation, and subject to statutory inspection (Table 21).

Table 21 – Accreditation and Certification definitions (Source:(230))

Process	Issuing Organisation	Object of evaluation	Components /Requirements	Standards
Accreditation (Voluntary)	Recognised tools, usually a Government Organisation	Organisation	Compliance with published standards, on-site evaluation; compliance not required by law and/or regulations	Set at a maximum achievable level to stimulate improvement over time
Certification (Voluntary)	Authorised body, either Government or non Government organisation	Individual	Evaluation of predetermined requirement, additional education, training, demonstrated competence in speciality area	Set by national professional or speciality boards
		Organisation or component	Demonstration that the organisation has additional services, technology, or capacity	Standards (e.g. ISO 9000 standards) evaluate conformance to design specifications

The two methodologies are used in healthcare to recognise the quality of care provided by an organisation. The most commonly used in healthcare as external mechanism for standards-based quality improvement assessment is accreditation. Most of the countries are using national accreditation systems programmes to provide accreditation services to primary care centres, community services and hospitals, in a statutory base or voluntary base. Later in this chapter some of accreditation and certification models applied in Portuguese healthcare organisations will be analysed.

Quality in Healthcare Definition

It is important to start by defining the meaning of "Quality in Healthcare"[41]. Among many others, three definitions are identified as the most widely used and globally recognised. The first, presented by the IoM from USA, defines quality in healthcare as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (11, p.21). For the WHO, quality in healthcare was presented, in its report published in 2000, as an integrated set and planned activities based on the definition of explicit goals and performance evaluation, covering all levels of care, with the objectives of continuous quality improvement of care (12). The third definition was established by the DH from UK, in 1997, and defines quality in healthcare as "doing the right things at the first time to the right people at the right time, in the right place at lowest cost " (13, p.23).

Several authors defined quality in healthcare, supporting and describing the concept according to different dimensions, as presented in Table 22.

Table 22 – Dimensions of quality in healthcare (Source: (231))

Dimensions	Donabedian (1988)	Maxwell (1992)	DH-NHS (1997)	Council of Europe (1998)	IoM (2001)	JCAHO (2006)
Effectiveness	X	X	X	X	X	X
Efficiency	X	X	X	X	X	X
Access	X	X	X	X		X
Safety	X			X	X	X
Equity	X	X	(X)		X	
Appropriatenes	X	X		X		X
Timeliness			X		X	X
Acceptability		X		X		
Responsiveness		Respect			Respect	
Satisfaction			(X)	X		
Health	X		X			
Continuity					X	
Other		Technical Relevance		Efficacy		Availability Prevention/

As shown, "Effectiveness" and "Efficiency" are the two dimensions considered by all authors. Effectiveness can be defined as the extent to which an intervention produces the intended effects and the efficiency can be defined as the extent to which objectives are achieve by minimizing the use of resources. The concept of "quality in healthcare" supported by several dimensions and especially by these two, although is strongly connected to the concepts of 'results' and 'outcomes', needs to be considered under additional perspectives. As argued by Donabedian, quality in healthcare can be analysed from the perspectives of

[41] In the scientific literature the terms "Quality in Healthcare", "Quality in Health" and "Quality of Care" are used often without distinction. In this work it will be used the term "Quality in Healthcare".

structures, processes, as well as outcomes, and its "measurement and evaluation" may encompass all three simultaneously (14, 232). However, this approach needs to be applied not only to measurement and evaluation, but also to the entire service delivery process, including design, planning, and production/delivery of product/service. According to the actual requirements for healthcare services it is expected that PDCA cycle is systematically applied to ensure continuous quality improvement.

In any case, a set of structures and processes suitable to enable healthcare providers to achieve excellent results are, according to the definitions given in terms of effectiveness, efficiency and adding the safety dimension, considered as a guarantee for the success of any healthcare system. This is supposed to be a common sense issue for health sector as well for any other sector. Industrial organisations, due to several factors including the need to ensure the competitiveness and sustainability over time, developed quality mechanisms that promote quality improvements, quality of the product or service and, consequently, achieve the satisfaction of all interested parties. In a similar way, healthcare providers are also under pressure to ensure continuous quality improvement balanced with management factors such as i) the need to increase the effectiveness and efficiency while maintaining equity, ii) the promotion of accountability and confidence in health systems, iii) lack of motivation in all professional careers involved, iv) increase of demand and criticism of users, and the need to increase patient satisfaction, iv) restrained health budget requirements and the need to ensure the sustainability of systems (9, 233).

The Quality in Healthcare World Framework

Healthcare organisations are committed to ensure the highest quality of care but, nevertheless, by definition, it is always possible to improve it. A multitude of methods and tools were developed and used (at all healthcare system levels from the individual practices to the organisational practice as a whole), to promote the quality of care. Some of them evolved and contributed for the design and development of internationally recognised quality models, all supported on planning and systematisation of activities, quality control activities, and monitoring and evaluation tools. Some examples are pointed out to illustrate the evolution of this concept in healthcare.

The first evidence of the application of quality tools in health can be traced to the military hospitals from the Roman Era. In the Modern Era, during part of the XIX Century the role of Florence Nightingale, a nurse considered by many as the Quality apostle of the XIX Century, can be highlighted, namely in the application of concepts related with quality management in military hospitals. During her life as a nurse, she led the implementation of many tools and

methodologies that promoted quality in healthcare including systematisation of activities, analysis of processes and their optimisation, the use of basic statistical tools concern with continuous improvement, among others (6, 15).

Since the end of the XIX Century several tools have been developed to promote quality in healthcare and initially applied in countries such as the UK and the USA. In other countries and until recently, healthcare quality was supported basically by the quality of education and training of health professionals, of unquestionable excellence, managed by professional groups and according to applicable labour regulation/legislation. Nevertheless, these efforts are clearly not enough to ensure the quality of the entire value chain. The acknowledgement of this fact, although evident, was quite hard to be assumed by some health sector stakeholders.

The change on the slow motion development and application of quality management issues in healthcare started to occur in 1979 when the WHO issued the report called "Formulating Strategies for Health for All by the Year 2000", presenting recommendations for the formulation of policies and strategies at health systems level, aiming to promote better healthcare in the XXI Century (234). This initiative emerged in 1984 and from the defined a set of targets, target 31 established that all WHO Member States should develop and implement mechanisms to ensure the quality in healthcare, and that by 2000 should establish and have available structures and processes that ensure the continuous quality improvement of care, development and adaptation of new technologies. Following this movement, a set of recommendations were issued to governments, promoting the establishment of the structures and processes required to fulfil their goals, such as the introduction of quality assurance systems in their national health policies.

In 1988 the WHO recommended Member States to include quality assurance programmes and the development of comprehensive quality assurance mechanisms in their national health systems, as a mean to improve the quality of care. In 1994, the WHO, based on a review of hospital performance determinants, launched a set of recommendations to improve hospital performance supported through the development of quality initiatives and the implementation of management processes within health systems (235-237).

The recognition of the added value introduced by quality improvement systems, which appeared late in healthcare sector compared with other sectors, gained new 'momentum' when it was finally associated with patient safety. In a report by the IoM, produced to identify the components of quality in healthcare for the XXI Century, it was established that safety should be the 'cornerstone' in which quality of care should be built (10, 238).

The World Health Assembly (WHA), at the beginning of the XXI Century, was confronted with the worldwide evidence of public health harm due to inadequate patient safety policies, and the importance of quality systems to promote patient safety. Following this concern a resolution was adopted in 2002, related with quality of care and patient safety[42] and, in accordance, countries were asked to strengthen the safety of healthcare and monitoring systems. This resolution requested WHO to take the lead, to set global standards and to support countries efforts in preparing patient safety policies and practices. This is considered as the moment when healthcare quality management systems was acknowledge as indispensable for the development of any healthcare system based on quality and patient safety.

After these recommendations, and with the propose to inventory applied quality management tools/best practices, in 2003 ISQua[43] and WHO triggered a survey to map structures and activities used all over the world to promote quality of care, as well as to identify concepts and terminology used, and any initiatives launched at the level of accreditation systems and quality assurance (237). From this work it was possible to understand how countries established their national strategy for accreditation, based on structures and processes.

Other studies were promoted by the WHO to identify national quality policies and best strategies for ensuring quality in healthcare, capable of stimulating systemic management, implement standards and guidelines, implement accreditation/certification and evaluation models, implement total quality models, promote benchmarking with comparable indicators and introducing mechanisms for risk management and safety. These studies identified a set of strategies to promote the quality in healthcare but there was no scientific evidence on the best strategy to be selected. The main conclusion from these studies is that successful quality programmes depend more on behavioural science than on technical solutions and the most important issues to promote effective quality improvement systems are culture, attitude, training and management of human resources (230, 239). The concern with healthcare systems and the effectiveness of quality improvement tools implemented led WHO to publish in 2006 a guide with a systematic process to help decision-makers and managers at country level to design and implement effective interventions to promote quality in health systems. This guide included a self-assessment questionnaire for choosing interventions for quality and a matrix to map quality interventions by roles and responsibilities in a health system (240).

In the beginning of 2012, at European level, the European Joint Action on Patient Safety and Quality of Care was created with the main objective to identify best practices in patient safety

[42] World Assembly Resolution (WHA55.18).
[43] ISQua is the International Society for Quality in Healthcare. This organisation was created in 1985 with the mission "to inspiring, promoting and supporting continuous improvement in the quality and safety of healthcare worldwide" (source: http://www.isqua.org/who-we-are/isqua-mission).

and quality of care across EU. The main outcome of this Joint Action was established as the consolidation of a permanent network for patient safety.

European Framework

Over the past 30 years the concern with the effectiveness of quality improvement methodologies in healthcare and its impact in patient safety increased, and became important to know which quality and patient safety strategies have been developed and implemented (241).

In relation to this concern about quality in healthcare issues, the EU established in 1995 a committee of experts on quality that in 1997 issued a set of recommendations to Member States on the creation, and development, when appropriate, of policies and structures to support the definition and implementation of quality improvement systems. Three major dimensions for quality improvement systems were identified: procedures and processes, organisation of quality improvement and responsibilities and some key issues were presented in relation with: practice guidelines, technology assessment and quality improvement, quality indicators and information systems, patient's perspective, and managing changes. Some supporting issues were also identified as relevant for the success of quality improvement systems implementation projects: support structures (agencies, boards, committees, and networks); pre- and post-graduate education for healthcare providers (to promote knowledge and skills in quality assessment and improvement systems); and finally evaluation of quality improvement systems, research and development (242).

A substantial financial support was granted to assist EU countries to develop their healthcare quality improvement systems. This was accomplished through the Community Support Framework III (CSF III), for the period 2000-2006. This CSF III was operated through a set of operational programmes for different areas, including Health XXI. In this programme a specific measure was defined, measure 2.3 – Certification and Quality Assurance, with the main objectives: 1) creation of quality assurance systems in health, 2) provide health services conditions for their compliance with quality assurance standards, and 3) develop network knowledge within and between healthcare organisations.

Many European countries used CSF to promote their quality improvement systems at national, regional and organisational level. This also promoted the development, at European level, of several projects to evaluate which quality strategies were defined and implemented and on its effectiveness.

Between 1990 and 1997 a study was initiated to assess the quality assurance in hospitals, called "COMAC / HSR / QA[44]" and triggered in 262 hospitals in 15 European countries. This project aimed to study the different quality assurance strategies implemented and its effects on improving clinical care in the following areas: file medical records, use of prophylactic antibiotics before surgery, assessment and prevention preoperative and treatment of pressure ulcers. This scientific project aimed to provide a framework for the development of quality assurance activities in hospitals in different European countries. Assessments were performed at three levels: national (report), hospital and healthcare topic. In Portugal, as well as in other three countries (Belgium, Spain and Israel) the project was seen as a national effort to promote quality assurance issues with the involvement of a high number of hospitals. The study showed that in all countries this project was considered as a valuable support but the extent of its application was considerable different among the involved countries, for reasons associated with quality culture and organisational structure. As so, conditioning factors for the success of these programmes were identified: management involvement, professional motivation, collaborative management (medical and nursing) and incentives (243).

Subsequently to this set of initiatives the BIOMED programme was launched in 1994 including a set of projects to promote healthcare systems. One of these projects was the Project External Peer Review Techniques (EXPERT), carried out between 1996-1999, to assess the development and implementation of four external quality models used in the EU hospitals: ISO, EFQM, Accreditation systems and *Visitatae*[45]. The main objectives of this project were: 1) to promote benchmarking between organisations about their quality models experience, 2) to establish mechanisms for collection and dissemination of quality improvement knowledge, and 3) to define criteria framework for healthcare quality evaluation. This study concluded that these four models were seen as control mechanisms in healthcare systems and there was a general convergence between them, although their different evolution and adaptation to new challenges. Some barriers to the future convergence process were also pointed out, such as bureaucratic tendencies and too much focus on efficiency and patient empowerment compared with the attention to medical effectiveness (243, 244). This study also allowed the verification that, regarding different interested parties, the quality mechanisms were considered from different perspectives. Healthcare services, although acknowledging that it is important to promote accountability, the main interest lies on the increase of efficiency, promotion of competitive advantages and external incentives for quality systems development. For healthcare professionals, quality mechanisms can be

[44] COMAC / HSR / QA is an European concerted action programme on quality assurance in hospitals developed and implemented from 1990 to 1993.

[45] The Peer Review or Visitatae model originated in The Netherlands has been established as a standards-based onsite survey conducted by medical professionals in order to assess the quality of professional performance of peers, and improve the quality of patient care.

understood as promoting a reformulation of their professional autonomy and as interference in clinical work. Patients consider that their influence on healthcare systems can be increased through the implementation of external quality mechanisms because these models have a clear focus on transparency and are patient-centred. Financers understand the implementation of these mechanisms as a major challenge because, although supporting the quest for new accountability mechanisms, they doubt on promoting more investment in administrative activities for which the cost-effectiveness ratio is uncertain and considering that the competition amongst insurers can reduce their competitive advantage (233, 244-246).

All things considered, in the scientific context, a paradigm shift is noticed in research questions: "how can quality be measured" is no longer applicable, replace by "how can quality be improved". Regardless of responsiveness to these issues, safety problems persist and became increasingly important to accelerate patient safety issues through quality improvement strategies. In the last 10-15 years there was an important focus on the effectiveness of quality improvement. It is clear that research is now focused on questions like: "Does quality improvement leads to better quality of care?", "Which quality tool is more effective?", "How can quality tools be integrated in a quality and safety programme?" or "Which factors have impact in the implementation of quality strategies at hospital level?". Related programmes and projects developed between the end of 90s and today clearly reflect this shift of paradigm.

In 2003 the ENQual project (European Network on Quality Management in Healthcare) was launched as a collaboration network of research experts in quality assessment and quality and safety management in European countries, supported by the European Commission. The aim of this project was to facilitate the exchange of knowledge and expertise among European countries in two areas, quality/safety policy and quality/safety management, and had the ambition to prepare an EU research proposal to compare quality management tools within the European countries. In 2006 a survey was developed based on EFQM model to obtain, in a systematic way, information about: policy and strategy, personnel, protocols and procedures, elements of quality and safety management systems, collaboration and quality of care chain, involvement of patients, perceived effects, culture and structure of hospital (247, 248).

Between 2005 and 2007, supported in the 6th Framework Research Programme from EU, the MARQuIS project was launched. This project was promoted by the EU mainly due to the free movement agreements, of people, goods and services between European countries. This movement also conditioned the exchange between patients, practices and strategies for quality improvement, which were unknown, in general, for most of the EU countries. Thus, in order to acquire a better understanding of the European reality in this field, the MARQuIS was developed with the primary purpose to map and describe quality policies and strategies in

health in the EU Member countries. After an exhaustive literature review a questionnaire was proposed, called "Quality Improvement Policies and Strategies", which covered six dimensions of interest: Environment / National Context, Objectives / Values of Quality Policies, Resource / Support, Policies for Implementation, Information / Communication and Evaluation, and finally, Impact Generated. It was also established, given the subjectivity and scope of the concept, that "quality improvement strategies" would be those related with healthcare quality and concepts covered in quality control, quality assurance and quality management concepts (24).

The project was developed at two levels: national and hospital. At national level there were 25 countries participating through a questionnaire covering six important domains: national quality improvement framework and context; policy objectives and values of quality; resources and support; policy implementation; information, communication and evaluation; and impact. The existence of facilitators and barriers for the progress of healthcare quality improvement was confirmed and the most important priorities identified for quality improvement were: development of quality standards and guidelines (18 Member States); improving patient safety, orientation, and involvement (16 Member States); improving the assessment and evaluation of quality improvement (9 Member States); improving information and reporting systems (8 Member States); achieving better value for money (6 Member States). "Establishing national accreditation", "quality assurance systems", "national society for quality in healthcare " and "improving the training and assessment of professionals" were also identified as the most important achievements in quality improvement in relation to healthcare systems. The main conclusion stated that policies on quality improvement in healthcare were largely developed at a national level in EU Member States. Additionally, some degree of policy convergence was observed in areas such as the widespread adoption of legal or statutory requirements for healthcare organisations to put quality improvement systems in place, the development of specific mechanisms, such as accreditation programmes, and the recent policy priority accorded to patient safety in many Member States.

At hospital level this project was applied to 389 European hospitals with the intent to evaluate the implemented quality improvement strategies under the following dimensions: organisational quality management programmes; systems for obtaining patient view; patients safety systems; audit and internal assessment of clinical standards; clinical and practices guidelines; performance indicators and measurements; external assessment. In relation with "organisational quality management programmes" the use of ISO for management system, EFQM and team circles for organisational total quality management programmes was identified. The most used tool was the ISO management standard and the EFQM model was the least frequently used tool. The results for "obtaining patient view", "patient involvement"

seemed to be undeveloped and the most used was the "patient survey". Regarding "patient safety systems" it was noticed that only 39% of the hospitals had a risk management programme in place. "Clinical and practice guidelines" (preoperative procedures) were applied by 75-90% of the hospitals (laboratory areas were noticed as highly standardised but a less common scenario was identified at a department level); Some clinical indicators were identified on relation to "performance indicators or measures"; Regarding "external assessment", 88% of the hospitals were externally assessed, by accreditation (59%), by certification (49%), and government inspection. The project allowed the identification of factors that promoted the implementation of tools for quality improvement (professional involvement and training; legal and statutory requirements; public expectations or requirements) as well as factors that difficult the implementation process (lack of funding; lack of political leadership; no strategic planning; lack of initiative or professional motivation).

The conclusions of this study included the confirmation that quality strategies were widely used in European hospitals and that the most widely applied was the "external assessment". The "patient involvement" was the lowest used tool and "patient safety structures, activities and outputs" issues were considered less developed than reported in other international studies. However, these results reinforced the conceptualisation of patient safety as one of the healthcare quality dimensions, a finding that is online with other studies (24, 249).

Supported by this study a classification model was developed, based on the maturity of hospital quality improvement systems, and defined as the total set of quality improvement activities performed. This classification model was named "Quality Improvement Maturity Index". The maturity index is calculated by scoring 113 items divided in seven domains: policy, planning and documents; leadership; structure; general quality improvement strategies; specific quality improvement activities; patient involvement; accountability. The results showed that the countries with more maturity were The Netherlands and the UK (250, 251).

Also supported by the results from MARQuIS project, a new study was performed, focused on the association between MARQuIS implementation strategies and hospital outputs. For this four dimensions were proposed for hospital outputs (clinical, safety, patient centredness, and cross-border patient-centredness). Some important conclusions from this study can be presented: all seven strategies identified by the MARQuIS project were moderately inter-correlated and all hospital outputs dimensions were inter-related; the implementation of quality improvement strategies in hospitals seems to have an effect in promoting positive change in organisations; patient safety systems, performance indicators, and clinical guidelines are the strategies most clearly associated with hospitals outputs and this supports

their potential value in understanding and improving healthcare quality; voluntary accreditation and ISO certification are associated with outputs (252).

Also based in this project a study in 43 Spanish hospitals was performed, to analyse the association between MARQuIS strategies and patient safety. Four patient safety indicators were analysed (adjusted hospital mortality index; adjusted hospital complications index (the HAI infection is included); adjusted hospital readmissions index; adjusted hospital length of stay index.) The conclusions pointed to the existence of a statistical association between "adjusted hospital complications" and hospitals quality improvement systems. It was observed that hospitals with more mature quality improvement system presented lower complication rates and that improved hospital outputs depended on the combination of several tools instead of using only one. The results of this project emphasised the importance of external assessment in hospitals (external pressure) as a positive strategy to promote better outputs (251).

The MARQuIS was closed in 2007 and, although its contribution to identify important relations between patient safety and quality improvement strategies, it left some unaddressed issues, such as the uptake of quality improvement strategies in hospitals, the impact of quality improvement systems on patient outcomes, and the relation between quality improvement systems and some of their dimensions (professional involvement, patient empowerment and organisational culture).

In order to answer the unaddressed questions the DUQuE project (Deepening our Understanding of Quality Improvement in Europe) was launched in 2009. Eight countries were randomly selected to participate, through their hospitals, in the project. In Portugal, the *Hospital de Guimarães – Centro Hospitalar do Alto Ave*, was invited to participate. The main objective of this study was to evaluate in which extent improving the quality of organisational systems, culture, professional involvement and empowerment of patients were related with the quality of care, evaluated in terms of clinical effectiveness, safety and patient involvement. This main objective was deployed into specific objectives: 1) to develop a classification model for assessing the maturity of improving organisational quality systems in European hospitals, 2) to investigate associations between the maturity of systems quality improvement and measures of organisational culture, professional involvement, empowerment of the patient (hospital level), 3) to investigate associations between the maturity of quality improvement systems and clinical effectiveness measures, safety/patient involvement (patient level) and 4) to identify factors that enhance quality improvement activities in hospitals, as well as external pressure imposed by accreditation, certification programmes or external evaluation (30).

The development of this project was supported by other projects previously launched, such as ENQual and MARQuIS. One of the deliverables from this project was a guide to help hospitals to choose more effective quality improvement system and to inform customers. Implications at policy level were also expected.

The impact of hospital performance in healthcare quality is considered since the 90's as a very important issue for health systems policies, at international, national and local level. Although it was important to identify the quality improvements systems and tools implemented to improve quality of care, it was also important to identify how to measure it. For that purpose the development of mechanisms to measure and monitoring health systems performance, and more specifically, hospital performance was strongly recommended (performance concept was seeing as the integration of quality, efficiency and effectiveness concepts) (253-259).

This matter was initially approached by the WHO in a Hospital Advisory Group meeting in 1994, and recommendations were formalized to be taken into account regarding hospital performance issue: develop a national strategic policy framework for hospitals with clearly defined roles, functions and targets; hospitals and other healthcare providers should implement a management process involving all healthcare careers; develop and implement quality improvement initiatives (including quality assurance programmes) using available expertise. It was also clear from this report the importance of identifying management tool that could be used to identify "what", "why" and "how" to measure (260).

As stated in the WHO 2000 report, the Member States are responsible to provide optimal health services to their population, but to achieve this monitoring systems and regulation should be developed (12). To promote this recommendation, WHO Regional Office - Europe presented some strategic orientations for the measurement of hospital performance and for the development of health policies[46]. The Performance Assessment Tool for Quality Improvement in Hospitals system (PATH) was created by a group of international experts based on an extensive literature review and supported by a survey about the importance, usefulness and data availability of potential indicators in 20 European countries. This project was developed in three stages: analysis of existing models for hospital performance evaluation (2003), pilot implementation of PATH in eight countries (2004), and setting guidelines for implementation / creation of international network benchmarking (2005). The first stage included the analysis of several models from: Canada (Balanced Scorecard model, based on four dimensions, from

[46] Since the publication of the WHO2000, several countries expressed interest in collaborated with WHO to assess the performance of their own systems and to use the evidence to formulate policies to improve performance. To meet countries request, WHO decide to create the initiative "Enhancing Health Systems Performance Initiative" (EHSPI) with the main goals of link evidence to actions to improve performance and develop greater national capacity to monitor and to improve performance.

Ontario Hospital Association and the model from Montreal University (based on the Parson Social System Theory and compatible with EFQM model)), Denmark (Patient-centred model, based on three dimensions), France (the Montreal University model, but simplified, only with three dimensions), USA (the Quality Improvement Project (QIP)[47] is not based on any specific model, but on epidemiology of performance and the assumption that all measurement is comparative). From this model analysis the PATH model was created, incorporating six main dimensions: two transversal dimensions (safety and patient centeredness) cutting across four dimensions of hospital performance (clinical effectiveness, efficiency, staff orientation, and responsive governance). 17 sub-dimensions were also identified and a set of indicators defined for performance assessment. One of the sub-dimensions of safety dimension was "hospital-acquired infections" (7, 9, 261).

24 general performance indicators and 27 performance indicators "tailor made" were identified. The general performance indicators were created to allow future comparison between hospitals from different countries. In addition to the primary objective of assessing hospital performance associated with the identified dimensions, PATH aimed, in the medium and long term, to lead hospitals into an attitude change from "simple measurement" perspective (only the indicator application) to an interpretation and triggering actions for quality improvement posture (7, 8, 261).

This model was again analysed again in 2008, when a study to identify identical projects developed for hospital performance assessment was launched. The authors performed a literature review to analyse indicator definition projects for hospital performance assessment and compare them with PATH. 11 projects that have developed a common methodology for indicators design and selection were included in the study. Even considering that there were major differences in the philosophy, scope and coverage of the analysed projects, the authors concluded that performance assessment was becoming more common worldwide and that these initiatives should be well coordinated. They also referred the importance of national authorities' coordination on the implementation of PATH model in order to avoid overlaps in indicators definition. They suggested to map areas of interest to avoid similar areas to be covered by different indicator definitions (262).

OECD did the same in 2004 when launching the "Quality Indicator Project". It included a proposal for quality indicators, associated with patient safety, identified among indicators already used in different OECD countries. This project identified 17 indicators that were targeted at results (clinical and politicians) not covering structure indicators and processes.

[47] QIP was launched in USA by a hospital in Maryland in 1985 and internationally is coordinated by the Centre for Performance Sciences (CPS). The Quality Indicator Project® IQIP) serves as a tool to assist healthcare organisations to identify opportunities for improvement in patient care.

The first draft for patients safety indicators was published in 2004 and these sets of indicators were constructed taking into account three key dimensions of quality in healthcare (dimensions from PATH project): effectiveness, safety and patient centredness. Nevertheless, OECD warned that quality indicators were only capable to make a difference in health system performance if they were clearly linked to national strategies and policies. This project also included a set of indicators related with HAI (255, 263).

Evolution of Quality in Healthcare in Portugal

National Context

In Portugal the first steps related with quality in healthcare were taken in the 80's (1985-1989), through several dispersed activities, such as: an international seminar developed in collaboration with the National School of Public Health, the Free University of Brussels and the WHO, entitled "*Evolution des services de soins de santé primaries*"; the seminar "Evaluation and control of quality in health services" co-organised by the WHO and the Directorate - General of Primary Healthcare; the Portuguese-Spanish Programme for Quality Assurance in Healthcare, which promoted six seminars for physicians, involving local and regional management responsible, with the aim of training and sharing experiences, already in place in Spain. The introduction of quality assurance contents in the curricula of some Institutes of Medicine courses was also noticed (264). Although quality in healthcare started its motion in Portugal during the 80's, its development was strongly conditioned by the absence of adequate health policies at national level. As so, the referred actions were developed supported by professional groups' initiatives, without any assistance from a strategic programme at national or regional level.

As well as in other European countries, it was only during the 90's that quality in healthcare started its movement in a systematic way, supported by the Health Law published in 1990, that emphasised that quality and quality control in all healthcare providers is subject to the same level of requirements (265) and that a continuous evaluation process of NHS should be promoted (266).

In general there was a strong investment in quality assurance training and education as well as the creation of several projects, by the DGH at national and regional level, to promote quality assurance in healthcare organisations.

In 1992, as defined in the 1990 Health Law about the establishment of mechanisms for quality healthcare evaluation, a project to evaluate hospital quality (supported by a specific questionnaire) was launched by the Centre of Studies and Research in Health - University of

Coimbra. The main goal of this project was to provide to hospital top management data to allow quality improvement monitoring over time and benchmarking with other similar organisations. This mechanism was improved with several modules: outpatient evaluation; evaluation of nursing care in hospital; Evaluation of adults inpatient; evaluation of paediatric hospitalisation; emergency service for adults rating; and rating service for paediatric emergency (267).

In 1993 important structures to the promotion of quality in healthcare were developed: according to a normative from DGH, hospitals should establish quality committees (in most of hospitals these structures were inexistent); the Directorate for Quality Assurance Promotion was created, responsible for the promotion of evaluation projects, such as the performance monitoring project developed for primary care providers (264); and the National Commission for Humanisation and Quality in Healthcare was also created by the Ministry of Health, which, among other things, established local committees responsible for the implementation of quality activities in healthcare organisations (it is noticed that this Commission did not reach the expected outcomes and was later deactivated) (268).

In 1995, the Government XIII Programme established quality in healthcare as an important issue to be included in healthcare policies and stressed the importance to create a legal framework for quality assurance, mainly for accreditation and licensing of healthcare providers. The general awareness increase about quality issues and the importance of unifying practices and programmes launched till then, promoted, in 1996, the creation of a Sub-Directorate General of Health responsible for the promotion of quality assurance.

In 1997, and following the international recommendations for quality in healthcare issued by the WHO since 1979 (e.g. in its Declaration "Formulating strategies for health for all by the year 2000"), and by European Ministers Council (e.g. in its recommendation nº17/97), the need to create a national healthcare quality system was identified. This was considered the cornerstone for the development of quality improvement systems in healthcare in Portugal.

After this, quality improvement was seen as a key issue for health system strategy. Consequently, the plan submitted by the Ministry of Health, called "Health, a Commitment - Health Strategy for the turn of the Century (1998-2002)", assumed the quality in health as part of national health policy. The main objectives pointed included the promotions of healthcare quality assurance systems, effectiveness, efficiency, continuity and "user" satisfaction (269). In 1998 the National Healthcare Quality System (NHQS)[48] was created with the main objectives to promote quality in healthcare and to ensure the citizens

[48] The National Healthcare Quality System, as the structure responsible for Quality in Health in Portugal, as well the National Quality Council as part of the health policies and strategies were discontinued in the period 2000-2002.

satisfaction with the healthcare system. To achieve these objectives it should be driving a set of actions that allowed: to design healthcare services in order to meet health needs; to provide resources (financial, human, material, information) and sustainability; to ensure the performance and the efficiency in healthcare, the quality culture based on the continuous improvement and evaluation. The development of this system required the support of adequate planning, control, management activities and involvement of all interested parties. These interventions should be developed at all levels: national - establishment of appropriate policies and legislation and development of guidelines and quality criteria for quality assessment; regional - monitoring healthcare organisations effectiveness; healthcare organisation - planning, projects execution and improvement monitoring; professionals – training and education. The model selected to support this system was supported in three areas: Attributes (continuous improvement, accountability, involvement and cooperation), Structures (National Council for Health Quality (NCHQ), Health Quality Institute (HQI), National Accreditation Council (NAC), sub-systems for pharmaceuticals products and others) and Procedures (Letter of Quality, user satisfaction, clinical guidelines, quality assurance processes, programmes to improve accessibility, accreditation programme, licensure,...) (270). After its creation NHQS started to developed national programmes in a systematic way for the promotion of healthcare quality concepts and activities, all of them in a voluntary basis. In 1999 in spite of another Government change, quality in health was considered again a key issue for health policies. The new Government included in its programme the need to promote patient empowerment (and this could be done through better access to healthcare providers), Letter of Quality definition, and through the right to participate in audit process of admission and referral services (271). Following the recommendation for the NHQS structure, the Portuguese Healthcare Quality Institute, the National Council for Health Quality and the National Accreditation Council were finally created in 1999.

The HQI was created by law with the NHQS management as the main responsibility, including the definition and development of standards, procedures and strategies to promote continuous quality improvement in healthcare organisations. The main objectives for healthcare quality improvement were also defined: promotion of research and development of methods, tools and programmes for continuous quality improvement; promotion and development of methodologies for quality accreditation and certification in healthcare; promotion of training and education; provision of technical support to healthcare organisations (272).

The NCHQ emerged as a HQI advisory body in 1999. Its mission was to advice the Ministry of Health on quality issues and to develop recommendations for the development of NHQS. This advisory body included representatives from the National Health Institute Dr. Ricardo

Jorge, INFARMED[49], Portuguese Blood Institute, professional associations, patient associations, and several experts from other entities.

The NAC was also created in 1999 to develop the accreditation system and to coordinate and manage the programme for accreditation and certification systems in healthcare organisations.

The Community Support Framework III, launched in 2000, was fundamental to support the implementation of this strategy: the Health XXI – Operational Programme for Health 2000-2006, Priority II - Improving Access the Health Care Quality, measure 2.3 - Certification and Quality Assurance was developed, establishing healthcare quality improvement as an important issue for national health strategy, supported by the implementation of quality assurance systems and human resources development. This programme also included some recommendations from other health system programme (1994-1999) with special emphasis in measures for promotion of safety, quality improvement and efficiency (273).

The golden years of quality in health remained supported by CSF III (almost 3,5 million €as defined in the Operational Health Programme 2000-2006. In 2002, even considering yet another government change, part of health strategy was reinforced, such as, the reorganisation of the Charter of Rights and Duties of Healthcare Users and the Quality Manual for Admission and Referral in NHS (274).

As mentioned, regardless of government changes through the years, the health policies related with quality issues increased. In 2003 three important milestones in the new health system reform were launched - the creation of the National Regulatory Authority of Health (RAH) (275) (supported by international recommendations), the National Strategy for Health, presented by the "National Health Plan 2004-2010 - More Health for All" (276), and the development of continuous care network (277), among others. Regarding the first milestone the Government XV Programme established the creation of a regulator for the health sector. As an independent authority, the duties of RAH included, among others, compliance with the standards of quality and safety and promotion of users rights. The main objective for the regulation work was to ensure adequate standards for quality in healthcare services. In the field of quality assurance, RAH was responsible for the evaluation of healthcare quality standards and indicators, and to verify their implementation, monitoring compliance with accreditation processes in healthcare providers (275).

In relation to the second milestone, the National Strategy for Health was developed taking into account several social interested parties (professionals associations, healthcare providers and others), WHO, OECD and the European Council. This strategic plan was also supported by the Operational Programme 2000-2006 Health (273). Based on the Portuguese health

[49] INFARMED is the Portuguese entity responsible for the medication and therapeutics issues management.

system framework established at that time, a set of main objectives and activities were presented to eliminate several identified gaps, as the absence of quality culture in healthcare organisations. Some of the defined strategic objectives were: to promote hospital accreditation based on the partnership with KF-HQS from UK and audit training programmes for healthcare; to transform the MONIQuOR project (monitoring the organisational quality of primary care centres) into a national system for evaluation and external recognition of primary care centres; to develop a quality management project (QualiGest), with reference to the organisational excellence model EFQM for public services and officially approved by the European Commission - the Common Assessment Framework (CAF)[50].

Regardless of the previously detailed developments, the Portuguese Healthcare Quality System suffered constant setbacks and advances since 2006. Health policy was conditioned by public administration restructuration triggered by the Government XVII Programme and operated by Central Administration. This restructuration resulted in some important changes between 2006-2008, such as the extinction of HQI in 2006[51], and consequently the slowdown of some global quality projects and self-management projects by healthcare organisations.

In 2008-2009, there was another government intervention to established priorities for quality in healthcare, to restructure healthcare quality management attributions, roles and responsibilities at national level. Following some organisational changes, the healthcare quality system management stood under DGH responsibility, more specifically, the Health Quality Department. This department was also responsible for the coordination of patient safety programmes and projects, as HAI prevention and control projects and AMR projects (278, 279).

It is important to emphasise that, at this time, Portugal was living in a crisis scenario that promoted a general deficit of motivation and additional barriers to improve quality culture. Nevertheless, international developments on quality issues and the permanent focus on patient safety and healthcare user satisfaction were an incentive for the introduction of legal regulation related to the implementation of quality management tools in blood banks and for Assisted Human Reproduction Centres, as examples. In the case of blood banks a related law[52]

[50] The Common Assessment Framework was launched in 2000 by the Innovative Public Services Group of EUPAN (European Public Administration Network). It is a self-assessment framework for organisational performance, specifically designed to help European public sector organisations to apply total quality management techniques to improve their level of performance and service delivery.

[51] The HQI was extinguished by the Decree-Law nº 219/2007 of May 29 and it was replaced in the same year by the Agency for Quality in Health, a service from the Central Administration for Health Systems.

[52] Law-Decree nº 267/2007 published at 2007-07-24, establishes the legal regime for quality and safety of human blood and blood components, their technical requirements, traceability requirements and notification of adverse reactions and events and the standards and specifications relating to a quality system for blood establishments, to ensure a high level of protection of public health.

was published (transposed from a European Directive[53]) establishing the need to quality management system implementation as integral part of quality and safety policy for blood and blood components production[54] (280). The same was applied to Assisted Human Reproduction Centres, according to the exposed in chapter V, Article 13 of the legal framework for quality and safety on the donation, procurement, testing, processing, preservation, storage, distribution and application of tissues and cells of human origin (281).

A new stage for healthcare quality started in 2009. Considering that the reform of health sector was at "cruise speed" and the need to accomplish the main goals for health quality established in National Health Plan 2004-2010, a new discussion started among interested parties to promote a quality in health approach as a whole. The Ministry of Health launched the National Strategy for Quality in Health with the main goal to promote the improvement of quality in healthcare organisations. This strategy was defined as a five years strategy for several areas - clinical quality and organisational quality, patient safety, qualification and national accreditation of healthcare organisations, integrated disease management, innovation, complaints management, among others – focused in citizens, in different healthcare providers and in professionals. The DGH, through Health Quality department, was responsible for coordinating the implementation of several activities, such as: dissemination of clinical orientation standards (COS); development of indicators to monitoring levels of clinical quality and organisational quality; development a national system for reporting adverse events; dissemination of safety standards; coordination and control of HAI and AMR; development of a new national healthcare accreditation programme based on a national and independent model; coordination and evaluation of health projects in innovation and research areas (282, 283).

Considering the health strategy defined by the Ministry of Health, it was necessary to create some important structures to assure its success, namely the National Council for Health Quality as an advisory body of Health Quality Department (284), and the accreditation model for National Healthcare Accreditation Programme. The accreditation model was imported and adopted from the Health Quality Agency of Andalucía. The Ministry of Health, after a comparative analysis between the two existing accreditation models in Portugal and this new model, concluded that the last one was more adequate to ensure financial sustainability and to be implemented in all type of healthcare services of the NHS (285).

[53] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components

[54] It was established in Chapter IV, Article 11 of this law, the need to create, maintain and operate a quality system for blood and blood components, based on good practices. The standards and specifications for the quality system are defined in this document.

This model was created in 2000 as a consequence of quality policies implemented by the *Consejaria de Salud de Andalucía* and was developed with the logic of integrated care. The principal advantages pointed to this model are: its applicability is broad spectrum; its application to all types of healthcare providers in full (a hospital, a primary care centre) or partially (only clinical management units inside a hospital) scope; it is targeted to professional skills and all activities, programmes, and training centres. The following characteristics also apply: uniform - aligned with the strategies and elements of the management system providers; horizontal - analyse the organisation from the perspective of the citizen (healthcare process) taking into account the continuity and transversally of its healthcare needs, total - encompasses all health system agents; comprehensive - covers all areas of accreditation in the same perspective; progressive - establishes different levels of standards; results-oriented - the goal is efficiency; shared improvement - accreditation supports on the people and incorporates self-evaluation as a motivational and proactive tool.

The accreditation process, such as verified for the two other accreditation models, is supported in: preparation and learning - internal diagnostics, training among others; implementation of standards and norms - the adequacy of the organisation stipulated by reference from the standpoint of self-evaluation and introduction of improvement measures and external assessment - assessed by independent bodies and promotion of new PDCA cycle (286, 287).

Following the definition and establishment of these structures, the strategy could now be implemented in the field, starting with the adaptation process (a related coordinator team was also created).

In 2010, and after an initial period of training and education, the model was implemented through a pilot-project in four healthcare family units (a primary care service).

It is important to refer that this decision could not limit the introduction and / or maintenance of any of the other models used by healthcare organisations until then. More, if a healthcare organisation decided to be accredited by a quality model, there is no obligation or incentive to choose the Andalucía model.

In 2010, and following the defined quality strategy for Portuguese health system, DGH launched a Microsite for Health Quality Department support, with the main objective to promote and disseminate quality improvement culture within healthcare organisations (288). On that site several informations about quality issues can be found, from the mission of this department to projects development and/or implementation issues. Everyone can check any of the DGH projects. DGH is currently promoting 10 projects: the National Campaign for Hand Hygiene, the public campaigns for rational use of antibiotics (e-Bug), best practices in

medication safety, among others. For those projects (some still in design and development stage), it is noticed that the DGH is analysing a new methodology for monitoring users and professionals satisfaction, projects and e-Health, COS and organisational standards, national quality indicators framework, establishing an organisational model for hospital outpatients, among others actions (289).

A special attention is given to quality in healthcare in the new National Health Plan 2011-2016. According to the presented conceptual model that defines a new strategy for 2011-2016 period, quality is one of the cornerstones, along with Citizenship, Access, and Healthy and Sustainable Health Policies (290).

From the analysis presented by the team responsible for national diagnosis as support to the development of the "cornerstone quality", it was clear that, regardless of health gains achieved with health policies, mechanisms and models developed in the past to promote quality in healthcare, some deficiencies were still identified in areas such as medical practice, access to continuous care, best practices implementation, and monitoring /evaluation systems (291).

This document presented some important issues to frame the defined strategies, such as an appropriate definition of quality in health and others[55] (12), looking into the nature of the Portuguese health system[56] and the constraints imposed by specific health market (292, 293). It also stated that health determinants should be fit into three levels: a) micro level - performance, clinical research and disease management; b) intermediate level - lifestyles, individual prevention programmes and risk behaviour changes; c) macro level - health policies, social and economic issues, environmental and physical issues. A recommendation that the "quality" concept should be analysed from the general to the individual level: healthcare system, organisation system, and team/person, was also noticed.

The framework also includes the need to clarify what are quality management "activities", encompassing all activities ranging from the "drawing and design systems", through "measurement, monitoring and control", to "evaluation and improvement". And, in order to

[55] Several definitions associated with Quality in Health are presented. The definition of Health from WHO published in 1946 is "Health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity." Regarding to the Quality in Health definition accepted nationally for the development of NHP it is associated with the Iberian Programme (Portuguese-Spanish Programme implemented between 1986-1990), where "care (accessible and equitable), with a optimal professional level, taking into account available resources and the achievement of compliance and user satisfaction".

[56] The nature of Portuguese health system, classified as "Complex adaptive" is supported by the systemic paradigm that advocates a logical action simultaneously cooperative and conflict, both coexisting within the system. According to Nolan (1998) a healthcare provider, as any service provider, must be analysed as a complex set of actors that interact, regardless they develop cooperative efforts for the common interest, they don't stop to engage in conflicting disputes (Source: (292)) But, in general, persons who have their own interests and motivations support services providers and the provision cannot be automatic or nonpersonnal as in the Industry. In health this becomes even more complex when the nature of the provider-user relationship is characterised as "subjective, random and unpredictable" (Source: (293))

"standardise" healthcare quality measurement, some studies were developed, addressing several models and quality dimensions considered as most appropriate for healthcare quality (as pointed before). Besides the importance of the dimensions and models definitions, for measuring and assessing healthcare quality it is fundamental to identify the different perspectives of evaluation: healthcare user, healthcare professional (clinic or non-clinic) and healthcare service payer.

This strategic plan emphasised the fact that quality in health not only depends upon the efforts triggered by the Ministry of Health related with strategies and policies or by healthcare professionals in their work, but it is strongly related with programmed interventions in critical areas, such as governance, continuity and integrated care.

Regarding the first area, the implementation of an Integrated Governance, to promote synergies between all relevant governance dimensions: clinical, financial, reporting and risk management is reinforced (294).

To achieve the proposed goals, it is important to promote a sustainable development at structure level (architecture, environment, financial system, resource management, among others), at process level (human resources planning, monitoring and control methodologies, assessment processes, external recognition - certification and accreditation) and results level (health gains, promotion of chronic illness self-management, among others). Opportunities and threats that may promote/difficult the development and implementation of quality strategies were also identified, covering all interested parties. As opportunities the increase of: citizen empowerment, professional safety, recognition of quality and effectiveness of care provided by the healthcare organisations and finally the importance of health for the policymakers can be highlighted; As threats the time and bureaucracy needed to implement quality processes that strongly influence the professional work, lack of quality culture at organisational level, and time limitations of the policy cycle that may condition the follow-up of policies to improve quality were pointed out.

Finally NHP 2011-2016 emphasises the importance of creating a structure independent from the Government, reporting directly to Parliament, to assess, monitor and promote the quality of care at all health system levels. A careful examination of the contents of these two important strategic documents - NHP 2011-2016 and Strategy for Quality in Health - that somehow dictate the future of quality in health – shows, nevertheless that they are not aligned with the strategic priorities proposed and on whom will be responsible for quality in health global management. However, as NHP 2011-2016 is in public discussion and open to suggestions, it will probably still be revised, taking into account what was established in 2009 by the Government.

Programmes and Projects developed in Portugal

One of the first quality project developed in Portugal was the "Quality Improvement Project" supported on an USA programme for hospital management implemented in the 80s to improve hospitals productivity. This project was based on continuous improvement techniques, with big success among industrial organisations, such as PDCA cycle, solving problems methodologies, root-cause analysis (RCA), Deming principles (80% of errors are associated with the process and just only 20% are associated with human error), Zero Error Theory and Quality Value Chain (optimal clinical outcomes, user satisfaction, professional development), all of them with great success in industry. This project was developed in two phases, each phase involving four different hospitals. In these hospitals the project created 40 quality improvement teams focused on the identification of problems, their causes and their improvement actions. The hospital areas involved in the project were: Emergency services (7), Operating Room (5), External Consultation (5), Inpatient (5), Clinical Procedures (3), Materials Management (3) Medication use (3), Archive and coding (2) and Human Resources management (1) (295).

At same time, another national project was launched, developed by DGH to monitor organisational quality of primary care centres, the "MONIQuOR". This project was based on a global strategy for organisation improvement, procedures validation, systematic multidisciplinary reviews, improvement of internal communication, and the establishment of actions plans. The evaluation was supported on 163 criteria for six areas: management, citizen rights, health promotion, health delivery, continuous education and quality development, and infrastructures (296). The project initiated in 1998, and was used for self-assessment in 1998, 1999 and 2004, and for peer assessment in 1999. The initial adherence to the project by the 357 primary care centres existent at that time was very high in 1998 (81%) but fell drastically in 1999 (only 29% for self-assessment and 31% for peer assessment). This decrease can be explained by the lack of motivation created by the inconstancy of primary care reform at that time, emphasised by the turn off of the implementation of 3rd generation primary care centres project, which was characterised by healthcare professionals strong involvement and healthcare professionals dedication.

As mentioned before, based on the definition of the Health National Strategy in 1999 the HQI started to developed several projects as mentioned before, such as: the COS; the QualiGest, the Procurement Hospital Services Qualification project; the Patient Care Admission and Referral Manual; the National Hospital Accreditation Programme; and the international Quality Indicator Project (QIP).

The COS project started in 1999 to promote the development of tools to support clinical decision, to improve clinical outcomes and minimising its variability. With regard to health systems, COS contributed to the identification of new needs, promote education and training, fair resources distribution and improve services efficiency (297, 298).

QualiGest was a project based on the EFQM model with the main objective to evaluate the quality of top management. With this project, and to support it, was established a set of training programmes were established and a connection was promoted between the EFQM Healthcare Working group and the Portuguese Association for Quality (national manager of the EFQM model). This implementation contributed to the identification of several problems: deficit in professional training, shortage of resources provision and resistance to implement changes in organisational culture. This programme included a pilot implementation in 1999-2000 in the primary care centres from the health sub-region of *Aveiro*. This programme, formally and consistently, presented no new developments.

The Patient Care Admission and Referral Manual, developed by the Ministry of Health and coordinated by HQI, was introduced in 2000 in hospitals and primary care centres from NHS in order to improve care and the admission and referral process through the establishment of procedures for identification, record, marking, admission, information, guidance and referral for healthcare providers. At the end of 2003 thirty services from 18 NHS public organisations have already joined to the project. The relevance of this project results supported the launch of a Phase II (2005-2006) that, among other activities, promoted the development of best practices guidelines in order to improve the relation between professionals and users. This project included a set of guidelines and procedures to improve telephone service as well as to support the handling of complaints and conflict situations (299).

The Procurement Hospital Services Qualification project began in 1999 as answer to the variability shown in different procurement departments / services, materials price, and quality level. This project intended to harmonise some buying process practices, storage practices, distribution and inventory management, specification standardisation, systematisation of procurement activities and the introduction of selection, qualification and evaluation of suppliers. It was introduced in 1999, in 12 hospitals from the region of Lisbon, due to the significant volume of purchases that these hospitals represented in the total budget of NHS (23.3% of total purchases in 1998). The methodology was based on standard ISO 9001:1995 (Purchase requirements).

As the quality evaluation of primary care centres evidenced relevant developments, a similar approach was necessary regarding hospitals. In 1999 a collaboration protocol was established with King's Fund- Health Quality Service (KF-HQS) from the UK, to support the Portuguese

NHQS in the development of a national accreditation programme for hospitals (300, 301). This programme was supported by the King's Fund, which included criteria and standards for five dimensions: institutional management, resource management, the rights and needs of patients, the course of patient and specific services.

The protocol considered the creation of two programmes: a programme for quality evaluation and organisational improvement and a benchmarking programme, to promote the organisational performance comparison between national and international organisations. This partnership lasted six years, divided in three phases: learning process, model implementation and subsequent evaluation (audit); establishment of management infrastructures, as the national accreditation body, and independent system evaluation/collaboration by the HQS from the UK. It was introduced in Portugal at first - Pilot phase - in seven hospitals (302, 303).

Another major project developed in Portugal by HQI was the international version of QIP Project - Portugal. This project resulted from a similar one developed in USA in 1985, called the "Quality Indicator Project" which voluntarily, brought together seven hospitals, in order to test a set of clinical performance measures stimulate the use of this information in activities to improve healthcare quality and patient safety. This set of indicators covered four major areas: i) acute care, ii) psychiatric care, iii) continuous care, iv) and home care. With the increasing number of national and international organisations interested in this project the QIP coordinator decided, in 1997, to extend the project scope, thus resulting in an International QIP, which enabled the involvement of eight European countries (Austria, Belgium, Germany, UK, Hungary, The Netherlands, Portugal and Switzerland) and Asia (Singapore and Taiwan). The contribution made by the participants from these countries, along with participants from the USA, led to the creation of the largest comparative database of indicators for healthcare quality and safety, and to the development of an effective programme for clinical performance evaluation. Portugal joined International QIP, in 2001, under the coordination of the *Hospital S. Sebastião - Santa Maria da Feira* and the HQI. Initially (pilot project) this project was introduced in eight national hospitals and emphasised the benchmarking importance for the continuous quality improvement process. In Portugal this tool was supported by a set of 20 clinical indicators and 200 measures, divided into two major groups: Inpatient and Outpatient. These indicators were described in detail and aimed to promote the performance of medical and nursing professionals (304). In 2005, the coordination of International QIP in Portugal was transferred to HQI and began its development in 27 national hospitals and three psychiatric clinics (305). In 2009, the last year of the partnership with Portugal, only ten hospitals were involved. This partnership was not revalidated and ended in 2009.

It is important to emphasise that a general national system for quality indicators monitorisation never existed in Portugal. However in 1999, with the creation of contracting agencies, some indicators were defined by the Regional Healthcare Administration to monitor hospitals. This strived to survive for several years but it was reactivated in 2006 when some quality indicators defined by Central Administration of Health System (CAHS), were included in the contracting process of hospitals (291). Additionally the New Strategy for Quality in Healthcare presented in 2009 by the DGH also contemplated the creation of an indicators system to allow monitorisation of healthcare services. This strategy pointed out the importance of an indicator based evaluation system, and like in any measurement and evaluation process, it complies with the saying: "measure implies acting". This system was so important that if not seen as a step forward towards change and improvement, could discredit the entire healthcare quality improvement process (282).

In addition to the specific projects presented previously, others could be identified as having a more general aim of promoting a commitment and evaluation culture. One of these was the so called "Letter of Quality", implemented in 1999 to promote the commitment culture in healthcare organisations. This project aimed to introduce the concept of public commitment between healthcare organisations and users regarding to quality. This commitment letter should be supported by the quality policy of each healthcare organisation (resources management, communication, tasks and responsibilities) and by the quality improvement systems established (270).

Subsequently to the project developed in 1992 by the Centre for Studies and Research in Health - University of Coimbra, to evaluate hospital quality, at least three hospital quality evaluation projects were introduced between 2000 and 2005. In 2000 a project was launched in Lisbon region, to evaluate the practice of general practitioners. This project was supported by the "EUROPEP"[57] questionnaire composed by 23 standard indicators, developed by an international expert group between 1995 and 1998. The instrument was adapted and validated in several languages, including Portuguese, and used in more than 20 countries. The questionnaire was structured in three parts: key indicators - with several dimensions such as communication, healthcare, information and support, continuity and cooperation, and organisation of services; indicators for "specific areas of satisfaction" – with dimensions such as accessibility, professional services and centre facilities; and "user" indicators – including socio-demographics data, health data, and after experience attitudes dimensions (306). The initial application of this instrument in 2000 was followed by two more applications centred

[57] EUROPEP is an instrument validated and internationally standardised to measure patient evolution, associated with general practice care.

in primary care: evaluation of users satisfaction from primary care centres in 2001-2002, and "The voice of user in primary care centres" in 2003-2005.

Two additional new evaluation projects were introduced in 2002, one aiming to evaluate the user satisfaction of private services and another focused on healthcare professionals satisfaction evaluation (instrument for assessing professional satisfaction, at hospitals and primary care centres). All these projects were supported by a self-assessment process with standard questionnaires and the results intended to be used internally by top management to improve internal quality system and to promote benchmarking between identical organisations (307).

A clear commitment to improve performance indicators based on sustained evaluation of users' satisfaction, professional performance, and performance of critical care units was evident and supported by the development of benchmarking indicators for clinical process and results of hospitals. The quality of diagnosis and therapeutic areas was also promoted by the development of COS to support technical decision. The first approach to medical error and patient safety was noticed, with collaboration of professional healthcare associations, and including some relevant activities: research and reflection in this area, encouraging the systematic medical error reporting, and development of safety systems within healthcare organisations. To assist with healthcare safety the revitalisation of the National Humanisation and Quality in Health Services Committee was proposed. A focus on improving the quality of laboratory, through the development of quality assurance systems in accordance with ISO 9001 and ISO / IEC 17025[58] was also noticed.

Another project launched in 2003 with the HQI support was related to the certification service of Paediatric Emergency at *Hospital Santo André, Leiria*. This certification service was part of the phase II of the project Quality Manual for Admission. This project was considered a challenge with several implications in care organisation, process standardisation, quality of information and continuous evaluation. This certification was supported by the development and implementation of a technical specification service based on a set of commitments, requirements and specification limits for each requirement (308).

From 2003-2004, the Ministry of Health, with the support of a government agency responsible for corporate hospitals, introduced several projects related with quality in hospitals that had recently adopted a corporation management model. The purpose was to validate their decision to implement this hospital management approach (named "*Hospitais SA*" and then "*Hospitais EPE* – public corporate entities"). Among the mentioned projects the Programme *Conforto can be highlighted*. The programme consisted in an environment

[58] ISO /IEC 17025 is an international standard with general requirements for the competence of testing and calibration laboratories.

evaluation programme with a set of indicators in order to assess facilities of 31 public hospitals with corporate management, taking into account infrastructures, cleanliness and maintenance of spaces. The results of this evaluation process promoted the implementation of a wide range of improvement measures in order to assure better comfort for the users of the services provided by these hospitals (309).

A systematic user satisfaction evaluation for hospitals was also launched in 2003, focused on the admission process. The Institute of Management and Financial Information developed, in collaboration with the Institute of Statistics and Information Management from New University of Lisbon, a scientifically validated methodology based on ECSI[59], which allowed the evaluation of perceived quality and user satisfaction in areas such as inpatient, emergency room and outpatient. The main objectives of this study were: to promote the participation and involvement of user in health systems; to promote performance assessment on non-clinical areas and to promote improvements at care level; to promote improvement in communication and comfort; to promote benchmarking data to identify best practices and promote the user satisfaction convergence between different services.

The results of this project, presented in 2006, showed that user satisfaction remained positive for all three dimensions. Regardless of these good results some areas to improve were identified: hospital image, complaints management, facilities improvement and benchmarking promotion to identify best practices. This project was discontinued but the Portuguese Quality Institute demonstrated interest in its reactivation in the future.

Following the hospital accreditation programme established by HQI and based on the KF model, a new model developed by JCI was introduced in Portugal in 2004, based on the JCAHO model, established since 1994. As referred before, this model was introduced in some public hospitals recently transformed in public corporate hospitals by the responsible government organisation. The model was considered more adequate for this type of hospitals because it emphasised the importance of organisational performance improvement as whole and including, therefore, care improvement, safety and quality commitment, competitive advantage, confidence improvement and the promotion of evidence-based learning process of healthcare professionals (310).

With a new hospital accreditation model being applied in national hospitals and considering the end of the partnership established between HQI and KF-HQS, an analysis on the future of Hospital Accreditation Programme became fundamental. As so, a meeting promoted in 2004 involving the two-accreditation programmes managers, as well as representatives from accredited hospitals (or in the accreditation process), with RAH (regulator body) and the

[59] European User Satisfaction Index (ECSI).

representative of ANAES (French accreditation entity), to promote the analysis of strategic issues for healthcare accreditation process in Portugal. From this meeting some issues were raised: national experiences from the two models; future of hospital accreditation programme; legal framework definition; national development and review of standards and criteria; incentive scheme for promote the adherence to a voluntary model or mandatory requirement; relationship with the Portuguese Quality System; financing programme - direct State funding or self-financing; application to private sector; focus programme and relationship with specific programmes; audit system (standards, training); link to other systems – e.g. ISO and EFQM.

Some recommendations were also formulated: to create an accreditation body outside the NHS, to ensure impartiality; to use accreditation programme to promote financial incentives; to maintain the accreditation model linked to international programmes (regardless the model used) and to establish international partnerships to facilitate international recognition; to open market consultancy for the implementation of the national accreditation programme; to develop a pool of international auditors to ensure the external recognition. Unfortunately these recommendations were never implemented in practical terms.

In 2005 HQI introduced another project for continuous improvement in healthcare organisations, following the Patient Care Admission Manual project and supported by the Gemba Kaizen[60] methodology. The main goal was to reinforce continuous improvement through new practices associated with eliminating useless, redesigning workspaces, among other factors. In the beginning this project was developed in three hospitals and three primary care centres in *Aveiro* region.

Between 2004 and 2005 a study was carried out by the RAH entitled "Diagnosis of Quality in Portuguese National Health Service", although its scope was limited to public sector. The aim was to map the application of quality tools in public healthcare organisations (hospitals and centres) and to provide support for the definition of a strategic action for RAH about quality issues. Supported by data, obtained from all public hospitals (103) and all primary care centres (357), this work concluded that 80% of NHS hospitals (public service) participated in the quality projects promoted in Portugal by HQI and others healthcare organisations and in certification and/or accreditation processes supported by ISO 9001, ISO 17025 and others. It was also found that 36% of NHS hospitals were already in an accreditation process by one of the models JCI and KF-HQS. With regard to primary care centres it was found that only 22 centres were not involved in quality projects. In general there was also observed that in some

[60] The Japanese word "Kaizen" means continuous improvement and the word "Gemba" means "where the action is happening". In this sense, the project called 5S, is established around five "senses" - Seiri - Sense of Use; Seiton - Sense of storage; Seiso - Sense of cleaning; Seiketsu - Sense of Health and Hygiene and finally Shitsuke - Sense of self discipline.

healthcare areas the development of quality projects was already part of the organisational culture, such as laboratory area, more specifically those related with blood – where the legal framework is quite restricted - and the sterilization area (303).

Between 2005 and 2007, Portugal was involved in the European project MARQuIS but only participated in the first part. From this study it could be concluded that Portugal, as nine other European countries, had quality improvement policies developed and set at national level for whole country, and there were legal or statutory requirements for healthcare organisations to define quality improvement policies and strategies (24).

In 2006 the Portuguese Association for Hospitals Development, in partnership with the Central Administration of Health System, presented the Best Practices Award with the main purpose to reward healthcare professionals for their contribution to promote quality improvement with equity, efficiency and effectiveness. Currently the DGH is still promoting this award as an engine for exchange innovative experiences exchange and to foster added value for different levels of care (311).

In 2008, following the creation of Primary Care Clusters Centres (PHCC) as a measure associated with Primary Care Reform, the Ministry of Health and the government organisation coordinator of Primary Care Reform launched a registered trademark, the AQR®, to recognise the quality of service provided by healthcare organisations. This recognition mechanism was only applied to primary care providers. The attribution of this brandmark aimed to promote and foster quality improvement service in two main strategic areas: the "process voice" focused in the quality of back-office activities and the "user voice", focused in the quality of front-office activities and represented by user perceptions about attitudes and behaviours.

By the end of 2008 and early 2009 RAH developed the "National System for Quality Assessment in Healthcare" programme (NSQAH), with the main objective to evaluate healthcare providers through selected indicators that allowed the definition of a provider rating system. This rating system goal was to provide, to healthcare services users, some important information to support the decision-making process. The assessment tool, compiled in a manual with a set of indicators, was created with strictly collaboration of Joint Commission and Siemens (312). In this programme two different projects, SINAS@Hospitals and SINAS@Oral Health were launched.

The SINAS@Hospitals presented five evaluation dimensions: clinical excellence, patient safety, facilities and comfort, user centred, and costumer satisfaction. Several indicators were established for each dimension, and in patient safety dimension two national indicators could be identified as related with HAI prevention and control: HAI associated with central catheter

and HAI associated with sepsis postoperative. The SINAS@Oral Health was also supported by five dimensions: registration and licensure, organisation and procedures; patient safety; facilities and comfort; and user satisfaction. This project was launched in 2010 to promote the quality in oral care, an area subjected to several user satisfaction complaints related with clinical procedures and insurance problems. The information collected through these projects was considered of great advantage to user (through knowledge about best classified providers in terms of rating) and for payment systems (as a fundamental tool for the contracting process).

Also in 2010 Portugal joined the project from European Union "Deepening Understanding our Quality Improvement in Europe" (DUQuE) through the participation of *Hospital de Guimarães - Centro Hospitalar do Alto Ave*. This hospital participated in this European research project, developed between 2009-2013, with the main objective to study the extent to which the quality improvement organisational systems, culture, professional involvement and patients empowerment were related with healthcare quality, measured in terms of clinical effectiveness, safety and involvement of the patients (study applied to European hospitals). The specific objectives were: 1) development of a classification model for assessing the maturity of improving organisational quality systems in European hospitals, 2) association analysis between quality improvement systems maturity and measures of organisational culture, professional involvement, and patient empowerment (hospital level), 3) association analysis between quality improvement systems maturity and measures of clinical effectiveness, safety and patient involvement (patient level), 4) Identification the factors that potentiate the activities of quality improvement in hospitals (e.g. external pressure imposed by accreditation, certification and external programme evaluation).

Quality Management to Improve Healthcare Organisations

There is a strong evidence of the positive impact of quality management tools in healthcare organisations. As identified by Berwick (313) quality management methods can be successfully used in healthcare organisations to improve processes and consequently the clinical practice, but only with the active participation of healthcare professionals, specially, physicians. This work emphasised in this work the intellectual similarity between clinical practice to improve health of individuals and quality management to improve working processes. These important similarities include the scientific combination of theory and evidence, the avoidance of blaming, the systematic variability, the use of experiments, and the refinement and use of measurement. However the importance of understanding healthcare as an infinite (almost) number of interrelated and interconnected processes, and learn that these

processes can be analysed, managed, and improved was also demonstrated. This new approach, according to several authors, may result in an increased of customer satisfaction and reduction costs (224, 227).

Studies conducted by Gowen *et al.* (314) referred the frequency and severity of clinical errors reduction in hospitals where quality programmes were implemented. According to Kazandjian and Lied (315) the qualitative outcomes associated with quality models also include a better understanding of these errors.

Hellings *et al.* (316), in their before-after study about patient safety culture, concluded that organisational culture cannot be tackled in isolation from organisational structures (financial arrangements, resources) or processes (control lines and accountability, strategy formulation or personnel initiatives), but it must be ensured by integrated management promoted by quality management systems. They also found that it was important to create a multidisciplinary patient safety committee and involve hospital managers (changing a culture, even a few practices and policies, requires a common vision and a strong hospital leadership, and management support for patient safety is essential), intensify healthcare professionals education and training about patient safety, to raise awareness about culture role for a safer hospital environment. Patient safety culture change was considered a huge challenge mainly because of the combination of complexity and professional fragmentation and an individual tradition were identified as are strong barriers to hospital patient safety culture; and to improve clinical care requires organisational change at all levels, which can not possible without understanding how the system works, how to promote it and assuring the right skills to implement the changes. To promote these findings the authors developed a patient safety framework package, based on seminars, papers and literature for all hospital professionals, and strived for focused improvement projects**.** They recommended that safety culture should be measured every three years. Three conceptual dimension clusters to analyse safety culture were identified: supervisor expectations and actions promoting patient safety and management support, combined with working on non-punitive culture; communication openness, stimulating event reporting, feedback and organisational learning can be integrated; teamwork in/across units can be combined with improvement projects.

Considering quality *vs.* innovation in health, the XXI Century, pushed organisations to the difficult task of survive in an environment where medical information, technologies, and relationships are changing at speed of light. These changes, when combined with governmental pressure to reduce costs and improve quality of services, promoted the introduction of new mechanisms and technology, combining quality and innovation, and enable healthcare services improvement. However it is also cleared that its introduction in the

sector will require re-thinking organisational processes, from the identification of needs/expectations of all interested parties to their satisfaction.

According to West (317, p.9) innovation can be defined as "the intentional introduction and application within a group or organisation of ideas, processes, products or new procedures designed to significantly benefit an individual or an organisation". This definition brings together three basic characteristics of the concept: the novelty, the application component and the intention to benefit. For this author and other co-workers management changes can be also regarded as innovation. New human resource management strategies, organisational policies on health and safety, or the introduction of teamwork are all examples of management innovations (317).

According to the national standard NP 4456:2007 (318), innovation "is associated with the implementation of a new or significantly improved solution for the organisation, new product, process, organisational method or marketing, with the aim of strengthening its competitive position, increase performance, or knowledge"[61]. According to this definition four different types of innovation can be identified: product innovation, process innovation, organisational innovation and marketing innovation. A more detailed analysis of the meaning of each of these types of innovation shows that in the health sector all of them can be seen as added value for all interested parties. The first type of innovation is defined as the "market introduction of new or significantly improved products or services". This includes significant changes in technical specifications, components, materials, incorporated software, user interface or other functional characteristics (319). The innovation of the product / service can be supported by new knowledge or technology or just by a combination of existing knowledge or technology. It may also include significant improvements in the way it is manufactured / supplied (e.g. speed, efficiency) and new features. The second type of innovation can be seen as "the implementation of new or significantly improved production processes, logistics and distribution" (319). This means new methods, new activities or significantly improved supporting processes can be promoted (e.g. maintenance systems, information systems, accounting systems, etc…). Organisational innovation is defined as the "implementation of new organisational methods in business practices, work organisation and/or external relations". New organisational methods can imply the implementation of new methods for organising routine activities and development of new procedures (among other new training processes, evaluation and development of human resources or quality management system, information management, etc.). According to this definition it can be assumed that the implementation of new methods for responsibilities allocation, decision-

[61] This definition was adapted from the Oslo Manual (see OECD, Oslo Manual: Guidelines for collecting and interpreting innovation data, EUROSTAT, Editor 2005, OCDE/EUROSTAT. p. 166).

making, new concepts for structuring activities, such as integration of different units (systems implementation "build-to-order", new systems for decision-making, etc.) are related with the concept of organisational innovation. The implementation of new forms of relationships with other companies, establishment of new forms of collaboration, new methods of integration with suppliers, new forms of subcontracting or advising can be considered rereading external relations (318).

In the healthcare sector "innovation" can be related to the development of new services, new forms of work and the introduction new technologies. In terms of benefits related with patient satisfaction, it can be concluded that the introduction of innovative factors should promote health and reduce pain during illness, and in relation to organisational issues innovation should promote the efficiency of internal processes and/or quality of care.

The analysis of quality management models and its development over time, from industrial application to health sector, shows that, in fact "quality" can be framed as a tool promoting innovative "ways of working", driving the creation of new services and new technologies in order to achieve all the defined proposes. According to these definitions and concepts, innovation has a strong connection with quality management issues. This can be verified in several papers presented by renowned researchers in the area of quality management in health, with emphasis on the work by Berwick and Nolan (320) that stated that one of the paths to follow in order to promote the improvement of healthcare and to decrease practices variability is inventing new forms of care.

Previously in this work, several international projects developed to identify and analyse the existing quality management models and tools for the implementation of healthcare quality improvement systems were identified. The general benefit associated with quality management systems was stated to be related to the promotion of a framework to develop and implement systems for operational improvement of structures, processes and outcomes. This could result in an increase of effectiveness and better health outcomes.

For each healthcare quality dimensions several studies that emphasise the important role of quality management systems were also identified (321).

For "Structures – who we are" and "Processes – how we do" levels quality management system were considered responsible for:

- Sustaining improvements in quality and organisational performance;
- Promoting organisation compliance with quality and safety standards and legal regulation;
- Stimulating organisational sustainability and better resources allocation;

- Leading to improvement of internal practices, by codifying policies and procedures and decreasing variability in practices among healthcare professionals;
- Promoting self-assessment and self-analysis of standards;
- Improving communications and internal collaboration;
- Decreasing variability in practices among healthcare professionals, by codifying policies and procedures;
- Strengthening interdisciplinary team effectiveness;
- Promoting professional development and organisational education and training.

When it comes to "Results – What we get" level quality management system were linked to improvement in:

- Data collection, treatment and analysis;
- Reporting systems;
- Patient outcomes.

JCAHO/JCI Model

At the beginning of the XX Century, in 1917, the first version of the accreditation programme applied to healthcare was released in the USA, the "Minimum Standard for Hospitals", as a mechanism for recognition of training in surgery and quality in delivery service. This programme, supported in a set of minimum standards and recommendations, was the precursor of the Joint Commission on Accreditation of Healthcare Organisations model (JCAHO) founded in 1951. This programme, called "Hospital Standardisation Programme", supported in a standards manual, was initially established to recognise institutions with "minimum essential standards of quality" in organisational processes to support clinical practice, but in 1970 the standards were revised to represent "optimal achievable" levels of quality. The infection control was not directly approached as part of the standards until in 1976, when a chapter with infection control standards was published in the Accreditation Manual for Hospitals, highlighting the importance of infection control programme, the infection control committee and its roles and responsibilities, policies and standards (322). In 1987 JCAHO launched its Agenda for Change with the main goal to create a modern and sophisticated accreditation process based on an organisational performance approach, which emphasised performance-focused standards and performance measures/indicators and a more interactive and consultative survey process. In 1992, the accreditation manual for hospitals introduced, for the first time, performance improvement concepts. In 1996 the "Sentinel Event Policy" was established for the evolution of sentinel events in accredited organisations and their relationship to accreditation status. This tool was revised in 1998 and in 2000 to

promote self-reporting of medical errors and encourage healthcare organisations to perform root causes analysis of these events.

In 1997, the JCAHO introduced a new project in the accreditation process, called "ORYX: The next evolution in accreditation", to integrate the use of outcomes and other performance measures into accreditation programme. The aim of this project was to identify and develop key performance measures and analyse the growing importance of the use of performance indicators in medical practice. In 2002 hospitals that have applied this new project started collecting data on key measures in the following areas: acute myocardial infarction; heart failure; pregnancy; and pneumonia. The successful implementation of these key measures led to the development and implementation of new measures relating to the prevention of SSI. In 2006 JCAHO developed a new set of measures associated with intensive care, pain management and paediatric asthma.

In 2009, the growing concern and focus on patient safety, led JCAHO to include in its accreditation manual a set of goals to promote specific improvements in patient safety. Actually this set of goals, named "National Patient Safety Goals" has six goals, including Goal 5 oriented to "Reduce the Risk of Healthcare-Associated Infections". This goal has three specific requirements addressing HAI prevention and control.

Since early time the interest for this model spread into other countries and in the European context, the first adoption occurred in 1981 in a Spanish hospital from the Catalonia region did the first adoption. In the middle of the 80's this model began to be adopted at international level, promoted by the Joint Commission International (JCI), and on a large scale in Europe, being more evident its use in the UK, Spain, The Netherlands, Finland, Germany, Switzerland, France and Italy (in these last two countries as a statutory requirement (301, 323). In Portugal this model was introduced in 2004 by a government organisation responsible for the public corporate hospitals from NHS. The first Portuguese hospital to be accredited by this model was the *Hospital Padre Américo* in 2008.

In a general way, the implementation of these measures in healthcare organisations is considered to promote the collection of data over time, allowing continuous monitoring and evaluation intra and inter organisations, and promoting the comparison of best practices. The JCAHO standards have the intention to provide high levels of performance to healthcare organisations in key areas such as patient rights, patient care and infection control. Although the main objective is to improve the capability to provide high quality of care it is also an important objective to improve their performance. This model was created based on a market-oriented healthcare, such as the USA healthcare market, support in insurance plans. Thus, the

development of standards was accomplished taking into account all interested parties: patients, providers, and professionals from healthcare services, among others.

Advantages of JCI accreditation model are identified: the promotion of confidence about healthcare quality and safety; the promotion of risk management improvement; the promotion of training; the decrease promotion of insurance costs.

This model included standards and accreditation programmes for different types of healthcare organisations: hospital care, ambulatory care, primary care centres, continuous care, clinical laboratories and medical transport organisations.

The hospital accreditation standards are compiled in a manual divided in two sections: section I - Patient-Centred Standards, and section II - Health Care Organisation Management Standards. In the first section includes eight major processes with standards for: International patient safety goals (IPSG); Access to care and continuity of care (ACC); Patient and family rights (PFR); Assessment of patients (AOP); Care of patients (COP); Anaesthesia and surgical care (ASC); Medication management and use (MMU); and Patient and family education (PFE). The second section has six processes with grouped standards: Quality improvement and patient safety (QPS); Prevention and control of infections (PCI); Government, leadership, and direction (GLD); Facility management and safety (FMS); Staff qualifications and education (SQE); and Management of communication and information (MCI). These sections are transversal and must be applied to entire organisation as well as to each department/service within the organisation (310, 324).

In the accreditation manual, each of these groups of standards is presented taking into account the specific requirements, its intent and measurable elements to measuring and assessing its compliance. This allows a better comprehension of the standard, "How to apply?", "Why to apply?", and "How to measure compliance?". The manual can be used to help to implement standards and to promote self-assessment, as supporting external assessment process.

The accreditation process is divided in several parts as previously explained: 1) the implementation of the manual standard in the healthcare organisation and conducting self-assessments: this can be done with external consultancy assistance contracted by the healthcare organisation and the self-assessment can occur in any moment as decided by the organisation. Normally it should occur at in the beginning of the project to define an organisational diagnosis and prepare for the external survey[62] made by JC surveyors (external audit process); 2) the on-site survey process: this process is fundamental to verify the "Say-Do-Proof" approach implemented in the organisation and it is supported by on-site

[62] The term "Survey" can be defined as the assessment of the organisation compliance with JCI standards and their intent statements. This assessment process is similar to the Audit process.

observation, documentation analysis, interviews with patients and staff. These methodologies are necessary to analyse the standards compliance throughout the entire organisation since the accreditation decision is based on the overall level of compliance found (this model is based on process approach). When a standard compliance is related with law or regulation, the higher or stricter requirement prevails. A higher qualified Surveyor - consisting of physician(s), nurse(s), and administrator(s), should perform the on-site survey

These manuals are reviewed periodically to ensure their suitability to demands, and external and internal oriented tools promote changes. The 3rd edition of the accreditation manual published in 2007 and applicable from January 2008 to December 2010 presented some important changes such as new policies related to accreditation decision process, focused surveys approach, tracer methodology implementation, sentinel events goals, a new chapter focused on patient safety goals, new chapters to better organise the process approach (Medication, Management and Use (MMU) and, Anaesthesia and Surgical Care (ASC)), and some chapters were revised to reflect the healthcare changes. The Prevention and Control Infection Chapter was significantly reorganised reflecting some new expectations according with laws, regulations and improvement of patient safety (324).

The introduction of survey-focused approach was also related with patient safety assurance: this survey to be performed following a full survey, when potentially serious standards noncompliance related with patient care or safety are detected.

The tracer methodology is an evaluation methodology developed and applied by the JCI since 2003 and included in on-site survey. Two tracer methodologies were identified: the Individual Patient Tracer and the Individual-Based System Tracer. The Individual Patient Tracer is a framework to evaluate and analyse the healthcare services provided to patients and their compliance with international standards. JCI defines as “the process used by JCI to evaluate an individual patient total care experience within a health care organisation” (324, p.239). In other words, patient care tracer follows patients through their care experience, focusing on applicable standards. This is done by records, documents and interviews analysis. The Individual-Based System Tracer is a performance evaluation focused in a specific (and relevant) system or process across the organisation. Three major processes use this methodology: data use, infection prevention and control, and medication management. JCI defines as “a session during the on-site survey devoted to evaluating high-priority safety and quality of care issues on a system wide basis throughout the organisation” (324, p.239).

The worldwide concern with sentinel events[63] associated with healthcare services and their negative impact on patient safety led JCI to review all the organisational activities to promote their reduction/elimination. For that, JCI decided to include the Sentinel Event Policy in the hospital accreditation programme and developed a specific standard, which helps organisations to manage this type of events. This policy is based on a set of goals: to have a positive impact on patient care; to focus the organisational attention in understanding the causes and to promote necessary changes to eliminate/reduce; to increase general knowledge about the sentinel events, their causes and strategies to prevention; to promote public confidence in accredited organisations. This policy somehow changed in the beginning of July 2013 to encompass also in the organisational safety culture all people within a healthcare organisation (staff, visitors, vendors) in the organisational safety culture and not just the individuals served, such as patients. The specific standard, from the Standard Quality Improvement and Patient Safety group[64], established new rules for identifying and managing sentinel events, with the inclusion of three different types of events in the organisational sentinel events definition; application of RCA on every event that meets the definition; a real time analysis process; and, finally evidence that hospital top management have promoted actions according to results of RCA application (310, 324).

The introduction of Patient Safety Goals incorporated, as main objectives, the promotion of specific improvements in healthcare problematic areas, and the identification and proposal of evidence-based and expert-based consensus solutions. One of the goals identified was "Goal 5 - Reduce the Risk of Health Care–Associated Infections" (310, 324).

The actual hospital accreditation standards are compiled in the 4th edition manual and no conceptual changes could be noticed. The identified changes are at standard level: some language adjustments (eliminate vague words such appropriateness), new measurable elements, standard scope expansion, and new standards related with patient safety (Assessment of Patients standard to promote better reporting of critical laboratory test results) and with healthcare organisation management (Prevention and Control of Infection standard related with the reuse of single-devices).

This hospital accreditation programme has a set of specific standards for infection prevention and control. However, as the whole accreditation process is based on a process approach,

[63] Sentinel event can be defined as an unanticipated occurrence that may involve death or major permanent loss of function of a patient or individual receiving care. This event definition includes: unanticipated death unrelated to natural course of the patient illness or underlying condition; major permanent loss of function unrelated to the natural course of the patient illness or underlying condition; and wrong-site, wrong-procedure, wrong-patient surgery. In 2012 JCI decided to include in this definition certain harm events to staff, visitors, and vendors that occur while they are on the premises of a healthcare organisation.

[64] In the 3rd edition manual it was the standard QPS.5. In the actual hospital accreditation manual, the 4th edition, it is the standard QPS.6. In this manual version it was also included in the sentinel event definition the "infant abduction or infant who was sent home with the wrong parents".

interaction between the process Prevention and Control of Infection and other processes identified in this manual exists and are fundamental.

This model and its contribution to HAI prevention and control system will be subject to a more detailed analysis in the following chapters.

In Portugal several public hospitals are accredited by this model: *Centro Hospitalar Tâmega e Sousa, E.P.E. (Hospital Padre Américo), Centro Hospitalar da Cova da Beira, E.P.E. (Covilhã), Centro Hospitalar do Alto Ave, E.P.E. (Hospital Senhora da Oliveira – Guimarães), Centro Hospitalar de Trás-os-Montes e Alto Douro, E.P.E., (Vila Real) e Centro Hospitalar de Leiria-Pombal E.P.E. (Hospital de Santo André – Leiria).*

Other models developed by recognised international organisations can be presented, such as the KF accreditation model, ISO 9000 series from ISO (in 1987 ISO initiated the development of standards for quality assurance) and the Total Quality model EFQM, which were quickly adopted by healthcare providers.

KF Model[65]

The Prince of Wales created the KF model in 1897 with the main goal to contribute to the implementation of best practices and innovation in main aspects of healthcare and management in the UK hospitals. This model was supported by a set of standards and criteria divided in six sections - which include management and leadership, administrative functions, patient-centred healthcare services, local services and resource management, provision of services, and clinical services - in order to promote benchmarking, evaluation and continuous quality improvement to healthcare delivery. In each of these six sections standards were included, as presented in Table 23.

A total of 69 standards, with 1200 criteria, must be fulfilled if the organisation wants to be accredited by CHKS. These standards were reviewed to reflect changes in healthcare policies, good practices identified by WHO and other international organisations. Each standard has a set of criteria that can be measured through a self-assessment process and external audit process. These criteria establish the service/department objectives and the organisation team must decide on what must be done to implement them.

[65] The KF model was accredited internationally by the Healthcare Quality Service till 2005. Since 2005 the CHKS acquired HQS and started to work in the international market.

Table 23 – KF model standards from the CHKS accreditation manual, 3rd edition (source: International Accreditation Programme for Healthcare Organisations (325)).

Section	Standards
Management and leadership	- Leadership - Quality and governance - Financial management - Management and information technology - Medical service - Nursing service
Administrative functions	- Risk management – general - Patient Safety - Occupational health and safety - Fire safety - Resuscitation/reanimation - Medication management - Infection control - Sterilisation/decontamination services - Waste management - Security - Clinical record management - Human resources - Volunteer service - Occupational medicine - Procurement of goods and services - Transportation services - Infrastructure management
Patient-centred healthcare services	- Patient rights and needs - Complain management - Accessibility of patients - Care of terminally ill - Spiritual assistance service - Funeral services
Local services and resource management	- Food service - Cleaning service - Administrative services - Telecommunications
Provision of services	- Service management, laborwork, and teamwork - Service objectives and planning - Service environment - Treatments and healthcare - Working with administrative functions - Working with clinical administrative functions
Clinical services	- Outpatient services - Imaging service - Clinical pathology service - Pharmaceutical services - Physiotherapy service - Transfusion medicine service - Day hospital - Surgical / anaesthesia service - Outpatient surgery - Surgery service - Oncology – chemotherapy - Oncology – radiotherapy

(Cont.)

Section	Standards
Clinical services	- Service medicine and surgery of childhood and teenage - Maternity service - Emergency medical service - Clinical services, medical physics and biomedical engineering - Special care services - Service of minor injuries - Cardiology service / ischemic cardiac disease - Mental health services - Dependency treatment service - Ambulance services - Specialist palliative care services - Social services - Nephrology service - Strokes service - Diabetes service - Rehabilitation medicine - Content of patient clinical process - Contents of the mental health clinical process

These criteria have two different classifications: "A" level for all criteria applied to professional requirements, best practices, patient safety issues and professional safety issues, guidelines and recommendations; "CQI[66]" level for all criteria applied to quality improvement and best practices improvement. "ISO" criteria are also defined, supporting the correspondence between some KF criteria and ISO requirements and can be used in the ISO based certification process.

Most of the criteria include orientations to assist teams in better understanding. The implementation of these standards must be supported by a training programme for professionals, and by establishing internal structures, such as work groups, that are responsible for this process. This model has a specific standard for the infection control (standard 13) (325). This standard and its contribution to HAI prevention and control systems will be subject to more detailed analysis in following chapters.

In Portugal the healthcare organisations accredited by this model are (302):

- *Centro Hospitalar de Lisboa Central EPE, Hospital Dona Estefânia*,
- *Centro Hospitalar de Setúbal, EPE* (including Pathology Services ISO certification)
- *Centro Hospitalar do Porto, Hospital Geral do Santo António,*
- *Centro Hospitalar de Lisboa Central EPE, Hospital de Santa Marta,*
- *Hospital da Prelada, Porto* (including Clinical Pathology, Anatomy Pathology, Immunohaemotherapy, Pharmacy, Imaging and Sterilisation Service - ISO certifications),
- *Hospital de Magalhães Lemos, Porto,*
- *Hospital do Divino Espirito Santa de Ponta Delgada, Açores,*

[66] CQI – Continuous Quality Improvement.

- *Hospital Garcia de Orta, E.P.E.* (including Clinical Pathology, Supply Service, Anatomic Pathology, Operating Theatres - ISO certifications),
- *Hospital Prof. Doutor Fernando Fonseca* (including Anatomical Pathology Service, Clinical Pathology Service, Immunohaemotherapy Service, Diagnostic Imaging Service, Pharmacy Service, Sterilisation Service, Central Operating Theatres, Ambulatory Surgery Unit, Obstetrics/Gynaecologic Emergency Service, Contract Negotiation and Management Unit, Logistic Management Unit - ISO certifications)
- *Instituto Português de Oncologia Francisco Gentil, Centro de Oncologia de Coimbra,*
- *Instituto Português de Oncologia Francisco Gentil Centro de Oncologia do Porto* (ISO certification).

ISO Based Model

For more than 25 years, ISO 9001 standard helped organisations all over the world by establishing an organisational model, by clarifying concepts, by defining requirements and guidelines regarding the establishment and efficiency of quality management systems.

ISO 9001 is the most well known standard in the world, used by more than a million organisations from all activity sectors, promoted (or not) by second or third party certification schemes. ISO 9001 specifies requirements for a quality management system that can be used for internal application by organisations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

It all started in 1987 with its first edition, followed by a second one during 1994, a third edition (with relevant changes) in 2000 and the last one in 2008. The fifth edition is currently under discussion, and according ISO, procedures are expected to be published during 2015. The ISO 9001 management system standards are prepared and revised by a specific technical committee: ISO/TC 176, Quality management and Quality Assurance, Subcommittee SC 2, Quality Systems.

Periodically, the revision process promotes the introduction of relevant changes on the guidelines and requirements, as for the 2000 edition and as also expected for the new 2014/2015 ongoing revision. The 1994 edition included three different standards, ISO 9001, ISO 9002 and ISO 9003 with different scopes and applicability, depending on the nature and interest of each organisation (ISO 9003 was limited to product inspection, ISO 9002 included production control and ISO 9001, additionally, considered product design and development activities).

The 2000 edition (326), and further consolidation with the 2008 edition (327) introduced a new approach, the process approach (328), changing the previous focus on management system documentation and records (considers that, for an organisation to function effectively, it has to identify and manage several linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next), and a new concept: requirement exclusions (exclusions are limited to requirements within clause 7 – product realization, and cannot affect the organisations ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements) (327).

The ISO 9001:2008 requirements structure includes some introductory sections. Quality management requirements are included from section 4 to section 8 (included) (327-329).

The section 4, Quality Management System requirements, explains the requirements for specific documentation to control the quality management system. This is to ensure that the company implements a system that is both auditable and those records are kept by which conformance can be verified. It also provides a basis for continuous improvement. This section also requires the definition and maintenance of a quality manual, and other procedures, as well as defining how documents and records will be controlled. Process approach requirements, including subcontracted processes management and control dispositions, are also considered in this section. In this section is also established the importance of design and implement a quality system and to manage and to maintain it in all situations.

The section 5, Management Responsibility requirements, requires top management commitment with quality management system, considering a top level PDCA cycle for the whole organisation. Top management must define policy, objectives and plan how to achieve customer satisfaction, (Plan). Then responsibilities and authority must be assigned to involved personnel (Do). Effective communication and revision should be accomplished through the management review by top management and monitored by the management representative. Adequate input data and information must be available (Check). Any related action plan should be reviewed as part of the output of the management review meeting and communicated through the organisation (Act).

The following section, section 6 - Resource management, establishes as part of the planning for quality management system, that top management must also ensure that the required resources are in place to promote the system effectiveness, including physical infrastructure, environment and competent people. Competence needs should be identified and adequate

actions taken to overcome competence gaps (e.g. training plan). The effectiveness of related actions defined by the organisation must be evaluated.

Section 7 - Product realisation, the largest section of the ISO 9001 standard, covers the planning, product development, purchasing and production. This is the part of the business that regulates the main interactions with the customer; the handling of customer specified requirements, as well as the planning and delivering of products and services. Product and/or service design and development activities must be realised according to the requirements referred in this section, including the need for adequate revision, verification and validation of the process and its results. The handling of customer property (including intellectual) as well as product identification, traceability, handling, storage and delivering are also regulated by a comprehensive set of requirements. Finally, the need for reliable product measurement and data that will support related decision (e.g. product conformity and acceptance) is also considered through the establishment of equipment calibration requirements. As previously stated, an organisation can justify the exclusion of some of these requirements although the application of these criteria is limited, in practical terms, just to a few (e.g. design and development, customer property, calibration of equipment).

Finally section 8 - Measurement, Analysis and Improvement, is not just about providing gauges and equipment to check production output and controlling defective product, it is also about putting in place ways to monitor objectives compliance, measuring customer satisfaction, and auditing the conformity of the implemented quality management system. This can be done with other ISO standard, developed to support audit process for management systems (330). It is also required that preventive action is taken before errors occur as well as corrective action when things go wrong. On top of all of this, the organisation is required to continuously improve quality management processes.

Previous editions of this standard focused on documentation requirements. It promoted confusion among users and an image of bureaucracy related to quality management systems structure. The actual requirements for specific documents within ISO 9001 are actually very small, although not always applied. The standard requires that written procedures be put in place where there would be an adverse effect to quality if they were not there. If the process is clear, the people are trained and experienced, and then there is no need for comprehensive written procedures.

Most companies structure their system as a typical “pyramid”, the company’s quality policy, objectives and manual being at the top, as the aims of the organisation. The next level could be the procedures, what the organisation will do, when it will be done and by who. The next level could be the work instructions or standard operating instructions that explain how to do

it. The final level would, probably, be constituted by the forms and records required to produce the necessary evidence that quality management system is implemented, that requirements are met and that improvement is accomplished.

Along with the ISO 9001:2000 edition, two other standards were also published with the purpose of helping organisations in their pursuit of excellence: ISO 9000 (fundamentals and vocabulary) and ISO 9004 (performance improvement). Both were also revised: ISO 9000 was revised in 2005 and ISO 9004 was revised in 2009 (225, 331).

The quality management principles are the foundations for the management system standards and support an appropriate organisational focus. From eight principles established on the 2000 and 2008 editions, the draft of the future fifth edition proposes seven (management as a system was dropped due to the fact that is implicitly included in several other principles), as such (332):

- Customer Focus: the primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations;
- Leadership: leaders at all levels establish unity of purpose and direction and creates conditions in which people are engaged in achieving the quality objectives of the organisation;
- Engagement of People: it is essential for the organisation that all people are competent, empowered and engaged in delivering value. Competent, empowered and engaged people throughout the organisation enhance its capability to create value;
- Process Approach: consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system;
- Improvement: successful organisations have an ongoing focus on improvement;
- Evidence-based Decision Making: decisions based on the analysis and evaluation of data and information are more likely to produce desired results;
- Relationship Management: for sustained success, organisations manage their relationships with interested parties, such as suppliers.

During 2011, ISO promoted a survey among quality management standards users all over the world, to identify their needs, expectations and suggestions. A more friendly and compatible standard structure, the revision of requirement applicability (or exclusion) and the reinforcement of process approach were among the comments received.

The draft of the future 2015 edition introduces, again, some relevant approach and requirement changes, supporting the establishment of a three-year transition period for adoption after its publication. Main changes could include (332):

- Continued omission of specific reference to “services” was considered to be unsustainable if relevance to the service sector was to be enhanced. On that basis, “product” has been replaced by “goods and services” when specifically referring to the deliverables for the customer;
- Two new clauses relating to the context of the organisation “Understanding the organisation and its context” and “Understanding the needs and expectations of interested parties”. Together these clauses require the organisation to determine the issues and requirements that can impact on the planning of the quality management system and can be used as an input into the development of the quality management system;
- The 2008 edition promoted the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system. The 2014/2015 proposed revision to the standard makes this more explicit by including clause “Process approach” specifying requirements considered essential to the adoption of a process approach;
- To require risk based thinking and a risk driven approach to preventive action throughout the development and implementation of the quality management system. This has also facilitated some reduction in prescriptive requirements and their replacement by performance based requirements;
- The terms “document” and “record” have both been replaced throughout the requirements text by “documented information”.

The proposed changes will ensure a better alignment with users expectations so that, even after 25 years, ISO 9001 can continue to be a reference for organisations and entrepreneurs when establishing the path for business performance, respecting the needs of customers and other interested parties. All these will be focused on:

- Demonstrating its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements;
- Enhancing customer satisfaction and added value through the effective application of the quality management system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements;
- Promoting the establishment of adequate organisational strategies and its deployment through the quality policy, quality objectives, processes and improvement action plans;
- Increasing information and data transparency, accuracy and confidence, as a fundamental factor to the decision making activities;

- Improving personnel commitment, participation and contribution and building a competence based organisational structure.

Additionally, ISO 9001 and similar management system standards support first, second and third party conformity evaluation activities and services. Regarding to independent evaluation, third party quality management system certification services, this standard provide a worldwide recognised framework for an organisation that wishes be recognised and differentiate from competitors (marketing focus), access specific business opportunities and fulfil contractual requirements (business focus) or, simply consolidated continuous product and process improvement (internal focus).

As clearly evidenced by international and national surveys, a significant number of organisations choose to adopt and certify their quality management systems. More than 1.111.000 organisations worldwide had valid ISO 9001 certificates by the end of 2011. This numbers denote a slight reduction, and for the first time since 2003, of the ISO 9001 market penetration. Unfavourable economic environment in Europe seems to be one of the most discussed justifications but the certification data also support the need for a coherent standard revision, as already identified by ISO (333, 334).

Health and social work represent, according to these sources, approximately 19.000 quality management system certificates, representing approximately 2% of the total of issued certificates around the world, a figure more or less stable since 2008.

By the end of 2011, 6.821 valid certifications were accounted in the Portuguese market, representing 14,57% of organisations with 10 or more employees and evidencing a strong concentration in North and Lisbon regions. The certificate trend is similar to the global evolution, falling 5,1% in comparison with 2010. The most up to date reliable survey performed in Portugal regarding sector distribution of third party certification occurred on 2010, showing a 7% health and social work quota (524 valid certificates) and consolidating this sector as one of the most significant (4th place among all industrial and service sectors). Apart from health related organisations, the contribution of social work organisations is considered to be relevant to these numbers, due to governmental incentives in past years (333, 335).

The certification process is accomplished by certifying organisations that operate on a for-profit basis and are recognised by national accreditation bodies. The ISO model takes a system and process approach to improve organisational and financial performance, focused on quality management, planning, process control and quality assurance techniques to achieve planned outcomes and prevent non quality outcomes.

These standards have been introduced in several European countries, with application in

specific technical department such as a laboratory or radiology department, rather than to clinical departments/services. For some authors when applied to healthcare, it helps to strengthen the process approach of healthcare service but doesn't include specific standards or criteria for the clinical process, such as the KF model or JCI model. More, in healthcare organisations the focus is related to management processes surrounding clinical decision-making than in clinical processes, and this is considered to be a limitation. With this limitation the systems based on ISO standards seem to be more adequate to services without direct interaction with patient, such non-clinical services (244, 336). These disadvantages, in a first glance, led the movement anti-ISO movement in some countries, such as Germany, although some other countries (such as The Netherlands and Switzerland) decided to integrate this model in other models more healthcare-oriented. According to the experience in these countries the process approach model plays a more important role than a set of requirements as defined in KF model or JCI model, highlighting the systemic management approach. For these reasons some authors consider this model to have a stronger customer-orientation and, for that, it could be most popular in healthcare areas where some degree of competitiveness exists, like some technical department such as a clinical laboratory or a radiology department (233). Nowadays this perspective is changing and several healthcare services initiated with accreditation models have decide to expand ISO based model to all organisation taking the place of accreditation model.

This model and its contribution to HAI prevention and control systems will be subject to more detailed analysis in following chapters.

Quality Management Tools to Promote Healthcare-Associated Infections Prevention and Control Systems

Nowadays several available recommendations and guidance for specific actions that need to be taken to minimise the HAI impact in health systems were developed, most of them to promote clinical processes effectiveness (313). But this is considered not enough when the main objective is to promote better healthcare services in complex organisations with complex clinical settings. Healthcare systems are operated and managed by great healthcare professionals, but alone, they cannot build up great healthcare. Great healthcare professionals, interacting adequately with all other elements of the healthcare system, can produce great healthcare. The infection control system should be analysed through a holistic and systemic management approach given the implications of multiple variables in the healthcare quality dimensions, as established by Donabedian (232) (structures, processes and results) or according to the three organisational management perspectives identified by Liyanage (17)

(facilities management, knowledge management and performance management). It is also important to consider other dimensions, such as environment, organisational context and organisational behaviour in which care services are delivered (337).

A revolution is going on in information and communications technology that can offer new powerful tools to help patient safety and quality of care. For example electronic health records and personal health records should, theoretically, offer standardised and timely information. This can improve accessibility by healthcare professional (clinicians and nurses) to notes, images, therapeutics, and pathology results in real time and improves the effectiveness of their interventions. Likewise, this technology should enable top management with adequate information for the decision-making process about organisational management issues and then improve resources allocation, structures management, clinical processes management and all organisation issues related with quality of care and patient safety. Some lessons can be taken from other industries, such as civil aviation and nuclear power production, where quality improvement tools have proved their value. But when it comes to health, it is not enough to implement them, it is important to minimise or eliminate a set of organisational barriers from healthcare organisational culture that prevent healthcare from becoming a safer system. For Storey and Buchanan (338) Six major barriers were identified: performance and productivity focus; professional autonomy (less autonomy, more supported in guidelines); craft worker mind-set (team work); overprotection of professionals; complacency and the complexity of extant systems (need to simplify and eliminate non-productive safety regulations); the legitimacy or otherwise of audit and advice. For Goldstone (224) one of the major barriers to the continuous quality improvement success is the healthcare focus. To ensure the patient-centred approach and the quality of healthcare it is necessary to modify healthcare professionals' way of thinking, and to promote the process approach instead of people approach. Healthcare services must be seen as interrelated and interconnected processes, and learn that these processes can be analysed, managed, and improved using continuous quality improvement theory and tools.

In previous work the most common HAI prevention control systems barriers were identified mainly those associated with other dimensions than clinical processes (See Annexes Chapter – Annexe II) (337). On these conclusions, it was considered necessary to identify which quality management tools could be useful for the improvement of effectiveness and efficiency of HAI prevention and control systems.

Quality Management Tools Applied to HAI Prevention and Control

Several studies that highlighted the importance of quality management tools in HAI prevention and control (339, 340). The SENIC study developed in the 70s was the first to alert for the importance of quality management tools, such as audit and feedback, education and training, definition of standards and guidelines, planning systematisation, monitoring and evaluation of actions, and reporting system to promote the HAI prevention and control (PDCA cycle) (16).

Griffiths *et al.* (22) conducted a study supported in a literature review, analysing the impact of organisation and management factors on infection control in hospitals. From this study they concluded that several organisational and management factors can influence HAI prevention and control systems. As for example positive leadership has been identified as a necessary prerequisite to maximise action related with infection control systems. The characteristics of leadership were also referred: it must be proactive and based on shared vision between leaders and healthcare professionals, rather than reactive when leaders take action only when required and try to avoid leadership responsibilities. Also for Gowen *et al.* (314) the positive leadership could be very important to establish and to clarify lines of clinical management and responsibility from ward to board, minimising excessive "span of control" among clinical leaders, improving their active involvement and compliance with management issues and accountability for infection control. These issues were considered fundamental for the promotion of healthcare professionals commitment and their control, and also for the success of good practices implementation. The importance of implementing clinical governance principles to promote the link between clinical and corporate management was also referred. As mentioned by Berwick (313) any management or improvement tool will only be effective with the active participation of clinicians. The importance of modern matrons as middle-level clinical management to reduce cases of MRSA was also identified. Nevertheless this kind of leadership could be effective only if role boundaries and responsibilities were clear to promote the leadership visibility (22, 152). Leadership issues were also corroborated by other authors such as West (341).

Other important issues related with healthcare professionals, such as multidisciplinary teams, education and training, and healthcare professionals' ratios for HAI prevention and control were also pointed. It is important to identify and implement organisational mechanisms to promote training, to ensure good staff morale, effective communication and effective practice (342). Over the years there has been a strong investment in healthcare professionals education, but for Young *et al.* (343), it is fundamental that any methodology ensures the right human behaviour in each situation. This can be possible if a process-approach is implemented instead an individual-approach, to systematise and harmonise individual

attitudes and behaviours. In their prospective study about CLABSI, a process approach was implemented, based on maximal sterile barrier precautions and the use of chlorhexidine for skin antisepsis during insertion, as well as supported by education and training of healthcare professionals, HAI prevention and control indicators definition and monitoring systems. This led to a statistically and clinically significant reduction of HAI rate that was sustained throughout the 15-month intervention period and to a significant costs decrease.

Pratt and O'Malley (344) in their work, that describes the impact of guidelines from DH and NICE in England, identified the importance of education and training methodologies, such as e-learning/blended learning programmes, to support the evidence-based approach for HAI prevention and control systems. These learning methodologies were developed to ensure that healthcare professionals effectively use the evidence in their daily work, when/where it was necessary, supported by communication technologies, such as, Internet and mobile phone and other communication methodologies (such as promotional events, onsite train-the-trainer workshops and by producing adoption tools and Frequently Asked Question guides). For Pellowe (345) benefits for students, programmes developers and managers associated when using e-learning methodologies for education and training of healthcare professionals were also referred: the student has the opportunity to study independently at a time and place convenient and having access to multimedia-rich resources; developers can adapt and update content easily when necessary; and managers can monitor staff compliance rates at distance. In this work the author also emphasised the importance of risk management tools, planning and monitoring tools, evaluation tools, and reporting tools to promote clinical governance, and indirectly, HAI prevention and control systems.

Regarding HAI prevention and control professionals ratios, significant evidence support the conclusion that higher nurse-patient ratios result in with positive patient outcomes (21). Also evidenced is the fact that if workload increases it potentially decreases the care quality and can contribute for increase infection ratios. To avoid this effect, the introduction of unfixed ratios for HAI healthcare professional in all units and departments but according to effective needs was suggested. The ratios should be monitored in order to tailor their use to each service needs.

For Kollef (346), and based on the Peter Drucker management theory, a SMART approach was proposed as the key for the success of HAI prevention and control in ICU. For this author to support action in SMART objectives (Specific, Measurable, Achievable, Relevant and Time bound) was considered fundamental, as it allows defining and quantifying desired outcomes, as well as measuring and monitoring activities. Naturally this should be supported by healthcare professionals education and training, periodic audit and feedback systems, and information systems to collect, treat and reporting data.

Brannigan *et al.* (347), in their review work, analysed the use of performance management tools in relation to infection control metrics and the use of HAI as a proxy indicator for deficiencies of system management. For these authors "HAI prevention and control cannot be the role and responsibility of a single individual or a small-dedicated team, but it should be addressed as a core part of governance and must maintain a high clinical profile alongside a high management profile" (347, p.392). Several quality management tools and other issues that can help to improve HAI prevention and control system were identified: process approach to integrate HAI prevention and control into hospital management and quality agenda; the BSC to allow the alignment of performance measures with the hospital strategic mission and goals, measuring performance with validated indicators (348-350); strong corporate accountability and hospital leadership; operational leadership promoted by the coordinator of HAI prevention and control team to ensure internal reinforcement, board-to-ward engagement, as well as to provide role modelling and exemplify corporate responsibility; risk management tools based on those developed in industry; usage of HAI rates as proxy indicators of healthcare professional levels, training levels, organisational stress, management system failure, inadequate process approach, reliability, and organisational resilience.

Mangino *et al.* (351) also identified the importance of several quality management tools in the success of their Pathway Assessment of Critical Therapy in Hospital-Acquired Pneumonia (IMPACT-HAP). This performance improvement tool was developed based on a literature review and benchmarking of best practices for HAI pneumonia prevention and control, definition of quality indicators to evaluate best practices compliance, and continuous multimodal education and training of healthcare professionals. From this before-after study they could verify an improvement in the diagnostic criteria for HAI pneumonia compliance, and empiric antibiotics compliance with American Thoracic Society guidelines.

Coffin *et al.* (352) in their analysis about practical recommendations designed to assist acute care hospitals in implementing and prioritising their VAP prevention efforts, identified several clinical best practices and management tools, such as: healthcare professionals education and training; introduction of risk management tools to assess VAP risk; internal reporting to promote feedback and external reporting to promote compliance with state regulation and requirements. Indicators were also identified as an important tool to evaluate best practices compliance rates.

The positive impact of audit and feedback of information tools for healthcare professionals, at all organisational levels, is mentioned in the literature. Hay (353) and Fournel (354) also pointed the evidence and importance of these tools in HAI prevention and control and presented some issues to promote the effectiveness of HAI prevention and control systems:

sample size and the representativeness of audit sample, well-designed audit programme with explicit, evidence-based criteria and multifaceted interventions, and involvement at organisational and professional levels.

In a study developed by Ransjo *et al.* (355) audit tool seemed to be a relevant factor to minimise the impact of an outbreak of multidrug-resistant *Klebsiella pneumoniae* and it was fundamental for suitable interventions identification and then for their effectiveness evaluation. Other important interventions were identified such as facilities management (to control bed occupancy and overcrowd wards, environmental cleanliness and disinfection, layout changes), personnel management (dress code campaign), documentation implementation (policy document and case records forms introduced in intranet), and antibiotic policy changes. The case study performed by Bryce *et al.* (356) showed the importance of audit process to access the consistency of healthcare prevention and control systems approaches. Their audit process was designed and developed along with a set of support tools, such as checklists, record software and questionnaire to access routine precautions, education and training frequency, infection control knowledge and its application, and control procedures application. With this tool there were identified 257 recommendations were proposed, with an implementation ratio of 95%, in areas such as environmental cleaning, proper equipment cleaning protocols, correct use of personal protective equipment, hand-hygiene procedures, separation of clean and soiled supplies. This audit approach provided an impartial, organised and uniformed method to assess and improve HAI infection prevention and control systems and allowed benchmarking of practices across all hospital.

Another work developed by AHRQ on quality improvement strategies and their impact in prevention of HAI systematically reviewed several studies related to the effectiveness of interventions in SSI, CLABSI, VAP, and CAUTI. The main quality improvement strategies identified were clinical education, patient education, audit and feedback, clinicians' reminder systems, organisational change, and financial or regulatory incentives for patients or clinicians. Most of the studies were not conclusive about the effectiveness of quality improvement tools in the adherence improvement or to reduce HAI infections due to different reasons, such as design of the study, and methodology. However some quality improvement interventions related indirectly with some improvements in HAI prevention and control systems were presented: printed or computer-based reminders to healthcare professionals, staff education including the use of interactive tutorials and checklists, coupled with audit and feedback to improve adherence to best practices related with CLABSI and with VAP (357). This was also verified by the prospective study developed by Walshe *et al.* (358) where a sustained ongoing education/audit programme was associated with an incidence reduction of

CLABSI in a large in-hospital total parenteral nutrition population from 33 in 1997 to 6,8 episodes per 1000 central venous catheters days in 2008.

The MARQuIS project also identified audit process as an important strategic issue for quality improvement in healthcare. Lombarts *et al.* (249) identified internal audit as a fundamental tool for assessment and improvement, clinical audit as a mechanism to improve the clinical practice and directly patient safety, and the external audit as a mechanism to promote external recognition of best practices adoption. The last one was also seen as an important mechanism to pressure healthcare organisations to comply laws, regulations and external recommendations (30, 252).

Griffiths *et al.* (22), in their literature review about organisational factors that have impact in HAI prevention and control systems, also concluded on the importance of audit and feedback in the improvement of these systems. These tools were considered to have a major importance in clinical governance issues.

Shouten *et al.* (359) emphasised, in their systematic literature review, the importance of quality improvement collaborative tools. For these authors, collaborative tools were fundamental to promote benchmarking between healthcare organisations and to improve education and training, and change of experiences in real time.

In a work developed by Ferguson (360) potential risks for HAI prevention and control systems were identified specially when quality systems or tools were not implemented or partially implemented. In this work different organisational issues were documented and their risk related with HAI prevention and control systems identified. For example, the risk of uncontrolled documentation (such as out-of-date guidelines or legislation/regulations) was classified as high and the inexistence of audit process or with inadequate periodicity has considered as being medium risk. Other issues were also presented and rated, such as, infection control training (extreme risk), variability with compliance with hand hygiene (high risk), variability of practice standards, and variability of cleaning staff training (high risk).

Alhatmi (361), in his case study developed in an Oman hospital, verified, through systematic internal audits, noncompliance with the international recommendations for skin antiseptic, that could lead to an increase of CLABSI rates. This study also identified the benefits of introducing the audit process, PDCA cycle, and Ishikawa fishbone diagram (cause-effect diagram) to promote the identification of organisational improvement opportunities and non-conformities, their cause-effect relations, and RCA, in several hospital areas.

In a case study developed by Hariharan and Dey (362) in an operating room, an Accident and Emergency Unit, and an ICU, quality improvement logical framework, supported by brainstorming methodologies, Ishikawa fishbone diagram, problem tree diagram and audit

process were identified to identified improvement issues and to assess the logical framework implementation and effectiveness. This methodology was fundamental for the identification and elimination of major problems such as: lack in treatment protocols resulting in treatment not based on current evidence-based guidelines; a dearth of admission/discharge protocols resulted in moribund inpatients and increased stays; non-existent antibiotic protocols led to a wider choice of antimicrobials, which predisposed higher resistance rates and infection rates; poor infection control measures in place. The logical framework development was based on PDCA cycle, and there were defined goals and objectives, and expected outputs were defined, as well as actions to develop, and tools to monitor and assess the implementation compliance (such as, indicators, audit process, checklists, satisfaction surveys, and data record analysis) (362, 363).

Carrico and Ramirez (364), in their study about deaths due to HAI, highlighted the importance of risk management tools, RCA and of monitoring systems in sentinel events analysis. They proposed a risk management tool, based on a process diagram, to simplify the process of identification and analysis of sentinel events, such as deaths due to HAI. With this tool it was possible to drill down through organisation systems and processes and identify risk sources and minimise their effect. This risk management tool was supported by document form to record data, Ishikawa Fishbone Diagram and Brainstorming tool to identify improvement areas. The importance of RCA in HAI prevention and control was also demonstrated in the review done by Wald and Shojania (365). For these authors this tool could be used a qualitative methodology for the identification of latent errors, such as sentinel events. Nevertheless, the validity of its application depended on the implementation methodology it was supported in: multidisciplinary team, education and training, data collection methodology, and data analysis methodology. For these authors no scientific evidence could be fund that this tool directly promoted patient safety, although they agree that, when used with other methodologies, it could improve risk management process, and thus, promote patient safety.

A retrospective cohort study developed by Wirtschafter *et al.* (366) in a neonatal ICU the evaluation of the quality improvement model implementation and its effectiveness in neonatal infection control was the ain goal. This quality improvement model included some measures in clinical area (identification of best practices and compliance with the diagnostic criteria and measurements standards for HAI prevention and control; hand-hygiene compliance; stringent insertion practices and catheter maintenance routines) carried on with organisational best practices, such as education and training with collaborative tools, and quality audits with a defined periodicity. The collaborative tool promoted communication among participants and ensured social networking, recognised as essential to knowledge implementation. Upon

the implementation of this quality improvement model HAI decreased from 16,9% in 2002 to 14,5% in 2006.

A review about hand hygiene techniques developed by Gould and Drey (367) identified hand hygiene audit by direct observation as a "golden standard" method, as also mentioned in WHO Guidelines on Hand Hygiene in Health Care (64, 66). The Cheng *et al.* (368) study identified the electronic monitoring system for hand hygiene as more effective than direct observation. Nevertheless, the authors considered that both methods could complementary to minimise method barriers could also be complemented by other actions such as self-reported hand hygiene compliance, peer reporting hygiene compliance, and product uptake. The electronic reporting system presents as advantage, the possibility of real time data and as principal disadvantages, costs and maintenance could be stressed. Although several studies identified hand hygiene audit by direct observation as an important method to minimise HAI, no direct scientific evidence about the method effectiveness in HAI prevention and control was verified.

A process approach model for clinical process management was analysed by Rohner (369) on a case study applied in a medium-size German hospital. The main hospital approaches, which support "process approach", were clinical pathways, patient-focused care, and quality management models. The focus of interest in process orientation for hospitals is related to processes that provide revenues through patient treatment, referred as "pathways". Process management can cover continuous improvement at different levels: optimisation of individual sub-processes or activities; optimisation of processes within a department and/or a clinic; optimisation of individual interfaces between departments and/or clinics, or between these and cross-disciplinary services or support services; optimisation of interfaces with external partners; and optimisation of patient flow by means of processes throughout the entire hospital. With this process approach an additional net profit of several million euros per year could be verified, without quality reduction.

In a systematic literature review developed by Ivers *et al.* (370) in the Cochrane Database of controlled trials, 140 studies were analysed and conclusions pointed out that audit and systematic feedback generally leads to small, but potentially important, improvements in healthcare professionals practices. These two issues seemed to depend on baseline performance and on how the feedback was provided.

Caputo *et al.* (371) in their study about the incidence of SARS transmission to healthcare professionals who intubated patients, concluded that protection guidelines failed to prevent SARS transmission to healthcare professionals due to several barriers, such as, lack of compliance with strict protocols, communication, and awareness from healthcare

professionals. To minimise these barriers a data derived risk management tool was developed, supported in three key dimensions: process, people and infrastructures/technology. For each of these dimensions the breakpoint, related problem and recommendations to minimise or eliminate the problem were identified.

Several studies emphasise the importance of risk management tools in HAI prevention and control systems, and some tools successfully applied to health were identified, such as FMEA (Failure Mode and Effects Analysis) (372, 373), HACCP (Hazards Analysis and Critical Control Points) (374) and ISO standards based model (375, 376). As an example, Griffith (377) supported by a general review work, analysed the application of HACCP to HAI prevention and control. In this work, the author identified HACCP application in clinical areas, and specially, in HAI prevention and control. The application of HACCP and Pre-Requisite Programmes was analysed, particularly how these programmes differ and how the approaches and terminology could be adapted in healthcare. Benefits from the use of these tools were presented: consistency and systematisation promoted by documents and records, data and procedures transparency, promotion of audit systems, comprehensive and specific tool with proactive and preventive characteristics. Several barriers to its implementation were, nevertheless, also identified: attitudes and behaviour changes, and costs.

Nori and Williams (378) presented, in their work about risk management and HAI for all respiratory infection outbreaks, a general framework for general practice. The framework was based on recommendations from WHO and Federal and South Australian Government infection control guidelines and relevant literature, and included three major dimensions as well as related actions to be implemented: governance and risk management (clear definition of policies, cultures, procedures, education, information and communication with feedback systems); planned, practised and habitual infection control (communication, patient flow, hygiene, occupational health and safety); and published checklists and recommendations. This risk management framework, developed to classify outbreak severity, was designed to be applied by HAI healthcare professionals.

Ookalkar *et al.* (373), in their study about quality improvement in Haemodialysis process, demonstrated the importance of applying FMEA. A proper checklist was adopted for work monitoring and training was provided to enhance patient and staff awareness. This risk management tool was found to promote two types of process control: prevention (prevents the cause/mechanism of failure or the failure mode from occurring) and detection (detects the cause/mechanism and lead to corrective actions). All fundamental FMEA approach steps were implemented (team, processes, failure mode identification, potential effects and severity assessment and occurrence assessment) and the effectiveness of the implemented controls was verified. As defined by FMEA methodology, different evaluation scales were applied: a

"Severity" evaluation scale (1 for none severity and 10 for hazardous without warning), a "Detention" evaluation scale (1 for almost certain and 10 for absolute uncertainty) and an "Occurrence" evaluation scale (1 is for an unlikely failure and 10 is for a failure almost inevitable). After the application of the three scales for each failure mode and effects, the priority risk number was calculated. Additionally, upon the FMEA application improvement areas could be identified, such as, rescheduling patients, equipment disinfection, compliance with best practices, and others. With this case study the authors concluded that parameters with potential risk were mainly related with behaviour of healthcare professionals and patients, and, as so, several recommendations were also presented, regarding education of resident nurses, formal reporting process, supervision of treatments, and improving notification systems.

Gill *et al.* (379) in their prospective study about HAI prevention and control applied to Neonatal Unit, described the implementation of quality improvement activities and infection control bundles in a large perinatal centre over a seven-year period. They developed a set of actions and bundles for HAI prevention and control such as: Hand Hygiene Campaign, audit and feedback to healthcare professionals, revision of best practices related with clinical procedures, benchmark strategies, and facilities management. To monitor HAI prevention and control a "Statistical Process Control" using control charts was implemented. They concluded that such activities, supported by the positive feedback obtained from control charts application, were responsible for HAI rate decrease, mainly due to and increased awareness about asepsis, hand hygiene, central lines use surveillance, blood culture collection techniques and general environment improvement.

Sánchez *et al.* (380) in their descriptive study about EFQM model implementation in 31 healthcare organisations from the Basque Health Service, identified some relation between the implementation of EFQM as well as the positive evolution of some outcomes. The authors highlighted the importance of ISO standards as a tool for process definition in the EFQM model implementation. The majority of EFQM criteria showed improvements, especially those related to "processes" dimension and to "people results" dimension. The improvement to the first was due to the development of several actions oriented to process improvement. The results related to the second were due to people satisfaction and motivation measurement. As conclusions, some advantages from this application could be identified such as activities systematisation, indicators development, and motivation to improvement. Associated with HAI prevention and control two performance indicators are noticed: the length of stay in acute care hospitals had a small decreased between 2000-2003 (it is an indirect indicator but, the literature evidenced the relationship between the increase of length of stay and the HAI

prevalence) and the prevalence of patients admitted with a HAI episode decreased (small variation but it was observed).

Evaluation Models

Several studies demonstrate scientific evidence on the impact of external evaluation, promoted by quality management systems, in HAI prevention and control systems. As mentioned before, between 1996 and 1999 the EXPERT project to study external quality improvement tools applied to healthcare was developed in Europe. This study identified four models that could promote quality improvement in healthcare: accreditation, certification supported by ISO standards, Visitatae and EFQM. Subsequently to these studies, several other authors analysed specifically the impact of these models in HAI prevention and control systems.

Accreditation and Certification

As mentioned, accreditation models were used in healthcare since the beginning of the XX Century, as a tool for quality improvement in healthcare organisations. Since the 70's some models began to incorporate in their manuals HAI prevention and control standards as well as criteria for monitoring and evaluation.

For many experts, this kind of quality management tool was considered to be the most adequate in promoting quality improvement in healthcare organisations (29, 233, 244).

For example, Chen *et al.* (381) in their study cohort analysed the association between JCAHO model and survival among Medicare patients hospitalised for acute myocardial infarction. From this study, they concluded that hospitals not surveyed by JCAHO had, on average, lower quality (less likely to use aspirin, beta-blockers, and reperfusion therapy) and higher thirty-day mortality rates than surveyed hospitals. However the authors also concluded that additional key elements were necessary for an accreditation process to ensure a substantial and lasting public role for monitoring hospital quality. They identified three key elements: publication of quality measures (public data will allow patients to make decisions based on quality and providers could use explicit measures of quality to negotiate contracts), reward for success (purchasers are amenable to pursuing reimbursement that rewards superior quality), and Government influence (government is positioned to motivate changes in accreditation models because of accreditation role in safety hospitals reimbursement).

Sekimoto *et al.* (382) developed a study to analyse hospital accreditation impact in HAI prevention and control programmes implemented in Japanese teaching hospitals. The results were obtained by a survey conducted between 2004-2005 in 638 teaching hospitals (all

teaching hospitals in Japan) to characterise the current situation of hospital infection control activities and identify the impact of accreditation on infection control structures such as: organisation of infection control provision and ICCs, the presence of infection control doctors and infection control nurses, and time allocated for infection control activities by healthcare professionals; infection control processes and activities: surveillance, standard precautions, isolation precautions, needle-stick prevention programmes, hospital food hygiene, medical waste management, catheter-related infection control, sterilisation, antimicrobial therapy use and regulation, infection control in operating rooms and ICU and occupational infection control. This study also aimed to analyse the impact of accreditation evaluation on infection control performance. A questionnaire was prepared, based on Japan Council for Quality Health Care (JCQHC) accreditation standards. From this study the authors concluded that Hospital accreditation had a significant impact on hospitals infection control infrastructures and performance.

Greenfield and Braithwaite (321) developed a systematic literature review to analyse the impact and effectiveness of accreditation programmes in healthcare organisations. This analysis was conducted in 10 categories: professionals attitudes to accreditation, promote change, organisational impact, financial impact, quality measures, programme assessment, consumer views or patient satisfaction, public disclosure, professional development and surveyor issues. Results demonstrated that there were mixed views and inconsistent findings and that only in two categories consistent results could be observed: promote change and professional development. Inconsistent findings were identified in five categories: professions attitudes to accreditation, organisational impact, financial impact, quality measures and programme assessment. In the remaining three categories - consumer views or patient satisfaction, public disclosure and surveyor issues - studies were inconclusive.

Another study from these authors analysed the association between accreditation performance, self-reported clinical performance, and independent ratings on four aspects of organisational performance: organisational culture, organisational climate, consumer involvement, and leadership. An independent blinded assessment of these variables was performed in a random, stratified sample of acute healthcare organisations in Australia. They verified that accreditation performance was significantly positively correlated with organisational culture and leadership; that there was a trend between accreditation and clinical performance; and, finally, that accreditation was unrelated to organisational climate and consumer involvement (383).

Shaw *et al.* (29), in their compliance analysis of quality measures applied in 89 hospitals from six countries, as part of the EC-funded MARQuIS project, aimed to identify systematic differences in quality management between hospitals that were accredited, or certificated, or

neither. They identified and measured six dimensions: management, patient safety, patient rights, clinical organisation, clinical practice and environment. From the results analysis it seemed that quality and safety structures and procedures were more evident in hospitals with some type of external evaluation. The study also showed that hospitals with ISO standards based certification or accreditation were safer than those without any accreditation/certification system. The results also suggested that accreditation had more impact in hospital management, patient safety and clinical practice than certification based on ISO standards. Infection control was evaluated in two different dimensions: management and patient safety. In the first dimension (management) Infection control had a score of 72% for accreditation system, 53,4% for certification system and 43,7% for neither of these systems. In the second dimension (patient safety) the accreditation score was 71,9%, certification was 55,9%, and 49,4% for neither of these systems. From MARQuIS project, conclusions demonstrated that, for individual hospitals, higher level of patient safety was associated with accreditation rather than with ISO related certification but both systems were significantly better than none. It could also be proved that mandatory accreditation programmes had higher impact on health systems only by involving a greater proportion of hospitals. As final conclusion for these authors, hospital accreditation system and ISO related certification offer alternative mechanisms for improving safety and quality, or as a mark of achievement.

Heuvel *et al.* (384), in their study about ISO 9001 implementation and certification in a Dutch hospital, verified some advantages for this kind of external evaluation: identification of all processes and restructure of some existing processes to promote patient safety and patient-centred system; well described documentation and a documentation control system, that promote the reduction of bureaucracy in organisations especially in hospitals where a certain degree of documentation is required. Performance measurements could also be noticed, supporting an overall and integrated picture of their results. The systematisation of measure and monitoring subsequently led to quality of care improvement and to quality management system improvement.

Discussion

Many quality management models and tools have been applied in healthcare (220, 362, 385-387). Regardless the model/tool used to promote quality improvement in healthcare, one thing is certain: it requires change. Several authors state in their work that the introduction of these mechanisms requires changes in the organisation, at micro level - an approach to the individual in terms of behavioural, and at macro level - an approach to processes, organisational cultures, management methodologies, political system among others (313, 320,

360). This is considered to involve first and foremost a cultural change, that according to some authors, it is the greatest barrier to the whole system (10, 14, 230, 237-239, 320).

However it is still evident that there are some barriers feed the empirical analysis of "Success *vs*. Failure "of any project in this area: the existence of difficulties in using the terms "error" and "quality" to "clinical process", organisational culture in health in general, and in particular the culture of healthcare professionals, failure in infrastructures and resources allocation, among others (320, 388, 389).

Nevertheless, a positive impact of quality management tools in quality of care can be demonstrated, promoting patient safety culture through the improvement of several issues, including HAI prevention and control issues. This review demonstrated that the introduction of these tools in healthcare providers is a challenge that should be considered as innovator.

CHAPTER V – Multi-case study analysis

Introduction

The results from field research – multi-case study (interviews and documentation analysis) are presented in this chapter.

General Characterisation

As mentioned in Chapter II - methodology, and after the application of inclusion and exclusion criteria, three hospitals with three different quality management models implemented were chosen and identified by the following fictitious names: "KF-CHKS Hospital", "JCI Hospital" and "ISO Hospital". The general characterisation of these hospitals is in Table 24.

Table 24 – General characterisation of hospitals selected for multi-case study.

Hospital	Type	Number of beds	Population covered
KF-CHKS	Central-General	737	405 764
JCI	District-General	459	520 056
ISO	District-General	349	174 931

Several members from ICC and Quality Management Department from each hospital were interviewed, as presented in Table 25.

Table 25 - Members from ICC teams interviewed for the multi-case study.

Hospital	ICC		Quality Management
	Executive Team (ICT)	Technical Team	Quality management team
KF-CHKS	Coordinator, Doctor Nurse specialist Nurse specialist	Microbiology, Doctor ICU, Doctor Inpatient service, Doctor	Director, Doctor Accreditation manager, Engineer
JCI	Coordinator, Doctor Nurse specialist Nurse specialist Microbiology, Doctor	Facilities management, Engineer Hotel services, Hospital Occupational Health and Risk Management service, Engineer Pharmacy department, Pharmacist	Director, Hospital Administrator
ISO	Coordinator, Doctor Nurse specialist Nurse specialist Microbiology, Doctor	Facilities management, Engineer Hotel services, Hospital Occupational Health service, **Facilitators** Neonatal service, Doctor ICU service, Doctor	Director, Hospital Administrator

KF-CHKS Hospital

Characterisation

This is a central-general hospital, one of the biggest hospitals in Portugal, part of a hospital group that has one more hospital (but only the central-general hospital is accredited). Its concern and involvement with quality management systems started in 1996 with the implementation and certification of the quality management system of Clinical Haematology service. By this time the law/regulation and standardisation for this clinical area started to be developed at European level by the resolution of the European Parliament on blood safety in the EU (1995) and the Council resolution on a strategy towards blood safety and self-sufficiency in EU (1996)[67]. This regulation was well accepted by this clinical area and they saw quality management system certification, supported by ISO 9000 series, as a tool to help to comply with the expose.

The accreditation process initiated in 2000 when it joined to hospital accreditation pilot programme developed and coordinated by Healthcare Quality Institute (HQI) and based on KF- CHKS model (at that time KF-HQS). The first total accreditation was obtained in 2005 and the last reaccreditation was obtained in 2011. This hospital has been involved in several quality projects and ISO models also certify some hospital services/departments, as show in Table 26.

Table 26 – Hospital services certificated and quality projects developed in KF-CHKS Hospital.

Service	Certification model
Clinical Haematology	ISO 9001 (since 1998)
Sterilisation	ISO 9001 (since 2004)
Hotel related services – Food and Dietetics	DS 3027 (since 2005)
Day Hospital	ISO 9001 (since 2006)
Nephrology	ISO 9001 (since 2006)
Hotel related services - General	ISO 9001 (since 2007)
Emergency service	ISO 9001 (since 2008)
Central Laboratory	ISO 9001 (since 2010)
Corneal transplantation	ISO 9001 (since 2010)
Centre of Assisted Human Reproduction	ISO 9001 (since 2011)
Hotel related services – Food and Dietetics	ISO 22000 (since 2011)
Microbiology	ISO 9001 (implementation process)
Pharmacy	ISO 9001 (implementation process)

[67] In this strategy was defined that "Blood establishments should establish and maintain quality systems involving all activities that determine the quality policy objectives and responsibilities and implement them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system, taking into account the principles of good manufacturing practice as well as the CE conformity assessment system". Later, the directive from the European Parliament and the Council established the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. In this directive, in its chapter IV – Quality management, article 11, it was define that "Member States shall take all necessary measures to ensure that each blood establishment establishes and maintains a quality system for blood establishments based on the principles of good practice" (Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. Official Journal of European Union. European Parliament and the Council of the European Union; 2003).

(Cont.)

Service	Project
All hospital	IAmetris (benchmarking indicators)
Outpatient service	Kaisen project (LeanCE)
Operating room	Kaisen project (LeanBO)
Pharmacy	Kaisen project
Logistic and supply services	Kaisen project

This hospital has a Quality Department with four major areas: quality management, risk management, occupational health service and environment. This department is responsible for the management of accreditation process and all certification processes.

HAI Prevention and Control System

STRUCTURE (Who we are)

As established by national regulation the KF-CHKS Hospital has an ICC composed by executive group (executive and technical), and advisory group as shown in Table 27.

Table 27 – ICC composition from KF-CHKS Hospital.

EXECUTIVE TEAM (ICT)	TECHNICAL TEAM	ADVISORY TEAM
Coordinator - Doctor, Internal Medicine	Microbiology, Doctor	Provision department
Nurse specialist, Chief	Intensive care unit, Doctor – Anaesthesiology	Quality, safety and risk department
Nurse specialist	Inpatient service, Doctor - Internal Medicine	Hotel services
Nurse specialist		Pharmaceutical Services
		Facilities and equipment management
		Sterilisation

A facilitator team composed by several members of different services/departments of the hospital complete this ICC.

This hospital is one of the first national hospitals to have an ICC, founded in 1978 as "Infection Control, Hygiene and Safety Team". Some changes occurred, not only in members' roles but also in its structure (three teams), since the national regulation for ICC was published.

As established by national regulation about ICC meetings the executive team and technical team meet every two weeks, and with advisory team, every month.

PROCESSES (How we do)

The core processes of HAI prevention and control system and other issues such as Communication, Interactions with other services, Interactions with quality management systems, Management tools, were analysed.

As defined by National Programme for HAI prevention and control (NPIPC), ICC is responsible for the development, implementation and evaluation of four key processes: a) best practices and standards development, b) epidemiologic surveillance, c) education and training, d) and monitoring and evaluation. Each year ICC develops an action plan for HAI prevention and control that includes activities for all these key processes.

A) Best practices and standards development

As recommended by national regulation this hospital has an infection control manual and it is available for analysis through the intranet or paper.

ICC made the manual, based on standards provided at national level (DGH) and defined by the NPIPC. Due to the absence or lack of information provided in accordance with national recommendations, ICC has improved its manual with several international recommendations and best practices published by recognised international organisations, such WHO, HICPAC, CDC and ECDC.

Although the structure of this manual answers to all NPIPC requirements, almost all of its content was established and developed before, promoted also by the accreditation process.

B) Epidemiologic surveillance

KF-CHKS Hospital participates in all epidemiological surveillance programmes, prevalence and incidence studies, established by DGH for HAI prevention and control. A prevalence survey is developed twice a year and applied to all hospital. Several incidence studies were developed: HELICS surgery (all year and applied to several surgery services, including gynaecology, obstetrics and vascular surgery), HELICS ICU (all year), nosocomial bloodstream infection (all year and applied to several services including ICU, nephrology, surgery, neonatology), Neonatal ICU (all year and applied to neonatology and paediatrics services), Dialysis (Nephrology), Medicine and Neurology services, and Laboratory-based epidemiologic surveillance (all year and applied to all hospital). This hospital developed also other type of epidemiologic surveillance focused in some important agents, named “agent problem” and epidemic outbreaks. Due to their importance in HAI prevention and control the manual has some specific chapters with recommendations and surveillance methodologies for them.

Prevalence survey is developed in each service by a nurse and validated by a doctor. ICC coordinates all process.

Incidence studies are developed and coordinated by each service involved, except the nosocomial bloodstream infection and the laboratory-based epidemiologic surveillance that are developed and coordinated by ICC, with the collaboration of microbiology laboratory.

To help therapeutic process the KF-CHKS Hospital develops each year a "Microbiologic Chart" for all microbiologic isolations with agent identification and its susceptibility pattern. This tool is a support to doctors for appropriate therapy.

The KF-CHKS Hospital joined "Hand Hygiene Campaign" and promoted its monitoring and evaluation through audit process, as defined by NPIPC.

C) Education and training

The KF-CHKS hospital developed several types of education and training programmes for HAI prevention and control. Training sessions are included in the annual hospital education and training programme when the education and training department requests for ICC collaboration. Specific education and training programme for healthcare professionals from Hotel Services department is developed with the collaboration of Hotel Services department. A specific programme for new facilitators and for the integration of new healthcare professionals (clinical and nonclinical but working in clinical areas) is also developed. A "training in service" is developed for facilitators and applied in their service whenever necessary and can be triggered by needs identified by facilitators, results from monitoring and evaluation process and surveillance process.

The KF-CHKS Hospital also developed several open conferences where HAI prevention and control issues are presented and discussed.

D) Monitoring and evaluation

As established by NPIPC the monitoring and evaluation is supported in audit process. The hospital develops an audit programme for hand hygiene, waste disposal and cleaning and hygiene of clinical services.

A multidisciplinary team, with participation of ICC, Quality Management department, and Hotel Services department and Risk Management service, does the waste disposal audit.

An external audit process is promoted by CHKS and associated with accreditation process. This model has specific standards and requirements related with HAI prevention and control whose compliance assessment is part of external audit scope.

Several indicators were defined by NPIPC to monitor HAI prevention and control activities: indicators for incidence epidemiological surveillance processes (HELICS and others); indicators for prevalence epidemiological surveillance; indicators for structures (facilities, equipment, environment and storage); and indicators for processes (hand hygiene issues, best practices compliance, antimicrobial and antiseptics policies compliance, sterilisation process, disinfection process). Indicators for the education and training process and for best practices and standards development were implemented to evaluate the compliance rate of these two key-processes.

In the past other HAI indicators (as presented before in the Chapter II – Evolution of HAI prevention and control systems) were defined by Regional Administration of Health – North related with the contracting programme established between Portuguese State and these hospitals. Good results were associated with financial incentives for the hospital. This was applied between 2008 and 2011, but then was removed.

Communication

The communication process has two dimensions: the external communication and the internal communication.

Internal communication is done by email, intranet and through facilitators. All standards and best practices published by ICC can be accessed through hospital intranet. Some IT tools were developed by the hospital to promote data communication between microbiology laboratory and ICC. Communication is also supported by clinical software that provides patient record information. Some information about HAI prevention and control is provided through posters, such Hand Hygiene Campaign and other to promote awareness of professionals, patients and families.

External communication (from ICC to an interested party) can be done directly by ICC to external interested parties (email, post or by phone), such as DGH, National Health Institute Dr. Ricardo Jorge, Regional Health Administration or others, for technical issues, or by HELICS record platforms where each service reports data from their surveillance. The institutional communication can be done through Administration Board.

Communication from external interested parties can be done through: Administration Board, which forwards for each service involved; directly to ICC; and by Internet platforms (such DGH microsites). For example, new COS published by DGH are communicated by email and by SMS to service/department directors and are available on DGH microsite.

When DGH publishes a legal/regulation document related with HAI issues it is communicated to hospital through the Administration Board that communicates to ICC. Then ICC analyses and then promotes its internal application.

Interactions

From the interviews analysis was verified a good interaction (somehow) between ICC and all hospital services. Infection control facilitators promote interaction between ICC and each service:

"Facilitators promote the involvement of each service in infection control and in ICC work"

"Facilitators are active participants in HAI prevention and control and promote better communication between services/departments and ICC"

ICC interacts with all services as established by regulation or by accreditation process (such as Facilities Management department, Occupational Health service, Risk Management service). This only is done upon request (sometimes there is no request).

For Quality Management director, HAI prevention and control is seen as an important issue for all hospital and this promotes its general acceptance.

For ICC nurse interactions between Occupational Health service and Facilities and Equipment department must be promoted in everything that is regulated.

From Inpatient Service doctor (ICC technical team) ICC interaction is not uniform across all hospital services:

"Clinical services have good receptivity of recommendations, more nurses and other health professionals, than doctors."

For another ICC technical team member the opinion is different saying that, due to the rhythm of internal activity,

"…Some technical services, such as surgery and ICU, can look to ICC work with much less attention".

When questioned about the relation between managers and clinical professionals the opinion was uniform, most of the interviewees said that the interaction was good enough, having some improvement in time:

"…In the beginning this relation can be difficult because of differences in language, knowledge and way of thinking. But it is possible to overtake with the involvement of all interested parties."

Interactions with Quality Management System

Quality Management director interview highlighted the importance of clinical governance in this accreditation programme:

"…Is the organisational engine for the implementation of infection control best practices in the service requirements… infection control system interacts at technical level with KF best practices".

The Clinical manager from Quality department is member of ICC - advisory team. As it could be seen the Quality, Safety and Risk Management department cross over several infection control issues, and helps ICC and other services and departments to answer to KF-CHKS requirements.

The ICC nurse specialist also referred that HAI prevention and control practices have been applied since the 80s and the accreditation process helped to organise and implement most of the requirements established by NPIPC when it was required by DGH. ICC had an integrative role supported by Quality Management service and quality helped to establish roles and responsibilities. When questioned about interaction between accreditation and certification models with HAI prevention and control system she mentioned the absence of barriers in the implementation of any recommendation or best practice advised by ICC, independently of the quality management model implemented, and all was supported in:

"…Trustworthiness and competence of ICC…"

For another ICC member (technical team) Quality Management department is more related with risk management, especially clinical risk, than with HAI prevention and control system.

Several interviewees identified quality management system as an organisation binder.

The interaction between hospital accreditation and services/departments certification was also subject of analysis in order to understand whether these two systems could interact without redundancy and without creating barriers for processes such as HAI prevention and control system. As observed by a member of Quality department there was no redundancies and both systems can coexist and complementing each other:

"ISO can be seen as the skeleton and accreditation as the body".

This interviewee also referred that certification is more focused in management practices based on process approach, and accreditation is more focused in clinical practices based on departments/services approach, and any service certificated could easily meet the requirements of accreditation but the inverse was not so easy.

For certified services/departments, HAI prevention and control system was not identified as a process but as part of other processes:

"From the perspective of certificated services/departments, HAI prevention and control is not seen as a process but as an intrinsic service activity."

Management Tools

Several management tools associated with HAI prevention and control system were identified from the interviews, most of them associated with monitoring and evaluation process. Checklists associated to NPIPC and checklists based on the accreditation programme (applied to general risk management and clinical risk) were used to support data collection during the audit process. Several indicators from the NPIPC, and indicators from accreditation programme (such as clinical emergency) and indicators from contracting process were identified to perform data treatment.

The importance of quality plans for the accreditation programme as management tools applied to hospital and not directly related with HAI prevention and control were referred. A strategic plan for all hospital is established and then each service/department must define and implement a plan with a set of objectives/targets and actions to achieve the proposed objectives. The audit process evaluates the plan compliance rate. Other tool referred as used for some services/departments was benchmarking (internal and external).

It was also mentioned the existence of external quality control tools (NEQAS[68]) for the microbiology laboratory.

For risk management was referred the use of the problem analysis, cause-effect analysis, RCA, but not used in a systematic way (such FMEA, HFMEA, lean tools or other).

RESULTS (What we get)

All the results from internal epidemiologic surveillance studies are obtained and treated in a daily bases. ICC nurse analyses data and, based on laboratory information, goes to clinical service, speaks with patient doctor and analyses patient clinical records and the antibiotic therapeutic. After this ICC identifies and establishes a set of recommendations to be apply in each case. This is reported monthly to each service.

From the results obtained for all other HAI prevention and control epidemiologic surveillances (and when ICC has information about them) ICC promotes indicators analysis

[68] NEQAS is the UK National External Quality Assessment Service.

to evaluate trends and to promote internal actions. Most of this information is reported on DGH IT platforms (HELICS platform and others) and the reporting system from DGH to hospital has some delay. The results from monitoring and evaluation of specific process from a service/department are reported to that service/department and the results related with surveillance applied to all hospital (e.g. prevalence study) are reported to ICC and then published in intranet. Sometimes ICC doesn't have access to all epidemiologic surveillance data.

Barriers

Several barriers associated with HAI prevention and control system were identified from the interview process. These barriers were organised following the three dimensions defined before: "who we are" (structures), "how we do" (processes) and "what we get" (results). All the barriers are presented in Table 28.

Table 28 – Barriers identified at KF-CHKS Hospital (from interviews).

Dimension	Sub-dimension	Content	Barrier
Who we are	**Resources**	Time	- Not enough allocated time (or nothing at all) for some ICC members (such as facilitators) for implementation of HAI prevention and control activities
	Culture and values	Compliance Careers relation Culture issues	- No compliance with culture and policies associated with HAI prevention and control (more doctors than nurses) - Some career conflict between doctors and nurses - Although the real name of ICC is "HAI prevention and control committee", the name used is "Infection control team" and "control" is seen as pejorative and negative, like inspection
How we do	**Clinical processes**	Clinical practices Therapy	- Not enough knowledge about the most representative type of sample for HAI identification to avoid report errors - No compliance with clinical best practices associated with HAI prevention and control (more doctors than nurses) - Some difficulties to promote therapeutic evidence-based decision instead empirical-based decision

(Cont.)

Dimension	Sub-dimension	Content	Barrier
How we do	**Management processes**	Leadership	- Absence of top management leadership - Absence of penalties or incentives for compliance with HAI prevention and control recommendations - No top-down definition of strategies for HAI prevention and control systems - No decision-making tools to support department/services directors management
		Team management and relationship	- Inexistence of expected interaction between Quality department and ICC because of conflicts caused by the redundancy of activities and overlapping roles (such as occupational health and safety) - Inexistence of expected interaction between ICC and other nonclinical services (such as facilities management department), as define by NPIPC and accreditation programme - The relation between clinical and manager can be difficult due to differences in language, knowledge and way of thinking
		Knowledge, education and training	- No training related with audit process. The hospital solved this problem because it has the quality accreditation system - Lack of knowledge related with HAI prevention and control at all levels
		Awareness and individual behaviour	- The "sensitivity" for HAI issues is related with lack of knowledge. - Application of "has always been like this" or "its good enough" to justify no action - Most professionals assume that control of infection is done by ICC and not by each one in their daily work - General lack of motivation and lack in professional involvement
		Communication	- Lack on information flow - Inexistence of a well-defined communication system, between services (internal) and with interested parties (such as DGH) - The communication at regional level and national level is not as expected (with delays or inexistent)
		Monitoring /evaluation	- No evidence between a programme/activity implementation and outcomes
What we get	**Data**	Data Analysis limitations	- Some difficulties in data treatment because of absence of IT system - Some difficulties from services to analyse information from ICC (knowledge, time) - HAI prevention and control data are not used to promote better management (there is not internal service data analysis)
	Reporting	Feedback	- No feedback from some services - Not all data related with infection control are reported to ICC (such as reporting from HELICS survey, adverse events notification, occupational incidents)
		Reporting system	- Existence of a significant delay in DGH reporting system - The reporting system doesn't allow comparative analysis between services/departments because each service has access to global data report and to its individual data report - The reporting system sometimes is limited to service/department directors (not shared with other professionals from that service/department)

Improvement Suggestions

Several improvement suggestions for HAI prevention and control system were identified form the interviews. They are presented in Table 29.

Table 29 – Improvement suggestions identified at KF-CHKS Hospital (from interviews).

Dimension	Sub-dimension	Content	Improvement suggestions
Who we are	**Resources**	Human Resources	- Inclusion of an epidemiologist in ICC
	Culture and values	Compliance	- An incentive system to promote compliance with recommendations must be developed - Must be introduced a penalisation system for noncompliance
		Culture issues	- Change the name of "infection control committee" to "infection prevention team"
How we do	**Clinical processes**	Therapy	- Introduction of internal indicator to monitor medication prescription and its relation with usual service ecology
		Surveillance	- It is important to implement CAUTI surveillance at national and hospital level
	Management processes	Leadership	- The HAI prevention and control coordinator must be the president of Administration Board or a member of this board to ensure top management commitment - All standards and recommendations from top management (internal and external) should start with "must do" instead "should do". HAI prevention and control requirements must be implemented on a mandatory basis
		Education and training	- To promote better knowledge is important to include, in basic education learning programmes (all the areas) and in higher education (health areas), specific content related with HAI prevention and control - Education and training by promoting internal and external benchmarking - Hospital incorporation of a new professional must take into account HAI prevention and control knowledge (a new clinical auxiliary must be introduced into a service with less susceptibility of infection) - The choice of facilitators must be made based on objective criteria related with the three dimensions of competence: knowledge, "know how to do" and "know how to be"
		Teams management and relationship	- Better definition of roles and responsibilities for multidisciplinary teams working on HAI prevention and control issues (such as risk management, occupational health management, ICC and quality management)
		Communication	- ICC must have more information about clinical process (patient records) to promote a better work (ICC information is based on laboratory information). It must be developed an IT tool to do this - Better information channels - internal (between services) and external must be established
		Monitoring and evaluation	- The laboratory information included in patient clinical record must have an alert system related with information updates - HAI prevention and control indicators in the hospital contracting process with Regional Health Administrations must be introduced again
What we get	**Data**	Data treatment and analysis	- An IT tool to help ICC on data treatment and analysis must be developed - Introduction of comparative analysis between productivity indicators and effectiveness indicators (not only enhance high occupancy rate of operating room – a productivity indicator, but analyse together with HAI rate – an effectiveness indicator)
	Reporting	Reporting system	- All nonconformities must be reported in the same platform coordinated by one department that ensures the effectiveness of the reporting system for all services/departments involved - The Administration Board must participate in meetings promote by ICC to validate results and to understand better ICC work (monthly or quarterly)

Global Perception

The overall perception about HAI prevention and control system implemented and its interaction with quality management issues was analysed during the interviews. The Table 30 resumes these perceptions.

Table 30 – Global perceptions from KF-CHKS Hospital about HAI prevention and control system and its interaction with quality management system.

Interviewee	Perception
ICC coordinator	"NPIPC is conceptually well designed and structured. It is quite complete. However its implementation at regional and hospital level needs to be revised and improved" "We can say that the know-how in this area has improved a lot and now we have a legal framework that can be considered quite good and extensive"
ICC nurse (specialist)	"The accreditation process forced organisation and people to be always up to date" "ICC performed an integrator service but clearly helped by the fact that this hospital was already accredited"
ICC nurse	"The audit process is fundamental for improvement process. However it must be taken seriously… we don't have an evaluation culture" "Our interaction with quality management system should be improved… We should be involved in audit process for HAI prevention and control evaluation in services/departments… this was important to improve our knowledge about our HAI prevention and control system"
Microbiology, Doctor	"Our ICC has a very good responsiveness" "The hospital organisation has been fundamental to promote internal improvement. The quality management system came and highlighted the best practices that were already implemented, providing a systematisation"
Intensive care unit, Doctor	"The Hand Hygiene Campaign was important because it demystified the fact that all people know how to wash hands thoroughly, is innate" "There is a global perception of healthcare professionals regarding that quality is good ... However I understand that this is the way, although I think that these systems, as they are used, don't ensure excellence but only to achieve a standard"
Inpatient service, Doctor	"The quality management system came to promote HAI prevention and control culture because quality is seen as a goal and not as a consequence of all the rest. However the concern about the certificate often exceeds the real concern with promoting change" "The ICC is well respected for its tradition, "seniority" and not rotation of its members. This created some endurance that helps to overcome daily difficulties." "ICC must be seen as a partner rather than a barrier"
Quality Director, Doctor	"The accreditation process was very important for this hospital because manuals came and put "titles" and thereby helped to organise what already existed… It served as the lever that promote more systematic responses from internal teams"
Accreditation manager, Engineer	"The responsiveness to standards/regulations and its introduction is easier because we have the house organised… In accredited organisations it becomes much easier to respond to the needs and recommendations published by recognised organisations" "… I can see this as follows: ISO is the skeleton, the structuring element, on which I can build what I want based on the accreditation model. Using best practices recommended by the accreditation process I can give "body" to quality management system according to ISO process approach" "What I can say is that ISO is a management tool in order to promote improvement, and accreditation only intends to promote improvement, but without effective capacity because it fails in closing the PDCA cycle (there is no Act) "In my point of view accreditation has the advantage of being "user friendly" for healthcare professionals because it is designed as a "collection of recipes" based on the "how to do" and not interfere in the organisational structure, not being uncomfortable. The ISO requires a change of organisational paradigm"

JCI Hospital

Characterisation

This hospital is a district-general hospital, from the north of Portugal. Their concern and involvement with quality management systems started in 2004 with the implementation and certification of a quality management system in services/departments of Imunohaematology and Sterilisation.

The accreditation process initiated in 2004 when the hospital joined the hospital accreditation pilot programme developed and coordinated by a government organisation responsible for the corporative public hospitals and based on Joint Commission model, (the international version, JCI). The first accreditation was obtained in 2008 and it was the first Portuguese hospital to be accredited by this model. This hospital has a Quality department responsible for management of accreditation process and support all certification processes.

HAI Prevention and Control System

STRUCTURE (Who we are)

As established by national regulation JCI Hospital has an ICC compose by executive group, advisory group (Table 31) and facilitator group.

Table 31 – ICC composition from JCI Hospital.

EXECUTIVE TEAM (ICT)	ADVISORY TEAM
Coordinator - Doctor, ICU Nurse, Specialist Nurse, Specialist	Quality department, Hospital Administrator Pharmaceutical services, Pharmacist Occupational Health and Risk Management department, Engineer Microbiology laboratory, Doctor Facilities and equipment department, Technical Directors of all services

A facilitator team composed by several members of different services/departments of the hospital complete this ICC.

PROCESS (How we do)

As done before for JCI Hospital the core processes of HAI prevention and control system and other issues such as Communication, Interactions with other services, Interactions with quality management systems, Management tools, were analysed.

ICC is responsible for the design, implementation and evaluation of four key processes related with HAI prevention and control: a) best practices and standards development, b) epidemiologic surveillance, c) education and training, d) and monitoring and evaluation.

Each year ICC develops an action plan for HAI prevention and control with the collaboration of several hospital services/departments that includes activities for all these key processes.

A) Best practices and standards development

As recommended by national regulation this hospital has an infection control manual and it is available through the intranet or on paper.

The ICC, with the collaboration of Quality Management department, Risk Management and Occupational department and Facilities and Equipment department, did this manual and it was done based on the national legal framework and recommendations provided by NPIPC and according to accreditation model requirements. This work was done in 2007 and has been clearly simplified due to the similarity between national requirements and requirements established by JCI accreditation model. Due to the absence or lack of information provided in accordance with national recommendations in some important areas (for example in risk management and basic precautions), ICC has improved its manual with several international recommendations and best practices published by recognised international organisations, such WHO, HICPAC, CDC and ECDC.

Due to accreditation process this hospital had to improve its risk management process and to develop and to implement a risk management manual associated with HAI prevention and control system.

All standards and recommendations from ICC are made with the collaboration of Quality Management department.

B) Epidemiologic surveillance

JCI Hospital participates in several epidemiological surveillance programmes, prevalence and incidence studies, established by DGH for HAI prevention and control and others. For prevalence study the hospital develops a prevalence survey, applied to all hospital. This hospital has several programmes for incidence study: HELICS surgery (all year and applied to total hip prosthesis surgery and knee prosthesis surgery), HELICS Intensive care (all year), Neonatal service (all year), nosocomial bloodstream infection (all year and applied to inpatient services), urinary infections (three months, Medicine service), respiratory infections (three months, Medicine service), infections associated to intravascular device (three months, Cardiology service). The Neonatal ICU is an internal option because this service does not meet the inclusion criteria defined by national programme.

The epidemiologic surveillance of JCI Hospital is focused on some important agents, named "agent problem" and epidemic outbreaks. Due to their importance in HAI prevention and control the manual has some specific chapters with recommendations and surveillance methodologies for them.

The prevalence survey is developed in each service with the collaboration of service directors but ICC coordinates all process. This gives to ICC a total knowledge about HAI prevention and control data from all hospital services. The HELICS participation is strongly supported and promoted by ICC. This was the way that ICC found to involve actively different services on HAI prevention and control. Data are collected every day by facilitators (supported by a sheet) and then they are treated with software developed specially for that. It was also created, supported in the classification of multi-resistant organisms developed by the CDC, an alert system applied to laboratory data that enable more easily and in real time the ICC analysis of these platforms, promoting a faster action. Internal software that connects the Pharmacy service, the Clinical Pathology service and ICC was implemented. This is completed with the information from patient clinical record platform.

The JCI accreditation model requires ICC members (doctors and nurses) to have access to patient clinical record. For that it was defined a password for ICC to access to patient clinical record platform. All the results are analysed by ICC nurses to monitor and evaluate trends. After this ICC identifies and establishes a set of recommendations to be apply in each case.

To help in therapeutic process, JCI Hospital develops each year a "microbiologic Chart" for all microbiologic isolations with agent identification and its susceptibility pattern. This tool is a support to doctors for the selection of appropriate therapy.

The JCI Hospital joined the "Hand Hygiene Campaign" and promoted its monitoring and evaluation through audit process.

C) Education and training

JCI Hospital develops several types of education and training programmes for HAI prevention and control. Training sessions are included in the annual education and training programme established in accordance with JCI requirements.

A specific programme for new facilitators and for the integration of new healthcare professionals is also developed (this is mandatory). A "training in service" was developed and applied in services/departments. This training methodology is applied whenever necessary and can be triggered by needs identified by facilitators, results of monitoring and evaluation process and surveillance process.

Several training programmes are developed *in situ*, for example hand hygiene training is performed service-to-service in the internal service meeting and HAI issues are part of the meeting agenda. ICC takes this opportunity to inform and to train healthcare professionals about new methodologies, recommendations and other issues related with HAI prevention and control. With this training process are achieved two targets: healthcare professionals of each service clarify doubts with ICC and between them; the increase of adherence in HAI prevention and control activities.

D) Monitoring and evaluation

As established by NPIPC the monitoring and evaluation is supported in audit process. The hospital developed an audit programme for clinical services, hand hygiene, waste disposal, cleaning and hygiene, structures (such as Provision department, storage and emergency cars), patients with peripheral venous catheters and patients with bladder catheters.

The JCI accreditation process promoted a very robust monitoring and evaluation process supported in audit process and indicator analysis. This audit process has internal and external audits: A multidisciplinary internal audits every 15 days, with the participation of Quality department, ICC, Facilities and Equipment Management department, Occupational Health and Risk Management department and Pharmacy service. To promote the exchange of ideas and to identify best solutions/actions for nonconformities this multidisciplinary team does the report with improvement suggestions. These actions are presented to services/departments and then, after a month, this team performs new audit and checks the effectiveness of the implemented actions. This multidisciplinary team is mandatory for JCI.

An external audit is promoted by JCI accreditation process where infection control is part of the audit process scope. The audit of HAI prevention and control is supported by the "patient tracer" methodology.

As mentioned before several indicators were defined by NPIPC to monitor HAI prevention and control activities: indicators for incidence epidemiological surveillance processes (HELICS and others); indicators for prevalence epidemiological surveillance; indicators for structures (facilities, equipment, environment and storage); and indicators for processes (hand hygiene issues, best practices compliance, antimicrobial and antiseptics policies compliance, sterilisation process, disinfection process). Indicators for the education and training process and for best practices and standards development were implemented to evaluate the compliance rate of these two key-processes.

Data information is obtained through incidence studies developed by the hospital. Facilitators, in a daily basis (on the calendar sheet), collect all information about invasive procedures and devices related with HAI. This procedure allows to monitor and to promote some actions in

real time to minimise HAI problems. After data analysis and when necessary actions, ICC presents to services/departments some suggestions to be implemented.

As mentioned before in the past other HAI indicators were defined by Regional Administration of Health – North and related with the contracting programme established between the State and these hospitals. Good results obtained in these indicators were (somehow) related with financial incentives. This was applied between 2008 and 2011 but was removed and replaced by "ceaserean" rate and "first visit" rate.

A satisfaction survey is applied to all services to evaluate the internal and external customer satisfaction. This is performed in accordance with JCI accreditation process.

External interested parties do some evaluations and inspections, such as the inspection from IGHA, DGH evaluation and audit from RAH (SINAS project).

Communication

As in previous hospital, the communication process has two dimensions: external and internal communication. The communication process is very identical to the presented for KF-CHKS Hospital.

Email, intranet, internal newsletters and facilitators support the internal communication. All standards and best practices published by ICC can be accessed by intranet.

Internal software connects the Pharmacy service, the Clinical Pathology service and ICC. This is completed with the information from Patient Clinical Record Platform.

As mentioned before some information about HAI prevention and control is provided through posters, such Hand Hygiene Campaign and others to promote awareness of professionals, patients and families.

External communication (from ICC to an interested party) is the same performed by the two other hospitals. It can be done directly by ICC to external interested parties (email, post or by phone), such as DGH, National Health Institute Dr. Ricardo Jorge, Regional Health Administration or others (for technical issues), or by national record platforms where each service, coordinated by ICC, reports surveillance data. The institutional communication can be done through the Administration Board, which then forwards for each service involved or directly to ICC.

Internet platforms such DGH microsites are also available. For example COS are published by DGH and are communicated by the microsite.

Interactions

From interviews analysis was verified an excellent interaction between ICC and all hospital services. Infection control facilitators promote the interaction between ICC and each service:

"Facilitators are fundamental pieces for a HAI prevention and control system… they promote best practices inside each service every day"

ICC interacts with all services as established by regulation or by accreditation process (such as Facilities and Equipment Management department, Occupational Health service, Risk Management service). A strong interaction between clinical services (through facilitators) and nonclinical services is mentioned. ICC has an active participation in all processes associated with building maintenance, material and equipment provision, cleaning and disinfection of equipment and structures.

For Hotel services director the collaboration between these two services is fundamental to ensure adequate cleaning and disinfection process:

"The contract between hospital and an external cleaning provider is based on objectives defined with the collaboration of ICC… ICC helped also in the definition of cleaning methodologies, products and all necessary to ensure HAI prevention and control"

For the responsible for Facilities and Equipment department an important work is done together with ICC to promote HAI prevention and control best practices in facilities management:

"Facilities and Equipment Management department has total support from ICC and work together promotes synergy between our departments/services"

"ICC is involved in all supply market consultation and in all commissions for equipment / material acquisition"

For Quality Management department director the interaction with ICC is fundamental for JCI accreditation process:

"HAI audit process and quality audit process is done by multidisciplinary teams"

"ICC is seen as a partner"

For ICC nurse HAI prevention and control system must be seen as a support to all services:

"It is expected that ICC has more know-how than the professionals about HAI because it can see HAI prevention and control system in a holistic way… so ICC can be used as a "crutch" even for things that are not related with HAI"

The ICC nurse team also referred that ICC began to standardise and to eliminate the provision of products that were unnecessary. Disinfectants in the hospital were reduced to only five different types. Some cleaning products are only allowed to a limited number of services by ICC suggestion and supported by Administration Board. This interaction between Provision service, ICC and Administration Board saved a lot of money to hospital.

For Occupational Health and Risk Management director the interaction is very good and is developed in a daily basis:

"The interaction between these services is excellent, we have a strong connection and daily talk and participate in activities together ... the two annual meetings between the executive team and advisory team are just a formality"

The general opinion is the existence of feedback from services to ICC work. For most of the interviewees this is due to ICC credibility and to excellent proactive attitude and behaviour from ICC executive team members. Is also said that ICC operates always supported on evidence, and doesn't use the theory of "I think that... I suppose that…".

For ICC executive team coordinator the interaction with Administration Board is also considered very good because ICC is seen as an advisory body of top management.

"… Until now ICC had not difficulty to be heard… when problems arise they are always presented with supported evidence and consistent data and also with possible solutions"

They also referred that this relation depends on the "sensitivity" of top management members.

"We lived in a golden period in which the hospital nurse director had an enormous sensitivity to HAI prevention and control issues and gave great importance to ICC work. He was the link between ICC and Administration Board… and also participated actively in ICC meetings".

The relationship between ICC and managers is also considered very good and no difficulty in communication process was identified.

Interactions with Quality Management System

As mentioned by Quality Management director, interaction between HAI prevention and control and quality management was fundamental for the improvement process and it was implicit in this accreditation model:

"When we started the accreditation process there was already much work done about infection control, but everything was disperse and without any systematisation. Each service had its own rules… "

"The accreditation process helped to systematise issues related with general terms and specific terms of infection control. First of all their requirements were established before the requirements defined at national level... there were some situations in which JCI is more demanding than national standard"

For ICC executive team members there was much work done but the accreditation process added value by organising and systematising that work:

"The JCI accreditation gave a huge help for infection control. From the moment that infection control nurse was invited to implement HAI prevention and control system recommended by accreditation model she found that everything was greatly simplified because there was a manual with guidelines to follow."

The interaction between ICC and Quality Management department is also evident in other services, like Sterilisation service that is also certified. ICC promoted the full centralisation of sterilisation (the endoscopic reprocessing was done in gastroenterology service, without the sterilisation control) to ensure compliance with certification process and accreditation process, and at the same time promoted a better equipment control to ensure HAI prevention and control:

"… ICC launched a challenge to sterilisation service to be fully centralised and they embraced the project adapting in gastroenterology service the whole process already established in sterilisation service. So they could either comply with ISO and JCI requirements and with better results for HAI prevention and control."

All standards developed by ICC are validated and implemented by Quality Management department.

"ICC is a part of quality management system"

For Facilities and Equipment Management responsible, the accreditation process promotes much more than legal compliance:

"Before the accreditation process we had something done. However it was improved due to accreditation requirements: maintenance and calibrations with tight periodicity, tight control, tight specifications…"

For ICC coordinator the accreditation process was very important to improve HAI prevention and control system. One of the most important issues was the importance given by accreditation process to risk management:

"Regarding risk management we improved our process with a risk plan and a manual for risk management. This is required by JCI"

As mentioned before for previous hospital the interaction between hospital accreditation and services/departments certification was also subject of analysis in order to understand whether these two systems could interact without redundancy and without creating barriers for processes such as HAI prevention and control system. Quality Management director also referred the inexistence of redundancies and both systems could coexist and complementing each other and accreditation process implementation was easier in the two services with ISO certification. More, it was also referred that some requirements from certification process, such as documentation control, were extended to all hospital services:

"The JCI accreditation process does not require the internal and external documentation control (explicitly) but certification requires. So I developed a documentation control process based on ISO model and implemented all over the hospital."

It was referred that JCI accreditation process requires certified providers of services and products to the hospital.

Management Tools

Several management tools associated with HAI prevention and control system, most of them are associated with monitoring and evaluation process, were identified during the interviews. Data collection, in the audit process, was done with checklists associated to NPIPC and checklists based on the accreditation programme (also verified in other hospitals). Several indicators from the NPIPC, indicators from accreditation programme and indicators from contracting process were identified to support the monitoring process. The application of decision tree and RCA for the analysis of sentinel events was also identified.

Some management tools, not directly related with HAI prevention and control, were identified. For example, it was referred the importance of quality plans at all levels (strategic, management and operation). A strategic plan for all hospital (related with the contracting process) is developed and then each service/department must define and implement a management plan with a set of objectives/targets and actions to achieve the proposed main objectives. Operational plans such as maintenance plans are used. The audit process evaluates these plans compliance rate.

The existence of internal and external quality control tools (NEQAS) for the microbiology laboratory was also referred.

For risk management applied to HAI prevention and control system was referred the use of the problem analysis methodology, cause-effect analysis, and RCA all supported by a

systematised methodology developed and supported in FMEA and William Fine methodologies[69].

Occupational Health Management director referred the application of FMEA methodology to develop a risk management plan for general risk and this year they were developing the risk management plan for patient identification.

RESULTS (What we get)

ICC does the treatment of data collected by epidemiologic studies. From the results obtained ICC promotes indicators analysis to evaluate trends and to promote internal actions. These reports are communicated individually to each service (each service has direct access only to its data and results, and has access to global report by intranet).

As mentioned ICC is responsible and/or coordinate all epidemiologic surveillance related with HAI prevention and control system. Therefore it has access to all data on real time, which promotes the development and implementation of action plans on real time.

Multidisciplinary teams, with the participation of ICC, Quality Management department, Occupational Health and Safety and Risk Management department, do most of monitoring and evaluation activities. These teams perform data treatment and report the results through the intranet (globally) and individually when it is applied to specific services.

Barriers

Several barriers associated with HAI prevention and control system. These barriers were organised following the three dimensions defined before: “who we are” (structures), “how we do” (processes) and “what we get” (results). All the barriers are presented in Table 32.

[69] William Fine methodology is a systemtic risk assessment method applied to identify probable hazards, to estimate the risk level in risk management, and to reduce into an acceptable level.

Table 32 – Barriers identified at JCI Hospital (from interviews).

Dimension	Sub-dimension	Content	Barrier
Who we are	**Resources**	Costs Time	- HAI prevention and control costs - Not enough allocated time (or nothing at all) for some ICC members (such as facilitators) for the implementation of HAI prevention and control activities
Who we are	**Culture and values**	Compliance Careers relation Culture issues	- No compliance with culture and policies associated with HAI prevention and control (more doctors than nurses) - Existence of some careers conflict between doctors and nurses - Although the real name of ICC is "HAI prevention and control committee", the name used is "Infection control team" and "control" is seen as pejorative and negative, like inspection - The ICC name is not adequate for marketing
How we do	**Clinical processes**	Clinical practices Therapy	- No compliance with clinical best practices associated with HAI prevention and control (more doctors than nurses) - Existence of some difficulties to promote therapeutic evidence-based decision instead empirical-based decision
How we do	**Management processes**	Leadership Team management and relationship Knowledge, Education and Training Awareness and individual behaviour Communication Monitoring /evaluation	- Absence of top management leadership - Absence of penalties or incentives for compliance with HAI prevention and control recommendations - ICC recommendation are not mandatory - Change resistance promoted by top management noncompliance - The organisational vision into functional departments hinders the implementation of a transversal process - No top-down definition of strategies for HAI prevention and control systems - The rotation of cleaning teams - Inexistence of a therapeutic committee and ICC must be part of it - The relation between clinician and manager can be difficult due to differences in language, knowledge and way of thinking - Gap associated with clinical knowledge and competence of nurse professionals that can not validate imaging results - The "sensitivity" for HAI issues is related with lack of knowledge - General lack of motivation and professional involvement promoted by the economic crisis - Application of "has always been like this" or " its good enough" to justify no action - Most professional assumes that control of infection is done by ICC and not by each one in their daily work - Lack on the definition of information and communication policies and flow - Inexistence of a well-defined communication system, between services (internal) and with interested parties (such as DGH) - Communication at regional and national level is not as expected (with delays or inexistent) - The level of evidence of ICC service in terms of costs / gains is very low and cannot be used as a negotiation weapon
What we get	**Data**	Data Analysis limitations	- Existence of data susceptible of error - Existence of some limitations to ICC nurses related with data analysis from patient clinical records analysis
	Reporting	Feedback Reporting system	- No feedback from some services - Significant delay in DGH reporting system - The reporting system doesn't allow comparative analysis between services/departments because each service has access to global data report and to its individual data report

Improvement Suggestions

From interviews there were identified several improvement suggestions for HAI prevention and control system. They are presented in Table 33.

Table 33 – Improvement suggestions identified at JCI Hospital (from interviews).

Dimension	Sub-dimension	Content	Improvement suggestions
Who we are	**Resources**	Human resources	- Inclusion of an epidemiologist in ICC
	Culture and values	Compliance	- Must be introduced an incentive system to promote compliance with recommendations - Must be introduced a penalisation system for noncompliance with recommendations and best practices
		Culture issues	- Change the name of "infection control committee" to "infection prevention team"
How we do	**Clinical processes**	Therapy	- Promotion of discussion and analysis of therapeutic issues in a more frequent and systematic basis
		Surveillance	- It is important to implement CAUTI surveillance at national level
	Management processes	Leadership	- All standards and recommendations from top management (internal and external) should start with "must do" instead "should do".
		Education and training	- It is important to include in basic education learning programmes (all the areas) and in higher education (health areas) specific content related with HAI prevention and control to promote better knowledge about HAI prevention and control - Promotion of education and training related with risk management - Promotion of training by exchange experiences with other sectors (risk management in industry, objective-based management in banking sector, and others)
		Team management and relationship Communication	- It is important to introduce in ICC competences not only "know-how" and "know how to do", but also "know how to be" - Promotion of interaction with primary care centres - It must be established better information channels - internal (between services).
		Monitoring and evaluation	- It must be introduced again HAI prevention and control indicators in the hospital contracting process with Regional Health Administration
What we get	**Data**	Data treatment and analysis	- It must be developed an IT tool to help ICC on data treatment and analysis

Global Perception

As referred before, the overall perception about HAI prevention and control system implemented and its interaction with quality management issues was analysed during the interviews. Table 34 resumes these perceptions.

Table 34 – Global perceptions from JCI Hospital about HAI prevention and control system and its interaction with quality management system.

Interviewee	Perception
ICC coordinator	"Quality tools are essential. These tools opened horizons, promoted systematisation and helped to think differently and have time to do it. Helped to look for better solutions and always encouraging improvements based on search for solutions… created internal dynamic and promoted practices innovation. The quality was important for better acceptance of HAI prevention and control practices. The quality has created some internal competitiveness and increase the sensitivity of people to improve" "HAI prevention and control began to be a daily concern for all healthcare professionals" "There were indicators for HAI prevention and control in the hospital contracting programme until 2 years ago… it was during this period that administration awareness about HAI prevention and control issues increased because its relationship with funding and costs. At that time Administration Board saw fundamental HAI prevention and control as an important strategic issue"
ICC nurse (specialist)	"Work together with quality management and risk management must be seen as an advantage because different point of views promote better solutions, more complete" "Things are all in place" "The Provision department constantly refers that ICC supports in acquisition of material and equipment saved money" "The accreditation standards are based on process approach not by departments. This is an advantage for all organisational processes, in especial HAI prevention and control process."
Microbiology service, Doctor	"We have a huge resistance to change…" "I see many advantages in the implementation of quality management systems for all type o services, especially in laboratory services/departments because everything is procedure-based and you can track everything: what was done, who, when, where, the equipment used, everything is traceable"
Pharmacy, Pharmaceutic	"The ICC does a good job at all levels and is well seen and understood by clinicians and non-clinical professionals" "Improvement systems bring many competitive advantages. It may seem very bureaucratic and complicated, a lot of paperwork, but I think they bring effectively advantages. People are starting to know what to do and how to do and have everything documented facilitates the realization processes. This is applied to all hospital services!"
Facilities and Equipment Management department, Engineer	"ICC is proactive... It is easy to work with ICC and this is the only way to make things work" "This job requires people to be involved in all dimensions, clinical and nonclinical areas". "The accreditation process clearly came to help facilities and equipment management and its interaction with ICC. Everything is written and is defined what to do, setting responsibilities, defined the circuits, all on detail, everything till the last screw"
Risk Management and Occupational Health Department, Engineer	"ICC is well recognised essentially because of ICC nurse work that has know-how and has excellent communication skills… ICC is seen as a peer because normally is interventive, but always evidence-based". "Accreditation process was very helpful to all organisation. The audit process allows seeing the continuous improvement over the years. "They made an effort to introduce procedures and processes supported on best practices and now all services are much more organised and systematised." "The quality imposed organisation, all documented and recorded, and activities planned. This prevents errors!" "The quality is a binder"
Quality Director, Administrator	"The major advantage of these processes is the promotion of professionals involvement and the intrinsic knowledge of the organisation"

ISO Hospital

Characterisation

This hospital is also a district-general hospital, from the north of Portugal. The accreditation process initiated in 1999-2000 when the hospital joined to hospital accreditation pilot programme developed and coordinated by Healthcare Quality Institute (HQI) and based on KF model (at that time KF-HQS).

The first accreditation was obtained in 2002 and was reaccredited in 2006. When this hospital was transformed in a corporate hospital, the Administration Board decided to change quality management model to ISO 9001 because it was more adequate to new reality. In 2012 the entire organisation quality system was certified by ISO 9001:2008.

This decision was promoted by the fact that the contracting process defined by State to corporate hospitals and ISO 9001 were both objective-based models. The contract programme established with each hospital is supported on a strategic plan, with SMART objectives to be fulfilled. Those objectives must be deployed to all organisation levels. To meet this management requirement the Administration Board decided to implement the internal contract programme applied to hospital services. To help defining SMART objectives and monitoring them it was also decided to apply the Balanced Scorecard (BSC) tool to strategic plan and for each internal contract programme. The Quality Management department is responsible for monitoring those indicators with established periodicity. Quarterly Quality department reports the indicators results, the deviations and trends are analysed in order to define which strategies must be implemented to ensure compliance with established. In the A process indicator to evaluate HAI prevention and control is presented in the global BSC (HAI prevention and control rate). So, as each process has to contribute to target achievement, this indicator is unfolded for each service BSC (for example, in the Emergency service, HAI prevention and control indicator is "Hand hygiene compliance rate"). The unfolding of HAI prevention and control general indicator in services indicators was done with the collaboration of ICC. The BSC monitoring process is supported in management software and Quality Management department coordinates all monitoring process.

As the ISO certification is process-approach-based, internal processes (key-processes and support processes) were defined and established the process matrix with all processes and their interactions.

This hospital is part of a group of healthcare providers that provide all care levels: primary care, acute care and continuous care. For this reason ICC had to develop its work across all

healthcare levels. But then were identified some problems to implement and coordinate HAI prevention and control system within levels and promote interaction between them. The first problem was the very few information about how to perform HAI prevention and control in primary care and continuous care (lack on best practices and recommendations). The other problem was that healthcare professionals from these two levels had less knowledge, awareness and "sensitivity" for HAI issues than acute care professionals. To minimise these problems, and as verified to acute care, ICC decided to "build" and to support HAI prevention and control system applied to these two levels based on KF-CHKS standards and recommendations and supported by ISO model.

The certification scope includes all levels and ICC does its work across all the three levels of care.

HAI Prevention and Control System

STRUCTURE (Who we are)

As established by national regulation the ISO Hospital has an ICC compose by executive group, advisory group and facilitator group. The first two groups are presented in Table 35. The executive team meets weekly.

A facilitator team composed by several members of different services/departments of the hospital complete this ICC.

Table 35 – ICC composition from ISO Hospital.

EXECUTIVE TEAM (ICT)	ADVISORY TEAM
Coordinator, Doctor	Surgery, Doctor
Nurse specialist (Hospital)	Public health, Technical professional
Nurse specialist (Primary Care)	Primary care, Doctor
Clinical Pathology, Doctor	Continuous care, Doctor
Microbiology, Technical professional	Pharmacy, Pharmacist
	Clinical risk, Doctor
	General risk, Engineer
	Logistic service, Engineer
	Sterilisation, Nurse
	Facilities management, Engineer
	Hotel services, Administrator
	Occupational and Health service, Engineer

PROCESS (How we do)

As done before for the other two hospitals, the core processes of HAI prevention and control system and other issues such as Communication, Interactions with other services, Interactions with quality management systems, Management tools, were analysed.

As mentioned before ICC is responsible for design, implementation and evaluation of four key processes related with HAI prevention and control. Each year ICC develops an action plan for HAI prevention and control, supported on BSC management tool, with the collaboration of several hospital services/departments that includes activities for all these key processes.

A) Best practices and standards development

As recommended by national regulation this hospital has an infection control manual and it is available for analysis through intranet or on paper. Initially all standards were compiled in the "normative book for HAI prevention and control". But then ICC concluded that it was sealed not allowing changes. Quality management system established that, 5 in 5 years, all documents must be reviewed and updated, and ICC decided to replace the book by folders that allow new standards insertion. Each department has a set of folders and all this information is available in the intranet.

ICC, with the collaboration of Quality Management department, Risk Management and Occupational Health department and other departments/services, developed general standards (hand hygiene standard for example) and more specific standards (such as Isolation standards). All this was done based on requirements from KF-CHKS accreditation model, from national legal framework and recommendations provided by NPIPC. Most of this work was done in 2007 and has been simplified by KF-CHKS accreditation model. ICC has improve its manual with several international recommendations and best practices published by recognised international organisations, such WHO, HICPAC, CDC and ECDC.

When DGH publishes a new recommendation an internal group associated with that topic develops an internal technical procedure, rule or regulation that reflects the external requirement. This development must comply with the internal documentation rules established by quality management system requirements according to ISO 9001. After the technical development, top management must approve this document and then it is published in intranet. Quality Management department is the development coordinator for all standards.

ICC is also very proactive in research field and this year ICC is competing for national prize of best practices in health, with a research project related with HAI prevention and control systems.

B) Epidemiologic surveillance

ISO Hospital participates in several epidemiological surveillance programmes, prevalence and incidence studies, established by DGH for HAI prevention and control and others. For prevalence study it is developed the national prevalence survey, and hand hygiene compliance, both applied to all hospital. Several programmes are promoted for incidence study: HELICS surgery (four months and applied to colicistectomy, colon surgery, caesarean and hip prosthesis), HELICS Intensive care (all year), neonatal service (all year), nosocomial bacteraemia (all year and associated to invasive device: central bloodstream catheter, assisted ventilation and urinary catheter).

The epidemiologic surveillance is focused in "agent problem". This surveillance is based on microbiology laboratory analysis and in IT software that sends an alert to ICC and to patient clinical record whenever an "agent problem" is detected. For example for an impatient, with this system, patient doctor and ICC are informed at the same time about HAI existence and it is possible to apply isolation best practices and appropriate therapeutic in real time. After this ICC can present therapeutic suggestions (in collaboration with microbiology laboratory) and verify compliance with the isolation best practices. HAI prevention and control policy defines that must be given equal attention to infected patient and to colonised patient because both are potential transmission vectors.

In the Emergency service, if a patient is flagged because he meets the risk factors criteria associated with MRSA (colonised or infected), he is immediately isolated, nasal screening is done, microbiologic analyses are processed and, when the results are available, the isolation is re-evaluated.

These clinical measures and others recognised as best practices, supported by education and training for healthcare professionals and families, use of personal protective equipment, and adequate management of support processes, are responsible for HAI rate decrease (in 5 years decreased from 15% to 10.6%).

ICC coordinates prevalence and incidence surveillance, with the support of clinical pathology laboratory and facilitators from all services (all these is supported by HAI prevention and control manual where the best practices are presented and the roles and responsibilities are totally defined). This gives to ICC a total knowledge about HAI prevention and control data from all hospital services. The HELICS participation is strongly supported and promoted by ICC and Clinical pathology laboratory.

As in the JCI Hospital, the hospital data associated with invasive devices are collected every day by facilitators (supported by a sheet) and then treated with software developed specially for that.

To help in therapeutic process ISO Hospital develops each year, since 1998, a "Microbiologic Chart" for all microbiologic isolations with agent identification and its susceptibility pattern. This tool is a support to doctors for appropriate therapy. The particularity of this chart is that it is developed for HAI and for community-associated infection (CAI).

More, it is usual a daily discussion and analysis of some HAI cases between a member of Clinical Pathology laboratory (ICC member) and doctors from other services, such as ICU, to promote adjustments on therapeutic plan for patients with HAI.

The ISO Hospital joined the "Hand Hygiene Campaign" and promoted its monitoring and evaluation through audit process (this campaign is considered part of prevalence studies developed by hospital).

C) Education and training

The Hospital ISO develops several education and training programmes. Initially there was a specific programme, with basic concepts, for all new healthcare professionals admitted to hospital. This programme had some participation incentives, such as participation in external conferences. Then this programme was abandoned and now it was established a new one, mandatory for any professional (clinical and nonclinical), student, even volunteer working in the hospital or for new healthcare professionals. A specific training programme for operational assistants and for cleaning and disinfection professionals was also developed.

A specific programme for new facilitators and for the integration of new healthcare professionals was implemented (this is mandatory). A "training in service" was developed and applied in services/departments. This training methodology is applied whenever necessary and can be triggered by needs identified by facilitators, results of monitoring and evaluation process and surveillance process.

Education and training is also promoted through research developed by ICC and by its participation in international conferences. This ICC is the national ICC with more scientific production.

D) Monitoring and evaluation

As established by NPIPC monitoring and evaluation are supported in audit process. Hospital developed an audit programme for clinical services, hand hygiene, waste disposal, cleaning and hygiene, and sterilisation of medical devices reprocessing. There also audit to MRSA infection.

An external audit process is promoted by ISO certification process where infection control is part of the audit scope. The audit of HAI prevention and control system is based on ICC work analysis and in the "patient tracer" methodology.

Other monitoring tools related with HAI prevention and control are applied (directly and indirectly). For example a BSC applied to all organisation, where hospital HAI rate is one of the indicators and a BSC for each service with different indicators to be monitored (such as compliance with cleaning plans on all services; compliance with hand hygiene - first and second moment - in surgical services, among others). Supplier evaluation, such as cleaning and disinfection service and laundry service, is implemented.

As mentioned before several indicators were defined by NPIPC to monitor HAI prevention and control activities: indicators for incidence epidemiological surveillance processes (HELICS and others); indicators for prevalence epidemiological surveillance; indicators for structures (facilities, equipment, environment and storage); and indicators for processes (hand hygiene issues, best practices compliance, antimicrobial and antiseptics policies compliance, sterilisation process, disinfection process). Indicators for the education and training process and for best practices and standards development were developed to evaluate the compliance rate of these two key-processes.

Data information is obtained through incidence study developed by the hospital. Facilitators, in daily basis, collect data about invasive procedures and devices that can be related with HAI. Data are treated by ICC and transformed in process indicators.

As mentioned before in the past there were HAI indicators defined by Regional Administration of Health – North and related with the contracting programme established between the State and these hospitals. Good results obtained in these indicators were related with financial incentives for the hospital. This was applied between 2008 and 2011 but then it was removed. However for this hospital this type of evaluation was maintained, as already mentioned, and it is reflected in the strategy developed to promote compliance with the contracting programme established with the State, both in terms of global indicators and indicators developed for each service/department.

This hospital is also subject to evaluations and inspections from external interested parties such as the inspection from IGHA, DGH evaluation and audit from RAH (SINAS project).

Communication

As in previous hospitals, communication process has two dimensions: external and internal communication. Although the communication process is very identical to other hospitals, in this hospital, and according to ISO requirements, all communication channels (internal and external) are defined and established.

Email, intranet, and facilitators support the internal communication. All standards and best practices published by ICC can be accessed in hospital intranet. The results from each monitoring and evaluation process are reported individually to each service by email (to its director) and globally for all hospital through the intranet and information sessions.

Internal software connects Clinical Pathology service, ICC and Patient Clinical Record Platform.

Some information about HAI prevention and control is provided through posters, such Hand Hygiene Campaign and other to promote awareness of professionals, patients and families.

The external communication (from ICC to an interested party) is the same preformed by the two other hospitals. It can be done directly by ICC to external interested parties (email, post or by phone), such as DGH, National Health Institute Dr. Ricardo Jorge, Regional Health Administration or others (for technical issues) by HELICS and other national record platforms where each service, coordinated by ICC, reports surveillance data. The institutional communication can be done through the Administration Board, which then forwards for each service involved or directly to ICC.

Internet platforms such DGH microsites are also available. For example COS published by DGH and communicated by the microsite.

Interactions

The interviews showed an excellent interaction between ICC and all hospital services.

Quality Management director expressed that exists a partnership between ICC and Quality Management department:

"The ICC is independent, as well as the Quality department. However we are partners acting together when necessary to ensure a common goal: customer satisfaction…"

"… It is important to highlight that our customer satisfaction depends on patient safety and risk management, effectiveness of care, adequacy of the structures equipment, adequacy of the environment, the competence of healthcare professionals and everything that is triggered on a daily basis and what must be done from best practices perspective."

For ICC coordinator HAI prevention and control system is well accepted by all, because it is something implicit in their activities. This is possible because ICC demand collaboration and active participation in HAI prevention and control system by all services.

"Here, what ICC says is law"

"We generally advocate a participative management"

For the Neonatal service facilitator ICC is proactive and its interaction with services/departments is strongly supported by facilitators. No barriers related with ICC recommendations are identified but it is important to reinforce "*in situ*" their importance.

"… However it is very important to reinforce "*in situ*" the importance of following best practices. For example in hand hygiene, I just pick up the checklist and the behaviour changes"

"The ICC is very proactive and supports the hospital on a daily basis"

The interaction established to support quality improvement is mentioned by the director of Hotel Services department:

"We must predefine specifications and rules before the contest. We, ICC, and Occupational and Health department establish technical requirements. Besides this we also establish operational procedures in collaboration with the ICC and Occupational Health Services and others when necessary."

This was corroborated by the responsible of Occupational Health and Safety department and also added that ICC is also involved in the purchase of individual protective equipment.

Interactions with Quality Management System

The analysis of interviews from this hospital showed that, for all interviewees, quality issues were always implicit in any hospital activity. It could be seen that this hospital has a quality management culture and this is the support for all their activity.

For ICC coordinator HAI prevention and control system is part from the quality management system. Everything is done according with system requirements.

"We have a Quality department to coordinate the development of standards in general… each service can make standards like us. Then we, and Quality department, must validate them. Institutional best practices are validated, in general, by the two departments before top management approval."

"We have several standards published in the intranet. For example we have standards for specific microorganisms such as MRSA… this is in the quality management system as a standard that we must comply."

For Clinical Pathology laboratory director, quality brought several management tools to promote and change some organisational culture issues such as those related with evaluation.

"…Here in the laboratory we see audit process as a fundamental tool to identify what we can not see and, then we can not improve. It is important to have eyes from outside to see what we can not see due to routine."

For Occupational Health and Safety department responsible, quality management system is the centre of all activity and its interaction with HAI prevention and control and with all other services must be implicit.

"We are a hospital certificated by ISO. So we can say that quality management system is the centre of all hospital activity. Therefore all areas must feed it, and are fed by it, to improve continuously."

Management Tools

This hospital referred the application of several management tools to support HAI prevention and control system and internally promoted by quality management system.

Tools related with planning and monitoring issues were identified: maintenance plans developed by Facilities and Equipment Management department, Hotel Services department and Clinical Pathology laboratory; Risk Management plans developed by Occupational Health and Safety department and based on matrix method, cause-effect diagram and RCA, decision tree; audit plans developed to ensure the monitoring and evaluation process; education and training plans; Hygiene and disinfection plans for all organisation; strategic plan, supported by BSC methodology, to support hospital contracting programme with the State; activity plans developed by each service/department. This latest plan is developed to ensure the compliance with each service with the internal contracting programme. This is also supported in the BSC.

Management tools are applied for monitoring and evaluation, such as checklists, applied to audit process, nonconformities treatment, documentation control, satisfaction evaluation, providers evaluation, and indicators (required by external interested parties and those developed internally).

Some methodologies were also identified: benchmarking (internal and external), 5W2H[70] methodology to solve problems.

[70] 5W2H methodology is based on a set of questions about a process that includes What, Why, When, Where, Who (5W), How and How much (2H). This methodology is very useful for plan development.

RESULTS (What we get)

From the results obtained ICC promotes indicators analysis to evaluate trends and to promote internal actions. Indicators, defined externally and internally, obtain the results and the results are reported through information sessions promoted during the year. Only global results are presented in these sessions. Each service has access to its own results.

ICC is responsible or/and coordinate of all epidemiologic surveillance (trough the clinical pathologic laboratory), has access to all data from these surveillance and is responsible for data treatment and analysis. Global results are reported in open session to all hospital and published in intranet. Specific results are communicated individually to each service.

Results from quality management audit are also report in an open session and published in the intranet.

All information from monitoring and evaluation process is available in the intranet and can be access for all professionals.

Results from BSC monitoring process are coordinated and analysed by quality management department. Trends can be analysed on a daily basis and when a service has deviations from expected values, Quality Management department communicates to the director and corrective actions must be performed.

Barriers

Several barriers associated with HAI prevention and control system were identified. All barriers are presented in Table 36.

Table 36 – Barriers identified at ISO Hospital (from interviews).

Dimension	Sub-dimension	Content	Barrier
Who we are	**Resources**	Costs Time	- Acquisition of material not adequate (associated with HAI prevention and control costs) - Not enough allocated time (or nothing at all) for some ICC members (such as facilitators) for implementation of HAI prevention and control activities
	Culture and values	Compliance Careers relation Culture issues	- No compliance with culture and policies associated with HAI prevention and control (more doctors than nurses) - Existence of some careers conflict between clinical and nonclinical professionals - Although the real name of ICC is "HAI prevention and control committee", the name used is "Infection control team" and "control" is seen as pejorative and negative, like inspection - The ICC name is not adequate for marketing
How we do	**Clinical processes**	Clinical practices Therapy	- No compliance (or less than expected) with clinical best practices associated with HAI prevention and control (more doctors than nurses) - Lack on HAI prevention and control best practices and recommendations from DGH apply to primary care and continuous care - Existence of some difficulties to promote evidence-based decision instead empirical-based decision
	Management processes	Leadership Team management and relationship Knowledge, education and training Awareness and individual behaviour Communication Monitoring /evaluation	- Top management makes short-term plans and it is difficult to demonstrate some advantages associated with HAI prevention and control activities in the short term - Absence of penalties or incentives for compliance with HAI prevention and control recommendations - The roles and responsibilities for NPIPC coordinator group and for regional coordinator group are not so well defined as done to hospital ICC - Meetings with all national ICC are not established - Inadequate conflict management - The relation between clinician and manager can be difficult due to differences in language, knowledge and way of thinking - The "sensitivity" for HAI issues is related with lack of knowledge - Most professionals assume that infection control is done by ICC and not by each one in their daily work - Inexistence of a well-defined communication system with interested parties (such as DGH) - The communication at regional level and national level is not as expected (with delays or inexistent) - Lack of information about operation recommendations and standards - The level of evidence of ICC service in terms of costs / gains is very low and cannot be used as a negotiation weapon - Existence of some difficulties in indicators definition - Monitoring and evaluation tools, such as audit process, are seen as "witch-hunt"
What we get	**Data**	Data	- Inexistence of sufficient data information from DGH in IT platforms
	Reporting	Feedback Reporting system	- Existence of significant delay in DGH reporting system - The reporting system doesn't allow comparative analysis between services/departments because each service has access to global data report and to its individual data report

Improvement Suggestions

Several improvement suggestions for HAI prevention and control system were identified from interviews. They are presented in Table 37.

Table 37 – Improvement suggestions identified at ISO Hospital (from interviews).

Dimension	Sub-dimension	Content	Improvement suggestions
Who we are	**Resources**	Human Resources	- Inclusion of an epidemiologist in ICC
	Culture and values	Compliance Culture issues	- Must be introduced an incentive system to promote compliance with recommendations - Change the name of "infection control committee" to "infection prevention team" or "infection prevention service"
How we do	**Clinical processes**	Therapy Surveillance	- Promotion of discussion and analysis of therapeutic issues in a more frequent and systematic basis - Promotion of research about more adequate therapy associated with gender and age - It is important to implement CAUTI surveillance at national level and hospital level
	Management processes	Leadership Knowledge, education and training Communication Monitoring and evaluation	- HAI prevention and control requirements must be implemented on a mandatory basis instead on a voluntary basis - To promote better knowledge about HAI prevention and control it was important to include in basic education learning programmes (all the areas) and in higher education (health areas) specific content related with HAI prevention and control - Introduction of collaborative tools to promote education and training - Introduction of benchmarking tools (internal and external) to promote education and training - Promote some education and training about indicators definition and development - Promote training by exchange experiences with other sectors (risk management in industry, objective-based management in banking sector, and others) - It is important to introduce in ICC competences not only "know-how" and "know how to do", but also "know how to be" - It is important to establish better communication channels (internal and external) - It is important to promote HAI prevention and control image through marketing techniques. It is important to innovate in this area - Establishment of ranking/rating systems to promote internal and external evaluation and to promote competitiveness between services and hospitals
What we get	**Data**	Data treatment and analysis	- It must be developed an IT tool to help ICC on data treatment and analysis

Global Perception

As referred before, during the interviews it was asked to the interviewees their perception about HAI prevention and control system implemented and its interaction with quality management issues (Table 38).

Table 38 – Global perceptions from ISO Hospital about HAI prevention and control system and its interaction with quality management issues.

Interviewee	Perception
ICC coordinator	"The key to manage a successful ICC is staff motivation… continuous knowledge update through research, participation in events and scientific production. We are the national ICC with more scientific production" "We verified that, the best way to do HAI prevention and control is always to engage people in change process, because the resistance decreases, compliance increase and, above all, value is added to practices, rules, everything in general."
ICC nurse (specialist)	"Work together with quality management and risk management must be seen as an advantage because different point of views promote better solutions, more complete" "Things are all in place" "The provision service constantly refers that ICC support in material and equipment acquisition saved money" "The certification standards are based on process approach not by departments. This is an advantage for all organisational processes, in especial HAI prevention and control process."
Microbiology service, Doctor	"I think that the biggest problem about quality management systems is concerned with the certificate (only with the paper) and not with the competitive advantages that it can bring… Here we can see that quality brought a "tidy home"
ICU, Doctor	"Barriers always exist but we are fortunate to be in an organisation where ICC works very well, Appropriate policies and procedures, defined and written, are implemented" "Our relation with ICC is on a daily basis and this is the key of success. Informal meetings are promoted every day between an ICU doctor and ICC (most of all with clinical pathology laboratory professional)" "… As I've worked in other hospitals, here I can see that HAI prevention and control culture exists and people are motivated and determined to improve. Of course there are difficulties, mainly because we don't want only to comply with requirements but rather to improve them"
Hotel Services department, Administrator	"Today, for this hospital is unthinkable to live without the quality management system. We can improve, we can simplify processes but "how to do it" is undoubtedly critical to organisation survival, and of course to continuous improvement" "ICC in this hospital has a strong recognition and its decisions are "rule" and always well received" "The quality, i.e. the quality systems are undoubtedly the aggregating element the binder"
Facilities and equipment department, Administrator	"From experience acquired here and in other hospitals, the advantage of a good management system is related with the existence of multidisciplinary teams, involving several areas such as occupational health and safety, environmental management, hotel services, quality management, ICC and clinical areas in order to settle things effectively" "The internal culture allows us to have an open relation between different areas. People are very close, the is a very good team who often want things that are not possible but quickly accepted to discuss a solution which is not ideal but it is better than no solution" "ISO 9001 is a fantastic tool for quality management systems… However I came from a hospital with JCI accreditation and I consider that is a better system because it is designed exclusively for healthcare organisations. In the JCI accreditation system there are standards already defined and we can discuss them but we comply with them, like it or not. In that case infection control standards are very strict, and say exactly what are the requirements and what has to be done to be achieved"
Risk management and occupational Health service, Engineer	"Much work is needed and awareness is critical to successful application of risk management tools. But the way we work here, with quality as a binder, promotes awareness"
Quality Director, Administrator	"The quality system potentiated and stimulated the implementation of best practices even before they have been established by national authority. Infection control is an example. Our proactivity is above national requirements" "In this hospital quality is not seen as an "office" but as a reflection of the work done by all" "This is just to say that in this management process everyone is involved with different roles and responsibilities, and exists a participative management"

Quality Management Models Analysis

There were performed a exhaustive analysis of each quality management model, taking into account issues related to HAI prevention and control and a comparative analysis with national framework for HAI prevention and control.

KF-CHKS model

The KF-CHKS, as presented in previous chapter, is a quality management model developed for healthcare organisations, specifically designed for hospitals.

From the documentation analysis was identified a specific standard, the standard 13, for infection control in this accreditation model. High correspondence was identified when the criteria from this model were analysed with national framework for HAI prevention and control, more specifically with NPIPC (Table 39).

Table 39 – Correspondence between KF-CHKS quality management standard and national framework for HAI prevention and control.

KF-CHKS IC standard (13)	**National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)**	
CRITERIA	**DOCUMENT**	**CONTENT**
13.1 There are defined roles and responsibilities for infection control management in the organisation	***Despacho nº 18052/2007 de 14/08/2007 -*** *Reestruturação das Comissões de Controlo de Infecção (CCI). Diário da República, 2ª Série, nº 156 Direcção Geral de Saúde; 2007.*	This document requires that healthcare organisations restructure their infection control committees with technical capabilities in four dimensions: surveillance, development of standards and recommendations, compliance monitoring and training of professionals. Also requires that internal recommendations and action plans developed by ICC are binding upon approval of top management.
	Despacho n.º 2902/2013 de 22/02/2013 - *Atribuições em relação ao Programa de Prevenção e Controlo da Infeções e de Resistência aos Antimicrobianos, Gabinete do Secretário de Estado Adjunto do Ministro da Saúde. Ministério da Saúde; 2013.*	This document requires that healthcare organisations from NHS ensure the implementation of infection control committees and the development and approval of an annual plan for HAI prevention and control.
	Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde - *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	In this document it is established ICC roles and responsibilities.
13.2 There is a multi-professional infection control committee (ICC), which advises and supports the infection control team	***Circular Normativa nº 18/DSQC/DSC de 15/10/2007*** *- Constituição e Operacionalização das Comissões de Controlo da Infecção, Divisão de Serviços da Qualidade Clínica, Divisão da Segurança Clínica. Direcção Geral da Saúde; 2007.*	This document establishes rules for the operation of NPIPC in each healthcare organisation. Guidelines are given for composition and responsibilities of different teams and members of ICC.

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KF-CHKS IC standard (13)	National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
CRITERIA	**DOCUMENT**	**CONTENT**
(Cont.) 13.2 There is a multi-professional infection control committee (ICC), which advises and supports the infection control team	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up in the field the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account different levels of healthcare and type of organisations.
13.3 The infection control committee meets no less than four times a year as a minimum, and documents its meetings.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up in the field the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account different levels of healthcare and type of organisations.
13.4 There is a documented infection control team with designated roles and responsibilities for infection control.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	In this document it is established that ICC must be defined and approved by top management.
13.5 There is a qualified professional who provides advice on infection control.	***Circular Normativa nº 18/DSQC/DSC de 15/10/2007*** *- Constituição e Operacionalização das Comissões de Controlo da Infecção. Divisão de Serviços da Qualidade Clínica, Divisão da Segurança Clínica. Direcção Geral da Saúde; 2007.*	In this document it is established that ICC must be able to give advice and support to healthcare organisation in HAI prevention and control issues. The ICC is a multidisciplinary team compose by experts in infection control (ICT with a coordinator doctor or nurse, nurses experts in HAI and administrative personnel) and healthcare experts in other healthcare areas (advisor team and facilitator team).
13.6 There is a qualified/experienced nurse with designated responsibilities for infection control (included in a documented job description) and there is a defined time commitment for infection control activities.	***Circular Normativa nº 18/DSQC/DSC de 15/10/2007*** *- Constituição e Operacionalização das Comissões de Controlo da Infecção. Divisão de Serviços da Qualidade Clínica, Divisão da Segurança Clínica. Direcção Geral da Saúde; 2007.*	The ICT, as defined by this national regulation, must be composed by a coordinator (doctor or nurse), infection control nurse and administrative personnel. It is referred in this document and established by international recommendations (CDC and NHSN) that healthcare organisations must have a fulltime IC nurse for 110-140 beds and one more for each 250 beds beyond this capacity.
13.7 Each service/department has a link nurse that promotes the link between ICC and other services/ departments	***Circular Normativa nº 18/DSQC/DSC de 15/10/2007*** *- Constituição e Operacionalização das Comissões de Controlo da Infecção. Divisão de Serviços da Qualidade Clínica, Divisão da Segurança Clínica. Direcção Geral da Saúde. 2007.*	The ICC, as defined by this national regulation is a multidisciplinary team compose by experts in IC (infection control team with a coordinator doctor or nurse, nurses experts in HAI and administrative personnel) and healthcare experts in other healthcare areas (advisor team and facilitator team). Healthcare professionals with competences, sensitivity and interest in HAI prevention and control issues, as defined in this document, must compose this facilitator team.

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KF-CHKS IC standard (13)	National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
CRITERIA	**DOCUMENT**	**CONTENT**
13.8 There are dated, documented infection control policies and procedures on universal infection control precautions. The policies and procedures have been written/reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes in the regulation-type that ICC must develop and disseminate best practices recommendations contained in HAI prevention and control manual and must be ensured a triennial review or when levels of evidence justify it.
	Norma 029/2012 de 28/12/2012 *- Precauções Básicas do Controlo da Infeção. Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2012.*	This document establishes a set of basic precautions for HAI prevention and control, that includes: HAI prevention and control issues are included in each department activities plan and in healthcare professionals performance evaluation; identification and record of infection risk for all procedures with exposure to bloodborne and body fluids and is defined an improvement plan to control those risks; stock-out record and communication of individual protection equipment (IPE); transmission risk assessment on inpatient admission; use of IPE; procedures for equipment and environment use, decontamination and cleaning; procedures for safe handling of used clothing/linen and waste; there are also presented some criteria for handling patients. Finally a set of quality indicators to compliance assessment is defined.
13.9 There is a dated, documented procedure for aseptic techniques. The document has been written or reviewed within the last three years.	***Norma 029/2012 de 28/12/2012*** *- Precauções Básicas do Controlo da Infeção. Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2012.*	This document establishes that is important to promote aseptic techniques for: hand hygiene, clinical procedures such as injections and vaccines.
13.10 There is a dated, documented infection control procedure on hand washing, including the use of alcohol-based antiseptic solutions for rubbing hands. The document has been written or reviewed within the last three years.	***Circular Normativa Nº: 13/DQS/DSD de 14/06/2010 -*** *Orientação de Boa Prática para a Higiene das Mãos nas Unidades de Saúde. Departamento da Qualidade na Saúde. Divisão de Segurança do Doente. Direcção Geral da Saúde; 2010.*	This document establishes a set of best practices for hand hygiene, based on WHO recommendations. This document aim to: update the current recommendations for National Hand Hygiene Campaign; support best practices implementation in healthcare organisations; and support implementation of the National Campaign for Hand Hygiene.
13.11 There are dated, documented infection control procedures for disposal of clinical and non-clinical waste. The procedures have been written/reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must develop and implement a HAI prevention and control manual. In this manual must be established procedures for waste management. It is also established that HAI prevention and control manual must be reviewed on a triennial basis or when levels of evidence justify it.
	Despacho n.º 242/96 ,de 05 de Julho do Ministério da Saúde - *Gabinete da Ministra: triagem e tratamento de resíduos hospitalares. Diário da República. Ministério da Saúde; 1996.*	This document establishes the rules for clinical and no-clinical waste in healthcare organisations. There are defined waste categories and criteria to identify and classify waste.

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KF-CHKS IC standard (13)	National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
CRITERIA	**DOCUMENT**	**CONTENT**
13.12 There is a dated, documented procedure for handling outbreaks of infection, written/reviewed within the last three years.	***Plano de intervenção na possibilidade ou suspeita de surto -*** *Programa Nacional de controlo da Infecção. Instituto Nacional de Saúde Dr. Ricardo Jorge. Ministério da Saúde; 2007.*	This document establishes some recommendations for ICC to handle with outbreaks of infection. ICC is responsible for outbreak research and development of policies and best practices.
13.13 There is a dated, documented procedure for isolation techniques and barrier nursing, written/reviewed within the last three years.	***Recomendações para as precauções de isolamento -*** *Precauções básicas e dependentes das vias de transmissão. Ministério da Saúde; 2007.*	This document presents isolation concepts and definitions, and set of measures that must be met consistently by all healthcare professionals and to all people that have contact with patients in all places of a healthcare organisation whatever the diagnosis or suspicion diagnosis. These basic Precautions are apply to: blood and body fluids; secretions and excretions (except sweat); breaks in skin and mucous membranes.
13.14 There are dated, documented procedures and guidelines on the prevention or spread of blood-borne viruses and post-exposure prophylaxis, written/reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for basic precautions (not so specific).
13.15 There is a dated, documented procedure for dealing with sharps incidents (including needle stick injuries), written/reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for basic precautions (not so specific).
13.16 There is a dated, documented procedure for the control of antimicrobial resistant microorganisms such as Multi-Resistant *Staphylococcus aureus* (MRSA). The procedure has been written/reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must include in HAI prevention and control manual the Antimicrobial Use policy.
	Programa Nacional de Prevenção das Resistências aos Antimicrobianos - *Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2009.*	This document establishes the development of a surveillance system that allows early detection of important microorganisms and ensures communication of resistances between healthcare organisations by an alert system. This surveillance system must promote knowledge an ongoing consumption of antimicrobials in healthcare organisations from NHS.
	Norma 04/2013 de 21/02/2013 *- Vigilância Epidemiológica das Resistências aos Antimicrobianos. Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2013.*	This document establishes the mandatory reporting system to DGH for microorganisms "alert" and "problem" for all clinical Pathology / Microbiology laboratories from NHS. There are presented some important definitions and classification of microorganisms.
	Orientação nº 028/2011 de 15/07/2011 *- Comissões de Antimicrobianos para Serviços prestadores de cuidados do Sistema Nacional de Saúde. Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2011.*	This document establishes that all healthcare organisations must have an antimicrobial committee responsible for implementation of National Programme for Prevention of AMR. This programme must promote the appropriateness of antibiotic prescription and avoidance of overuse of antibiotics, and the incidence reduction of multi-resistant microorganisms.

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KF-CHKS IC standard (13)	National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
CRITERIA	**DOCUMENT**	**CONTENT**
13.17 There is a dated, documented policy on antimicrobial prescribing. The policy has been written/reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must include in HAI prevention and control manual the Antimicrobial Use policy.
	Programa Nacional de Prevenção das Resistências aos Antimicrobianos - *Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2009.*	This document establishes the development of a surveillance system that allows early detection of important microorganisms and ensures communication of resistances between healthcare organisations by an alert system. This surveillance system must promote knowledge an ongoing consumption of antimicrobials in healthcare organisations from NHS.
	Norma 04/2013 de 21/02/2013 *- Vigilância Epidemiológica das Resistências aos Antimicrobianos. Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2013.*	This document establishes the mandatory reporting system to DGH for microorganisms "alert" and "problem" for all clinical Pathology / Microbiology laboratories from NHS. There are presented some important definitions and classification of microorganisms.
	Orientação nº 025/2011 de 28/06/2011 *- Utilização de Ampicilina, Amoxicilina e Amoxicilina/Ácido Clavulânico. Resistência aos Antimicrobianos. Departamento da Qualidade na Saúde. Direcção Geral de Saúde; 2011.*	This document establishes guidance for the use of these three antibiotics to prevent AMR.
13.18 There are dated, documented procedures that cover working with high-risk patients (for example immunosuppressed) and those with communicable diseases. The procedures have been written/reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for special care with special services/departments (not so specific).
13.19 There is a dated, documented procedure on control of tuberculosis, including multi-drug resistant tuberculosis, written or reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for special care with special services/departments (not so specific).
13.20 There is a dated, documented procedure for the use of medical devices for interventions in patients with Creutzfeldt Jakob disease. The procedure has been written or reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for special care with special services/departments (not so specific).
	Orientações para a elaboração de um manual para as boas práticas em Bacteriologia. *Instituto Nacional de Saúde Dr. Ricardo Jorge; Ministério da Saúde.2005*	This document establishes a set of best practices for bacteriology, to ensure the quality of data and the compliance with occupational health and safety issues.

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KF-CHKS IC standard (13)	National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
CRITERIA	**DOCUMENT**	**CONTENT**
13.21 There are dated, documented procedures covering the control and prevention of infection during collection, packaging, handling and delivery of laboratory specimens. The procedures have been written or reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde*** *- Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for products collection for microbiologic analysis (not so specific).
	Orientações para a elaboração de um manual para as boas práticas em Bacteriologia. *Instituto Nacional de Saúde Dr. Ricardo Jorge; Ministério da Saúde; 2005.*	This document establishes a set of best practices for bacteriology, to ensure the quality of data and the compliance with occupational health and safety issues.
13.22 There are dated, documented infection control procedures for control of infection in housekeeping, laundry and catering. The procedures have been written/reviewed within the last three years.	***Higienização do Ambiente nas Unidades de Saúde*** *- Recomendações de Boa Prática. Ministério da Saúde; 2007.*	This document establishes a set of principles and criteria for the improvement of cleaning services with specific objectives: to recall the general principles of environment hygiene; to define criteria for cleaning equipment and the rules of packaging.
	Recomendações para Controlo do Ambiente *- Princípios Básicos. Ministério da Saúde; 2007.*	This document establishes some important measures to control the environment, making it safer for professionals, patients and visitors.
	Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde - *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for sorting, transport, packaging and treatment of clothing and linen.
13.23 There are dated, documented procedures giving guidance on last offices and mortuary work processes with regard to infection control. The procedures have been written/ reviewed within the last three years.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for care post-mortem and mortuary houses.
13.24 The infection control policies and procedures are distributed throughout the hospital.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must be disseminated, covering all services and departments and their compliance must be monitored.
13.25 The Infection control policies/procedures are centrally indexed and compiled into a policy manual that includes details of circulation.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must be disseminate, covering all services and departments and their compliance must be monitored (this is not so specified in this document).
13.26 There is an ongoing education programme on infection control for all staff within the hospital.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes four areas for development of an effective HAI prevention and control systems, and training/education is one of them. Education and training must include policies, procedures and practices that guide HAI prevention and control in healthcare organisations, according to NPIPC and the HAI prevention and control Manual from healthcare organisation.

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KF-CHKS IC standard (13)	National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
CRITERIA	**DOCUMENT**	**CONTENT**
13.27 The infection control team or infection control link nurse is involved in the hospital induction programme.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document also establishes that education and training about HAI prevention and control must cover all groups of healthcare professionals, including professional on integration.
13.28 Throughout the organisation is posted information to remind and promote hand hygiene	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must be disseminated, covering all services and departments and their compliance must be monitored. This manual includes basic precaution, where can be included hand hygiene. Although there also a national Hand Hygiene Campaign.
13.29 Facilities are available for infectious patients and those requiring isolation.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008..*	This document establishes best practices for HAI prevention and control. It is also considered transmission or cross-infection problems and how to minimise/eliminate them.
	Recomendações para as precauções de isolamento. *Precauções básicas e dependentes das vias de transmissão. Direcção Geral da Saúde; Ministério da Saúde; 2007.*	This document establishes best practices for isolation precautions. There also a policy for Facilities and Equipment, to respond to the needs of prevention and control of HAI transmission or cross-infection.
13.30 There are hand washing facilities in all clinical areas, including alcohol-based antiseptic solutions for rubbing hands, designed to minimise the spread of infection.	***Circular Normativa Nº: 13/DQS/DSD de 14/06/2010*** *- Orientação de Boa Prática para a Higiene das Mãos nas Unidades de Saúde. Departamento da Qualidade na Saúde. Divisão de Segurança do Doente. Direcção Geral da Saúde; 2010.*	This document establishes best practices hand hygiene. There also a policy for Facilities and Equipment, to respond to the needs of prevention and control of HAI transmission or cross-infection.
13.31 There is an annual infection surveillance programme in place across the hospital that includes the collection, analysis and dissemination of data.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes four areas for development of effective HAI prevention and control systems and surveillance is one of them. In this document are defined objectives for epidemiologic surveillance, the National and European Epidemiologic Surveillance programmes, and the national network for HAI record.
	Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde *- Inquérito de Prevalência de Infecção. Protocolo Programa Nacional de Controlo da infecção - PNCI: Departamento da Qualidade na Saúde - Direcção Geral da Saúde; 2009. p. 53.*	This document establishes the methodology for national prevalence survey for NPIPC.
	Inquérito de Prevalência de Infeções Associadas aos Cuidados de Saúde e Utilização de Antimicrobianos nos Hospitais de Agudos na Europa *- Protocolo Versão 4.2, Inquérito completo. Direção Geral da Saúde; 2012.*	This document establishes the methodology for European prevalence survey.
13.32 In inpatient services hospital acquired infection rates are monitored and reviewed.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes a set of indicators to monitoring the HAI prevention and control systems. There are indicators for all national epidemiologic surveillance programmes and others.

(Cont.)

KF-CHKS IC standard (13)	National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
CRITERIA	**DOCUMENT**	**CONTENT**
3.33 Results from the surveillance programme are reported to the infection control committee and to relevant staff. There is evidence that results are acted on.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that healthcare organisations must promote the implementation of communication circuits to ensure effective communication between all services and departments. There are also some recommendations about external communication.
3.34 Large outbreaks of infection are classified as incident and reported through the incident reporting system used by the organisation	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes the creation of a national recording network for infection. All healthcare organisations must report adverse events to General-Directorate of Health, national coordinator for HAI prevention and control programme.
	Plano de intervenção na possibilidade ou suspeita de surto. *Programa Nacional de Controlo da Infecção. Instituto Nacional de Saúde Dr; Ricardo Jorge. Ministério da Saúde; 2007.*	This document establishes an intervention plan to manage outbreaks (not so specific).
3.35 There is an annual infection control audit programme.	***Circular Normativa nº 18/DSQC/DSC de 15/10/2007*** *- Constituição e Operacionalização das Comissões de Controlo da Infecção, Divisão de Serviços da Qualidade Clínica, Divisão da Segurança Clínica. Direcção Geral da Saúde; 2007.*	This document establishes that each healthcare organisation must establish a audit programme for areas of increased risk of HAI transmission. There are established audit programmes for structures (facilities and equipment), and processes (procedures and practices).
3.36 Results from the audit programme are reported to the appropriate group. There is evidence that results are acted on.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that each healthcare organisation must establish an audit programme for areas of increased risk of HAI transmission. There are established audit programmes for structures (facilities and equipment), and processes (procedures and practices). There is no reference to internal reporting system, only says that must ensured external reporting system.
3.37 Infection control has a remit to give advice as part of the contracting process for cleaning, catering, laundry and clinical waste services.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must participate in the definition of a Policy for housekeeping services (cleaning, laundry, food, internal and external transport of patients, decontamination, etc.).
3.38 Infection control has a remit to give advice on proposed building and engineering works, and the purchase of medical devices and equipment to ensure that they are in accordance with infection control requirements.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must participate in protocols, building, maintenance or renewal of facilities. There is also established that ICC actively participate in the definition of technical specifications for materials, equipment and services.
3.39 There is a service level agreement between the infection control team and the Occupational Health service.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must collaborate with the Occupational Health department on application of legal rules related with biological risks.
3.40 There is ongoing communication between the infection control team and the risk management multi-professional committee (or equivalent).	***Circular Normativa nº 18/DSQC/DSC de 15/10/2007*** *- Constituição e Operacionalização das Comissões de Controlo da Infecção, Divisão de Serviços da Qualidade Clínica, Divisão da Segurança Clínica. Direcção Geral da Saúde; 2007.*	This document establishes that ICC must collaborate with the Risk Management department.

Other standards from this model related with HAI prevention and control complement the exposed in this standard and also provide some answers to NPIPC requirements.

These are expose in standards: Leadership and organisation (standard 1, criteria 1.33 and 1.53), Quality and governance (standard 2, criteria 2.18, 2.25, 2.26), risk management (standard 7, criteria 7.4, 7.12), Occupational Health service (standard 9, criteria 9.4 and 9.14), Sterilisation and decontamination services (standard 14, criteria 14.5, 14.19, 14.48, 14.49), waste management (standard 15, criteria 15.2, 15.8, 15.19), Human resources (standard 18, criterion 18.27), Occupational medicine (standard 20, criteria 20.4, 20.13) Facilities management (standard 23, criteria 23.16, 23.17, 23.18), Post-mortem services (standard 29, criteria 29.2, 29.7, 29.8, 29.9, 29.10, 29.11, 29.13, 29.19, 29.20), Food service (standard 30, criteria 30.17, 30.21, 30.25), Cleaning service (standard 31, criteria 31.3, 31.6, 31.8-31.10, 31.12, 31.19, 31.20, 31.22, 31.24, 31.25). Service environment (standard 36, criterion 36.4), Administrative functions (standard 39, criteria 39.20, 39.89, 39.90-39.93, 39.95, 39.96), Imagiology service (standard 41, criteria 41.13, 41.15, 41.69), Clinical pathology service (standard 42, criteria 42.6, 42.32), Physiotherapy service (standard 44, criterion 44.28), Outpatient service (standard 46, criterion 46.28), Operating room (standard 47, criterion 47.29), Surgery service (standard 49, criteria 49.46), Oncology-radiotherapy service (standard 51, criterion 51.13), Maternity service (standard 53, criterion 53.78), Clinical emergency (standard 54, criterion 54.14), Special care service (standard 56, criterion 56.9), Ambulance service (standard 61, criteria 61.12, 61.14, 61.66).

JCI model

The JCI model, as presented in previous chapter, is also a quality management model design specifically for healthcare organisations accreditation. From the documentation analysis it could be identified that this accreditation model has a specific standard, the Prevention and Control of Infection (PCI) standard, design to promote HAI prevention and control system. A very good match between national framework for HAI prevention and control and this standard was observed (Table 40, Table 41, Table 42, Table 43, and Table 44).

Table 40 – Correspondence between JCI quality management standard for HAI prevention and control and national framework for HAI prevention and control – Group Programme Leadership and Coordination.

Prevention and Control of Infection (PCI)		National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
ST.	**REQ.**	**DOCUMENT**	**CONTENT**
PCI.1	There are individuals qualified (by education, training, experience, and certification or licensure) in infection prevention and control responsible for oversee prevention and control activities	***Despacho nº 18052/2007 de 14/08/2007 -*** *Reestruturação das Comissões de Controlo de Infecção (CCI). Diário da República, 2ª Série, nº 156 Direcção Geral de Saúde; 2007.*	This document requires that healthcare organisations restructure their infection control committees with technical capabilities in four dimensions: surveillance, development of standards and recommendations, compliance monitoring and training of professionals. Also requires that the internal recommendations and action plans developed by ICC are binding upon approval of top management.
		Despacho n.º 2902/2013 de 22/02/2013 - *Atribuições em relação ao Programa de Prevenção e Controlo da Infeções e de Resistência aos Antimicrobianos, Gabinete do Secretário de Estado Adjunto do Ministro da Saúde. Ministério da Saúde; 2013.*	This document requires that healthcare organisations from NHS ensure the implementation of infection control committees and the development and approval of an annual plan for HAI prevention and control.
PCI.2	There is designated a coordination group with physicians, nurses and others	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up in the field the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account different levels of healthcare and type of organisation.
		Circular Normativa nº 18/DSQC/DSC de 15/10/2007 - *Constituição e Operacionalização das Comissões de Controlo da Infecção, Divisão de Serviços da Qualidade Clínica, Divisão da Segurança Clínica. Direcção Geral da Saúde; 2007.*	This document establishes rules for the operation of the NPIPC in each healthcare organisation. Guidelines are given for the composition and responsibilities of different teams and members of ICC.
PCI.3	There is a HAI prevention and control programme based on the best practices and regulation, standards for sanitation and cleanliness	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up, in the field, the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account the different levels of healthcare and type of organisations. There are established criteria for evaluation of the plan implementation: composition and organisation of the ICC, surveillance, infrastructure monitoring, surveillance procedures, good practice recommendations, training and information. Finally it presents a set of indicators for monitoring the activities of HAI prevention and control.
PCI.4	There is adequate resources provision to support HAI prevention and control programme	***Despacho nº 18052/2007 de 14/08/2007 -*** *Reestruturação das Comissões de Controlo de Infecção (CCI). Diário da República, 2ª Série, nº 156 Direcção Geral de Saúde; 2007.*	This document requires that healthcare organisations from NHS ensure the implementation of infection control committees and the development and approval of an annual plan for HAI prevention and control.
		Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde - *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This documented establishes that healthcare organisation top management must provide adequate resources for HAI prevention and control system.

ST – Standard; REQ. -Requirement

Table 41 - Correspondence between JCI quality management standard for HAI prevention and control and national framework for HAI prevention and control – Group Focus On the Programme.

Prevention and Control of Infection (PCI)		**National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)**	
ST.	**REQ.**	**ST.**	**REQ.**
PCI.5	There is a programme designed and implemented to reduce the risks of HAI in patients and healthcare professionals	***Despacho n.º 2902/2013 de 22/02/2013 -*** *Atribuições em relação ao Programa de Prevenção e Controlo da Infeções e de Resistência aos Antimicrobianos, Gabinete do Secretário de Estado Adjunto do Ministro da Saúde. Ministério da Saúde; 2013.*	This document requires that healthcare organisations from NHS ensure the implementation of infection control committees and the development and approval of an annual plan for HAI prevention and control.
		Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde - *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up in the field the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account the different levels of healthcare and type of organisations. There are established criteria for evaluation of the plan implementation: composition and organisation of the ICC, surveillance, infrastructure monitoring, surveillance procedures, good practice recommendations, training and information. Finally it presents a set of indicators for monitoring the activities of HAI prevention and control.
		Circular Normativa Nº: 13/DQS/ DSD de 14/06/2010 - *Orientação de Boa Prática para a Higiene das Mãos nas Unidades de Saúde. Dep. da Qualidade na Saúde. Divisão de Segurança do Doente. Direcção Geral da Saúde; 2010.*	This document establishes a set of best practices for hand hygiene, based on WHO recommendations. This document aim to: update the currently recommendations for the National Hand Hygiene; support best practices implementation in healthcare organisations; and support implementation of the National Campaign for Hand Hygiene.
PCI.5.1	The programme is applicable to patient, healthcare professionals and visitors areas	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up in the field the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account the different levels of healthcare and type of organisations. There are established criteria for evaluation of the plan implementation: composition and organisation of the ICC, surveillance, infrastructure monitoring, surveillance procedures, good practice recommendations, training and information. Finally it presents a set of indicators for monitoring the activities of HAI prevention and control.
PCI.6	The organisation establishes the HAI prevention and control programme using a risk-based approach to identify the focus of HAI programme	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up in the field the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account the different levels of healthcare and type of organisations. There are established criteria for evaluation of the plan implementation: composition and organisation of the ICC, surveillance, infrastructure monitoring, surveillance procedures, good practice recommendations, training and information. Finally it presents a set of indicators for monitoring the activities of HAI prevention and control.
		Orientação nº 011/2012 de 30/07/2012 - *Análise de Incidentes e de Eventos Adversos. Lisboa, Departamento da Qualidade na Saúde. Direção Geral da Saúde; 2012.*	This document establishes some procedures for the treatment of adverse events, based on quality tools as cause-effect analysis and root-cause analysis. The main objective is to promote preventive actions design and implementation.

ST. – Standard; REQ. –Requirement

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Prevention and Control of Infection (PCI)		National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
ST.	**REQ.**	**DOCUMENT**	**CONTENT**
PCI.7	The organisation establishes the HAI prevention and control procedures and processes to reduce infection risks	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document aims to set up in the field the NPIPC. It is defined the value chain for HAI prevention and control, encompassing the existing structures at national, regional and organisational level and their articulation. Establishes the responsibilities of these different structures in detail (who does, when and what). Are also defined objectives and activities for each dimension of intervention, taking into account the different levels of healthcare and type of organisations. There are established criteria for evaluation of the plan implementation: composition and organisation of the ICC, surveillance, infrastructure monitoring, surveillance procedures, good practice recommendations, training and information. Finally it presents a set of indicators for monitoring the activities of HAI prevention and control.
PCI.7.1.	There are adequate equipment, cleaning and sterilisation, and proper laundry and linen management throughout all organisation	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for sorting, transport, packaging and treatment of clothing and linen.
		Higienização do Ambiente nas Unidades de Saúde *- Recomendações de Boa Prática. Ministério da Saúde; 2007.*	This document establishes a set of principles and criteria for the improvement of cleaning services with specific objectives: to recall the general principles of environment hygiene; to define criteria for cleaning equipment and the rules of packaging.
		Recomendações para o Controlo do Ambiente *- Princípios Básicos. Ministério da Saúde; 2007.*	This document establishes some important measures to control the environment, making it safer for professionals, patients and visitors.
PCI.7.1.1	The organisation establishes a policy and procedure to identify and manage expire supplies and defines conditions for reuse of single-use devices when law and regulation permit	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that healthcare organisations must implement a policy for the decontamination of medical devices and equipment (including cleaning, disinfection and sterilization) and it includes reprocess of single use medical devices.
		Orientação nº008/2012 de 04/06/2012 - *Reprocessamento em Endoscopia Digestiva. Lisboa, Departamento da Qualidade na Saúde. Direção Geral da Saúde; 2012.*	This document establishes some recommendations and criteria for reprocessing medical devices in Digestive Endoscopy.
PCI.7.2.	There is a proper disposal of waste to reduce the infection risk	***Despacho n.º 242/96, de 05 de Julho do Ministério da Saúde*** *- Gabinete da Ministra: triagem e tratamento de resíduos hospitalares. Diário da República. Ministério da Saúde; 1996.*	This document establishes the rules for clinical and no-clinical waste in healthcare organisations. There are defined waste categories and criteria to identify and classify waste (There are other important documents such as national strategy for hospital waste).
		Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde - *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must develop and implement a HAI prevention and control manual. In this manual must be established procedures for waste management. There is also established that HAI prevention and control manual must be reviewed on a triennial basis or when levels of evidence justify it.
PCI.7.3.	There is a policy and procedure for the sharps and needles disposal	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde*** *- Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that HAI prevention and control manual must have procedures for basic precautions (not so specific).

ST. – Standard; REQ. –Requirement

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Prevention and Control of Infection (PCI)		National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
ST.	**REQ.**	**DOCUMENT**	**CONTENT**
PCI.7.4.	There is infection prevention and control actions to reduce the risk associated with operations of the food service and mechanical and engineering controls	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must participate in the definition of a policy for housekeeping services (cleaning, laundry, food, internal and external transport of patients, decontamination, etc.).
PCI.7.5.	There is infection prevention and control actions to reduce the risk associated with demolitions, and renovation.	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde*** *- Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must participate in protocols construction, maintenance or renewal of facilities. There is also established that ICC actively participate in the definition of technical specifications for materials, equipment and services.

ST. – Standard; REQ. -Requirement

Table 42 - Correspondence between JCI quality management standard for HAI prevention and control and national framework for HAI prevention and control – Group Isolation Procedures.

Prevention and Control of Infection (PCI)		National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
ST.	**REQ.**	**DOCUMENT**	**CONTENT**
PCI.8	There is barriers precautions and isolation procedures to protect patients, visitors, and healthcare professionals from communicable diseases and protects immunosuppressed patients from acquiring infections	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde*** *- Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must develop and implement isolation precautions and report all HAI in the national HAI reporting network.
		Recomendações para as precauções de isolamento - *Precauções básicas e dependentes das vias de transmissão. Ministério da Saúde; 2007.*	This document presents isolation concepts and definitions, and set of measures that must be met consistently by all healthcare professionals and to all people that have contact with patients in all places of a healthcare organisation whatever the diagnosis or suspicion diagnosis. These basic precautions are apply to: blood and body fluids; secretions and excretions (except sweat); breaks in the skin and mucous membranes.

ST – Standard; REQ. -Requirement

Table 43 - Correspondence between JCI quality management standard for HAI prevention and control and national framework for HAI prevention and control – Group Barrier Techniques and Hand Hygiene.

Prevention and Control of Infection (PCI)		National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
ST.	**REQ.**	**DOCUMENT**	**CONTENT**
PCI.9	There are available (and correctly used) individual protection equipment, soap, and disinfectants	***Circular Normativa Nº: 13/DQS/DSD de 14/06/2010*** *- Orientação de Boa Prática para a Higiene das Mãos nas Unidades de Saúde. Departamento da Qualidade na Saúde. Divisão de Segurança do Doente. Direcção Geral da Saúde; 2010.*	This document establishes a set of best practices for hand hygiene, based on WHO recommendations. This document aim to: update the currently recommendations for the National Hand Hygiene; support best practices implementation in healthcare organisations; and support implementation of the National Campaign for Hand Hygiene.
		Norma 029/2012 de 28/12/2012 - *Precauções Básicas do Controlo da Infeção. Departamento da Qualidade na Saúde. Direcção Geral da Saúde; 2012.*	This document establishes a set of basic precautions for HAI prevention and control, that includes: HAI prevention and control issues are included in each department activities plan and in the healthcare professionals performance evaluation; identification and record of infection risk for all procedures with exposure to blood borne and body fluids and is defined an improvement plan to control those risks; stock-out record and communication of individual protection equipment (IPE); transmission risk assessment on inpatient admission; use of IPE; procedures for equipment and environment use, decontamination and cleaning; procedures for safe handling of used clothing/linen and waste; There are also presented some criteria for handling patients. Finally there is defined a set of quality indicators to compliance assessment.

Table 44- Correspondence between JCI quality management standard for HAI prevention and control and national framework for HAI prevention and control – Group Integration of the programme with Quality Improvement and Patient Safety.

Prevention and Control of Infection (PCI)		**National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)**	
ST	**REQ.**	**DOCUMENT**	**CONTENT**
PCI.10	The HAI prevention and control is integrated in the quality improvement and patient safety programme	***Despacho n.º 3635/2013 de 27/02/2013 -*** *Estabelecimento pelas entidades prestadoras de cuidados de saúde de um plano de ação anual de acordo com a Estratégia Nacional para a Qualidade na Saúde, segundo um modelo definido pelo Departamento da Qualidade na Saúde. Diário da República, 2.ª série, N.º 47 de 7 de março de 2013. Ministério da Saúde; 2013.*	This document establishes that healthcare organisations must develop an action plan in accordance with the National Strategy for Quality in Health, which included quality, patient safety and safety issues. A multidisciplinary committee must develop this plan with members from quality department, ICC, and occupational department.
		Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde - *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must collaborate with patient safety department, the Occupational Health department on application of legal rules related with biological risks, with risk management department and clinical risk management.
PCI.10.1	The organisation tracks HAI risks, HAI rates, and trends	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that healthcare organisations must implement epidemiologic surveillance and data collection must be used trend analysis, compare data and promote best practices improvement and research. This document establishes also some epidemiology surveillance programmes must be implemented and to feed the National HAI reporting network. All healthcare organisations must report HAI events to DGH, the coordinator of NPIPC.
PCI.10.2	Quality improvement methodologies includes using measures related to HAI issues that are epidemiologically important to the organisation	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that healthcare organisations must implement epidemiologic surveillance and data collection must be used trend analysis, compare data and promote best practices improvement and research. This document establishes also some epidemiology surveillance programmes must be implemented and to feed the National HAI reporting network. All healthcare organisations must report HAI events to DGH, the coordinator of NPIPC.
PCI.10.3	The organisation uses risk, rate and trend information to design or to modify processes to reduce HAI	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that healthcare organisations must implement epidemiologic surveillance and data collection must be used trend analysis, compare data and promote best practices improvement and research. This document establishes also some epidemiology surveillance programmes must be implemented and to feed the National HAI reporting network. All healthcare organisations must report HAI events to DGH, the coordinator of NPIPC.
PCI.10.4	The organisation compares its HAI rates with other organisations through comparative databases	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that healthcare organisations must implement epidemiologic surveillance and data collection must be used trend analysis, compare data and promote best practices improvement and research. This document establishes also some epidemiology surveillance programmes must be implemented and to feed the National HAI reporting network. All healthcare organisations must report HAI events to DGH, the coordinator of NPIPC.

ST – Standard; REQ. -Requirement

(Cont.)

Prevention and Control of Infection (PCI)		National Framework (LEGAL DOCUMENT/REGULATION/STANDARD/ RECOMMENDATION)	
ST	**REQ.**	**DOCUMENT**	**CONTENT**
PCI.10.5	The results of HAI prevention and control measurement in the organisations are regularly communicated to leaders and healthcare professionals	***Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde -*** *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that ICC must develop and implement an internal audit plan to monitoring HAI prevention and control programme compliance. There is also established that ICC must promote internal communication and external communication of data.
PCI.10.6	The organisation reports information on infection to appropriate external public health agencies	***Despacho nº 14178/2007 de 04/07/2007*** *- Aprovação do Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde (PNCI). Gabinete do Ministro da Saúde. Lisboa, Diário da República nº 127, 2ª Série: 19007; 2007.*	This document establishes the creation of national HAI reporting network.
		Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde - *Manual de Operacionalização. Direcção Geral da Saúde. Ministério da Saúde; 2008.*	This document establishes that healthcare organisations must implement epidemiologic surveillance and data collection must be used trend analysis, compare data and promote best practices improvement and research. This document establishes also some epidemiology surveillance programmes must be implemented and to feed the National HAI reporting network. All healthcare organisations must report HAI events to DGH, the coordinator of NPIPC.

ST – Standard; REQ. –Requirement

Other standards from this model complement the exposed and provide a response to the requirements of the national programme for infection control.

These are expose in the standards: international patient safety goals (goal 5), access to care and continuity of care (transportation standard ACC.5); quality improvement and patient safety (measure selection and data collection standard QPS.3.3); governance, leadership and direction (direction of departments and services standard GLD.5.4); staff qualifications and education (orientation and education standards SQE.7, SQE.8, SQE.8.3, and SQE.8.4); management of communication and information (aggregate data and information standard MCI.20.2).

From the analysis of this model manual it can be seen that this model promotes an intrinsic link between HAI prevention and control issues, quality and patient safety.

ISO Based model

The ISO 9001 model, as discussed before, is a management model applied to any type of organisation to support the development and implementation of quality management systems, based on the improvement PDCA cycle. As in previous models a direct correspondence between ISO requirements and national framework for HAI prevention and control is not presented. However HAI prevention and control system can be seen as a system with four

major processes, as identified before: best practices and standards development, epidemiologic surveillance, education and training, and monitoring and evaluation.

The development and implementation of this system is supported by PDCA cycle and process approach methodology: processes identification and interactions (Chapter 4 – Quality management system); identification of interested parties requirements, definition of roles and responsibilities, definition of SMART objectives, establishment of all ICC activities to achieve those objectives, definition of communication channels within hospital and between interested parties and hospital (Chapter 5 – Management responsibilities); provision of resources, including human resources (competences), infrastructures and work environment (Chapter 6 – Resources management); implementation of those activities in the field after planning (Chapter 7 – Product realisation); monitoring and evaluation of system effectiveness (through audit process, indicators analysis), development of action plans to eliminate nonconformities and to improve HAI prevention and control system (Chapter 8 – Measurement, analysis and improvement).

ISO 9001 model is based on "what to do" and doesn't specify "How to do". So if an organisation wants to implement a quality system supported in this model, it must define "how to do", based on best practices, legal/regulation framework, interested parties requirements and its capacity.

ISO Hospital, to define "how to do" decided to use requirements from national legal framework, from KF-CHKS accreditation model and from international recommendations (WHO, CDC, HICPAC, ECDC) to complement ISO requirements. And again as mentioned before, requirements ISO were used to draw a "skeleton" and the other, with more specific requirements, were used to fill this "skeleton".

When analysed the ISO 9001 standard some requirements are specified by this model but not by any of the other the accreditation models here presented. For example, this model is based on process approach and all process must be identified and their interactions established. Documentation control established by ISO is not a requirement for the other accreditation models.

Another important requirement of this model is the customer satisfaction evaluation that is not present (until this late version of KF-CHKS model) in the other two models.

For this model all processes must be measured, monitored, evaluated and continuous improvement must be ensured. The PDCA cycle must be closed.

CHAPTER VI – Discussion and Conclusions

Introduction

This chapter will discuss the results obtained from multi-case analysis and from the literature review.

A model for HAI prevention and control system applied to healthcare providers (in this case only to hospitals) will be detailed. Although it is always referred "HAI prevention and control system" it is important to highlight the fact that is a HAI and AMR prevention and control system. It is used only "HAI" as abbreviation.

At the end of this chapter conclusions of this work are presented.

Results discussion

As presented in previous literature review several barriers to HAI prevention and control systems were identified. These barriers were grouped in three major dimensions, based on Donabedian quality dimensions, but with some adaptations: Who we are (Structures), How we do (Processes) and What we get (Results).

From the multi-case study, performed in three national hospitals, a set of barriers was identified, some of them being the same as presented in international literature. The barriers identified in this study were previously related to each dimension and their correspondence with international literature review was established, as for suggestions (See Annexes chapter – Annexe V). Most of the barriers are the same in the three hospitals. The interactions between ICC and other services/departments are considered very good and according to the three hospitals, the relationship between ICC and Quality Management department, although satisfactory (more evidenced by the ISO and JCI Hospitals), should be improved in order to take advantage of synergies.

Based on the literature review and in the results presented a quality management model for HAI prevention and control system (at healthcare provider level) is presented, based on ISO 9001 (332) and process-approach (326) and incorporating international and national best practices identified in the literature, from the three hospitals (best practices applied and suggestions) and from management models applied and recognised in several different areas.

The model presentation is divided in:

- Process requirements (general requirements identified for each process);
- Literature review and multi-case study considerations about each process identified;
- PDCA cycle applied to model processes, which includes suggestions from mutli-case study and management tools suggestions.

It is important to analyse this model as a set of suggestions that can be adapted to each organisation and further improved according to specific characteristics. This model must, always, be seen as a support for legal/regulator framework and the existing programmes for HAI and AMR prevention and control, and never as a substitute.

It is also noted that the implementation success of this model (as any other tool) should be supported in education and training and related documented information.

Quality management model for HAI Prevention and Control System at Hospital level

The Quality management model chosen to develop, implement and continuously improve the effectiveness of HAI prevention and control systems is based on process-approach and on ISO 9001. The main reason why this model was chosen is because it is fundamental to see HAI prevention and control as a set of processes that flow across the hospital, rather than see it allocated to functional silos (service / hospital department) that has the responsibility of prevent and control HAI. The model structure is presented in Figure 9.

By definition, a process can be defined as a set of activities interrelated under controlled conditions, which transform inputs on added value outputs.

All these “boxes” are processes identified as fundamental to promote the effectiveness of HAI prevention and control system, as presented on literature review. As expected, these processes are related and their interrelations must be established to ensure that the expected outcomes are produced. This is understood as process-approach and several advantages can be observed: better understanding and meeting interested parties’ requirements, see processes in terms of added value, obtained results of processes performance and effectiveness, and promote continuous improvement of processes based on objective measurement.

Since HAI prevention and control system crosses the entire organisation as a “flow”, this model was identified as appropriated.

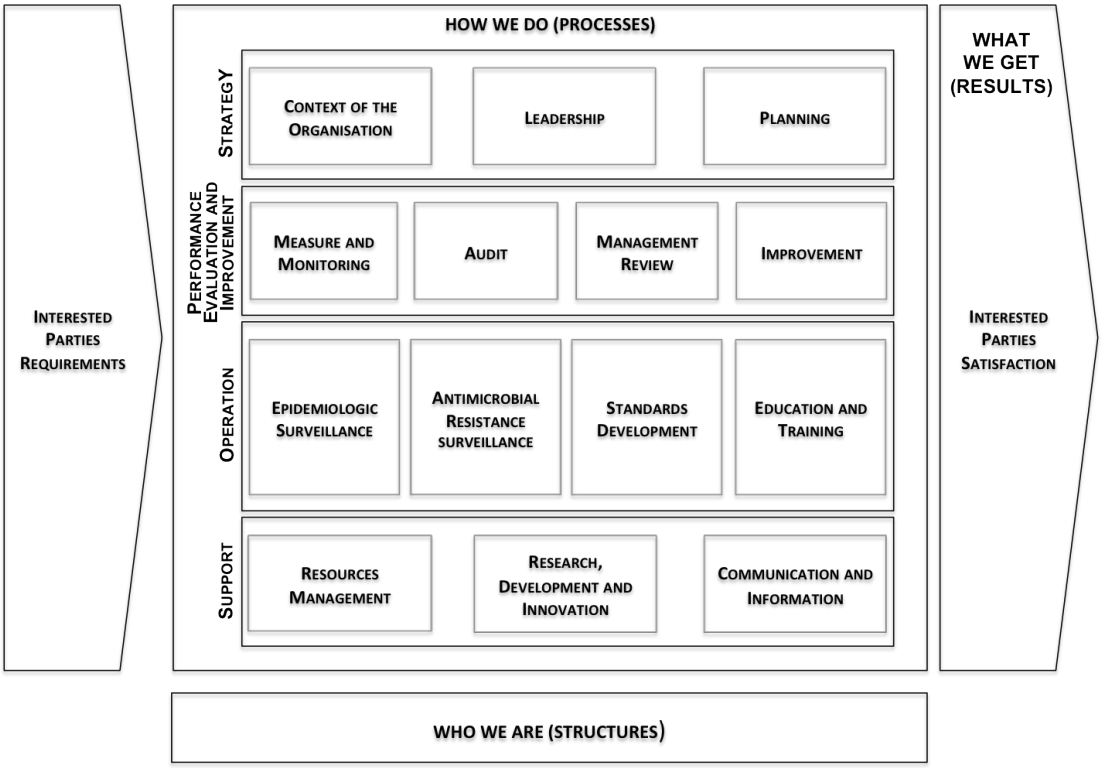

Figure 9 – Quality management model for HAI prevention and control based on process-approach.

Scope

The proposed model is based on the desired scope for HAI and AMR prevention and control system for a hospital, according to international and national recommendations and best practices identified in literature review and in the multi-case study results. This can be used/adapt to any type of healthcare provider. Although this model was designed to be applied at organisation level - Hospital, some suggestions and recommendations were also identified in the literature for HAI prevention and control system at national level.

As presented in the Figure 9, HAI prevention and control system begins with interested parties' requirements and several interrelated processes supported by structures are developed to achieve the expected result and consequently to achieve interested parties satisfaction. This model is dynamic and is supported on PDCA cycle, to ensure continuous improvement and sustainability.

Interested parties requirements

ISO 9001 defines interested parties as "person or organisation that can affect, be affected by, or perceive themselves to be affected by a decision or activity" and requirements as "need or expectation that is stated, generally implied or obligatory" (327).

Interested parties from HAI prevention and control system can be classified as internal and external. Users and healthcare professionals are internal interested parties (may included all healthcare organisation employees) and, additionally, several external interested parties were identified, grouped in two levels: at micro-context and macro-context.

Micro-context interested parties are all those entities that have a direct relation with healthcare organisations, such as suppliers, families/visitors (community), other healthcare organisations (e.g. primary care providers and continuous care).

Macro context interested parties are all those entities with a more distant relation such the Government, professional associations and other associations, and society in general.

To achieve an effective and sustainable HAI prevention and control system it is necessary to identified all these interested parties and their requirements.

Who we are (Structures)

The development and implementation of HAI prevention and control system must be supported in structures such as infrastructures, equipment, resources (financial, human resources, material), and work environment.

Structures for HAI prevention and control systems are well identified in literature and their requirements are based on technical requirements and legal/regulation requirements. A healthcare provider can find these requirements in national legal framework (for example building requirements - not specific for HAI prevention and control but also important such as space between beds in wards, air and ventilation, water system, building materials, and others), and in national and international recommendations established and design for HAI prevention and control systems. Recommendations for facilities management, environment management, occupational health and safety management are also presented, as associated with human resources (e.g. number of HAI prevention and control nurses per number of hospital beds).

The proposed model aims to ensure the adequacy of methodologies and tools related to the management of structures, processes and results, as identified.

How we do (Processes)

HAI prevention and control system must take requirements from internal and external interested parties into account and its processes must be designed in accordance with the scope of this system. Several processes were identified and divided into four dimensions:

strategic processes, performance evaluation and improvement processes, operation processes and support processes.

Strategic Processes

Three strategic processes were considered under this dimension: context of organisation, leadership and planning. These processes must be defined, implemented, maintained and improved to ensure the adequacy of HAI prevention and control system to internal and external context of the organisation. Their interrelations with other processes must also be defined.

Context of the Organisation

The identification of interested parties' must be accomplished along with the identification of their requirements and needs. To better understand who they are and their requirements it is fundamental for the organisation to analyse and understand issues such:

Internal environment – the organisational structure (culture, governance, roles and responsibilities, resources), processes (policies, objectives, strategies and processes established to achieve them, knowledge and awareness, team management, Education and training, information flows, standards and guidelines, monitoring and evaluation processes and tools) and results (existence of data, quality and validation, and reporting system effectiveness all over the chain).

External scenarios – Political, economic, social and technological (and scientific) issues (PEST[71] analysis) (other can be considered such as cultural, financial and environmental issues); legal and regulatory framework; society, key-players, suppliers and partners; relationships, values and expectations.

Literature review and multi-case study considerations

As previously observed in the NHS from the UK, this issue was analysed in detail and was considered as a main subject of the health policy agenda since 2004 (153). From NAO reports importance is given to: service agreements and the input from government and other interested parties to ensure that each healthcare provider meet controls assurance standards on HAI (for this it is important to ensure adequate data collection on HAI rates and trends, based on surveillance); accountabilities, including the role, membership and responsibilities associated with HAI prevention and control system of all interested parties (at all levels) (150, 153, 163).

[71] PEST analysis (Political, Economic, Social and Technological analysis) is a methodology used for the analysis macro-environmental factors, to help in strategic management.

Another important issue must be considered to effectively promote the effectiveness of HAI prevention and control systems: to install an appropriate culture at all organisational levels. Culture was identified as one of the "who we are" sub-dimensions and included as part of the model. For this it is obviously fundamental to know and understand the organisation culture.

The current ISO 9001 revision considers these issues in two new clauses – Understanding the organisation context" and "Understanding the needs and the expectations of interested parties". This is one of the most significant changes, as mentioned in previous chapter (332).

The three quality management models considerations and suggestions about this issue are presented in the following Table 45.

Table 45 – Quality management models considerations and suggestions about "Context of the Organisation" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership - "The hospital is clear about its values and aspirations and how these are to be communicated and achieved". Standard 2: Management and Governance - "Governance systems and a defined management structure are in place and enable the hospital to achieve its objectives including high quality patient care".
JCI	International Patient Safety Goals IPSG.6 Reduce the Risk of Patient Harm Resulting from Falls: "In the context of the population it serves, the services it provides, and its facilities, the organisation should evaluate its patients' risk for falls…". Governance, Leadership and Direction Standard GLD.1: "Governance responsibilities and accountabilities are described in bylaws, policies and procedures, or similar documents that guide how they are to be carried out". Standard GLD.3.1: "Organisation leaders plan with community leaders and leaders of other organisations to meet the community's health care needs". Standard GLD.3.2: "The leaders identify and plan for the type of clinical services required to meet the needs of the patients served by the organisation". Standard GLD.6: "The organisation establishes a framework for ethical management that ensures that patient care is provided within business, financial, ethical, and legal norms and that protects patients and their rights". Patient and Family Rights Standard PFR.4: "Staff members are educated about their roles in identifying patients' values and beliefs and protecting patients' rights".
ISO	Management Responsibility - 5.2 Costumer Focus: "Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction"
Hospitals Suggestions	To promote roles definition and accountability: "Definition of roles and responsibilities for multidisciplinary teams working on HAI prevention and control issues (such as risk management, occupational health management, ICC and quality management) and their interaction at national, regional and hospital level".

PDCA cycle

To support process management PDCA cycle and other identified management tools and methodologies can be used (390), such as presented in Table 46.

To ensure the success of the implementation of these tools it is necessary to ensure adequate training and education of top management members.

Table 46 – PDCA cycle and management tools suggestions for the implementation and development of "Context of the Organisation" process.

Plan	Do	Check	Act
Planning development supported by: - 5W2H methodology; - ISO 10005:2005 (Guidelines for quality plans); Identification of interested parties and their requirements: *Internal* - Healthcare professionals; - Users (Patients and others); *External micro context* - Suppliers; - Families/visitors; - Community; - Other healthcare organisations (such as primary care and continuous care organisations); *External macro context* - State; - Professional associations - Other associations, - Society; - International organisations (such as European Union, ECDC and others). Internal organisation analysis (capability analysis): - Organisational structure (culture, governance, roles and responsibilities, resources, including human resources); - Processes (policies, objectives, strategies and processes established to achieve them, knowledge and awareness, team management, Education and training, information flows, standards and guidelines, monitoring and evaluation processes and tools); - Results (existence of data, quality and validation, and reporting system effectiveness all over the chain).	Identification of interested parties and their needs and expectations through the application of methods and tools such as: - User identification and characterisation sheet; - Professional careers analysis *vs.* job description analysis (evolving professional associations when need); - User and professional satisfaction evaluation; - Contractual process map (definition and characterisation of all processes, including outsourcing processes); - Technological (scientific) developments; - Other healthcare organisations needs (such as primary care and continuous care organisations); - Legal and regulatory issues and control system implementation; - Partners and international relations analysis; Development of Internal organisation analysis of: - Management control maps for structures: infrastructures, equipment, and resources (provisions); - Processes/services-structures management map (needs); - Roles and responsibilities map (for internal structures and external structures); - Policies, objectives and strategies analysis map, such BSC; - Internal process approach matrix map; - Information system and flow map (for internal structures and external structures); - Standards and guidelines list; - SWOT[72] analysis, supported by PEST analysis and CANVAS model[73].	Analysis of compliance degree through: - Audit process.	For all issues: - Corrective actions implementation and effectiveness evaluation; - Preventive actions (when necessary).

[72] SWOT – Strengths, Weaknesses, Opportunities and Threats.
[73] CANVAS model – It is a strategic management tool for developing business models. It can be used to analyse, in detail, each organisational process.

Leadership

The output of "context of organisation" process is a partial input of this process. After all interested parties needs and expectations are identified, the organisation must translate them to HAI prevention and control system requirements. This must be done with the backup of an effective leadership.

Top management must demonstrate leadership and commitment through the total integration of HAI prevention and control system in the organisation system. For this it is important to establish:

- Governance and accountability chain definition;
- Policies and objectives definition and their communication within the organisation;
- Processes definition and their interaction;
- Resources allocation;
- People involvement and motivation;
- Roles, responsibilities and authorities definition and communication within the organisation;
- Compliance with interested parties' requirements;
- Performance management system;
- Continuous improvement culture;
- Effective communication and information at all levels of the organisation.

Literature review and multi-case study considerations

As presented, leadership is one of the most important issues (and barriers identified) for the success and effectiveness of HAI prevention and control system. An effective leadership is the cornerstone to promote the staff mindset change needed to install an adequate safety culture. Several authors have identified its importance in health systems, and more specifically in HAI prevention and control (339-341). As mentioned in the "Board to Ward" strategy published by NHS from UK, this mindset change can be done by: leadership focused drive by CEO[74] and Board; clear lines of accountability and authority at all levels of organisation; training and development programmes to build capability and competence; metrics at board, directorate and ward levels (162). One of the most important activities is to define a clear vision for the organisation that prioritise and integrate HAI prevention and control within organisation strategy and objectives. The approach must be supported by directorate accountability, performance management and clinical incident reporting[75].

[74] Chief Executive Officer.
[75] This last one shall be set up in a way that does not result in a blame culture.

The UK Department of Health identified related barriers and, with the collaboration of NICE and HPA, developed a quality improvement guide for organisational management issues related with HAI prevention and control. The main objective of this guide was to support top management (board administrations and senior managers). In this guide 11 statements were presented, focusing in considerations about leadership and some other issues related with other model processes (164).

In the USA, as pointed in Chapter II, leadership issues, from national level to hospital level, were considered as a concern. Although the model presented was applied to hospital level, these national suggestions are important to promote the implementation of recommendations at that level. CDC and ASTHO, for example, studied HAI prevention and control system developed and applied in different USA States and concluded that it is important to ensure policy interventions through a public health model that promotes adherence to evidence-based practices and focus on prevention efforts. This model must be based on some strategies, as presented: definition of Governmental role; implementation of financial incentives for HAI prevention and control compliance and financial disincentives for HAI prevention and control noncompliance; increase survey/certification activities across the spectrum of care; licensure and training requirements implementation; implementation or expand public reporting; insurance of appropriate regulatory oversight (84, 87). The Institute for Healthcare Improvement, included in its campaign associated with patient safety (5 Million Lives Campaign), launched a strategic quality improvement framework as a roadmap for leaders based on five core components: "Mission/vision – Foundations – Will – Ideas – Execution". This framework aimed to help leaders to develop the organisational will, generate or find strong ideas for improvement and then execute them. All this supported by an "execution" framework to help leaders to answer "but how…" questions (90, 91).

The same was done by the National Association for Healthcare Quality (NAHQ), that developed a guide with recommended actions to help leaders of healthcare organisations to implement protective structures that promote accountability for integrity in quality and safety evaluation, data collection, and reporting to internal and external bodies (92).

In ISO 9001:2008 most of these issues are presented in the chapter 5 – Management Responsibility, where top management leadership and commitment are identified as important requirements for the quality management system. The ISO 9001 revision considers also this issue as a chapter of clauses, with focus on leadership, Policy, Organisational roles, responsibilities and authorities (327, 332).

The analysis of the three quality management models considerations and suggestions about this issue is presented in the Table 47.

Table 47 – Quality management models considerations and suggestions about "Leadership" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership - "The hospital is clear about its values and aspirations and how these are to be communicated and achieved". Standard 2: Management and Governance - "Governance systems and a defined management structure are in place which enable the hospital to achieve its objectives including high quality patient care". Standard 34: Service management - "the service has sufficient personnel and is managed effectively to achieve its objectives.".
JCI	Quality Improvement and Patient Safety (QPS) The organisation must ensure that quality and patient safety "are leadership driven; seek to change the culture of an organisation; proactively identify and reduce risk and variation; use data to focus on priority issues; and seek to demonstrate sustainable improvements" (see standards from QPS.1 to QPS.11). Prevention and Control of Infections (PCI) Program leadership and coordination. Standards PCI.1 to PC.4, "One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training, experience, or certification". Governance, Leadership and Direction (GLD) Standard GLD.1: "Governance responsibilities and accountabilities are described in bylaws, policies and procedures, or similar documents that guide how they are to be carried out". Standard GLD.2: "A senior manager or director is responsible for operating the organisation and complying with applicable laws and regulations". Standard GLD.3: "The organisation's leaders are identified and are collectively responsible for defining the organisation's mission and creating the plans and policies needed to fulfil the mission". Standard GLD.5: "One or more qualified individuals provide direction for each department or service in the organisation". Standard GLD.6: "The organisation establishes a framework for ethical management that ensures that patient care is provided within business, financial, ethical, and legal norms and that protects patients and their rights". Patient and Family Rights (PFR) Standard PFR.4: "Staff members are educated about their roles in identifying patients' values and beliefs and protecting patients' rights".
ISO	Management responsibility - 5.1 Management commitment "Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by: establishing the quality policy; ensuring that quality objectives are established, conducting management reviews, and ensuring the availability of resources". Management Responsibility - 5.2 Costumer Focus: "Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction". Management responsibility - 5.3 Quality policy "Top management shall ensure that the quality policy: is appropriate to the purpose of the organisation; includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system; provides a framework for establishing and reviewing quality objectives; is communicated and understood within the organisation; and is reviewed for continuing suitability". Responsibility, authority and communication - 5.5.1 Responsibility and authority: "Top management shall ensure that responsibilities and authorities are defined and communicated within the Organisation".
Hospitals Suggestions	To promote compliance "Must be introduced an incentive and penalisation systems to promote compliance with recommendations and best practices". "All standards and recommendations from top management (internal and external) should start with "must do" instead "should do". HAI prevention and control requirements must be implemented on a mandatory basis instead on a voluntary basis". "The HAI prevention and control coordinator must be the president of Administration Board or a member of this board to ensure top management commitment". To promote roles definition and accountability: "Definition of roles and responsibilities for multidisciplinary teams working on HAI prevention and control issues (such as risk management, occupational health management, ICC and quality management) at ... hospital level".

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could also be used (90, 91, 162, 186, 328, 374, 375, 390, 391), such as presented in Table 48.

Table 48 – PDCA cycle and management tools suggestions for the implementation and development of "Leadership" process.

Plan	Do	Check	Act
Plan leadership process taking into account: - 5W2H methodology; - ISO 10005:2005 (Guidelines for quality plans); A) Governance and accountability B) Policies and objectives definition C) Processes definition; D) Resources allocation; E) People involvement and motivation; F) Roles, responsibilities and authorities definition and communication within the organisation; G) Compliance with interested parties' requirements; H) Performance management system; I) Continuous improvement culture; J) Effective communication and information.	Implement leadership process taking into account: A) - Inclusion of HAI prevention and control system as part of quality and safety management system (through the policy definition, strategic objectives definition, through business plan); - Risk management analysis (FMEA or other methodology, such as presented in HACCP methodology (ISO 22000:2005) or in ISO 31000:2009 methodology); - Strategic improvement framework from IHI; - Management review; - Collaborative governance, corporate governance together with clinical governance in decision-making process; - Tool from HCAI Cleanliness to embed HAI culture; B) - Definition and implementation of an organisational policy that includes quality, safety and HAI prevention and control issues (with the same relevance level); - Introduction of HAI prevention and control issues in the strategic plan and/or business plan of the organisation; - Establishment of objective-based management and definition of SMART objectives (e.g. BSC) C) - Establishment of organisational processes, their inputs, interactions and outputs, supported by the ISO Guidance on the Concept and Use of the Process Approach for management systems (ISO/TC 176/SC 2/N 544R2), and CANVAS model implementation; - Promotion of procedures and other documented information development; D) - Establishment of a resources allocation system in accordance with HAI prevention and control system requirements; - Development of cost-benefits analysis (e.g. application of ISO 10014 – Quality management. Guidelines for realizing financial and economic benefits);	Check leadership process taking into account: For all issues: - Implementation degree analysis; - Compliance degree analysis; - Audit process; B) For policy and objectives definition: - Appropriateness to the propose of the organisation; - Link between policies and objectives; - Available and communicated within the organisation and interested parties (when or if necessary); - Existence of objectives and targets for HAI prevention and control system in the strategic and business plans; C) - Analysis of procedures implemented and process matrix developed; D) - Trends analysis (supported by statistical techniques such as control charts and others); - Comparative analysis between stock and HAI prevention and control system requirements;	For all issues identification, development and implementation of Corrective and preventive actions taking into account: - Information collected from the Audit process; - Information collected form other processes, when necessary; - New or revised Objectives, indicators; - New or revised strategies.

(Cont.)

Plan	Do	Check	Act
	(Cont.) E) - Establishment of an Administration Board member as a coordinator of HAI prevention and control system; - Involvement of patient, staff and other interested parties in the definition of SMART objectives for HAI prevention and control system (empowerment of users and professionals); Staff involvement and motivation can be support by: - Objective-based management; - Education and training programmes development; - Team work; - Tutorials; - HAI prevention and control requirements must be implemented on a mandatory basis; - Introduction of incentive /penalisation system at service/department level; - Careers management; F) - Development and/or improvement of roles / responsibilities / authorities map and its communication for all organisation, taking into account the NPIPC; - Roles and responsibilities analysis *vs.* processes activities analysis with a matrix analysis; G) - Costumer relations management; - Supplier relationship management: contractual process definition (roles, responsibilities, evaluation methods); - Interested parties feedback system implementation; - Satisfaction surveys: implementation and analysis - Legal and regulatory issues: system implementation for identification, implementation and control of compliance; - Promotion of an identification system for: best practices and recommendations, new processes and new products, new technologies and new developments and innovation; H) - Performance management through: process approach implementation, development and evaluation; identification and development of indicators for measure and monitor; I) - Promotion of improvement culture through: cost-benefits analysis; productivity *vs.* effectiveness *vs*. efficiency analysis; - Implementation of an incentive system; J) - Promotion of communication and information system (internal and external, considering all interested parties).	(Cont.) E) Suggestions analysis; - Claims analysis; - Education and training programmes existence and compliance; - Mandatory compliance; F) (See also "Resources Management" process and "Communication and Information" process): - Analysis of organisational roles / responsibilities / authorities in the field; - Individual roles / responsibilities / authorities sheet; - Best relation between roles and responsibilities and process activities needs; G) - Customer satisfaction evaluation; - Complaints management; - Legal and regulation compliance; H) - Process approach matrix analysis; - Indicators trend analysis; I) - Trends analysis; J) - Communication and information flow analysis.	

Planning

Planning is critical to ensure the success of any system, from early stage of development (conception and design) to its evaluation and improvement. The organisation must deploy strategic objectives (see "leadership" process) for all relevant functions and levels in accordance with strategic plan and with HAI prevention and Control Policy. These objectives must be: consistent with interested parties and HAI prevention and control system requirements; measurable and monitored with a define periodicity; communicated to

interested parties involved; update when necessary. HAI prevention and control system planning must be done considering inputs from all processes.

The organisation must also consider management risks and opportunities when establishing these plans, to ensure their appropriateness and alignment to interested parties requirements. Contingency plans must also be considered when appropriate (service/department).

Afterwards the organisation must define action plans to promote HAI prevention and control system at all organisational levels and define how to evaluate the effectiveness of these actions. Each plan must include the definition of (5W2H methodology):

- Who (responsibilities definition);
- What (product/service, requirements);
- When (time, periodicity);
- Where (local, service/process);
- Why (justification, constraints, requirements);
- How (procedures and other documented information);
- How will be the results evaluated (evaluation).

The plans must be evaluated and reviewed in a systematic way to ensure its appropriateness and improvement.

The organisation must define plans for all relevant level/process/function of HAI prevention and control system.

Literature review and multi-case study considerations

As mentioned in the literature, it is fundamental the definition of objectives, targets, indicators and actions to promote HAI prevention and control systems, at all organisation levels.

The NHS, in their work about HAI prevention and control systems, as previously mentioned, identified the need to define SMART objectives and to measure and to monitor continuously their compliance (162, 164-166).

A similar conclusion was stated by the Directorate-General for Health and Consumer Protection from EU, that, through a consultation on strategies for improving patient safety by HAI prevention and control in 29 participating European countries, identified standards and related performance indicators (SPIs) for HAI and AMR prevention and control that could be used internationally and nationally to stimulate and review improvement in HAI prevention and control, and antimicrobial stewardship activities (135).

In Portugal several objectives and indicators were defined, at national and hospital level, to promote the HAI prevention and control systems (183, 186, 276). However, from the

identified studies it was clear that the definition of indicators is not enough. It is necessary to "start by the beginning", to define strategic objectives (SMART objectives, see leadership process), that must be deployed trough all functions of the organisation, and an effectiveness evaluation must also be performed. All this must be done considering interested parties requirements (see "Context of the Organisation" process), organisation capability (see "Context of the Organisation" process and all support processes identified) and risk management issues. For that, several management tools are identified in the literature as BSC and Tableau du Bord (TB) (347, 348, 392), guidelines for plans development (390), guidelines for implementation of indicators systems (393), FMEA and other risk management tools (345, 372, 377).

Planning requirements have been included in ISO 9001 since de first edition of the standard and was defined as one of the main elements of an important quality tool: the PDCA cycle.

The analysis of the three quality management models considerations and suggestions about this issue is presented in Table 49.

Table 49 – Quality management models considerations and suggestions about "Planning" process (source: (310, 325, 327)).

Model/ Suggestions	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership - "The senior managers plan, resource, and are involved in the implementation of quality improvement initiatives." Standard 2: Management and Governance - "Advice is systematically sought in the development of policy and plans, from medical, nursing and other clinical staff, from non-clinical staff and from specialists."... "The business plan includes the overall staff development and training required to achieve the objectives"... "The business plan is measurable, and results against the plan are reviewed by the executive management group"... "The audit of outcomes should be included as part of the planned programme of clinical audit activities"... "There is a planned programme to develop and implement clinical guidelines and/or care pathways or equivalents, across the hospital"
	Standard 7: Risk Management (General) - "The strategy should detail aims, objectives and individual responsibilities, and should cover areas such as business planning"..." Risk assessment findings and all other information about risk are collated and used to plan hospital-wide prioritisation and implementation of control measures", "The hospital has a major incident, all-hazards plan written/reviewed within the last three years", "The hospital tests the major incident plan at least every three years to ensure the efficacy of the plan and staff awareness of it" Standard 9: Risk Management (Health and Safety) - " There is a dated, documented health and safety plan, The plan should be disseminated to staff, who should be aware of their responsibilities and lines of accountability" Standard 18: Human resources - "There is a dated, documented human resource strategy that is developed in accordance with the overall business plan and is designed to provide work conditions conducive to good health and high performance. The strategy has been written/reviewed within the last three years", "There is a dated, documented training and development plan for staff in the hospital" Standard 34: Team Work, Management and Staffing - "The head of department/service manager plans staff development and training as an integral part of the service plan", "Health and safety inspections are carried out on a planned, systematic basis", "Each employee has a documented personal development plan, prepared annually. A copy is held by both the employee and the line manager" Standard 35: Services Objectives and Planning - "The individual service works to objectives that are consistent with the objectives of the hospital and which are reflected in the service plan" Standard 36: Service Environment - "There is a planned preventative maintenance and replacement programme for equipment and facilities within the service, "There is a documented facilities operational plan that is consistent with the objectives and business plan of the hospital"

(Cont.)

Model/ Suggestion	Standard
JCI	Prevention and Control of Infections (PCI) " The organisation designs and implements a comprehensive program to reduce the risks of health care–associated infections in patients and health care workers", "The program is guided by appropriate policies and procedures", "Risk-reduction goals and measurable objectives are established and regularly reviewed…", "The program is appropriate to the organisation's size and geographic location, services, and patients", "All patient, staff, and visitor areas of the organisation are included in the infection prevention and control program", "the organisation uses a risk-based approach in establishing the focus of the health care–associated infection prevention and reduction program. Care of Patients (COP) "Providing the most appropriate care in a setting that supports and responds to each patient's unique needs requires a high level of planning and coordination" Quality Improvement and Patient Safety (QPS) Quality Improvement and Patient Safety system... emphasises that continuously planning, designing, measuring, analysing, and improving clinical and managerial processes must be well organised and requires clear leadership to achieve maximum benefit. Governance, Leadership and Direction (GLD) "The needs of patients and communities usually change over time, and, thus, health care organisations need to engage their communities in the strategic and operational planning of the organisations" Facility Management and Safety (FMS) "Effective management includes multidisciplinary planning, education, and monitoring as follows: The leaders plan the space, equipment, and resources needed to safely and effectively support the clinical services provided..." Staff Qualifications and Education (SQE) "A health care organisation needs an appropriate variety of skilled, qualified people to fulfil its mission and to meet patient needs. The organisation's leaders work together to identify the number and types of staff needed based on the recommendations from department and service directors... The organisation's leaders carry out staff planning. The planning process uses recognised methods for determining levels of staffing" Management of Communication and Information (MCI) "The organisation plans and designs information management processes to meet internal and external information need... The planning also includes the organisation's mission, services provided, resources, access to affordable technology, and support for effective communication among caregivers" Access to Care and Continuity of Care (ACC) "... When indicated, planning for referral and/or discharge begins early in the care process and, when appropriate, includes the family... The discharge planning process includes the type of support service needed and the availability of such services"
ISO	Quality management system - 4.2 Documentation requirements "... documents, including records, determined by the organisation to be necessary to ensure the effective planning, operation and control of its processes. Management responsibility - 5.3 Planning "Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organisation. The quality objectives shall be measurable and consistent with the quality policy", "the planning of the quality management system is carried out in order to meet the requirements as well as the quality objectives." Product realisation - 7.1 Planning of Product realisation "The organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the quality management system. In planning product realisation, the organisation shall determine the following, as appropriate... quality objectives and requirements for the product... The output of this planning shall be in a form suitable for the organisation's method of operations; Product realisation - 7.3 Design and development "The organisation shall plan and control the design and development of product... Planning output shall be updated, as appropriate, as the design and development progresses." Product realisation -7.5 Product and service provision "The organisation shall plan and carry out production and service provision under controlled conditions" Measuring, Analysis and improvement - 8.1 general "The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed" Measuring, Analysis and improvement - 8.2 Monitoring and measurement "The organisation shall conduct internal audits at planned intervals to determine whether the quality management system... An audit programme shall be planned"

(Cont.)

Model/ Suggestion	Standard
Hospitals Suggestions	To promote Planning "BSC implementation as planning tool at all organisation levels (deployment from strategic level to operation level) with HAI prevention and control indicators" "It must be introduced again HAI prevention and control indicators in the hospital contracting process with Regional Health Administration"

PDCA cycle

To support the management of this process, the PDCA cycle and other identified management tools and methodologies (375, 390, 391, 393) could be used, such as presented in Table 50.

Table 50 – PDCA cycle and management tools suggestions for the implementation and development of "Planning" process.

Plan	Do	Check	Act
Planning development supported by: - 5W2H methodology; - ISO 10005:2005 (Guidelines for quality plans); - BSC conceptual framework and UNE 66175:2003 (Guide to implementation of indicators system); - SWOT analysis; - Risk management (supported by methodologies such as FMEA (FMEA), ISO 31000:2009 methodology or only risk matrix development and application); - Processes analysis (including outsourcing processes); - Organisation capability analysis; - Benchmarking strategies; - Tools and methods to evaluate their effectiveness.	Establish plans for all service/department with: - SMART objectives definition for all processes, including relevant roles and responsibilities; - Plan actions to address the risks and opportunities identified previously; - Scientific and technologic information (national and international requirements analysis); - Procedures and other documented information; This must be done taking into account: - Inclusion of HAI prevention and control issues in the organisation business plans (all organisation and for each service/department); - Identification and inclusion HAI prevention and control requirements in each organisation process stage: Design and conception; Operation; Measurement and monitoring (monitoring plans); Evaluation.	For all issues: - Implementation degree analysis; - Compliance degree analysis (Verify if HAI prevention and control issues are considered in all organisation processes that interact with HAI prevention and control system)	Identification, development and implementation of corrective and preventive actions taking into account: - Information collected from the Audit process; - Information collected from other processes, (when appropriate); - New or revised objectives, indicators; - New or revised strategies.

Performance Evaluation and Improvement Processes

Four processes related with evaluation and improvement issues were identified. These processes are considered as fundamental to ensure HAI prevention and control system and must be adequate to the organisation needs.

The organisation must ensure the definition, implementation, maintenance and improvement of these processes to promote HAI prevention and control system. Its interrelations with other processes must be defined.

Measure and Monitoring

The organisation must plan and implement measurement and monitoring methods (when appropriate), to demonstrate HAI prevention and control system conformity, objectives achievement, and user feedback/satisfaction, aiming to improve continuously its effectiveness and performance. These methods must demonstrate the conformity with applicable requirements and process suitability to achieve planned results. When planned results are not achieved, corrective and correction actions must be developed, implemented and evaluated for effectiveness.

For this the organisation must establish what (and how) to measure (inputs, processes, outputs) and how to monitor (methods). This process must include nonconformities control, data analysis and satisfaction evaluation (user and other interested parties).

The organisation must ensure that results from this process are communicated to interested parties.

Nonconformities Control

The organisation must ensure that nonconformities are identified, analysed and controlled. When applicable the organisation must take:

- Correction actions to eliminate detected nonconformity and the related effects or potential effects;
- Corrective actions to eliminate real cause of the nonconformity;
- Preventive actions to eliminate potential causes of nonconformities.

Data Analysis

The organisation must determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of HAI prevention and control system. Techniques (such as statistical techniques) and other tools (such as quality tools), considered appropriate by the organisation, must be identified to support data analysis. The organisation must identify data analysis methods suitable for each HAI prevention and control process (including outsourcing processes).

Satisfaction evaluation

The organisation must monitor and evaluate the perception of users and other interested parties in relation to the established requirements compliance (when appropriate). This must be supported by adequate methods/instruments to measure and monitor satisfaction.

Literature review and multi-case study considerations

Evidence in literature justifies the importance of this process. HAI prevention and control systems are "feed" by data from surveillance programmes, collected and analysed by measuring, monitoring and evaluation tools that must be adequately managed to ensure the effectiveness of HAI prevention and control systems.

Since 1998 the European Union has enforced the relevance of standardisation of measuring and monitoring methods to improve surveillance studies and reporting systems. Among the first related projects was the "HELICS" project, aiming to create a network able to collect relevant data, to develop and monitor through systematised methods (123). Subsequent projects and programmes emphasised the importance of measurement and monitoring of HAI prevention and control issues, such as the European Recommendation about patient safety, published in 2009. Some of the recommendations were related with the implementation of HAI prevention and control measures at national and regional level, the definition of indicators to monitoring and evaluate the implementation of HAI prevention and control systems (26). It was also necessary to improve surveillance methodologies, through the improvement of measuring and monitoring processes and results, taking into account data collection, treatment and analysis. For that, standardised surveillance methods were also defined (140).

The importance of indicators definition that could enable the evaluation of an objective-based HAI prevention and control action plan is applicable to the entire system and not only to surveillance studies. Supported in Donabedian quality of care perspectives, a measuring and monitoring plan for HAI prevention and control system must be able to support measuring, monitoring, evaluation and to promote improvement in three dimensions: structures, processes and results. For this it is fundamental to identified indicators for all these dimensions (263) and to promote their analysis. Internationally several indicators were identified with this purpose (135, 255, 259, 263). At national level, the NPIPC identified some indicators to be taking into account during the realization of related measuring and monitoring process (186, 190). To accomplish this, the organisation must identify the most adequate methodologies to implement, measure and evaluate these indicators and for

whatever is identified as necessary (associated to all organisational processes) to ensure HAI prevention and control system effectiveness (310, 325, 327).

As stated, this process is strongly related with the "Planning" process and, again, is one of the elements of the PDCA cycle. Measuring and Monitoring issues are also considered in the ISO 9001 standards since its first version.

The analysis of the three quality management models considerations and suggestions about this issue is presented in Table 51.

Table 51 – Quality management models considerations and suggestions about "Measure and Monitoring" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership - "The hospital is clear about its values and aspirations and how these are to be communicated and achieved". Standard 2: Management and Governance - "The strategy includes the following elements: definitions of the roles and responsibilities of the key personnel involved in the overseeing and monitoring of clinical governance", "...implementation and monitoring of the risk management strategy." Standard 13: Risk Management - Infection Control - " In inpatient services hospital acquired infection rates are monitored and reviewed.", "... monitoring of routine procedures, for example, ward cleaning," Standard 18: Human Resources - "The performance review system is regularly monitored and amended as necessary", "...Training provision is monitored and reviewed by a designated clinical tutor or speciality tutor" Standard 21: Buying and Selling Goods and Services - "Service Level Agreements - Compliance with internal service level agreements is monitored and reviewed." "Standard 34: Teamwork, Management and Staffing - "The head of department/service manager is responsible for ensuring that the quality of services provided is monitored and evaluated through the implementation of quality improvement objectives. "Standard 31: Housekeeping - "Cleaning effectiveness throughout the hospital is monitored."
ISO	Quality management system - 4.1 general requirements "ensure the availability of resources and information necessary to support the operation and monitoring of these processes... measure (where applicable), and analyse these processes" Product realisation - 7.1 Planning of Product realisation " required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance" Product realisation - 7.1 Production and service provision "the availability and use of monitoring and measuring equipment... the implementation of monitoring and measurement" Product realisation - 7.6 Control of monitoring and measuring equipment "The organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements" Measurement, Analysis and Improvement - 8.1 general requirements "The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed...", "The organisation shall monitor and measure the characteristics of the product to verify that product requirements have been met" Measurement, Analysis and Improvement - 8.2 Monitoring and measurement "Customer satisfaction -…the organisation shall monitor information relating to customer perception as to whether the organisation has met customer requirements. The methods for obtaining and using this information shall be determined", "Analysis of data – the organisation shall determine and collect appropriate data to demonstrate the suitability and effectiveness…" Measurement, Analysis and Improvement - 8.3 Control of nonconforming product "The organisation shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery"

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Model/ suggestion	Standard
JCI	International Patient Safety Goals (IPSG) IPSG.6 Reduce the Risk of Patient Harm Resulting from Falls: "Measures are monitored for results, both successful fall injury reduction and any unintended related consequences. Access to Care and Continuity of Care (ACC) "There is a process in place to monitor the quality and safety of transportation provided or arranged by the hospital, including a complaint process." Assessment of Patients (AOP) "There is a process for reporting critical results of diagnostic tests... and an established method for monitoring compliance.... and modified based on results of monitoring" Care of Patients (COP) "This is usually a multidisciplinary, coordinated effort of staff of a health care organisation, applying the principles of effective process design, implementation, and improvement to the selecting, procuring, storing, ordering/prescribing, transcribing, distributing, preparing, dispensing, administering, documenting, and monitoring of medication therapies.", "How well the system is working related to... selection and procurement of medications... administration and monitoring... Monitoring resulting from any changes in the formulary...", "...The organisation has a method, such as designating a committee, to maintain and to monitor the medication list and to monitor the use of medications in the organisation", "monitor the policies and procedures." Facility Management and Safety (FMS) "Effective management includes multidisciplinary planning, education, and monitoring... Evaluate... This includes a monitoring programme... Collection of data for utility management programme...Monitoring programmes provides data on incidents...monitoring data are used for improve the programme" Quality Improvement and Patient Safety (QPS) "Quality improvement and patient safety are data driven… Because most organisations have limited resources, they cannot collect data to measure everything they want… each organisation must choose which clinical and managerial processes and outcomes are most important to measure based on its mission, patient needs, and services... An organisation's leaders are responsible for making the final selection of key measures to be included in the organisation's quality activities.", "Quality Improvement and Patient Safety system... emphasises that continuously planning, designing, measuring, analysing, and improving clinical and managerial processes must be well organised and requires clear leadership to achieve maximum benefit. This includes define and establish what" must be measure and monitoring." Prevention and Control of Infections (PCI) "One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training, experience, or certification." Governance, Leadership and Direction (GLD) "Contracts and other arrangements are monitored as part of the organisation's quality improvement and patient safety program", "Directors monitor the department's or service's performance as well as staff performance", "...The quality of services by independent practitioners outside the organisation is monitored as a component of the organisation's quality improvement program." Prevention and Control of Infections (PCI) "There is a policy and procedure consistent with national laws and regulations and professional standards in place that identifies the process for managing expired supplies... The policy is monitored...", "Infection prevention and control activities are measured", "Quality improvement includes using measures related to infection issues that are epidemiologically important to the organisation.", " The results of infection prevention and control measurement in the organisation are regularly communicated to leaders and staff.", "The organisation identifies the procedures and processes associated...It is thus important for an organisation to measure and to review those processes and, as appropriate", "The organisation uses measurement information to improve infection prevention and control activities and to reduce health care–associated infection rates to the lowest possible levels. An organisation can best use measurement data and information by understanding similar rates and trends in other similar organisations and contributing data to infection-related databases." Staff qualification and Education (SQE) "Standard Ongoing Monitoring and Evaluation of Medical Staff Members"

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Model/ suggestions	Standard
Hospitals Suggestions	To promote compliance "Must be introduced an incentive and penalisation systems to promote compliance with recommendations and best practices, based on indicators analysis" "Establishment of ranking/rating systems to promote internal and external evaluation and to promote competitiveness between services and hospitals" Introduce comparative analysis between productivity indicators and effectiveness indicators (not only enhance the high occupancy rate of operating room – a productivity indicator, but also analysed together with HAI rate – an effectiveness indicator"

PDCA cycle

To support the management of this process PDCA cycle and other identified management tools and methodologies could be used (328, 390, 391, 394), such as presented in Table 52.

Table 52 – PDCA cycle and management tools suggestions for the implementation and development of "Measure and Monitoring" process.

Plan	Do	Check	Act
Planning development supported by: - 5W2H methodology; - ISO 10005:2005 (Guidelines for quality plans); Design measuring and monitoring plans taking into account: - Objectives, indicators and methodologies defined by international and national recommendations, such as NPIPC; - Other objectives and indicators considered relevant for the organisation; For that it must be established: - Mechanisms and tools to identify relevant data to measure and monitor processes (inputs, processes and outputs) such as scientific documentation analysis, national and international requirements analysis; Benchmarking strategies; - Mechanisms and tools to collect data and record data (such as: Software systems; Checklists; Audit process; Surveys; Interviews); - Mechanisms and tools to treat and analyse data (such as: Statistical tools; Diagrams (Cause-effect diagram, flow diagrams, RADAR diagram and others), checklists and charts to summarise information); - Mechanisms and tools to establish comparative analysis (ranking, rating systems); - Mechanisms for control nonconformities; - Mechanisms for the identification of interested parties to apply satisfaction and evaluation methodologies; - Responsibilities; - Resources needs; - Results expected.	- Perform measurement, monitoring and analysis of data as defined in the plans, taking into account procedures and other documented information; - Monitoring user satisfaction and other interested parties satisfaction, with the support of - UNE 66176:2005 (guide for measuring, monitoring and analysing customer satisfaction).	- Analysis of measuring and monitoring plans: - Results analysis; - Comparative analysis; - Implementation degree; - Compliance degree. - Suggestions and complains analysis; - Identification of nonconformities (plan analysis, complains analysis, no compliance with plans and audit process, as example); - Record of nonconformities; - Analysis of nonconformities with tools such: cause-effect diagrams as the fishbone diagram root-cause analysis, pareto diagram, statistical techniques (as example);	Identification, development and implementation of correction, corrective and preventive actions taking into account: - Information collected from Measuring and Monitoring process; - New or revised objectives, indicators; - New or revised measuring and monitoring strategies.

Audit

The organisation must conduct internal audits to verify HAI prevention and control system conformity and suitability against planned disposals and applicable requirements. The organisation must define, implement and maintain an audit programme taking into account: the importance of processes, services and areas to be audited; the results from previous audits; information from "context of the organisation" process; changes in the system. For each audit the specific scope, frequency, methods and audit team must be defined.

Auditors' selection must be done taking into account their competences, independence and impartiality (Auditors must not audit their own work).

The responsible for each audited process/service/area must ensure that correction/corrective actions are taken to eliminate the causes of any identified nonconformity.

The organisation must define all the documented information needed as input for audit process (including the necessary to perform audits) and as output.

Literature review and multi-case study considerations

Audit process is one of the most important methods to measure and monitor any management system. The importance of this process is implicit in HAI prevention and control systems as audit processes are considered as the main measurement and monitoring methodology to evaluate the effectiveness of HAI prevention and control systems.

This is conclusion is stated in several documents where HAI prevention and control issues are analysed. For example, in 2000, NAO from the UK, launched a set of recommendations related with actions to promote the HAI prevention and control system effectiveness, and one of them was to develop audit guidelines for infection control systems. NAO published another report where this issue was again considered very important to the effectiveness of HAI prevention and control system, stating that audit must be used to ensured best practices at local and national levels (163).

At national level, in NPIPC, the audit process is defined as a core component of ICC work. As mentioned before, it is recommended that ICC implement a regular audit programme for regular practices and for most significant structures, in order to improve clinical practice (186).

Audit processes support many quality improvement models, and the "audit process" is clearly related to the "measuring and monitoring" process. All three quality management systems analysed established the audit as one of the most important method/tool to support the evaluation process.

According to the ISO 9001 model, internal audits are part of the "measurement, analysis and improvement" chapter, and are considered as the most important methods to support the Check element of the PDCA cycle. Three audit types can be considered: internal audit (first part audit), external audit performed by the client (second part audit) and an external and independent audit performed by recognised entities, as associated with certification/accreditation processes (third part audit). All three are considered as important to ensure: HAI prevention and control system adequacy and suitability to the organisation (first part audit); better relations with external interested parties such as suppliers and to control outsourcing processes (second part audit); and external recognition of conformity with best practices and standards (third part audit).

In JCI model the term used for audit process is "survey" and several types of "surveys" were developed to promote system improvement. The standards from this model don't refer specifically this term but it is linked with "measure and monitoring through surveys".

The analysis of the three quality management models considerations and suggestions about this issue is presented in Table 53.

Table 53 – Quality management models considerations and suggestions about "Audit" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership – "The working methods are audited and compared with documented policies and procedures." Standard 2: Management and Governance - "Working practices are audited to ensure that they are consistent with the documented policies and procedures", "The strategy of quality improvement relates how the methods of administrative work are audited to ensure its consistency with the policies and documented procedures", "The clinical governance strategy includes clinical audit.", "The annual report may include summaries of audit results,…", "…There are documented procedures for carrying out clinical audit projects. The procedures have been written/reviewed within the last three years", "Organisational priorities for clinical audit are identified and documented in a clinical audit programme for the hospital", "The results of audit studies are disseminated to relevant staff", "Changes in practice are introduced as a result of clinical audit programmes" Standard 12: Medication management - " The organisation performs internal audits to evaluate the compliance with the plan of action for medication and can demonstrate that they implemented mechanisms to change their practices, as necessary" Standard 13: Risk Management - Infection Control - " The results from the infection surveillance programme must link into other clinical audit studies.", "…The committee reviews such items as the annual infection control programme, recent outbreaks, the results of infection control audits and all procedures in relation to infection control.", "There is an annual infection control audit programme.", "The audit programme could include environmental hospital hygiene audits, monitoring of routine procedures, for example, ward cleaning, audit of the surveillance programme and audit of infection control policies and procedures. The programme also includes a timetable for policies and procedures to be reviewed. Results from the audit programme are reported to the appropriate group." Standard 15: Risk Management - Waste Management – "The implementation of waste handling and disposal procedures is audited", "There is a procedure dated and documented for the waste audit, to ensure effective screening and compliance with regulations. This procedure has been drafted / revised the last three years." Standard 17: Clinical records management – "There is a regular audit programme of to procedures related with clinical records." Standard 25: Complaints management - "The organisation conducts audits to the complaints management system, by comparison with documented procedures…" Standard 30: Catering service - "There is an internal audit programme of regular audits to food service."

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Model/ suggestions	Standard
KF-CHKS	Standard 34: Teamwork, Management and Staffing - "The staff receives training in other areas relevant to the service, including updates of policies and procedures in response to adverse events, results of audits and risks identified", "The percentage of staff trained is presented as evidence in audit process." Standard 35: Service Objectives and Planning - "There is an ongoing training programme to ensure that auditors have the relevant skills relevant to the conduct audits", "There is a documented procedure for audit process", "There is a systematic audit plan that covers all policies and procedures", "The audit results are analysed and reported in team meetings.
JCI	"Patient trace methodology - process that JCI surveyors use during the on-site survey to analyse an organisation's systems by following individual patients through the organisation's health care process in the sequence experienced by the patients." "System tracer - A session during the on-site survey devoted to evaluating high-priority safety and quality-of-care issues on a system wide basis throughout the organisation"
ISO	Measurement, Analysis and Improvement – 8.2.2 Internal audit "The organisation shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organisation, and b) is effectively implemented and maintained." "An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. This selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work."
Hospitals Suggestions	"More involvement of quality department in the audit process developed and implemented by ICC and related with HAI prevention and control system" "Education and training associated to audit process for HAI prevention and control system"

PDCA cycle

To support the management of this process the PDCA cycle could be used, and for each its dimensions, several management tools were identified (330, 390, 391), as presented in Table 54.

Table 54 – PDCA cycle and management tools suggestions for the implementation and development of "Audit" process.

Plan	Do	Check	Act
Planning development supported by: - 5W2H methodology; - ISO 10005:2005 (Guidelines for quality plans); Definition of a audit programme tacking into account: - Objectives; - Requirements from NPIPC and other internal and external requirements, including legal and regulation requirements; - Data from previous programmes: compliance degree; effectiveness; - Information from management review process and improvement process; - Data from operation processes; - Audit frequency; - Resources needs; - Methods for audit, including audit procedures; - Responsibilities; - Previous plans; - Definition and establishment of education and training for personnel related with audit process; Definition of a audit plan for each audit considering: - Scope; - Audit team; - Criteria and requirements; - Documented information need such as: - Procedures to perform audits, auditor manual, forms and checklists; - Previous audit report and records; - Information from "context of the organisation" process; changes in the system; - Services/departments/areas to visit; - Methodologies for data collection, such as checklists, photos, record analysis, interviews; - Confidentiality and legal issues; - Preparation of audit stages: opening meeting, field audit and closing meeting. Establish mechanisms to ensure adequate report system from audit process, such as: - Communication to services /departments/areas involved; - Top management communication; - Communication with interested parties when necessary; Establish mechanisms and tools to ensure feedback of information from: - Services/departments/areas involved; - Interested parties, when necessary.	Application of Audit methodology as define in ISO 19011:2011 (Guide for auditing management systems) to implement the programme established and to implement each audit plan previously established taking into account: - Documented information needs (such as previous audit report, procedures and records); - Requirements of the Services/ departments/ areas to visit (such as access requirements); - Methodologies for data collection, such as checklist, photos, record analysis, interviews; - Confidentiality and legal issues; - Performance of audit stages: opening meeting, field audit and closing meeting; - Audit report; - Communication of audit process results to promote improvement actions.	Analyse results from Audit programme implementation taking into account: - Audit plan compliance degree; Analysis of results from each audit plan implementation taking into account: - Audit plan compliance degree; - Audit reports.	Identification, development and implementation of correction, corrective and preventive actions taking into account: - Information collected from the Audit process; Definition of new or revised programme and/or plans.

Management review

Top management must review HAI prevention and control system to ensure its suitability and effectiveness. The review must be performed in planned intervals and, as input, it must include:

- Information from strategic processes, including risk and opportunities management issues;
- Data from the other performance, evaluation and improvement processes;
- Data from operation processes;

- Data from support processes;
- Other information such as: previous management review information (follow-up), planning achievement, audit results, nonconformities analysis information, correction and corrective analysis information, user and other interested parties satisfaction,
- Organisational changes;
- Context of the organisation changes.

As a result from this review process, the organisation must: obtain decisions related with the effectiveness improvement of HAI prevention and control system; establish resources needs; promote policies and objectives improvement.

Top management must ensure adequate communication of these results within organisation and with external interested parties when appropriate.

Literature review and multi-case study considerations

In the literature this issue is related to top management role specially when related with leadership and planning. Top management involvement in the definition of adequate strategies and procedures to promote HAI prevention and control system is considered as fundamental including the evaluation of those strategies and procedures adequacy and its revision to ensure adequacy. As mentioned by the Institute for Healthcare Improvement, in its strategic quality improvement framework, leaders must develop the organisational will, generate or find strong ideas to execute them and then evaluate its adequacy to promote improvement. This was included in the report published by NAO (UK) in 2009, namely that top management review must ensure to adjust funds necessary for infection prevention and control system's (163). The NPIPC also referred that top management, with ICC support, must promote the implementation of the operational plan, taking into account its suitability to the institutional needs; discuss, analyse and approve the Report of Activities from ICC; assist in reviewing programmes to promote the adequacy (186).

According to the ISO 9001 model, management review is essential to ensure the adequacy and suitability of the system over time and to promote leadership through a commitment of top management to continuous improvement (329).

The analysis of the three quality management models considerations and suggestions on this issue is presented in Table 55.

Table 55 – Quality management models considerations and suggestions about "Management review" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership - " Information systems and processes are in place to regularly review progress in achieving the stated objectives for the hospital.", "Policies and procedures are subject to a systematic process review to ensure that all policies and all procedures are reviewed and revised as necessary". Standard 2: Management and Governance - " There is a dated, documented policy and procedure, written reviewed…", "The business plan is measurable, and results against the plan are reviewed by the executive management group.", "Policies and procedures are subject to a systematic review process…", "The quality improvement strategy and progress against objectives are reviewed on an annual basis", "The executive management group reviews quality, performance and outcome measures at least annually.", "…and a review mechanism.", "There is a systematic approach and review of clinical quality indicators across the hospital", "The reports are also disseminated to senior managers as appropriate for review and action." Standard 9: Human Resources - Occupational Health - "The Occupational Health service has regular meetings to review the service with senior management representatives from the hospital." Standard 13: Risk Management - Infection Control - "…The committee reviews such items as the annual infection control programme, recent outbreaks, the results of infection control audits and all procedures in relation to infection control." "There is an annual infection control audit programme.", "The audit programme could include environmental hospital hygiene audits, monitoring of routine procedures, for example, ward cleaning, audit of the surveillance programme and audit of infection control policies and procedures. The programme also includes a timetable for policies and procedures to be reviewed. Results from the audit programme are reported to the appropriate group." Standard 18: Human Resources – "There is a human resources strategy, dated and documented, developed and review in accordance with the overall business plan, which intended to provide working conditions conducive to good health and high performance. This strategy has been drafted / revised" Standards for specific services – "The audit data are shared for the purposes of review"
JCI	Governance, Leadership and Direction (GLD) "Those responsible for governance approve the organisation's plan for quality and patient safety and regularly receive and act on reports of the quality and patient safety program… Those responsible for governance ensure the periodic review of the organisation's mission.", "Leaders have a process for reviewing and approving, before use in patient care, those procedures, technologies, and pharmaceutical agents identified as experimental." Staff Qualifications and Education (SQE) "Planned and actual staffing is monitored on an ongoing basis, and the plan is updated as necessary… there is a collaborative process for the organisation's leaders to update the overall plan."
ISO	Management Responsibility – 5.6 Management review "Top management shall review the organisation's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives."
Hospitals Suggestions	"It must be more involvement of top management in HAI prevention and control system..."

PDCA cycle

To support the management of this process, the PDCA cycle and other identified management tools and methodologies could be used (390, 391), such as presented in Table 56.

Table 56 – PDCA cycle and management tools suggestions for the implementation and development of "Management Review" process.

Plan	Do	Check	Act
Planning development supported by: - 5W2H methodology; - ISO 10005:2005 (Guidelines for quality plans); - ISO 9001:2008 (Quality management systems - requirements); Planning the application of W5H2 methodology: - What: for example what data is relevant and sufficient; Input information identification; Expected outputs - When: collect Adequate and timely data for Strategic planning development; - Where to apply: identification of actual situation of "Performance, Evaluation and Improvement" processes, "Strategic", processes, "Operation" processes and "Support" processes; - Why: reason for improvement and to ensure adequacy and relevance of data in the improvement process - Who: who will be involved in the collection, treatment and analysis of data - How to improve: identification of possible solutions/suggestions/ recommendations; - How improvement will be communicate, tacking into account: - Members involved; - Communication structures: Channels and flows; - Availability of information;	The Management review must include: - Identification of Inputs to management review; - Mapping methods and tools used to analyse Inputs; - Identification of Outputs of management review; - Mapping methods and tools to analyse relations between results obtained and objectives defined: compliance degree, trends analysis; Identification of evaluation methods for management review must include: - Analysis of data from Context of the organisation and scientific community at national and international level; organisational processes and resources analysis; tools and techniques implemented; results from benchmarking activities; expected results from management review; other information identified by the organisation through audit process; results from satisfaction evaluation, suggestions and recommendations; - External evaluations: audit from clients, and from independent entities; peer review. Inputs analysis for management review must include information from: - Risk and opportunities identified with application of SWOT method and benchmarking activities (for example); - Research/development and innovation; - Objectives compliance (through indicators trend analysis), corrective and preventive actions effectiveness, audit results, nonconformities and complaints from costumer and other interested parties, feedback (including satisfaction evaluation), processes performance, nonconformities; - Suggestions and recommendations; - Costs analysis; Outputs analysis from management review must include: - Decisions related with system effectiveness improvement as new or reformulated objectives for processes and services performance; - Marketing strategies; - Resources needs; - Policies improvement; - Information for planning future organisation needs; - Establish and plan the implementation of activities as result of review management.	For all issues: - Implementation degree analysis; - Compliance degree analysis.	Identification, development and implementation of correction, corrective and preventive actions taking into account: - Output Information from all processes.

Improvement

The organisation must continuously improve the suitability, adequacy and effectiveness of HAI prevention and control system. For improvement, the organisation must use information from the "Management review" process and other processes, and must include the definition and implementation of corrective and preventive actions, new or revised processes and approaches, innovation methodologies, tools and others. When nonconformities occur, the

organisation must react, taking actions to eliminate them and to control and correct the effects. For this correction and corrective actions must be defined and implemented and its effectiveness must also be evaluated. (See "Measure and Monitoring" process).

Literature review and multi-case study considerations

The improvement process can be seen as the expected result of "performance, evaluation and improvement" processes. As previously mentioned, two of eight principles from ISO model are defined as "decisions supported in facts" and "continual improvement". To decide on improvement strategies it is fundamental to collect facts from every system processes and these facts can be obtained through the implementation of other "performance, evaluation and improvement" processes. This is also the expected result from the PDCA cycle, namely in relation to the "Act" dimension (327). Several authors refer the importance of improvement for HAI prevention and control systems: for example the "1000 Lives Plus" publication from NHS - Wales presented a set of improvement tools to support the improvement process of HAI prevention and control system (165). The Quality Improvement guide published by NICE related with the promotion of leadership in HAI prevention and control systems refers the importance of the board agreement on the development of an annual improvement programme on infection prevention and control which must be linked to the business planning cycle and include actions and resources (164).

The NPIPC noticed that ICC used the results of epidemiologic surveillance to improve the activity plan and organisational practices, including the improvement of relations between services/departments, communication issues, and relevant data from audit process. It was also referred that the improvement process must be annually analysed and evaluated (e.g. at the end of each calendar year), in order to establish current performance indicators that could be used in the definition of objectives for following years (186).

As mentioned, improvement of a HAI prevention and control system must be supported by relevant and reliable data from all system processes, such as: information from interested parties requirements, at hospital, national and international level (Context of the Organisation process), policies and strategies defined (Leadership process), plans developed and deployed from strategic level to operation level (Planning process), epidemiologic surveillance/AMR surveillance/Standard development and Education and training activities implemented and results obtained (Operation processes), resources including competences (Resources Management process), information of innovation and results from research developed (Research, Development and Innovation process). These processes must be supported by adequate communication and information strategies and mechanisms to ensure the effectiveness of communication and information.

Improvement process in quality models is, in general, part of the core components aiming the quality improvement of systems, processes, products and/or services. As so, these models consider improvement issues either explicitly or implicitly in the proposed requirements. For example, in KF-CHKS model, each standard has a specific content/criterion for quality improvement. In the ISO 9001 current revision, improvement issues are considered all over the standard and, naturally, more specifically is the improvement related chapter. This chapter stress the importance of nonconformities elimination, the need for process improvement and the relevance of assuring the system adequacy (329). According to ISO 9001:2008, the focus is placed in the development of corrective and preventive actions to promote continual improvement (325). In JCI model an entire standard with several requirements, the "Quality Improvement and Patient Safety (QPS)", describes a comprehensive approach to quality improvement and patient safety, where the two concepts are clearly linked. As referred, quality and safety are rooted in the daily work of individual health care professionals and other staff (310).

The analysis of the three quality management models considerations on this issue is presented in Table 57.

No specific suggestions were identified or in another perspective, all suggestions from hospitals interviews must be considered because most of them include improvement suggestions. Studied models consider this issue as linked to "Management Review", "Audit" and "Measuring and Monitoring" processes, since these processes are strongly interrelated.

Table 57 – Quality management models considerations about "Improvement" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 2: Management and Governance - " The people who run the organisation are accountable for the quality of services through quality and governance systems that enable the organisation to achieve the proposed objectives, including the provision of high quality care and safety and continuous quality improvement", "Is there a strategy to improve the quality of the organisation ... The strategy was developed in accordance with the aspirations and strategic objectives of the organisation and its business plan.", "The strategy of quality improvement and progress in achieving the goals are reviewed annually.", "Evaluation reports on initiatives results to improve quality are produced.", " The clinical governance strategy includes improving clinical quality", "… arrangements are monitored and revised, and improvements are made when necessary." Almost all standards have a sub-chapter related with quality improvement where "monitoring", "review", "evaluation", "audit" are terms associated with improvement issues.
JCI	Prevention and Control of Infection (PCI) "Integration of the Program with Quality Improvement and Patient Safety - The infection prevention and control process is integrated with the organisation's overall program for quality improvement and patient safety.", "Quality improvement includes using measures related to infection issues that are epidemiologically important to the organisation."
ISO	Measurement, Analysis and Improvement– 8.5.1 Continual Improvement " The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review."

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (331, 390, 391, 395), such as presented in Table 58.

Table 58 – PDCA cycle and management tools suggestions for the implementation and development of "Improvement" process.

Plan	Do	Check	Act
Planning Improvement supported in: - ISO 10005:2005 (Guidelines for quality plans); - Data collection and analysis; - Review; - Evaluation; - Planning the application of W5H2 methodology: - What to do: for example what data is relevant and sufficient; - When: frequency, for example for data collection; - Where to apply: identification of actual situation through data from "Performance, Evaluation and Improvement" processes, "Strategic", processes, "Operation" processes and "Support" processes; - Why: reason for improvement and to ensure adequacy and relevance of data in the improvement process; - Who: who will be involved in the collection, treatment and analysis of data - How to improve: identification of possible solutions/suggestions for example through data collection: methods and techniques, confidentiality and legal considerations; - How to evaluate: identification and selection of evaluation methods - Ensure communication and information issues.	Development and implementation of Improvement process supported by: - Application of ISO 9004: 2009 (Managing the sustained success of the organisation), UNE-CEN/TR 15592:2008 IN (Guide for EN ISO 9004:2000 in health services for performance improvement) and UNE 66178: 2004 (Guidelines for Improvement process management); Data collection and analysis must be supported in: - Information from processes; - Input analysis; - Output analysis; Establishment and implementation of: - Corrective actions; - Preventive actions; - Suggestions and Recommendations from interested parties, and management review; - Actions and activities identified from "Research, Development and Innovation" process"; - Other identified by the organisation. All these must be established in accordance with identified causes, tools, mechanisms and resources needs. The identification and selection of evaluation methods must include: - Analysis of data from: context of the organisation and scientific community at national and international level; - Organisational processes and resources; - Results from benchmarking activities; results from management review; other information identified by the organisation through audit process; results from satisfaction evaluation, suggestions and recommendations; - Tools and techniques already implemented in the organisation; - External evaluations. The communication and information must be ensure, internal and external (when appropriate) with the: - Definition of tools/mechanisms; - Definition of flows.	Evaluation of actions effectiveness through: - Process results analysis; - Data and trends analysis; - Complaints, - Implementation degree analysis; - Compliance degree analysis.	Identification, development and implementation of: - Corrections actions; - Corrective and preventive actions. - New or revised objectives, indicators; - New or revised strategies;

Operation Processes

Four operation processes were identified. The organisation must define, implement, maintain and improve these processes to ensure the adequacy of HAI prevention and control system to meet applicable requirements and to implement the actions identified in the planning process. All operation processes, including outsourced processes, must be adequately controlled by the organisation. The interrelations from operation processes with other processes must also be determined.

The Epidemiologic Surveillance process and the Antimicrobial Resistance Surveillance process are identical (in terms of management) and must be performed together.

Planning and control requirements

The organisation must plan, implement and control all operation processes according with national and organisational requirements. Planning and control must be done according to:

- Defined objectives (See "Context of the Organisation", "Leadership" and "Planning" processes),
- Risk and opportunities identification (see "Leadership" process),
- Criteria and requirements for implementation (see "context of the organisation" and "Research, Development and Innovation" process),
- Resources needed, including: roles and responsibilities definition for staff (See "Resources Management" and "Education and training" processes); to support communication (See also "Communication and Information" process); and to record, treat and analyse data (Software and hardware) (See "Measuring and Monitoring" process),
- Required monitoring and evaluation activities to verified effectiveness of planned and implemented actions including adequate methodologies to collect, to analyse and to report reliable data (See also "Context of the Organisation" process),
- Adequate reporting system, within organisation and with external interested parties (See "Context of the Organisation" process and "Communication and Information" process),
- Periodicity for implementation, evaluation and reporting (See "Planning" process),
- Verification and validation activities when necessary (see "Performance, Evaluation and Improvement" processes),
- Contingency plans, when necessary.

Epidemiologic surveillance

The organisation must ensure the development and implementation of adequate epidemiologic surveillance strategies to promote monitoring and control of diseases, pattern analysis, research and development of best practices, control and evaluation activities.

The epidemiologic surveillance strategies must reflect:

- Identified organisation and interested parties requirements (See "Context of the Organisation" process),
- Organisation policies and objectives (See "Leadership" process),
- Scientific and technologic issues (See "Context of the Organisation" process and "Research, Development and Innovation" process),
- Risk management issues,
- Resources and available technical capacity.

For this, the organisation must establish programme(s) suitable to HAI prevention and control system.

Programme Requirements

The epidemiologic surveillance programme(s) must be developed and implemented taking into account:

- Planning and control requirements,
- Type of epidemiologic surveillance,
- Documented information,
- Resources,
- Risk analysis and management,
- Data considerations,
- Periodicity for implementation and evaluation (See "Planning" process),
- Interested parties involved in epidemiologic surveillance for all stages: data collection and reporting system (See also "Context of Organisation" process),
- Results expected.

The organisation must ensure the compliance with national requirements related with HAI prevention and control issues, such as NPIPC requirements. International requirements must also be consider when appropriate.

Literature review and multi-case study considerations

As verified in previous chapters, Epidemiologic Surveillance was repeatedly considered one of the system core components. In 2002, WHO Practical Guide for HAI Prevention and Control pointed the importance of issues such as epidemiologic surveillance (definitions, type

of infections, criteria for disease classification, reservoirs and transmission) and hospital infection surveillance (strategies, network, prevalence/incidence studies, data collection and analysis, education and training) (55).

Since 1998, the EU published several recommendations and guidelines related with this issue and defined the importance of a network for epidemiological surveillance and control of communicable diseases in the EU (123) and more lately in its Patient Safety Recommendation (26), CDC guidelines for surveillance system (16, 46, 93, 106) and ECDC guidelines for prevalence surveys (139, 140). One of the most well known epidemiologic surveillance for MRSA, the "Search and Destroy" programme, was developed in The Netherlands and is one of the most successful programmes to combat HAI prevention and control (48, 167, 168). This programme is characterised by strong planning strategies and clinical strategies, such as "screening" and "isolation" strategies.

The analysis of the three quality management models considerations and suggestions related to this issue are presented in Table 59. Regarding this process, the analysis was focused in infection control standards.

Table 59 – Quality management models considerations and suggestions about "Epidemiologic Surveillance" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 13: Infection control – Infection control measures "There is an annual infection surveillance programme in place across the hospital that includes the collection, analysis and dissemination of data… The results from the infection surveillance programme must link into other clinical audit studies…"
JCI	Quality Improvement and Patient Safety (QPS) "Quality improvement and patient safety are data driven. Effective use of the data is best accomplished in the broader context of evidence-based clinical practices and evidence-based management practices… each organisation must choose which clinical and managerial processes and outcomes are most important to measure based on its mission, patient needs, and services… infection prevention and control, surveillance, and reporting…" Prevention and Control of Infections (PCI) "Integration of the Program with Quality Improvement and Patient Safety - The infection prevention and control process is integrated with the organisation's overall program for quality improvement and patient safety.", "Quality improvement includes using measures related to infection issues that are epidemiologically important to the organisation.", "…Responsibilities include, for example, setting criteria to define health care–associated infections, establishing data collection (surveillance) methods, designing strategies to address infection prevention and control risks, and reporting processes", "Current scientific information is required to understand and to implement effective surveillance and control activities and can come from many national or international sources…", "The programme includes systematic and proactive surveillance activities to determine usual (endemic) rates of infection.", "…risk-based approach uses surveillance as an important component for gathering and analysing the data that guide the risk assessment."
ISO	Product Realisation - 7.5.1 Control of production and service provision: "The organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include: the availability of information that describes the characteristics… the availability of work instructions, as necessary; the use of suitable equipment; the availability and use of monitoring and measuring equipment; the implementation of monitoring and measurement, and the implementation of product release, delivery and post-delivery activities."
Hospitals Suggestions	" It is important to implement CAUTI surveillance at national level and hospital level"

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (186, 391), such as presented in Table 60.

Table 60 – PDCA cycle and management tools suggestions for the implementation and development of "Epidemiologic Surveillance" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable plan supported by: - W5H2 method; - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal national framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation process" - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis; - Application of PDCA cycle to ensure the process improvement process. Establishment of Epidemiologic surveillance plans taking into account: - Selective epidemiologic surveillance (based on: most frequent infections and with higher costs, more easily prevent – related with procedure and equipment, or more aggressive pathogens – related with the microorganism); - Type of epidemiologic surveillance (prospective; active; continuous or periodic surveys); - Data collection and evaluation (methods, instruments, periodicity to collect and to evaluate); - Periodicity for implementation and evaluation (See "Planning" process); - Interested parties involved in epidemiologic surveillance reporting system (See also "Context of Organisation" process); - Map of resources needs: Work teams; Resources needs; - Interactions between services /departments; - Monitoring and evaluation of the process, including verification, validation activities when necessary; - Results expected; - Communication channels and documented information needed.	Implementation of the planned actions, taking into account: - Documented information development and implementation in the right place, with the right information, at right time and in the right "hand"; - Development of a manual and/or procedures to ensure adequate implementation of best practices; - Methods, techniques and procedures to support implementation such as: prevalence surveys and incidence surveys methodologies (See NPIPC and ECDC information about this issue), Laboratory data analysis, and others identified by the organisation; - Tools such as cause-effect diagram and RCA, decision tree and risk management tools; - Services/departments involved in the process: considerations, limitations. Identification of evaluation methods, based on: - Interested parties requirements for evaluation (such as defined by NPIPC): - Objective-based methodologies, indicators. Development of microbiologic charts with therapeutic susceptibilities to support therapeutic process.	Analysis of the epidemiologic surveillance process through: - Implementation degree analysis; - Compliance degree analysis; - Nonconformities identified; - Audit results; - Other relevant data.	Definition of correction and corrective actions when necessary: - Application of tools to identified causes and solutions such as cause-effect diagram, problems solving methodology, Kaisen methodology, brainstorming methodology; - Incentive and penalisation mechanisms applicable to the services /departments/areas related with compliance degree.

Antimicrobial Resistance Surveillance

The organisation must ensure the development and implementation of adequate antimicrobial surveillance strategies to promote monitoring and control of resistant strains, track changes in microbial populations and support the notification and investigation of outbreaks. The antimicrobial resistance outcomes are fundamental to support clinical therapy decisions, to guide policy recommendations, and to assess the impact of resistance containment interventions.

The antimicrobial resistance surveillance strategies must reflect:

- Identified organisation and interested parties requirements (See "Context of the Organisation" process),
- Organisation policies and objectives (See "Leadership" process),
- Scientific objectives (See "Context of the Organisation" process and "Research, Development and Innovation" process),
- Risk analysis and management,
- Research, development and innovation issues,
- Resources and available technical capacity.

For this, the organisation must establish suitable programme(s) to HAI prevention and control system.

Programme Requirements

The antimicrobial resistance surveillance programme(s) must be developed and implemented taking into account:

- Planning and control requirements,
- Type of organism,
- Type of surveillance (prospective; active; continuous or periodic surveys),
- Risk analysis and management,
- Data considerations,
- Periodicity for implementation and evaluation (See "Planning" process),
- Microbiology Laboratory role (See also "Context of the Organisation" Process and "Leadership" process),
- Interested parties involved in antimicrobial resistance surveillance for all stages: data collection and reporting system (See also "Context of the Organisation" process).
- Resources,
- Results expected.

The organisation must ensure the compliance with national requirements related with HAI prevention and control issues, such as the NPIPC. International requirements must also be consider when appropriate.

Literature review and multi-case study considerations

As the previous process, "Antimicrobial resistance surveillance" must be considered as one of the core components of HAI prevention and control systems. Initially different approaches and focus to these two processes were considered but, currently, they are linked and must be analysed as a "cause-effect" process.

Concerns with AMR are not a recent issue and since the first detection occurred several organisations suggested recommendations for its control. For example, since 1999, the European Council gave special emphasis to AMR as an important issue in HAI prevention and Control and to define a strategy against the microbial threat (129, 130, 139, 140). WHO also published some important recommendations about this issue in 2001 and reinforced them in 2012 (71, 334). In the related documentation the main management suggestions are similar as those established for HAI prevention and control process and are related with surveillance standard methods, resources (including competences), data collection/treatment and analysis, and finally communication and information issues. In Portugal, the National Strategy for Antimicrobial Resistance Surveillance recommended to that Portuguese NHS providers must implement AMR committees for the promotion of National Antimicrobial Resistance Programme and the adequate use of some antibiotics, such as Ampicillin, Amoxicillin and Amoxicillin/Clavulanic acid (190-193).

The analysis of the three quality management models considerations and suggestions on this issue is presented in Table 61. For this process, the analysis of quality models was focused in infection control and medication standards.

Table 61 – Quality management models considerations and suggestions about "Antimicrobial Resistance Surveillance" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Standard 13: Infection control – Infection control measures "There is a dated, documented policy on antimicrobial prescribing."
JCI	Medication Management and use (MMU) "The review allows organisations to understand the need and priority of continued system improvements in quality and safety of medication use.", "There is a plan or policy or other document that identifies how medication use is organised and managed throughout the organisation.", "The organisation has a method, such as designating a committee, to maintain and to monitor the medication list and to monitor the use of medications in the organisation", "Medication effects on patients are monitored.",
ISO	Product Realisation - 7.5.1 Control of production and service provision: "The organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include: the availability of information that describes the characteristics… the availability of work instructions, as necessary; the use of suitable equipment; the availability and use of monitoring and measuring equipment; the implementation of monitoring and measurement, and the implementation of product release, delivery and post-delivery activities."

(Cont.)

Model/ suggestions	Standard
Hospitals Suggestions	" Promotion of discussion and analysis of therapeutic issues in a more frequent and systematic basis", " Introduce internal indicator to monitor medication prescription and its relation with usual service ecology", "Development of microbiologic charts to support therapeutic process"

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (186, 190, 390), such as presented Table 62.

Table 62 – PDCA cycle and management tools suggestions for the implementation and development of "Antimicrobial Resistance Surveillance" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable programme with support of: - W5H2 method: - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal national framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation" process; - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis; - Application of PDCA cycle to ensure the improvement process. Establishment of Antimicrobial Resistance Surveillance programmes taking into account: - Type of organism tracking (organisms responsible for the most frequent infections, "alert" organisms and "problem" organisms); - Type of surveillance (prospective; active; continuous or periodic surveys); - Periodicity for implementation and evaluation; - Interaction with other services: Microbiology Laboratory role (as a key partner); Interested parties involved in antimicrobial resistance surveillance (implementation and reporting system); - Map of resources needs; - Work teams; - Interactions between services/departments; - Process monitoring and evaluation; including verification, validation activities when necessary; - Results expected; - Communication channels and documented information needed.	Implementation of the planned actions/programmes, taking into account: - Methods, techniques and procedures to support implementation; - Services/ departments involved in the process: considerations, limitations; - Implementation of a coordinated plan between AMR and Epidemiologic surveillance to better analyse cause-effect issues; - Analyse results from these two surveillances simultaneously. Comparative Analysis of therapeutic consumption with therapeutic chart, taking into account: - Pathogen agents; - Type of antibiotic; - Type of spectrum;	Analysis of the Antimicrobial Resistance surveillance process through: - Implementation degree analysis; - Compliance degree analysis; - Nonconformities identified; - Audit results; - Other relevant data.	Definition of correction and corrective actions when necessary: - Application of tools to identified causes and solutions such as cause-effect diagram, problems solving methodology, Kaisen methodology, brainstorming methodology; - Brainstorming methodology; - Incentive and penalisation mechanisms applicable the services/ - Departments /areas related with compliance degree.

Standards Development

The organisation must establish the standards needed to ensure the effectiveness of HAI prevention and control system (See "Context of the Organisation" process). These standards must be based on national and international recommendations and best practices (See also "Research, Development and Innovation" process).

Standards development must take into attention the need of:

- Adequate resources (See "Resources Management" process),
- Multidisciplinary teams, including internal and external competences (See "resources management" and "competences" process),
- SMART objectives (See "Leadership" and "Planning" processes),
- Evidence-based best practices (See "Context of the Organisation" and "Research, Development and Innovation" processes),
- Risk and opportunities management (See "Leadership" process),
- Simple and appropriate language to interested parties involved.

The organisation must also define:

- Roles and responsibilities for monitoring and evaluation process and for verification, validation (when required) and approval process, according with organisation and external requirements,
- Methodologies for development, monitor and evaluation processes,
- Documented information needed to all stages,
- Communication flows to promote the standard development and the dissemination of standard development outcomes.

The organisation must promote the application of the standards developed by the services/departments/areas involved. For this the organisation must ensure:

- Identification of Services/departments/areas covered by the standards;
- Resources needed for their application, including education and training needs;
- Adequate communication and information channels;
- Mechanisms for compliance evaluation and standard effectiveness evaluation;
- Incentive and penalisation mechanisms applicable to services/departments/areas related with compliance degree.

<u>Literature review and multi-case study considerations</u>

As verified for the two previous processes, this is also one of the core components of HAI prevention and control system, as identified by WHO (4) and other relevant organisations such CDC, ECDC, DH from UK and others. All these organisations have published several best practices and technical recommendations to support ICC in the development of HAI

prevention and control standards for healthcare providers. The development, dissemination and implementation of technical evidence-based guidelines for prevention of relevant risks and/or infections, adequate to the organisation, are part of the most important roles of ICC (46, 55, 66-69, 95, 98, 100, 113, 114). All these recommendations focused on clinical/technical and management issues.

Several related recommendations Can be presented, such as, for example, the importance of defining a standard development plan capable to respond to W5H2 questions and supported by "Data– Information –Knowledge –Action" chain. For this, it is important to ensure: that standards are supported in evidence-based practice validated and accepted by scientific community, and in accordance with "Context of the Organisation" analysis with special attention to organisation capability to developed and to implement; internal and external competences, research/development/innovation issues when possible and necessary, resources needs and organisation capability to disseminate.

The NPIPC highlights the importance of standards development in ICC roles. Based on available national standards, each healthcare provider must develop its HAI prevention and control manual, defined as a set of best practices and guidelines that determine the rules of implementation, taking into account the aseptic conditions, health and safety for professionals and users in order to prevent cross-transmission of infection and other risks (186).

As mentioned in NPIPC, multiple copies of the manual must be available at strategic and accessible locations in each service/department, to ensure its implementation. The ICC and the responsible from each service/department must promote open multidisciplinary discussion of standards in order to involve all professionals in their implementation. The standards implementation and application must be monitored (186).

For quality management system, documentation support is one of the most important activities to ensure systematisation of activities, education and training of professionals, and organisational learning and knowledge management.

The analysis of the three quality management models considerations and suggestions on this issue is presented in Table 63. For this process, the analysis of quality models was focused in infection control standards.

Table 63 – Quality management models considerations and suggestions about "Standard development" process (source: (310, 325, 327)).

Model/ suggestion	Standard
KF-CHKS	Standard 13: Infection control – "The infection control policies and procedures are distributed throughout the hospital", "Infection control policies and procedures are centrally indexed and compiled into a policy manual that includes details of the circulation of each policy and procedure.", "all these standards must be dated, documented infection control procedure…" and "have been written/reviewed within the last three years".
JCI	Prevention and Control of Infections (PCI) ""The infection prevention and control program is based on current scientific knowledge, accepted practice guidelines, applicable laws and regulations, and standards for sanitation and cleanliness.", "The organisation designs and implements a comprehensive programme to reduce the risks of HAI in patients and health care workers", "The organisation identifies the procedures and processes associated with the risk of infection and implements strategies to reduce infection risk."
ISO	Quality Management system – 4.2 Documentation requirements "The quality management system documentation shall include documents, including records, determined by the organisation to be necessary to ensure the effective planning, operation and control of its processes.", "The organisation shall establish and maintain a quality manual that includes the scope of the quality management system, documented procedures and records established for the quality management system… a description of the interaction between the processes", "documented procedure shall be established to define the documentation controls needed"
Hospitals Suggestions	"The standard must be in the right place, for the right professional, at the right time. This includes also its continuous improvement and adequacy"

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (186, 190, 390, 391, 396), such as presented in Table 64.

Table 64 – PDCA cycle and management tools suggestions for the implementation and development of "Standards Development" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable plan with support of: - W5H2 method; - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal national framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation process"; - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis; - Application of PDCA cycle to ensure the process improvement. Establishment of standard development strategies: - Type of standards, target-group, contents; - Methodologies for documentation development (see ISO/TR 10013: 2001 - Guidelines for quality management system documentation); - Map of resources needs, including competences (internal or/and external); - Work teams; - Interactions between services/departments; - Monitoring and evaluation of the process, including verification, validation activities when necessary; - Results expected; - Communication channels and documented information needed; Definition of mechanism to evaluate compliance and effectiveness of standards implementation, based on: - Interested parties requirements for evaluation (such as defined in NPIPC): - Objective-based methodologies, indicators; - Implementation degree analysis; - Compliance degree analysis.	Implementation of standards development strategies, taking into account: - Working plan application with the support of tools such as: meetings, flow diagram, brainstorming methodologies, problem solving methodologies, RCA, PDCA cycle; - Methods, techniques and procedures to support implementation; - Services/departments involved in the process: considerations, limitations; - Monitor standards development compliance: application of tools such as checklists, plan analysis; Implementation of Standards developed, supported by: - Map of Services/departments/ areas covered by each standard; - Map of resources needed for standard application; - Education and training programme application if necessary (See "Education and Training" process); - Adequate communication and information flows and channels.	Analysis of Standard development, based on: - Interested parties requirements (such as defined in NPIPC); Monitor results from standard implementation taking into account: - Objective-based methodologies and indicators; - Data from epidemiologic and antimicrobial resistance surveillances; - Recommendations from national and international organisations (such as recommendations from NPIPC); - Nonconformities identified in Epidemiologic and Antimicrobial Resistance Surveillances processes.	Definition of correction and corrective actions when necessary: - Application of tools to identified causes and solutions such as cause-effect diagram, problems solving methodology, Kaisen methodology, brainstorming methodology; - Incentive and penalisation mechanisms applicable the services/ departments/ areas related with compliance degree.

Education and Training

The organisation must ensure adequate education and training to consistently promote HAI prevention and control system. The development of education and training programmes must be determine taking into account:

- Organisational and interested parties requirements (See "Context of the Organisation" process),

- Needs identification (See “Context of the Organisation” process, “Resources Management” process),
- Skills and knowledge needs, according to roles and responsibilities established (See also “Resources Management – Human Resources” process),
- Resources (internal and external resources) (See also “Resources Management” process),
- Documented information (See “Communication and Information” process),

The organisation must develop and implement regular education and training programmes capable to ensure the adequacy of staff knowledge and skills for an effective HAI prevention and control system. This must be done according with competences requirements and definition for each organisational role (See “Resources Management – Human Resources” process).

Each programme must include:

- Objectives,
- Target-groups,
- Programme Contents (adequate to target-group),
- Type (in the classroom or on the job),
- Resources,
- Course duration,
- Evaluation methods,
- Action to be taken in case of nonconformity (noncompliance and in case of not achieving the objectives).

The organisation must consider the importance of Education and Training programmes not only for personnel but also for other interested parties, such as: users, families, visitors, suppliers, and community in general.

Literature review and multi-case study considerations

“Education and training” is a key process for the promotion of human capital of any organisation, and thus it can be considered as an important issue for knowledge management (397).

Knowledge gaps associated with HAI issues was identified as one of the most important barriers for the effectiveness of HAI prevention and control systems and for patient safety (241, 337). Several organisations have identified the need to improve knowledge on these issues through education and training programmes. For example, WHO referred the importance of education and training in HAI prevention and control programmes since its

first practical guide (55) and through several technical documents that followed. For WHO this process is also considered an important part of the core components of HAI prevention and control programmes (4). The European Union in 1972 pointed the importance of education and training issues for the curricula of medicine and nurse courses (120) and this concern promoted the development and implementation of international projects capable to evaluate the "state of art" and promote recommendations, such as IPSE and TRICE (142, 217). In 2008, based on information from these and other projects, a "Core Curriculum for Training for Infection Control Practitioners" was published (142).

NPIPC gave great importance to this issue and stressed that: Education/training must include policies, procedures and practices that guide the prevention and control of infection; The contents must be defined and adapted to the activities; Trainers must have knowledge about infection definitions, concepts, policies and practices; Training programmes must be targeted to clinicians and non-clinical support; Training must be targeted and specific to different target groups, organised by modules and must allow combining theory with practice; The courses, formal training, in the classroom, must be organised in collaboration with the training centres; Training must also include the findings of epidemiologic surveillance studies conducted and trend, including the analysis of the results; A basic curriculum associated to HAI prevention and control issues could be noticed (186).

ISO 9001 standards, according to the current version but also in the revision draft version, point to the importance of education and training to achieve conformity. Several requirements related with competence, training and awareness are included in the ISO 9001:2008 including the need to evaluate the effectiveness of actions taken (325). In the on-going ISO 9001 revision, the same requirements are included but additional emphasis is given to personnel awareness (329).

As identified in national and international literature, healthcare organisations must identify education and training needs (according with analysis of context, internal and external), design a plan with education and training activities (according with planning issues, needs identified, resources and results expected), implement the plan and, afterwards, evaluate its effectiveness (according with measure, monitoring and evaluation tools identified, results expected).

The analysis of the three quality management models considerations and suggestions on this issue is presented in Table 65.

Table 65 – Quality management models considerations and suggestions about "Education and Training" process (source: (310, 325, 327)).

Model/ suggestion	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership – "Senior managers participate in training and personal development activities to ensure they have the necessary skills to manage the hospital and to facilitate quality improvement within their own work." Standard 2: Management and Governance - "The business plan includes the overall staff development and training required to achieve the objectives.", "The strategy includes the following elements… the identification of training needs and details of how these will be met…", "There is training for staff in undertaking clinical risk assessments. Attendance at training is recorded." Risk management standards – "Any training needs highlighted during the development of action plans should be incorporated into the hospital's training and development plans.", "The hospital has systems in place for the management of health and safety issues and the training of staff in health and safety measures as required by their work.", "waste disposal strategy should include… the role of the infection control team, and staff training." Standard 13: Infection control – "There is an ongoing education programme on infection control for all staff within the hospital… All staff should receive regular updating on measures for infection control relating to their area of work. When new systems of work are introduced, consideration should be given to the need for infection control updating.", "The infection control team or infection control link nurse is involved in the hospital's induction programme." Standard 18: Human resources – "…human resource strategy should include staff training and development", "There is a dated, documented training and development plan for staff in the hospital.", "The plan addresses, for example, the training needs associated with the hospital's overall objectives; the training needs in response to changes in practice, the law and new technology; and meeting both the individuals' and organisational training needs as identified within the performance review system."
JCI	Assessment of Patients (AOP) "Supervisory staff and technical staff have appropriate and adequate training, experience, and skills and are oriented to their work. Technical staff are given work assignments consistent with their training and experience." Care of Patients (COP) "The leaders are responsible for training staff in implementing the policies and procedures." Medication Management and use (MMU) "Improvements in medication processes and staff training are used to prevent errors in the future." Patient and Family Education (PFE) "Education and training help meet patients' ongoing health needs." Quality Improvement and Patient Safety (QPS) "Staff are trained to participate in the program… There is a training program for staff that is consistent with their roles in the quality improvement and patient safety program.", " Staff members participate in the training as part of their regular work assignments" Prevention and Control of Infections (PCI) "One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training…", "The organisation identifies those situations in which masks, eye protection, gowns, or gloves are required and provides training in their correct use." Governance, Leadership, and Direction (GLD) "Directors provide orientation and training for all staff of the duties and responsibilities for the department or service to which they are assigned."
ISO	Resources Management – 6.2 Human resources "The organisation shall, where applicable, provide training or take other actions to achieve the necessary competence, evaluate the effectiveness of the actions taken."
Hospitals Suggestions	"To promote better knowledge about HAI prevention and control it is important to include in basic education learning programmes (all the areas) and in higher education (health areas) specific content related with HAI prevention and control" "Introduction of benchmarking tools (internal and external)" "Promotion of education and training related with risk management" "Promote training by exchange experiences with other sectors (risk management in industry, objective-based management in banking sector, and others)" "Introduction of collaborative tools to promote education and training." "Promote some education and training about indicators definition and development."

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (390, 391), such as presented in Table 66.

Table 66 – PDCA cycle and management tools suggestions for the implementation and development of "Education and Training" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable plan with support of: - W5H2 method: - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal national framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation process" - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis. Identification of evaluation methods, for Knowledge/skills acquisition such as: - Written tests, - Questionnaires; - On the job verification and validation.	Establishment of Education and Training strategies, taking into account: - Competences established; - Needs identification: interviews, suggestions, complaints treatment; nonconformities analysis, organisational requirements and other interested parties requirements, contracting processes; - Skills and knowledge needs: identified by HR documentation analysis, internal and external recommendations (Scientific community and other external member from the context of the organisation); - Resources (internal and external resources); - Documented information; - Methodologies for education and training: collaborative systems, benchmarking with the same activity area and other activities areas, traditional courses, Establishment of Education and Training programmes taking into account: - Objectives; - Target-group; - Programme contents; - Type of education and training sessions (in classroom, on the job, video-conference); - Map of resources (facilities, equipment- hardware and software, human resources needs such as teachers,); - Time; - Methodologies for teaching activity; - Map of resources needs, including competences (internal or/and external); - Monitoring and evaluation methodologies; - Results expected; - Communication channels and documented information needed; Implementation of Education and Training programmes, taking into account: - Working plan application with the support of tools such as: checklists; - Services/departments involved in the process: considerations, limitations; - Monitor education and Training compliance with the planned: application of tools such as checklists, plan analysis; - Documentation needs; - Results expected, including internal and external validation, for example certification.	Evaluation of effectiveness of Education and training programmes and plan, such as: - Objectives and indicators analysis, - Complaints analysis, - Performance evaluation (individual/ process/service), - Satisfaction evaluation, - Audit results, - Nonconformities analysis, - Trends analysis, - Compliance analysis, - Interested parties requirements for evaluation (such as defined by NPIPC). - For all issues: - Implementation degree analysis; - Compliance degree analysis;	Definition of correction and corrective actions when necessary: - Application of tools to identify causes and solutions such as cause-effect diagram, problems solving methodology, Kaisen methodology, brainstorming methodology; - Incentive and penalisation mechanisms applicable to services/departments/areas related with compliance degree.

Support Processes

Three support processes were identified. The organisation must define, implement, maintain and improve these processes to ensure the adequacy of HAI prevention and control system to meet identified requirements and to implement the actions identified in the planning process. All support processes, including outsourced processes, must be controlled by the organisation.

Resources management

The HAI prevention and control system must have adequate resources to ensure its success, as previously stated. "Resources" include:

- Infrastructures and work environment[76] (Buildings, workspace and utilities),
- Instruments and equipment (both hardware and software),
- Support systems (such as documentation, communication and information systems – see "Communication and Information" process).
- Provisions needed,
- Human resources.

General requirements:

The organisation must determine and provide the resources needed to implement and maintain HAI prevention and control system through identification and determination of:

- Organisation capability,
- Service needs (related with internal processes and external processes),
- Controls needs (when change occurs, has mentioned in "Planning" process, in external processes).

Regarding resources purchasing, the organisation must consider HAI prevention and control system requirements to ensure the expected results and effectiveness of the system.

The organisation must determine and maintain the adequate infrastructure and work environment needed to ensure HAI prevention and control system requirements. This means that adequate buildings, workspace and utilities must be available and maintained properly in accordance with requirements from interested parties (such as: legal framework, recommendations and best practices, agreements, contractual processes). When changes occur, the organisation must ensure that HAI prevention and control system requirements are

[76] "Work environment" includes the conditions under which work is performed, including physical, environmental and others factors (temperature, humidity, cleanliness, air quality, and others) (source: ISO 9001:2008 (325)).

not affected. As so, changes must be planed according with HAI prevention and control requirements.

Within relation to equipment, the organisation must ensure that adequate equipment and instruments are in place and are maintained properly (e.g. supported by maintaince plans). Measuring and monitoring instruments to verify the conformity of HAI prevention and control system requirements must also be controlled and maintained fit to purpose. Where necessary this must include verification and calibration processes.

The organisation must also ensure the provision of adequate resources taking into account the needs of HAI prevention and control system.

The organisation must ensure the adequate human resources management for HAI prevention and control system and that roles and responsibilities are established for all functions, communicated and understood (e.g. in accordance with "Leadership" process). Human resources management must consider all professional, competences and safety issues.

Human Resources - General requirements

The organisation must ensure the competence of personnel performing work related with HAI prevention and control system. Personnel requirements must be defined for each function, according with law/regulation and/or organisation needs. Competence must be established on the basis of appropriate education, training, skills and experience.

Human Resources Competences

The organisation must determine, provide and maintain adequate competences for personnel performing work affecting conformity of HAI prevention and control system. Competences for organisation roles and responsibilities related with HAI prevention and control must be determined in terms of:

- Core competences,
- Key competences,
- Critical competences.

These must be established, considering national and international recommendations, including legal framework, and organisational requirements.

The organisation must consider the provision of education, training actions or take other actions to achieve the necessary competences and awareness about HAI prevention and control (see "Education and Training" process).

Competences definition and characterisation requirements

The organisation must determine necessary competences taking into account:

- Professional skills,
- Behavioural skills,
- Knowledge,
- Experience and qualification.

In the definition of competences the organisation must consider different levels of responsibility, based on autonomy, influence, complexity and skills need to perform activities related with HAI prevention and control system.

The organisation must maintain the appropriate records about competences definition, job description and education and training of its personnel.

Literature review and multi-case study considerations

As identified in the literature, without adequate resources is difficult to perform an effective HAI prevention and control system. Barriers were identified regarding financial issues, facilities and environment issues, equipment issues and human resources issues (337). In the literature several recommendations for eliminate/minimise some of those barriers were also identified such as to develop costs studies and economic evaluations to evaluate financial issues associated to HAI prevention and control and to minimise the impact of unsourced HAI prevention and control programmes (151, 163); Several guidelines and recommendations for the promotion of adequate facilities and environment management to ensure the adequacy of physical conditions in HAI combat were also documented, as well as recommendations for hospital management of central sterilisation service, food service, laundry service, housekeeping service, maintenance service, and hospital hygiene service (19, 55, 60, 61, 98, 99, 398). Some of these recommendations also included equipment and medical devices management (399)); and finally several recommendations were noticed associated with human resources management issues such as team composition, competences, roles and responsibilities and education and training needs (138, 142).

Some management tools that can facilitate management activities were identified in the literature (17-19), including the importance of being considered as an input for the definition of policies and procedures associated with HAI prevention and control systems. It was also considered important to related "resources management" processes with other system processes, from the "Context of Organisation" process to "Improvement" process.

Several recommendations were related with human resources management systems in HAI prevention and control systems. The European Council recommends, since 1972, the

implementation of ICC with adequate skills, and the promotion, at appropriate level, of education and training of healthcare workers (20, 26, 120, 121, 130). In 2002 the WHO published some guidelines for the implementation of prevention and control infection systems. Some important components for the success of infection control programmes were identified, as the implementation of ICC with adequate competences, responsibilities and roles defined. In these guidelines responsibilities for each infection control team member were established (physicians, microbiologists, hospital pharmacists, nursing staff) (55). Since 1992 CDC referred the importance of healthcare workers knowledge, education and training for HAI promotion and control (16). In a study conducted in 2002 by CDC it was referred that one of the strategies for successful promotion of hand hygiene in hospitals was education (100). In 2008 the European council developed a European Core Curriculum for Training for Infection Control Practitioners (IPSE framework Project). The main objective of the project was to harmonise consensual core training for infection control professionals through a core curriculum that included new components such as quality and risk management, community acquired infections activities, etc. This is another evidence of the European willingness for the recognition of qualifications, launched by the Bologna process (Directive 2005/36/EC). This core curriculum is organised into three main areas: programme management, quality improvement and infection control. Each part consists in different professional tasks (16) from which 15 are common to Infection Control doctors and nurses. For each task the necessary competences/skills were identified (142). In 2009 WHO published a document with core components for infection prevention and control programmes. Some priorities were identified by the Infection Prevention and Control in Healthcare Informal Network: basic training for all healthcare professionals in infection prevention and control and specialised training for infection control professionals; adequate staff responsible for infection prevention and control activities; address biological risks and implement preventive measures (adaptation and implementation of the measures to prevent biological risks of staff during the healthcare processes) (4). The last priority identified in the document highlights the importance of the introduction of risk management at professional level, promote by the implementation of occupational health and safety management systems and risk management systems.

NICE has also identified these issues as fundamental for quality improvement systems in healthcare. In its quality improvement guide published in 2011, including eleven quality improvement statements related with management issues to promote HAI prevention and control, the Statement 4 “Workforce capacity and capability” recognised the need for a skilled, knowledgeable and healthy workforce that could deliver continuous quality improvement to minimise the risk from infections. This includes support staff, volunteers, agency/locum staff and those employed by contractors (164).

The importance of personnel competence for management systems is clear in literature. As define by ISO 19011:2011, competences can be seen as the ability to apply knowledge and skills to achieve intended results. It is noticed that education, training and experience can all lead to competence - they are the means to acquire competences (achieve intended results) (330). Education generally develops intellectual, moral, and social character (knowledge) and training is generally associated with mental and physical skills to apply acquired knowledge. Formal education often involves training in some degree, as there may be subjected, which are learnt more effectively by combining knowledge acquisition and application. Experience is defined as the demonstration of capabilities obtained by education and training. Individual attitudes and behaviour must be added to these dimensions.

Several organisations have analysed the competences related with HAI prevention and control: EU, in its Patient Safety recommendation, identified the need to develop core competences, knowledge, attitudes and skills for healthcare staff, through the implementation of common core of competences (curriculum) in specialised training and/or education programmes for infection control staff at national level, regular training for all healthcare workers at institutional level (26). ECDC, based on the IPSE work about core competences for infection control professionals developed by EU, proposed a set of core competences with the main goal of developing a basic training strategy at European level in this area (138).

Actually in USA some States are using certification in infection control or other methods to enforce training requirements (118, 119).

NPIPC introduced several of the recommendations adopted by these organisations. For example, it was clearly defined: the ICC composition, roles and responsibilities and some competences; the important role of ICC in the acquisition of services and products, facilities management, environment conditions, cleaning and disinfection services, food services and others relevant for the effectiveness of HAI prevention and control system; the reference to adequate budget for perform HAI prevention and control programme; education and training needs.

National HAI prevention and control framework established the composition of ICC at hospital level (181, 183, 186, 187). One of the suggestions from fieldwork was to include in ICC composition an epidemiologist as member of technical team or advisory team (on a permanent basis). Although NPIPC defined that in outbreak situations and wherever justified, ICC must rely on the collaboration of epidemiologists, infectiologists and public health physicians at hospital level and regional level, no compliance with this national suggestion is observed, although its recognized importance for ICC operation processes.

Human resources structures were established at regional and national level to support HAI prevention and control systems. Some suggestions related to these structures were presented such as that their roles and responsibilities must be defined with more detail, as the roles and responsibilities defined at hospital level.

The analysis of the three quality management models considerations and suggestions on this issue is presented in Table 67.

Table 67 – Quality management models considerations and suggestions about "Resources Management" process (source: (310, 325, 327)).

Model/ suggestions	Standard
KF-CHKS	Specific standards related with Resources Management issues: "Financial Management; Buying and Selling Goods and Services; Health and Safety Management; Teamwork, Management and Staffing;Human resources; Clinical Service Development; Service Environment; Buildings Management; Catering Service; Housekeeping; Transportation Service" Standard 1: Organisational and Service Leadership – "Senior managers participate in training and personal development activities to ensure they have the necessary skills to manage the hospital and to facilitate quality improvement within their own work", "The senior managers plan, resource, and are involved in the implementation of quality improvement initiatives" Standard 2: Management and Governance - "The business plan includes the overall staff development and training required to achieve the objectives.", "The strategy includes the following elements… the identification of training needs and details of how these will be met…", "There is training for staff in undertaking clinical risk assessments. Attendance at training is recorded.", "The strategy includes the following elements: definitions of the roles and responsibilities of the key personnel involved in the overseeing and monitoring of clinical governance; the identification of the required skills and knowledge; the identification of training needs and details of how these will be met; the identification of resources to implement the clinical governance strategy; a timetable for implementation; and a review mechanism. "There is a mechanism to provide the necessary resources to support the quality improvement and evaluation activities.", "Evaluation reports are produced on the outcomes of quality improvement initiatives…This includes assessment of cost reduction, increased activity, better use of staff resources", Risk management standards – "Any training needs highlighted during the development of action plans should be incorporated into the hospital's training and development plans.", "The hospital has systems in place for the management of health and safety issues and the training of staff in health and safety measures as required by their work.", "waste disposal strategy should include… the role of the infection control team, and staff training." Standard 13: Infection control – "There is an ongoing education programme on infection control for all staff within the hospital… staff, should receive regular updating on measures for infection control relating to their area of work. When new systems of work are introduced, consideration should be given to the need for infection control updating.", "The infection control team or infection control link nurse is involved in the hospital's induction programme." Standard 18: Human resources – "There is a dated, documented human resource strategy that is developed in accordance with the overall business plan and is designed to provide work conditions conducive to good health and high performance. The strategy has been written/reviewed within the last three years.", "…human resource strategy should include staff training and development", "There is a dated, documented training and development plan for staff in the hospital.", "The plan addresses, for example, the training needs associated with the hospital's overall objectives; the training needs in response to changes in practice, the law and new technology; and meeting both the individuals' and organisational training needs as identified within the performance review system.", "Resources include money, facilities, equipment, expertise, people and time."

(Cont.)

Model/ suggestions	Standard
JCI	Specific standards related with Resources Management issues: Staff Qualifications and Education (SQE), Facility Management and Safety (FMS) Assessment of Patients (AOP) and Assess to Care and Continuity of Care (ACC) "Supervisory staff and technical staff have appropriate and adequate training, experience, and skills and are oriented to their work. Technical staff are given work assignments consistent with their training and experience.", "The organisation designs and carries out processes to provide continuity of patient care services…Throughout all phases of care, patient needs are matched with appropriate resources in and, when necessary, outside the organisation". Care of Patients (COP) "The leaders are responsible for training staff in implementing the policies and procedures.", "Acuity of the patient's condition determines the resources allocated to meet the patient's needs." Medication Management and use (MMU) "Improvements in medication processes and staff training are used to prevent errors in the future.", "Medications, as an important resource in patient care, must be organised effectively and efficiently. Medication management is not only the responsibility of the pharmaceutical service but also of managers and health care practitioners" Patient and Family Education (PFE) "Education and training help meet patients' ongoing health needs.", "The organisation chooses how it organises its educational resources in an efficient and effective manner. Thus, organisations may choose to appoint an education coordinator or education committee, create an education service, or simply work with all staff to provide education in a coordinated manner." Quality Improvement and Patient Safety (QPS) "Staff is trained to participate in the program… There is a training program for staff that is consistent with their roles in the quality improvement and patient safety program.", " Staff members participate in the training as part of their regular work assignments" Prevention and Control of Infections (PCI) "One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training,…", "The organisation identifies those situations in which masks, eye protection, gowns, or gloves are required and provides training in their correct use.", "The organisation's leaders provide adequate resources to support the infection prevention and control program" Governance, Leadership, and Direction (GLD) "Directors provide orientation and training for all staff of the duties and responsibilities for the department or service to which they are assigned.", "these leaders must identify the organisation's mission and make sure that the resources needed to fulfil this mission are available…Those responsible for governance approve the budget and allocate the resources required to meet the organisation's mission", "Directors recommend space, equipment, staffing, and other resources needed by the department or service… Each department's leaders communicate their human resources and other resource requirements to the organisation's senior managers."
ISO	6. Resources Management. 6.1 General – " The organisation shall determine and provide the resources needed to implement and maintain the quality management system and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements"; 6.2 Human resources – "Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. "The organisation shall, where applicable, provide training or take other actions to achieve the necessary competence, evaluate the effectiveness of the actions taken"; 6.3 Infrastructure – "The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable: buildings, workspace and associated utilities; process equipment (both hardware and software); supporting services (such as transport, communication or information systems)." 6.4 Work environment – "The organisation shall determine and manage the work environment needed to achieve conformity to product requirements."
Hospitals Suggestions	"Definition of roles and responsibilities for multidisciplinary teams working on HAI prevention and control issues (such as risk management, occupational health management, ICC and quality management" " It is important to introduce in ICC competences not only "know-how" and "know how to do", but also "know how to be" "Inclusion of an epidemiologist in ICC"

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (186, 190, 390, 400-408), such as presented in Table 68 (Resources Management – General) and Table 69 (Resources Management – Human Resources).

Table 68 – PDCA cycle and management tools suggestions for the implementation and development of "Resources Management- general" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable plan with support of: - W5H2 method: - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal national framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation process"; - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis.	Identification of resources needs: - Type of Infrastructures and work environment; - Instruments and equipment, including devices; - Provisions needed; - Staff; Identification of resources needs taking into account: - Organisation objectives; - Organisation capability; - Service needs (related with internal processes and external processes); - Controls needs; Suppliers management, supported by: - Identification and classification of suppliers; - Market analysis; - Establishment of criteria for Classification and selection of suppliers and for evaluation; - Establishment of contracting processes with suppliers; - Evaluation of suppliers. - Maintenance of adequate resources – Equipment, devices and provisions; - Human resources management; Establishment of resources maps based on: - Activities established for each process: use of process diagram to describe processes; Identification of requirements of each process; application of QFD tool (planning tool); - Cost-analysis; - Levels of quality requirements; - Identification of acquisition information requirements; - Establishment of communication and information channels and flows; - Establishment of contract requirements, including requirements for after-sales service; Maintenance of resources, taking into account: - Stock requirements (provisions); - Equipment calibration and maintenance: development of calibration and maintenance plans; - Medical devices management: ISO 13485:2003 (Medical devices- quality management systems); - Legal framework. Change management taking into account: - All HAI prevention and control requirements; - Risk analysis (e.g. FMEA methodology).	Compliance analysis, supported by: - Objectives and indicators analysis; - Compliance with the implementation methodologies identified; Analysis of data from: - Audit process; - Processes Performance; - Complaints; - Nonconformities - Other information relevant for the organisation.	Definition of correction and corrective actions when necessary: - Application of tools to identified causes and solutions such as cause-effect diagram, problems solving methodology, Kaisen methodology, brainstorming methodology.

Table 69 – PDCA cycle and management tools suggestions for the implementation and development of "Resources Management – Human Resources" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable plan with support of: - W5H2 method; - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal National framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation process" - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis.	Human resources management supported by: - UNE 66173:2003 (Human resources in a quality management system), NP 4427:2004 (Human resources management system – Requirements), Investors in People improvement Framework[77], and SFIA 5 Framework[78] - Job description map, including roles and responsibilities definition; - Individual dossier; - Personnel allocation according with job description and competences; - Team work management; - Education and training identification: see "Education and Training" process; - Occupational safety management supported by OHSAS 18001:2007[79] and/or NP 4397:2008 (Occupational health and safety management systems); - Context analysis: professional offers, Legal framework requirements analysis: career rights and duties; Identification of human resources needs, taking into account: - Recruitment process; - Organisation processes description; - Job descriptions; - Context analysis: - Documented information; - Methodologies for identification; - Evaluation needs; Identification of Competences, taking into account: - Type of Competences needed; - Levels of responsibility; - Job descriptions; - Needs identification: resources (internal and external resources); - Documented information; - Methodologies for identification; - Evaluation needs; - Identification of communication channels; Development of a Competences map supported by: - SFIA methodology; - UNE 66173:2003 IN methodology; - NP 4427 methodology; Implementation of competences map, taking into account: - Resources needs: resources map, including costs; - Measuring, monitoring and evaluation methodologies;	Compliance analysis, supported by: - Objectives and indicators analysis; - Compliance with the implementation methodologies identified; Analysis of data from: - Audit process; - Processes Performance; - Complaints; - Nonconformities - Other information relevant for the organisation.	Definition of correction and corrective actions when necessary: - Application of tools to identified causes and solutions such as cause-effect diagram, problems solving methodology, Kaisen methodology, brainstorming methodology.

[77] Investors in People Improvement Framework is an UK government framework designed to promote business improvement through people management (see in Investors in People tools and resources: Investor in People International; 2009. Available from: http://www.investorsinpeople.com/tools-and-success-stories/tools-and-resources).

[78] SFIA 5 Framework is a tool to support the organisational skills management cycle (resource planning, recruitment, deployment, assessment, development, and remuneration) (See in SFIA 5 framework reference. Skills defined in categories and subcategories. SFIA Foundation; 2012).

[79] OHSAS 18001:2007 is an international occupational health and safety management standard developed to help organisations to minimise risk to employees, demonstrate diligence and gain assurance (See in British Standards Institution. OHSAS 18001:2007: Occupational Health and Safety Management Systems - Requirements. British Standards Institution; 2007. p. 36).

Research, Development and Innovation (RDI)

The organisation must develop, implement and maintain research, development and innovation actions to promote HAI prevention and control system. For this, the organisation must determine research scope, policies, objectives, and activities to ensure the suitability of the research related HAI prevention and control system to the organisation needs.

The organisation must plan research activities taking into account inputs such as: external and internal organisational context requirements (See "Context of the Organisation" process), internal and external competences (see "Resources Management – Human Resources" process), resources (see "Resources Management" process), and operations processes capability. Appropriate communication and information flow must be established to ensure information exchange between all interested parties.

RDI projects requirements

The organisation must establish procedures and criteria to capture, analyse and evaluate ideas that may include innovation opportunities. For this the organisation must consider the results from problem identification and opportunities evaluation.

For each innovation project the organisation must establish a plan including: project description, team identification, resources needed, activities/tasks to developed, milestones to achieve; evaluation activities, including verification and validation and, when appropriate, revision criteria, selection and result approval; operation and documentation control. When necessary the organisation must identify documented information concerning arrangements for protection of intellectual property (Se also "Planning" process, "Resources Management" process, "Measure and Monitoring" process, and "Communication and Information" process).

Note: These requirements are based on the Portuguese Standard for management of research, development and innovation management system (409).

Literature review and multi-case study considerations

As identified, the current state of the art of HAI prevention and control systems is the result of research, development and innovation carried out since the XIX Century. Evidences can be identified in the work of Florence Nightingale related to basic hygiene procedures and statistical tools applied to infection control and the importance of these tools in the current facilities management (17).

The antibiotic discovery in the middle of the XX Century promoted new developments in infection control mainly related with treatment and using the knowledge about AMR.

Most of this work was supported in research, development and innovation promoted by several organisations such as CDC-ECDC, WHO, EU, and others previously identified.

Although the acquired knowledge about HAI issues and all the best practices introduced to improve HAI prevention and control, the problem still persists and an emergent need to promote new research to answer to current challenges was identified.

The first practical guide published by WHO identified the importance to promote research (55). Subsequently, WHO launched the World Alliance Strategy for Patient Safety, considering research and innovation development as part of patient safety strategies. European Union also emphasised this issue with its recommendations about patient safety and by the promotion and support of several research projects to improve HAI prevention and control systems and patient safety (217). One of the main recommendations on Patient Safety issues at Member State level was to improve the information given to patients and support research (26). This recommendation promoted several developments on patient safety issues in European States such as the recommendation related to "support research" at national/regional level. One of the developed activities was the implementation of an inter-sectorial mechanism to define priorities for research and to coordinate the strategy for HAI prevention and control (137). This was also recognised by NICE in its quality improvement guide, where Statement 6 (from its eleven improvement statements) was defined as "Multi-agency working to reduce HAI - Trusts work proactively in multi-agency collaborations with other local health and social care providers to reduce risk from infection." (164). Another important issue related with "research, development and innovation" process was evidenced in the Statement 11 - New technology and innovation, through the recognition of the importance of trusts regularly review and evidence-based assessments of new technology and other innovations to minimise harm from HAI and AMR (164).

The development of an inter-sectorial mechanism can be seen as new challenge to promote not only the research in several relevant areas (such clinical- Human and Veterinary, education and training, resources – materials/equipment/facilities, environment, and others) but also the combination of synergies.

Again, it is important to promote HAI prevention and control research based on process-approach, where all interested parties are involved to promote the improvement of HAI research value chain.

Other issues must be considered and incorporated in this process due to the fact that pharmaceutical industry failed on antibiotic production and several microorganisms have an

increased resistance for their most common therapeutic choice. It is considered important to look for new therapies (human, veterinary and for food production), not just based in antibiotics, but also in innovative solutions such as phage therapy (410, 411). Phages can be used for detection of bacteria, for treatment and for cleaning of surfaces (412, 413).

At national level, NPIPC indicates that ICC must collaborate in the planning and implementation of events and scientific research at national and international level (186).

The analysis of the three quality management models considerations and suggestions on this issue is presented in Table 70.

Table 70 – Quality management models considerations and suggestions about "Research, development and Innovation" process (source: (310, 325, 327)).

Model/ suggestion	Standard
KF-CHKS	Standard 2: Management and Governance - "There is a dated and documented policy establishing whether or not the organisation conducted research", "If the policy states that research is carried out in the organisation, there are written procedures that define the requirements to be met by these research projects," "Health professionals have access to up-to-date information on research findings and evidence-based clinical practice.", " There is a record of all research projects are being conducted in organisation. "," Any research project involving the testing of new drugs or the use of new medical devices in people is notified to the appropriate national body if relevant.
JCI	Governance, Leadership, and Direction (GLD) "Those responsible for governance approve organisation strategies and programs related to health care professional education and research and then provide oversight of the quality of such programmes."
ISO	Product Realisation: 7.3.1 Design and development planning – "The organisation shall plan and control the design and development of product. During the design and development planning, the organisation shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organisation shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses."

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (318, 390, 391, 409, 414), such as presented in Table 71.

Table 71 – PDCA cycle and management tools suggestions for the implementation and development of "Research, Development and Innovation" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable plan with support of: - W5H2 method: - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal national framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation" process - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis; - Application of PDCA cycle to ensure the process improvement; Identification of research, development and innovation process requirements, taking also into account: - Scope; - Process activities; - Inputs; - Expected outputs; - Evaluation; - Identification of communication and information requirements.	Development of Research, Development and innovation process supported by: - NP 4456/4457:2007 (Management of Research, Development and Innovation (RDI) – Management system requirements of RDI), UNE 157601:2007 (General criteria for design activities-based projects); Planning of RDI projects: - Ideas management: Context analysis, benchmarking, brainstorming, suggestions analysis, conferences and other tools/mechanisms to capture, analyse and select innovation opportunities; - Establishment of resources, including internal or/and external competences and teams; resources and competences allocation map, process diagram; - Activities/tasks identification: flow diagram; - Results definition taking into account: objectives, requirements previously defined; - Evaluation activities, taking into account measuring and monitoring activities (measure, monitoring and evaluation plans, statistical tools), internal or/and external verification and validation (statistical tools, scientific validation by peer review and others); - Data/process/service protection definition: data protection legal framework, intellectual property protection through patent registration; - Feedback for other processes: definition of communication channels and information flow; - Implementation of developed plans.	Compliance analysis, supported by: - Objectives and indicators analysis; - Compliance with the implementation methodologies identified; Analysis of data from: - Audit process; - Processes Performance; - Complaints; - Other information relevant for the organisation.	Definition of correction and corrective actions when necessary: - Application of tools to identified causes and solutions such as cause-effect diagram, problems solving methodology, brainstorming methodology.

Communication and Information

Top management must ensure that appropriate internal and external communication and information processes are established and that communication takes place regarding the effectiveness of HAI prevention and control system. This must include:

- Flows and channels communication (how to communicate): design, identification and implementation (including infrastructures if necessary – See also "Resources Management" process);

- Information to communicate (what): information security level, importance level (this must be defined by the organisation),
- Communication periodicity (when communicate and periodicity),
- Communication between interested parties (who must be involve in the communication process);

The organisation must also ensure that theses issues are defined for both flow directions: to inform and to feedback (e.g. reporting systems).

Documented information requirements

The organisation must ensure that documented information from HAI prevention and control system is available when and where necessary for use. This includes:

- Legal/regulation and other documented information required by national law;
- Documented information required by NPIPC (e.g. procedures, work instructions, forms, checklists)
- Other important documented information determined by the organisation as being necessary to ensure HAI prevention and control system effectiveness.

The organisation must take into account control and protection issues defined by law and/or by the organisation to ensure:

- Proper data use,
- Preservation and integrity,
- Confidentiality,
- Data protection (This must also include control of changes, storage, retention and disposition).

Documented information must be created and updated when necessary. It includes:

- Identification and description;
- Appropriate format;
- Review and approval (by top management).

Literature review and multi-case study considerations

As observed in literature review, communication and information issues were normally considered a barrier to the effectiveness of HAI prevention and control (337). One of the most evident barriers associated with this issue is the "lack in reporting system". To deal with this problem several strategies at international, national and hospital level were introduced, such as: international surveillance networks (such as HELICS), mandatory reporting systems (in some USA States,) IT development for reporting systems at national and hospital level.

Communication and information process, as identified, is regarded as an important support for HAI prevention and control from the "Plan" stage to the "Act" stage, considering all the interested parties requirements. Additionally, "Communication and Information" process is identified as fundamental for organisational knowledge management and to ensure improvement of the value chain: Data-Information-Knowledge-Action.

In addition to the identification of management tools to promote better communication and information systems, it is considered important the identification of factors affecting the change in the entire health system. As so, one of the identified challenges of change management in hospitals is the implementation of effective communication tools, and the promotion of better communication between internal interested parties (patients, professionals), and external interested parties (family members, shareholders and the wider community) (415).

The concern about these issues promoted several recommendations by different organisations. For example, the EU in its Patient Safety recommendation, refers the development and promotion of the research agenda on patient safety, based on Information and Communication Technologies (26). The concern about these issues is also evident in some international projects, developed to promote better information and communication about HAI prevention and control systems between European States (217). NICE from UK, in its quality improvement guide, identified in its Statement 7 that "Trusts ensure there is clear communication with all staff, patients and carers throughout the care pathway about HAI, infection risks and how to prevent HAI, to reduce harm from infection." And in Statement 2 that "Trusts use information from a range of sources to inform and drive continuous quality improvement to minimise risk from infection." (164).

At national level four strategies for NPIPC were identified, including one related to the development and improvement of communication and reporting system. A HAI National Record System was created with this objective (186).

The importance of this issue was also identified by Regional Health Administration – North, in its hospital contracting evaluation process, including the definition of four SMART objectives related with HAI prevention and control systems, and another two related with information and communication issues such as "Existence of any formal communication mechanism between the Microbiology services and ICC to report information about microorganisms problem" and "Structure information systems capable of measuring outcome indicators" (188).

The analysis of the three quality management models considerations and suggestions on this issue is presented in Table 72.

Table 72 – Quality management models considerations and suggestions about "Communication and Information" process (source: (310, 325, 327)).

Model/ suggestion	Standard
KF-CHKS	Standard 1: Organisational and Service Leadership - "The organisation has a communication strategy, dated and documented. The strategy should refer to communication with staff, patients and the people who care for them, the local community and external agencies, as appropriate to the services provided, and would provide links with the local media and the use of technologies information on internal and external communications of the organisation. "There is a procedure dated and documented that sets guidelines for communication with external organisations, including the media, thereby ensuring the protection of confidentiality of staff, patients, their families and carers. This procedure has been drafted / revised the last three years. "... Should have guidelines for survey responses (e.g. requests for information on patients) and also guidelines on how to submit any information which the organisation wishes to transmit to the means of communication", "There are systems that span across the organisation and enable communication of the executive committee with staff at all levels.", "There are established channels for communication with superiors within the organisation, these being known by all levels of staff channels." Standard 2: Management and Governance - "There is a dated and documented policy establishing whether or not the organisation conducted research", "If the policy states that research is carried out in the organisation, there are written procedures that define the requirements to be met by these research projects," "Health professionals have access to up-to-date information on research findings and evidence-based clinical practice.", " There is a record of all research projects are being conducted in organisation. "," Any research project involving the testing of new drugs or the use of new medical devices in people is notified to the appropriate national body if relevant. Standard 13: Infection control –"There is ongoing communication between ICC and multidisciplinary risk management committee.
ISO	Quality management system: 4.2 Documentation requirements – "The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, and d) documents, including records, determined by the organisation to be necessary to ensure the effective planning, operation and control of its processes." Quality management system: 4.2.3 Control of documents – "Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the …", "A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organisation to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose." Quality management system: 4.2.4 Control of records – "Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organisation shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable." Management responsibility: 5.5.3 Internal communication – "Top management shall ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality management system." Resources management: 6.3 Infrastructures – "The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication or information systems)." Product realization: 7.2.3 Customer communication – "The organization shall determine and implement effective arrangements for communicating with customers in relation to product information, enquiries, contracts or order handling, including amendments, and customer feedback, including customer complaints." Product realization: 7.4.2 Purchasing information – "The organisation shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier."

(Cont.)

Model/ suggestion	Standard
JCI	Specific standard - Management of Communication and Information (MCI) Goal 2: Improve Effective Communication "The organisation develops an approach to improve the effectiveness of communication among caregivers." Quality Improvement and Patient Safety (QPS) "Quality improvement and patient safety information is communicated to staff.", "The regular communication of information about the quality improvement and patient safety program to staff is essential. The communication is on a regular basis through effective channels, such as newsletters, storyboards, staff meetings, and human resource processes." Governance, Leadership, and Direction (GLD) "Support good communication between professionals", "The organisational structure(s) and processes support professional communication."
Hospitals Suggestions	"It must be established better information channels internal (between services) and external this could be developed based on 5W methodology (why, when, where, who, what)." "The laboratory information included in patient clinical record must have an alert system related with information updates." "ICC must have more information about clinical process (patient records) to promote a better work (ICC information is based on laboratory information). It must be an IT tool to do this." "It is important to promote HAI prevention and control image through marketing techniques. It is important to innovate in this area"

PDCA cycle

To support the management of this process the PDCA cycle and other identified management tools and methodologies could be used (186, 390, 391, 401), such as presented in Table 73.

Table 73 – PDCA cycle and management tools suggestions for the implementation and development of "Communication and Information" process.

Plan	Do	Check	Act
Application of ISO 10005:2005 (Guidelines for quality plans) to define a suitable plan with support of: - W5H2 method: - SMART objectives definition (Methodology); - NPIPC: strategic and operation documents, and other interested parties requirements, including legal national framework; - Organisational policies and objectives; - Information from "Research, Development and Innovation process"; - International information (from ECDC, CDC, WHO, EU and other relevant organisations); - Risks and opportunities identified previously through SWOT analysis; - Application of PDCA cycle to ensure the process improvement; - Establishment of communication and information strategies; - Evaluation of communication and information strategies suitability to organisation and interested parties requirements.	Development of communication and information strategies supported by: - Communication structures map; - Job description map, competences map; - Resources (used and new ones); - Confidentiality and information protection legal framework; - Development of a communication and information map supported on W5H2 methodology for all HAI prevention and control issues; Suitability evaluation of: - Communication and information strategies implemented in the organisation: policies analysis, marketing strategies, objective-based plans analysis, diagram flows and others; - Communication and information security strategies implemented in the organisation: legal framework, ISO 27001 (information security management system); - Communication and information channels definition (internet, intranet, document information (paper or digital support, phone (calls, SMS, MMS), meetings, conferences, posters, mail and other relevant channels identified by the organisation): surveys, satisfaction evaluation, technical assays. - Documentation: - Needs (procedures, forms, records and other); - Control requirements definition for documents and for records.	Compliance analysis, supported by: - Objectives and indicators analysis; - Compliance with the implementation methodologies identified; - Analysis of data from: - Audit process; - Processes Performance; - Complaints; - Other information relevant for the organisation	Definition of correction and corrective actions when necessary; - Application of tools to identified causes and solutions such as cause-effect diagram, problems solving methodology, Kaisen methodology, brainstorming methodology.

What we get (Results)

A successful HAI prevention and control system must be evaluated by its results. The results can be analysed partially, considering the output of each process, or globally by the analysis of expected results for the entire system, such as the decrease or elimination of HAI. This will be reflected in clinical effectiveness improvement, costs reduction and, therefore, in main interested parties satisfaction.

But, as observed before, some barriers can still be identified as associated with this dimension, such as, data treatment and analysis, feedback of information and reporting system. Data is defined as output of a process and as input of other process.

It is important to understand the importance of "data-information-knowledge-action" chain in the improvement process. HAI prevention and control system supported by process-approach

is based on this “chain”. Regarding the “context of the Organisation” process the identification of information sources and relevant data to collect and analyse is crucial. Results will be important information and knowledge for the implementation of the “Strategic” process as well as “leadership” and “planning” processes, for development and implementation of all defined “Performance, Evaluate and Improvement” processes, “Operation” processes and “Support” processes. The management of these interconnected processes will promote actions that will eventually ensure continual improvement.

As presented in the model description expected results, communication and information issues are analysed as part of each process and as a support process for the entire system. Each process must ensured adequate feedback of information based on reliable data.

The final result of these processes (partially and globally) must be, always, analysed and evaluated, and feedback information must be introduced, again, as input to ensure improvement.

Conclusions

The main objectives of this work were to analyse HAI prevention and control systems and how quality management systems (accreditation and certification models) and tools could promote its improvement.

This work showed a wide development in HAI prevention and control systems since the end of the XX Century, both at international level and at national level. Internationally several recommendations international collaborative projects and networks to identify, develop, analyse and evaluate all the dimensions of HAI prevention and control systems were developed by recognized organisations. Portugal developed, in last few years, a framework with related regulation, technical procedures and evaluation mechanisms as a response to international recommendations and internal needs and expectations from the interested parties of the healthcare system. Participation in some of the international projects developed by WHO, ECDC, and others was also noticed.

In this work also analysed the evolution of quality management issues - models and tools – applied to healthcare and aiming to promote quality, and specially to improve HAI prevention and control systems. This was accomplished at international level and at national level. Several quality management models and tools were identified and could be applied to improve HAI prevention and control. Two of the most common accreditation models applied to hospitals (JCI and KF-CHKS), which include specific standards for HAI prevention and control, were also studied.

The development of HAI prevention and control systems is strongly supported by better knowledge and awareness on clinical issues such as agent transmission, therapeutic issues, best practices and best technologies. Nevertheless several barriers, related with management issues were also identified as relevant constrains to the improvement of HAI prevention and control systems. With this work some of these barriers at international level (by literature review) were identified. At national level, fieldwork was conducted in three hospitals with three different quality management models. The identified barriers were grouped in three dimensions: “Who we are – Structures”, “How we do – Processes” and “What we get – Results”. The highest number of barriers was associated with management issues (How we do – Processes).

A comparative analysis showed that national barriers are identical to those identified at international level.

The performed literature review allowed concluding that it does not seem to be a lack of pertinent recommendations and guidelines or even related solutions to tackle high levels of HAI. The key problem seems to be on how these are adopted, adapted, developed, implemented, maintained, and evaluated in healthcare organisations.

Through the analysis of the three quality management systems applied by three national hospitals (in the literature and in fieldwork) it could be verified that these models can effectively promote HAI prevention and control systems, but it was also demonstrated, by a global perception analysis, that the relationship between HAI prevention and control system and quality management system is good but not as strong as expected, as significant improvement potential was identified. It could also be verified, through the interviewees perception, that quality management systems are: used to support HAI prevention and control systems; an "engine" to promote the continuous improvement of the HAI prevention and control system; fundamental to ensure the systematisation of all activities in the organisation; relevant to bring competitive advantages; to be used to promote professionals involvement and the intrinsic knowledge of the organisation. In a general way, quality management systems are seen as a "binder" factor.

Fieldwork information also showed that several management tools can assist and improve HAI prevention and control systems, such as BSC, root-cause analysis, PDCA cycle, risk management tools and others. A set of suggestions and best practices to be incorporate in HAI prevention and control system at hospital level was also identified.

Finally with all the information obtained by the literature review about HAI prevention and control issues and quality management issues, a management model for HAI prevention and control system was developed. This model was design based on the ISO 9001 process approach methodology.

The result of this study must be seen as a set of suggestions that can be used by hospitals to promote the improvement of their HAI prevention and control system. This work must also be analysed as a tool to be adapted to the reality of each hospital. Regardless of the presented information, additional documented information, such as procedures for more detailed information, manuals and education and training programmes to assist the implementation of this model must be developed. It is strongly suggested the development of an operational manual.

This model was designed to be applied at hospital level, but it can be apply to national level (to the National Programme for HAI and Antimicrobial Resistance Prevention and Control) or to any other type of healthcare provider (primary care centre or continuous care centre).

Nevertheless, further research is needed to promote the adequacy and appropriateness of this model to other type of healthcare providers.

This study was subjected to several limitations that must be considered when discussing the results. With regard to literature review it can be referred the limitations imposed by: the use of review articles that lead to loss of information of the original data; the definition of inclusion and exclusion criteria for the selection that conditioned the research more than expected, among others. Regarding fieldwork limitations, restrictive criteria definition for sample selection, sample size (only one hospital for each model), and others, may have introduced bias results.

Regardless of these limitations, this study provides an extensive analysis on HAI prevention and control management issues and on quality management issues, at national and international level. Further research and development must be considered to support the implementation of this model into national public hospitals, such as cost analysis about HAI prevention and control systems.

The main result, defined as the model presented to help HAI prevention and control systems management, which incorporates the best practices applied till now and management tools, is innovative and highlights several possibilities of improvement as well as valuable information to health authorities.

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ANNEXES

The annexes of this thesis are the following:

ANNEXE I – Article "Challenging healthcare-associated infections: a review of healthcare quality management issues"

ANNEXE II – Article "Healthcare-associated infections: on developing effective control systems under a renewed healthcare management debate"

ANNEXE III – National Framework for HAI Prevention and Control Systems, applied to hospitals

ANNEXE IV – Interview Guidelines

ANNEXE V – Barriers and Suggestions: Comparative Analysis

ANNEXE I – Article "Challenging healthcare-associated infections: a review of healthcare quality management issues"

Challenging healthcare-associated infections: a review of healthcare quality management issues

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Abstract

Healthcare-associated infections (HAIs) are now a worldwide problem with devastating effects, both in economic and public health impacts in the medium and long term. In reality, this healthcare management problem became frightening when we became aware of large number of cases associated with this type of infection, especially the infections caused by agents for which the existing treatment no longer works effectively. This is the case of infections associated with healthcare caused by multi-resistant microorganisms, whose line of action in therapeutic terms may be exhausted. Several factors of growth have been identified, among which are the overuse of antibiotics (by direct intake or through food), environmental conditions, and the evolution of microorganisms. This means that, all over the world, rates of high prevalence and incidence for diseases caused by HAIs agents are now new contributions to rates of mortality and morbidity. Yet, already in 1959 a report on hospital infections by *Staphylococcus*, published by the Central Health Services UK, identified the prevalence of Staphylococcus as a major concern. Since then, this type of infection continued to occur, in spite of a growing understanding of the necessary measures for their control. It is known that, currently, the percentage of methicillin-resistant *Staphylococcus aureus* (MRSA) existing in the bacterial population of *S. aureus* associated with HAIs varies between 1% (Netherlands and Finland) and 44% (UK and Greece). However, regardless of advances in infection control systems, the incidence of HAIs remained relatively unchanged in the last 20 years (about 10%). The situation does not get better when we analyse the problem from the cost perspective. At this point, it is known that there is a direct impact in the hospitalization costs, in diagnostics (tests, examinations, etc.), and in treatments (antibiotics, surgery, and others). A 1992 CDC study estimated costs of HAIs and already suggested that the cost of infection control programs was approximately 6% of the total costs of the infections. In a 2003 report by the United Kingdom (UK) Department of Health, entitled 'Winning Ways: Working together to Reduce HAIs in England', it was estimated that the cost associated with HAIs per patient bed for a year was identical to the cost of an infection control program applied to a hospital with 250 beds. On what concerns quality management system, costs with HAIs may be comprised as non-quality costs. In this sense, an estimate by the Juran Institutes, suggests that non-quality costs can be approximately one-third of direct healthcare costs, and according to Nordgren *et al.* inflation of related costs is, in part, due to the increased length of stay and associated increased costs with providing the extra implicit care. This article explores these issues.

Keywords: Healthcare management, Quality management, Healthcare-associated infections (HAIs), Infection control, Patient safety, Accreditation-certification models

Introduction

Healthcare-associated infections (HAIs) are now a worldwide problem with devastating effects, both

in economic and public health impacts in the medium and long term.

In reality, this healthcare management problem became frightening when we became aware of large number of cases associated with this type of infection, especially the infections caused by agents for which the existing treatment no longer works effectively. This is the case of infections associated with healthcare caused by multi-resistant microorganisms, whose line of action in therapeutic terms is exhausted. Several factors of growth have been identified, among which are the overuse of antibiotics (by direct intake or through food), environmental conditions, and the evolution of microorganisms.

This means that, all over the world, rates of high prevalence and incidence for diseases caused by HAIs agents are now new contributions to rates of mortality and morbidity. Yet, already in 1959 a report on hospital infections by *Staphylococcus*, published by the Central Health Services from United Kingdom (UK), identified the prevalence of Staphylococcus as a major concern. Since then, this type of infection continued to occur, in spite of a growing understanding of the necessary measures for their control. It is known that currently the percentage of methicillin-resistant *Staphylococcus aureus* existing in the bacterial population of *S. aureus* associated with HAIs varies between 1% (Netherlands and Finland) and 44% (UK and Greece).[1] However, regardless of advances in infection control systems, the incidence of HAIs remained relatively unchanged in the last 20 years (about 10%).[2]

The scenario does not get better when we analyse the problem from the cost perspective. At this point, it is known that there is direct impact in the hospitalization costs, in diagnostics (tests, examinations, etc.), and in treatments (antibiotics, surgery, and others). A 1992 study by CDC estimated costs of HAIs and already suggested that the cost of infection control programs was approximately 6% of the total costs of infections.[3–8] In a 2003 report by the UK Department of Health, entitled 'Winning Ways: Working together to Reduce HAIs in England', it was estimated that the cost associated with HAIs per patient bed for a year was identical to the cost of an infection control program applied to a hospital with 250 beds.[1]

On what concerns quality management system, costs with HAIs may be comprised as non-quality costs. In this sense, an estimate by the Juran Institute, suggests that non-quality costs can be approximately one-third of direct healthcare costs, and according to Nordgren *et al.*[5] inflation of related costs is, in part, due to the increased length of stay and associated increased costs with providing the extra implicit care. This article explores these issues.

Patient safety and HAIs prevention and control

HAIs and its need for prevention and control have become an emerging health management issue because of its negative impact on the performance of healthcare organizations, specifically in the dimensions of effectiveness, clinical safety, and centrality of patient safety.[9–11]

The issue of patient safety related to healthcare management has become a prominent issue in a report published in 2000 by the United States of America (USA) Institute of Medicine (IoM), entitled 'To Err Is Human: Building a Safer Health System' in which the health management international community became aware of shocking numbers of harm associated with medical errors and adverse events arising from related clinical practice and in-patient stay in healthcare organizations. Among other data presented, the report estimated that, in the USA, 58% of deaths associated with medical errors could have been prevented. Hence, a further estimation is presented in which, at hospitals in the UK, each year about 40 000 people die due to lack of safety and quality care. In this report is also pointed out that the error rate in healthcare is higher than rates registered in other sectors as well as the delay of the risk management systems developed by organizations that provide healthcare compared to the developed for other high-risk sectors. In other words, the reported argued that the health sector lags a decade or more compared to other high-risk areas with regard to ensuring basic safety and security to users. This possibility should be a worrying possibility for all healthcare management communities.[12]

Quality systems in health and patient safety programs

For our reasoning, it is relevant to consider three definitions of 'Quality in Health'. The first, presented by the IoM, states that Quality in Health is the 'degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'.[13] To the World Health Organization (WHO), the quality of health is presented as 'an integrated set of planned activities based on the definition of explicit goals and performance evaluation, covering all levels of care, with the objectives of continuous quality

improvement of care'.[14] A third definition, published in 1997 by the Department of Health in the UK, defines that the quality of health is 'doing the right things at the first time to the right people at the right time, in the right place at the lowest cost'.[15]

Curiously, these definitions clearly relate to the need for any healthcare system to guarantee excellent results of care through appropriate structures and processes and the promotion of the satisfaction of all interested parties. This is common sense for the health sector but also for any other sector such as industry. Industry due to several factors, including the need to ensure competitiveness and sustainability over time, developed quality assurance mechanisms that promoted quality improvement organization, the quality of the product or service, and consequently the satisfaction of all stakeholders. Similarly, healthcare providers are also under pressure to ensure continuous quality improvement in balance with management factors such as (i) the need to increase the effectiveness and efficiency while maintaining equity, (ii) the promotion of 'accountability' and confidence in health systems, (iii) lack of motivation of the various professional categories involved, (iv) the increased demands and criticism of health services 'costumers' and the need to increase patient satisfaction, and (v) restrained health budget requirements and the need to ensure the systems' sustainability.[9,16]

In the past decades, in response to the industry needs concerning quality systems, several quality improvement models were developed supported by standards and/or potential requirements for standardization and systematization of the activities. In 1988, the European Foundation for Quality Management (EFQM) launched the Total Quality model. In the same year, in the USA, the Malcolm Baldrige National Quality Improvement Award was launched and in 1992 it was developed by the International Organisation for Standardisation (ISO) the model for quality assurance system, known as the 9000 standards. These models were readily accepted by different sectors and tailored to their needs, according to the suggestions and requirements of an evolutionary process. In areas of high-risk industries such as automotive and aerospace industry these models were adapted and optimized in order to respond to their needs, including the safety of customers.

In health, this trend was also observed even if with less speed and less recognition than in other industries. In healthcare systems, several mechanisms promoting healthcare quality improvement, among others developed by several authors, were introduced and included the accreditation and certification models.[17,18] One should, however, note that the first models associated with processes of hospitals accreditation, currently applied in the health sector, were developed in the nineteenth century (1897) by the King's Fund from UK and in the beginning of twentieth century by the Joint Commission Accreditation for Health Care Organizations – JCAHO (1917) in the USA (the last one at the request of the American College of Surgeons).

However, although there was some systematic use of these models for promoting quality improvement in healthcare in countries such as the UK and the USA, in other countries and until recently, quality promotion was mostly guaranteed by basic training, education, and professional requirements imposed by health professional groups and the existing work legislation. Change on this slow motion development started to occur from 1979 when the WHO issued the report called 'Formulating Strategies for Health for All by the Year 2000' which presented recommendations for the formulation of policies and strategies at the level of health systems to promote better care Health in the twenty-first century.[19] This initiative emerged in 1984 to define a set of targets, which stands out from its target 31, where all WHO member states should develop and implement staff mechanisms to ensure the quality of care, and by 2000 should establish and have available structures and processes to ensure continuous quality improvement of care and adaptation and development of new technologies. Following this movement, a set of recommendations were issued for governments to establish the structures and activities required to fulfil their goals.

In 2003, the WHO triggered a survey to identify what has been done nationally and internationally to promote the quality of care, which were the concepts and terminology used in this area and initiatives that were launched at the level of accreditation systems and quality assurance.[20] One key finding was that the need for these mechanisms was increasing, but the associated processes should be adapted to the demands of internal development of the organizations and the external national regulatory system. It was also identified that accreditation was the most widely used mechanism in terms of quality improvement compared with other models, for example, the certification according to ISO 9001, peer review, or the EFQM model.[17,18,20]

However, the recognition of the added value of quality improvement systems, which appeared late in the healthcare sector compared with other sectors, gained new 'momentum' when it finally associated with patient safety. In a report by the

IoM, produced to identify the components of the quality of care for the twenty-first century, key issues included the premises that healthcare should be delivered in a safe, effective, patient-centred, efficient, timely, and equitable manner. More, it was established that safety must be a 'cornerstone' in which quality of care should be built.[21]

The worldwide interest and public pressure developed around the concept of 'patient safety' and 'quality' and their link to 'HAIs' are today obvious and there are many healthcare organizations which have developed and proposed recommendations to improve the quality of healthcare. At the health systems level, we must highlight the work done by WHO, CDC, the OECD, and the Council of Europe to promote policies and strategies which may contribute to tackle the challenges of patient safety.[22–33]

It is also relevant to note that the implementation of these recommendations at international level have been made through the development of several projects (Table 1) with the participation of several countries in a joint effort to promote an integrated approach to quality of care, patient safety, and prevention and control of HAIs.

However, we need to pose the question of how can quality management systems contribute to patient safety through the promotion of HAIs prevention and control systems?

The concept of quality in healthcare, although strongly connected to the concepts of 'results' and 'outcomes', need not only be considered under this perspective. As argued by Donabedian, quality in healthcare can also be analysed from the perspective of structures, processes, as well as outcomes, and their 'measurement and evaluation' may encompass all three simultaneously.[34] This approach, however, need not be applied only to the measurement and evaluation, but to the whole delivery process, including design, planning, and production/delivery of product/service. According to the actual requirements for healthcare providing services it is expected that the logic of the PDCA cycle (Plan-Do-Check-Act) is adapted to ensure continuous quality improvement.

To further clarify this point, one can shortly mention several studies published in international literature arguing that quality health outcomes are achieved only with proper dedicated management structures, processes, and results.

Among them we note the relevance given to quality tools developed to promote the patient safety and control of HAIs. Already in the Eighteenth century, through the work of Florence Nightingale it became clear that organizational factors related to quality management (systematization, analysis of processes and their optimization, statistical process control, among others) were conditioning factors for the improvement in infection control in military hospitals.[35] In a more recent work published by the CDC about the efficacy/effectiveness and benefits of the implementation of infection control programs it is mentioned, as an example, how JCAHO introduced in 1976 a surveillance program and infection control in their hospitals accreditation program to promote the quality management and continuous quality improvement.[36]

In another study by Liyanage and Egdu about the appropriateness of facilities management in the prevention and control of HAIs, it is suggested that health professionals in general, see HAIs as a purely clinical problem, not giving much importance to other factors such as facilities/knowledge/performance management covering all organizational areas. According to these authors the quality management systems could function as an 'integrator' of different organizational factors in infection control.[37,38]

The Council of Europe has, in its recommendation (Rec/2006--2007) on patient safety, highlighted the importance of implementing a management systems approach in the design and development of safe structures and processes that ensure the appropriate patient management in terms of safety and prevention of adverse effects in the provision of healthcare.[24]

In a systematic literature review conducted by Stone *et al.* on the relationship between HAIs and variables related to 'nursing professionals' and 'structures', the authors found no evidence to assign the decrease in the risk of HAIs to the nurse in itself, but managed to assemble the following: (i) to identify a relationship between the use of permanent full-time nurses vs. the use of rotating nurses in an increased risk of HAIs and (ii) to verify the importance of interdisciplinary teamwork, communication channels established to ensure effective communication, and training in risk associated with HAIs.[39]

In another study by Griffiths *et al.* carried out in order to determine the impact of organizational factors and management in the control of HAIs (such as clinical management, leadership, human resources policy, and clinical governance, among others), a set of risks to the success of programs were identified and highlighted poor leadership, lack of clear definitions of management, and lack of defined responsibilities and appropriate measures for infection control.[40]

Table 1: International projects to promote quality improvement, patient safety and prevention and control of HAIs

Year	Project	Area	Organization	Aim
1985	IQIP	Q	Maryland Hospital Association, USA	The Quality Indicator Project (QIP), now transform in a international project kowned by International Quality Indicator Project (IQIP) was created in the USA to help member hospitals to identify opportunities for quality improvement in patient care. Now is an international project
1990	COMAC/HSR/QA	Q	EU	COMAC/HSR/QA -- Evaluation of quality strategies in hospitals that took place in 1990--1997 in 15 European countries
1996	EXPERT	Q	EU	The Project External Peer Review Techniques (EXPERT) was carried out between 1996--1999 to assess the development and implementation of peer reviews developde in quality models used in the European Union Hospitals: ISO, EFQM, accreditation systems
1997	HELICS	HAIs	ECDC	The project Hospital in Europe Link for Infection Control through Surveillance (HELICS) had two phases: the first phase (1997) aimed to lay the practical foundations for a European Network on hospital acquired infections and the second phase aimed to create a robust and validated surveillance system and establish reference data sets. The HELICS 2 implementation report was presented in 2005, and the surveillance network continued to operate through the 'Improving Patient Safety in Europe' (IPSE)
2002	HCQI -- Health Care Quality Indicators	Q-PS	OECD	The OECD Health Care Quality Indicators project, started in 2002, aims to measure and compare the quality of health service provision in the different countries. An Expert Group has developed a set of quality indicators at the health systems level, which allows to assess the impact of particular factors on the quality of health services
2003	*ENQual*	Q	EU	The ENQual network is a collaboration network of research experts in Quality assessment and Quality Management in European countries supported by the European Commission. The aim of the network is to facilitate the exchange of knowledge and expertise among European countries.The network concentrates in to areas, Quality Policy and Quality Management and has the ambition to prepare an EU research proposal to compare Quality Management within the European countries
2003	PATH	Q	WHO	The Performance Assessment Tool for Quality Improvement in Hospitals (PATH) was initiated by the WHO Regional Office for Europe in 2003. The PATH system was created by a group of international experts based on an extensive literature review and a survey of the importance, usefulness and data availability of potential indicators in 20 European countries. In the PATH II, 140 hospitals from 9 different countries committed themselves to change for improvement, collected data on 17 indicators and shared experience with other hospitals

Q – Quality; PS – Patient Safety; HAIs – Healthcare-associated infections

Continued

Table 1: *Continued*

Year	Project	Area	Organization	Aim
2003	PSI – Patient Safety Indicators	PS	AHRQ	The Patient Safety Indicators (PSIs) are a set of indicators providing information on potential in hospital complications and adverse events following surgeries, procedures, and childbirth. The PSIs were developed after a comprehensive literature review, analysis of ICD-9-CM codes, review by a clinician panel, implementation of risk adjustment, and empirical analyses
2005	IPSE – Improving Patient safety in Europe	PS	ECDC	In 2005 was created the project Improving Patient Safety in Europe (IPSE), which supports the surveillance and control of HAI's. The IPSE aggregates within the HELICS project
2005	First Patient Safety Challenge: Clean Care is Safer Care	HAIs	WHO	Project launched in 2005 as one of priorities from the Global Patient Safety Challenge from WHO with the aim to reduce HAIs. In this challenge, the main objective is to promote hand hygiene at all levels of health care
2005	MARQuIS	Q	EU	The objective of the Methods of assessment Response to Quality Improvement Strategies (MARQuIS) project was to identify and compare different quality improvement policies and strategies in health care systems across the member states of the European Union, and to consider their potential use when patients cross borders to receive health care. The project was closed in 2007
2005	SIMPATIE	PS	EU	The objective of the project Safety and improvement for patient in Europe (SIMPATIE) was to use Europe-wide networks of organizations, experts, professionals and other stakeholders to establish a common European set of vocabulary, indicators, internal and external instruments for improvement of safety in health care. The project was closed in 2007
2005	Europe4Patients	PS	EU	The campaign highlights a series of different healthcare and patient related policy initiatives of the Commission.The aim is to provide a simple entry-point to the often complex world of EU healthcare policies and actions
2006	TRICE	HAIs	ECDC	The Project Training Infection Control in Europe (TRICE) was developed by the ECDC in order to update the study conducted in the past on education and training of professionals about HAI's prevention and control (IPSE-Improving patient safety in Europe).The project was closed in 2010
2006	EUInfoPas	PS	EU	The project EUInfoPas – The Euorpean Information system on patient safety was developed to encourage and support Member States in establishing effective patient safety reporting and learning systems; to pave the way in time for EU wide collation analysis and sharing of information on patient safety problems drawn from national patient safety reporting systems
2007	MOSAR	HAIs	EU	The project Mastering hospital antimicrobial resistance and its spread into the community (MOSAR), funded FP6-LIFESCIHEALTH, aims to gain breakthrough knowledge in the dynamics of transmission of antimicrobial-resistant bacteria (AMRB), which account for an increasing number of HAI that are subsequently spreading into the community

Q – Quality; PS – Patient Safety; HAIs – Healthcare-associated infections *Continued*

Table 1: *Continued*

Year	Project	Area	Organization	Aim
2008	DEBUGIT	PS	EU	The project Detecting and eliminating bacteria using information technologies (DEBUGIT) focuses on risk assessment and patient safety and aims to develop a Medical Knowledge Repository, drawing on information and temporal patterns of patient harm provided through a virtualized Clinical Data Repository (open framework, focused on infectious diseases)
2008	TROCAR	HAIs	EU	The project Translation Research On Combating Antimicrobial Resistance (TROCAR), funded FP7-HEALTH) aims to investigate the fundamentals of the epidemiology of new highly virulent multi-resistant strains and recommend comprehensive control measures to limit or prevent the spread of highly virulent multidrugresistant clones
2008	Second Patient Safety Challenge: Safe Surgery saves lives	PS	WHO	The goal of the project Safe Surgery Saves Lives from the Second Patient Safety Challenge from WHO is to improve the safety of surgical care around the world by ensuring adherence to proven standards of care in all countries. The Second Global Patient Safety Challenge aims to foster improved surgical safety and to reduce deaths and complications during surgery
2009	Core Componentes for infection prevention and control programmes	HAIs	WHO	The aim of this work was to identify infection prevention and control (IPC) core components for national programmes and for the programmes of local health-care facilities, in order to contribute to the strengthening of capacity for the prevention of health care-associated infections (HAI) and to prepare an efficient response to emergencies involving communicable diseases, such as epidemics
2009	PILGRIM	HAIs	EU	The project Preventing community and nosocomial spread and infection with MRSA ST 398 -- instruments for accelerated control and integrated risk management of antimicrobial resistance, funded FP7-HEALTH, aims to provide deeper understanding of factors affecting pathogen-host interaction of resistant bacteria (MRSA ST398 -- an animal-adapted, zoonotic, resistant pathogen that causes colonization and infection in humans in community and health-care settings) and subsequent novel and more effective measures for the accelerated identification and control of resistant bacteria, in order to prevent and eradicate community-acquired and nosocomial infections
2009	DUQuE	Q	EU	The main goal of the project Deepening our Understanding in Quality Improvement in Europe (DUQuE) project is to study the effectiveness of quality improvement systems in European hospitals. This will be done by assessing the relationship of organisational quality improvement systems/management and culture, professionals' involvement, and patient empowerment with the quality of hospital care (including clinical effectiveness, patient safety and patient involvement)

Q – Quality; PS – Patient Safety; HAIs – Healthcare-associated infections *Continued*

Table 1: *Continued*

Year	Project	Area	Organization	Aim
2010	PROHIBIT	HAIs	EU	The aim of the project Prevention of Hospital Infections by Intervention and Training (PROHIBIT) is to understand existing guidelines and practices to prevent healthcare associated infections in European hospitals, identify factors that enable and reduce compliance with best practices, and test the effectiveness of interventions of known efficacy. The information will be synthesized to develop recommendations for the EU, policy makers, managers and medical professionals
2010	QUASER	HAIs	EU	The aim of project Quality and Safety in European Union Hospitals (QUASER) is the identification of cultural and organizational characteristics related to effectiveness and safety / patient experience in health care services. also aims to identify the qualitative and quantitative indicators used to date
2010	ORCAB	Q-PS	EU	The aim of the project "Improving quality and safety in the hospital: The link between organisational culture, burnout, and quality of care (ORCAB)" is to benchmarking the organisational factors that impact on health professionals well being, quality of hospital care and patient safety. It also aims at designing bottom-up interventions in order to improve patient safety and quality of hospital care
2010	BURDEN	HAIs	EU	The project Burden of Disease and Resistance in European Nations (BURDEN) funded DG SANCO was established to understand the dimensions of the economic and societal consequences of Antimicrobial Resistance (AMR). It worked on identifying information needs, determining the excess morbidity, mortality and costs attributable to AMR in hospitals and ICUs in different European countries, including a forecast of AMR based on data available through HELICS/IPSE
2011	HAI-Net	HAIs	ECDC	The main priorities of the project Healthcare-associated Infections Surveillance Network (HAI-Net) are the coordination of the European point prevalence survey of HAI and antimicrobial use in acute care hospitals, the European surveillance of surgical site infections, the European surveillance of HAI in intensive care units and the repeated prevalence surveys of HAI and antimicrobial use in European long-term care facilities

Q – Quality; PS – Patient Safety; HAIs – Healthcare-associated infections

In yet another study by Makai *et al.* about quality management models implemented in Hungarian hospitals and their effect on patient safety (supported by the ENQual project, see Table 1), it was concluded that there was a statistically significant relationship between the level of development of quality management systems in hospitals and the number of activities for patient safety. The authors also emphasized that, according to the data presented, the strategies for quality-management systems developed in the past did not guarantee the high level expected for patient safety, requiring the implementation of additional measures in the existing management models.[41]

In the study presented by Spencer and Walshe about the policies and strategies developed for quality improvement in European health systems (supported by the MARQuIS project, see Table 1), it was found that the main objectives and values identified by respondents were standards and guidelines development, promotion and integration of patient safety, promotion of systems for measuring/assessing and improving information systems, and registration. One of the main factors identified as responsible for the greatest impact in promoting quality improvement in health systems was the development and implementation of quality accreditation and certification systems.[42]

The authors Shaw *et al.* (2009) in their study about the quality and safety systems and their support structures (also based on the MARQuIS project, see Table 1) concluded that the organization and professional management were the determinant keys of quality systems in hospitals. The authors suggest the need for better definition of organizational services.[43]

In the 2009 recommendation of 6 September 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01) by the Council of Europe were defined lines of action towards the promotion of patient safety and control of HAIs, among which we highlight the use of indicators of structure, process, and results as well as the implementation of systems of accreditation/certification.[30]

In 2010, and following the previous Council of Europe's recommendation, the European Center for Disease Prevention and Control (ECDC) presented a report, written by experts on prevention and control of HAIs which suggested the five components of existing programs, identified as the most effective in the HAIs prevention and control were: (i) development of organizational structures that include management support, prevention, objectives, action plans, and multi-disciplinary committees (quality, safety, infection control), (ii) monitoring methods, detection of outbreaks and its management, goals achievement, (iii) training programs and education for professionals, (iv) behavioural change and quality of interventions, and (v) the local policies and provision of resources for the introduction of standard precautions and others. This report also suggests that it would be more appropriate to adapt and improve programs and practices, taking into account the recommendations presented than to elaborate new ones. For this purpose, the report also refers to the importance that the EU project 'Prevention of Hospital Infections by Intervention and Training (ProHIBit)' starting in 2010 could have on the recommendations of best practices to adapt for the prevention and infection control programs.[32]

In the work done by Shaw and co-workers,[44] based on the MARQuIS project (see Table 1) developed in European hospitals between 2005 and 2007 in order to evaluate different strategies to improve quality and its impact on healthcare in terms of effectiveness and safety, it was argued that the highest levels of patient safety in hospitals were associated with accreditation/certification systems, with significant differences from hospitals that had not presented any of these systems.[45]

Hence, Groene *et al.* presented a descriptive study about the DUQuE project (see Table 1), taking place from 2009 to 2013 and explored, in order to study to what extent the improvement of the quality of organizational systems, culture, involvement of professionals, and empowerment of patients is related to the quality of hospital care, measured in clinical effectiveness, safety, and patient-centred dimensions. In this project, and in order to answer questions like 'what is the most effective tool of quality in healthcare?' the authors identified two key objectives to the project development: (i) research about associations between the maturity of the quality improvement systems and clinical effectiveness and safety/patient involvement and (ii) identify factors that enhance the activities of quality improvement in hospitals, as well as external pressure imposed by accreditation, certification, and any external program evaluation.[46]

For future developments

There is a global interest in developing an integrated approach to healthcare quality management, patient safety' and control of HAIs. The availability of relevant and diverse research contributes to health policies, strategies, and their implementation. Several studies demonstrate the relevance of the

implementation of quality tools in improving the quality of performance and consequently on patient safety. Other studies demonstrate the importance of quality management tools in the control of HAIs and, as a consequence, on patient safety. Recent and current projects to analyse the effectiveness of these tools in clinical effectiveness and patient safety, also allow us to expect new important developments in the knowledge available for healthcare managers.

We expect future studies and research to identify the impact of quality management systems (accreditation and certifications systems) on patient safety, focused in the prevention and control of HAIs. We also expect further applied research considering the Donabedian model – structures, processes, and results – with an integrated management approach and taking into account the improvement of these models/mechanisms in order to ensure the continuous quality improvement of healthcare systems. These are emergent and urgent areas of knowledge development for contemporary healthcare management.

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ANNEXE II – Article "Healthcare-associated infections: on developing effective control systems under a renewed healthcare management debate"

Healthcare-associated infections – on developing effective control systems under a renewed healthcare management debate

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Abstract

Purpose: The development of control systems to sustain the level of healthcare-associated infections (HAIs) is an emerging issue for healthcare management. This is partly due to the perception that HAI became a serious negative impact factor on the performance of healthcare organizations and on related public health dimensions. Throughout the decade of 1990 a significant number of international programmes were developed to understand and to promote effective HAIs prevention and control systems: Patient Safety and the quality improvement of healthcare organizations became common concepts in healthcare management. However, regardless of advances in infection control systems, the rates of incidence of HAIs remained relatively unchanged in the last decades. The purpose of this study is to point out barriers that recent international literature has identified as factors hindering the successful development of control systems to prevent HAIs. The international debate on possible alternatives to strengthen this common healthcare management issue, benefits form one such update.
Methods: A literature review was conducted in a 3-month period by two investigators. The BioMed Central, Pubmed, Emerald, and B-on databases were searched for articles published between January 2006 and September 2011. A standard form was created for data extraction.
Findings: A total of 49 articles met inclusion criteria. Within the analysed articles, 26 were developed in Europe, 15 were developed in North America; 6 were developed in Asia, and 2 in Australia. Thirty (30) different barriers to effective HAIs control systems were identified. The barriers were clustered by dimensions and sub-dimensions. The largest number of barriers clustered, are associated with structures and processes and also barriers associated with healthcare management processes.

Keywords: Healthcare-associated infections, Control systems, Healthcare management, International review

Background

Concerns on healthcare-associated infections (HAI) are not a recent healthcare management issue. The work of Florence Nightingale already indicated that, in the nineteenth century, there was awareness of the need to control infections in military hospitals.[1] And of the fact that infections were a leading cause of death in hospitals lacking control and due to, among other factors, a lack of knowledge on the mechanisms of transmission which began to be identified at the end of the nineteenth century.[2,3] A structured approach to this problem promoted the adoption of methods of basic hygiene, along with the use of antiseptics during surgery, thus, originating the first hospital infection control systems. This problem, however, has become more distinct in its true dimension at the end of the twentieth century, and is now one of the major healthcare management challenges worldwide. A number of factors determined the increasing relevance of the issue in the past three decades: more patients are more susceptible to infections, increase of invasive procedures and related higher risks of infection, mixed populations of patients within the hospital environment promoting the risk of crossing transmission, increase of microbial resistance, inadequate methods of cleaning and hygiene, lack in healthcare management leadership to implement control systems, and

reduced commitment of top management to tackle the problem of hospital infections.[4,5]

We can argue that the year 2000 is a key moment in the recent history of health systems as the problem of HAIs acquired the status of being an emerging issue for healthcare management due to negative impact on performance of healthcare organizations, specifically in three dimensions of the *performance assessment tool for quality improvement in hospitals* (PATH): clinical effectiveness, safety, and patient-centeredness.[6,7] The dimension of 'patient safety' became a prominent issue in a report published in 2000 by the Institute of Medicine (IOM), entitled 'To err is human: building a safer health system', in which the international health management community became aware of shocking numbers of harm associated with medical errors and adverse events from related practice in healthcare organisations. It was also verified that the error rate in healthcare was higher than the error rate observed in others risk sectors (e.g. aviation) but the risk management systems were much more primitive than others developed for others risk sectors.[6–8]

In 2001, the Agency for Healthcare Research and Quality (AHRQ) initiated a large study on Healthcare practice and patient safety. Through a comprehensive analysis of literature and 'experts' opinion 79 types of practice were not only identified mostly related to inpatient setting but also including outpatient setting. Among various risk factors identified, the report highlighted some main problems related to incidents reporting, organizational issues on quality/safety (i.e. legislation, accreditation, market regulation requirements, professional regulation, and healthcare professionals' compliance levels), infection control systems and policies (i.e. surveillance systems at all levels and healthcare practice) and healthcare management systems (i.e. leadership, top management commitment, and team management) amongst the main areas identified.[9,10] Subsequently to this large study, new recommendations for hospital infection control systems were developed, especially aimed at healthcare professionals behaviour-related factors, as well as related to management of hospital structures (i.e. environmental and resources usage) and also aimed at reviewing clinical and healthcare management processes.[10–23]

In essence, as we presented in previous research, there have been a significant number of international programmes developed to understand and to promote the HAIs prevention and control systems and, consequently, improve patient safety and quality improvement of healthcare organizations.[24] In line with advances in implementing infection control systems, we assume that it is relevant to identify and discuss the constraints for the success of HAIs prevention and control systems. To contribute to this focussed debate, we developed a literature review aimed at producing an international update on barriers identified in recent published research.

Methods

Search strategy

The BioMed Central, Pubmed, Emerald, and B-on databases were searched for articles published from 2006 to September 2011 within a set of inclusion and exclusion criteria (Table 1).

A number of titles and abstracts were retrieved for each term and evaluated for relevance. From the relevant abstracts another set of free-text keywords were retrieved to focus the analysis. After selecting the relevant terms (7) and free-text keywords (12) it was then performed a universal search in the databases followed by retrieval of relevant articles, based on the title and abstract (Table 2).

Using a combination of at least one of these headings/terms and one of the free-text keywords as

Table 1: Inclusion and exclusion criteria

Inclusion criteria
(a) Contain abstract;
(b) Be published and available in a journal in public domain;
(c) Address an issue related to HAIs Prevention and Control Systems in hospitals;
(d) Contain a description about HAIs issue study;
(e) Contain a description of the barriers or constraints to prevention and control of HAIs;
(f) Discuss HAI's control systems relevant results about structures (resources, environmental conditions, organizational culture/values), process (clinical processes – best practices, therapy process, and management processes) and results (data, data quality, report);
(g) Contain quantitative data about at least one dimension of Healthcare-associated infection: Patient safety, infection type, hospital characterization (including dimension, structure, resource utilization, planning issues), management issues (programs/methodologies to control infection), communication issues (tools channels, processes, data available) and others;
(h) Have been published between January 2006 and September 2011
Exclusion criteria
(a) Articles not related with healthcare issues
(b) Articles analysing care processes
(c) Non Developed or Developing Countries
(d) Projects with main purpose of financial improvement
(e) Articles analysing change in software and/or hardware and Information Technology;
(f) Articles with description of methods, models and theories without empirical data.

Table 2: MeSH (headings), terms related and free-text keywords.

MeSH
Healthcare-associated infections
Healthcare-acquired infections
Nosocomial infection
Cross infection (MeSH)
Catheter-related infection (MeSH)
Hospital infection
Infection control (MeSH)
Free-text keywords
Prevention
Control
Best practices
Antimicrobial resistance
Surveillance
Hospitals
Patient safety
Barriers
Constraints
Programmes/tools
Standards

well as the inclusion criteria 'publication period', we identified 878 articles from Pubmed, 307 from BioMed Central, 281 from B-on, and 108 from Emerald. After this initial selection all the other inclusion/exclusion criteria were applied and the number of articles to be analysed was reduced to 74 articles from Pubmed, 46 from BioMed Central, 74 from B-on, and 14 from Emerald. Two reviewers independently scanned and evaluated all articles for consideration, and together decided whether or not to obtain the full text article. After this analysis a selection of 49 articles met all the inclusion criteria (see Fig. 1). Full publications of all selected abstracts or articles were obtained (electronic/printed form). All the articles were in English language.

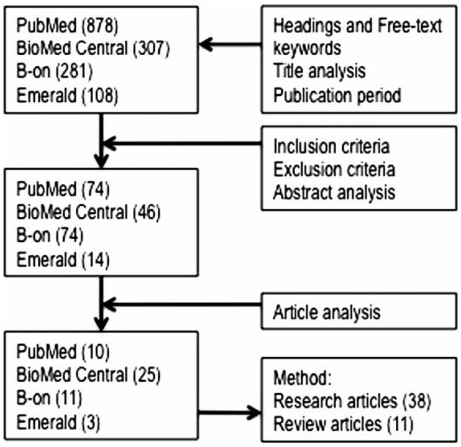

Figure 1: Search strategy.

Data collection and content analysis

A standard form was created for data extraction in Excel with the following labels:

- country or region;
- publication year;
- method
- study setting (hospitals, teaching hospitals, military hospitals, wards hospitals, and intensive unit care hospitals);
- barrier dimension/sub-dimension
- study objective
- key points;
- summary;
- barriers identified.

Table 3 summarizes data extraction results. A total of 38 articles were research studies and 11 were reviews. Of the articles identified, 25 were developed in Europe, 16 in North America; 6 in Asia, and 2 in Australia. One of the studies analysed more than one country (Switzerland and Germany). More than one study reported more than one country information. More than one article identified more than one barrier to HAIs control systems.

Results

From the literature review performed, we were able to identify a set of barriers to the success of HAIs' prevention and control programmes (see Table 4). These barriers were clustered in the three dimensions (structure, processes, and results), based in the Donabedian Triology developed to evaluate quality of care.[25,26] We assume that a healthcare organization is framed in an external context, divided into *macro context* (indirectly related with the organization, such as legislation/regulation, society, and others) and a *micro-context* (directly related with the organization, including suppliers, patients, patients' families, and others). Any analysis of an healthcare organization can be divided in answering to concrete questions such as 'Who we are…', and this includes 'structures' and its four sub-dimensions (infrastructures, resources, environmental conditions, and cultures/values), 'How we do…' being the 'processes' and its two dimensions (clinical processes and management processes), and 'What we get…' as results, divided in two sub-dimensions (data and reporting/communication) (Fig. 2). In this study we only analyse organizational barriers in relation to HAIs.

On the basis of this modelled approach we identified a number of barriers from the literature review undertaken. Below, the dimension and

Table 3: Data extraction results.

Country/region		Method	
Australia	2	Research article (38)	
Canada	1	Prospective study	23
Finland	1	Retrospective study	5
France	2	Modelling study	8
Germany	2	General research	2
Hong Kong	1	Review article (11)	
Italy	4	General review	7
Japan	4	Systematic literature review	4
The Netherlands	1		
Portugal	1	*Barriers per dimension/sub-dimension*	
South Korea	1	Structure (13)	
Switzerland	2	Infrastructures	3
Spain	2	Resources	7
UK	11	Environmental conditions	2
USA	15	Culture and values	1
		Process (14)	
Settings (Hospitals)		Clinical processes	7
Community hospitals	47	Management processes	7
Teaching hospitals	1	Results (3)	
Military hospitals	1	Data	2
		Reporting/communication	1

sub-dimension identified are presented with additional information concerning the published articles in which each set of barriers were identified (Table 4).

Discussion

A total of 49 articles met the inclusion criteria defined for the literature review performed. From these articles it was possible to identify 30 barriers, clustered by dimension/sub-dimension. A detailed analysis of the table shows barriers associated with structures and processes represent the bulk of barriers to implementing control systems to prevent HAIs followed by barriers associated with processes.

On the 'structures' there are the barriers related to infrastructures (hospital size and hospital level) and to resources, mainly associated with lack of health professionals -- especially nurses -- dedicated on a full-time basis to HAIs prevention and control programmes, as recommended internationally.[16,27] The barrier most identified in the largest number of articles pertains to 'environmental contaminations'. It was given the relevance of this barrier in the HAIs prevention and control, that CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) launched in 2003 and in 2008, respectively, a set of recommendations for Environmental Infection Control, Disinfection and Sterilization of Healthcare Facilities. Among the related recommendations it stands out, among other factors, the importance of the involvement of health professionals associated with the infection control programme at all stages of development of infrastructure/environment, as well as identification/risk assessment and related construction barriers. These organizations suggest the creation of multidisciplinary teams constituted by both those responsible for infrastructure and health professionals to maximize the effectiveness of infection control programmes.[13,28] Interestingly, the work carried out by Liyanage and Edgu[2] went further arguing for integrated management of infrastructure at the level of environmental contamination and clinical practice in order to better integrate processes and practices undertaken by both clinical and nonclinical activities in interventions for HAIs prevention and control. Also related to the 'structure' dimension a study commissioned in 2001 by the AHRQ on safe practice presents 'organizational culture' as key to improving patient safety. Other authors also argue that medical practice must also take into account the issues related to structures -- culture and values to improve the overall quality of healthcare.[29,30]

The review performed allows us to state organizational processes are the source of the largest diversity of barriers to successfully implement effective HAIs prevention and control programmes. On the 'clinical processes' sub-dimension, the barrier 'poor infection control practices' is a key point. This barrier encompasses a range of factors highlighted in the literature reviewed as being primarily responsible for the difficulty of the HAIs control

Table 4: Barriers identified in the studies.

Dimension	Sub-dimension	Barrier identified	Study*
Structures 'Who we are'	Infrastructures	Hospital level (type of ward, size, and type of services)	(2), (5), (22), (45)
		Structure limitations for isolation precautions	(30)
		Overcrowding wards	(8), (17)
	Resources	Under-resourced infection prevention programmes (budget, staff, etc.)	(3), (4), (38)
		Accessibility to hand-hygiene resources	(5), (17), (30), (35)
		Costs (implementation programmes, resources)	(11), (35)
		Temporary nursing staff and reduced number of FTE (fulltime equivalent) associated to infection control (less than the recommended standard)	(17), (19), (20), (35), (41)
		Time consumed by the surveillance programmes	(25)
		Home laundering instead of industrial laundering	(48)
		Workload (healthcare workers)	(5), (8)
	Environmental conditions	Environmental contamination (air, surfaces, floor, bed linen, and others)	(1), (6), (7), (8), (12), (17), (23), (30), (32)
		Clothes contamination (e.g. white coats)	(46), (48)
	Culture and values	No compliance with infection control culture, policies, and social norms (e.g. wearing uniforms in public spaces, resistance to apply rules/standards in practice -- more doctors than nurses)	(4), (14), (18), (22), (48)
Processes 'How we do'	Clinical processes	Poor infection control practices (guidelines inconsistently implemented, disinfection not appropriately performed on clinical practice, hand hygiene no compliance, insufficient use of protective equipment, lack in understanding the exact mechanism of pathogen transmission)	(1), (7), (8), (9), (11), (12), (13), (14), (17), (20), (22), (23), (31), (32), (36), (39)
		Biological factors, intubation process, blood transfusion, invasive procedures, and treatment duration (long stay in hospital)	(17), (21), (27), (29), (34), (43), (44)
		Risk factors identification	(26)
		Therapy (use of antibiotics, antimicrobial resistance)	(16), (26), (27), (31), (35)
		Reactive practice instead proactive practice	(30)
		HAIs definition (definitions, ICD codes limitations for HAIs classification)	(3), (41)
		Doctors as HAIs vector (link to different wards)	(46), (47)
	Management processes	Awareness, perceived risk, individual attitude, individual behaviour (healthcare professionals)	(5), (13), (22), (36), (39)
		Knowledge, education, and training	(5), (12), (13), (17) (36), (39), (41)
		Lack of information/quality of information (colonized patients in real time, persistence of pathogen agents on inanimate surfaces, swabs, or clinical samples quality in admission and during hospital stay)	(7), (15), (23)

Continued

Table 4: Continued

Dimension	Sub-dimension	Barrier identified	Study*
		Support operations (ward, bed occupancy, patient turnover, teams management and relationship, workload, domestic services, use of resources, and responsibilities definitions)	(1), (5), (8), (18), (19), (24), (28), (30), (35)
		Lack in the assessment/evaluation methods (ethical limitations, business case, cleaning spaces, hand hygiene, and cost-effectiveness analysis)	(3), (11), (12), (18), (22), (43)
		Lack in leadership	(19), (22), (26), (33)
		Lack in the surveillance methods (no standardized methodologies)	(15), (25), (35), (37), (38)
Results 'What we get'	Data	Lack of data (no data, susceptible to error, underestimated infections rates)	(8), (9), (10), (25), (37), (40)
		Data treatment/analysis limitations	(41), (49)
	Reporting/ communication	Lack in the reporting systems (including feedback, report errors)	(2), (10), (26), (35), (41), (42)

*The numbers pointed refer to the articles reviewed (see references in the Appendix).

systems, with emphasis on the noncomplicance of health professionals to hand-hygiene procedures. This behavioural factor has been identified as a key element for HAIs prevention and control and, although it is considered a simple action, the lack of compliance among healthcare providers is still problematic worldwide. The cause of this phenomenon is often associated with structural factors (i.e. workload, type of wards, and accessibility to hand-hygiene resources) and process factors (i.e. knowledge, training, perceived risk, and individual attitude). Aware of this problem, the CDC and the World Health Organization (WHO) developed a range of strategies for hand-hygiene promotion and improvement. For this purpose the WHO proposed the First Global Patient Safety Challenge, 'Clean Care is Safer Care', focusing part of its attention on improving hand-hygiene standards and practices in healthcare along with implementing successful

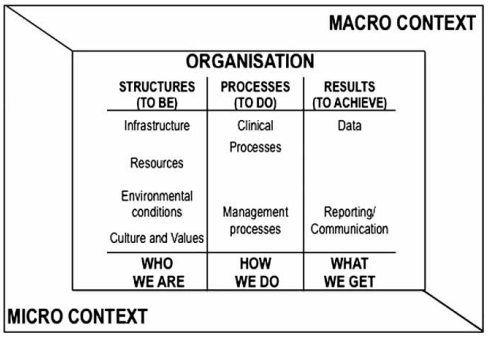

Figure 2: Healthcare organization model.

interventions.[11,31,32] Another important related phenomenon pertains to the poor quality of infection control programmes mirroring the fact that these are designed with no support from scientific evidence and inconsistently implemented including the lack of organisational epidemiologic surveillance programmes. For this reason the WHO developed, in 2009, guidelines on the core components of Infection Prevention and Control Programmes.[16]

Further to this, two other key factors are identified systematically in the international literature reviewed: clinical procedures (such as invasive procedures) and therapy. Related to the former we identified several articles dedicated to the subject. It stands out the analysis made by the AHRQ on patient safety practices. In this work, the interventions undertaken to minimize the effects of invasive procedures in patient safety are analysed in detail.[9] Given the importance of invasive procedures (surgery, invasive devices) in HAIs prevention and control the CDC developed in 2002 (updated in 2011) some guidelines for the prevention of intravascular catheter-associated infections[12,28] and guidelines for disinfection and sterilization in healthcare facilities.[28] The WHO, in 2009, also launched the Second Global Patient Safety Challenge – Safe Surgery Saves Lives.[33,34] On what concerns therapy, it has been argued that this is one of the major concerns worldwide and a large number of articles demonstrate that inadequate therapy, besides being one of the main responsible for HAIs, is also one of the main responsible for antimicrobial resistance, such as MRSA.[4,35–37] To combat the specific problem of therapy control, the CDC,

the WHO, and the European Union have been developing since 2001 a set of recommendations and programmes to assist healthcare organizations in the HAIs prevention and control.[24,38]

Related to 'processes' the literature reviewed allows to add further relevant barriers: 'support operations', 'awareness', 'knowledge', 'surveillance methodologies', 'leadership', 'assessment/evaluation methods', and 'surveillance programmes'. Factors considered to be the causes of failures in these healthcare management activities, include difficulties associated with ward management, healthcare team management, hospital and cleaning services management, role definition, and inadequate use of resources. Some authors also identified poor knowledge management as an important factor hindering organizations' capacity to better integrate processes and practices developed clinical and nonclinical activities, better team management and definition of roles for HAIs prevention and control programmes.[2,39–41] To assist with the resulting healthcare management challenges, as we presented in our previous work related with healthcare management issues, there have been serious developments worldwide to develop and implement programmes and guidelines to promote quality improvements in healthcare, such as accreditation and certification programmes.[24,42–48]

Related to the barriers here defined as 'assessment/evaluation methods' and 'leadership' in healthcare organizations, key international organizations (i.e. WHO, Organisation for Economic Co-operation and Development, Institute for Healthcare Improvement – IHI) have developed recommendations and guidelines to improve the quality of the care delivered.[49–51] Also, the lack of effective 'surveillance methods' is identified in the literature as a key barrier and it has been reported as a problem for HAIs prevention and control due to simple inexistence of any such effort or due to the poor quality of existing surveillance methods and programmes.[52,53] Surveillance programmes are fundamental for HAIs prevention and control systems. Inexistence or inappropriate surveillance systems imply that there will be no information and scientific evidence on the evolution of HAIs and no clear focus on measures to implement. To tackle this problem some international guidelines and programmes were developed to promote the implementation and the quality of organizational surveillance programmes, including those presented in 2009 by the WHO in the 'Core Components for Infection Prevention and Control Programmes' and by the European Union in related Council Recommendations.[16,24,43] On the basis of these recommendations many European countries are currently undertaking surveillance programmes.

Concerning the dimension defined as 'results' three barriers were identified: data quality, data treatment, and reporting/communication. These barriers are clearly related with the lack of effective 'surveillance methods' and related with the absence of reliable epidemiological data. In the USA, a report for 11 states argues that the quality of existing data is often questionable given the difficulties presented by the reporting methodology. Owing to this key healthcare management factor, during the last years a number of networks were established to support and promote the quality of healthcare management data and the quality of data reporting/communication methods.[37] One of the long-term networks dedicated to this purpose is the HELICS project created in 1997 (actually part of the Improving Patient Safety in Europe (IPSE) programme), the EUInfoPas created by the European Union in 2006 (to encourage and support member states in establishing effective patient safety reporting systems) and recently the HAI-Net Project developed at European union level in 2011.[24,37]

Conclusions

A set of healthcare management barriers to the development of effective HAIs prevention and control programmes has been identified in this study. This is a contribution to the international debate on healthcare management approaches to tackle HAIs. This study is a structured update on the key barriers and related recommendations and guidelines developed to overcome difficulties in implementing effective HAIs' prevention and control systems. From the recommendations and guidelines identified, it is clear that a bundle of actions and interventions have been developed both at organizational level and health system level since, at least, 2001. These recommendations and barriers were identified in our previous research that also looked into additional healthcare management issues. Yet, the problem persists. The literature review performed allows to state that it does not seem to be a lack of pertinent recommendations and guidelines and even related solutions to tackle high levels of HAIs. The key problem seems to be on how these are adopted, adapted, developed, implemented, maintained, and evaluated in healthcare organizations. In essence, it is now a problem of effective healthcare management.

The international healthcare management community should be open to critically appraise and

review the approaches adopted to tackle this key contemporary challenge of healthcare organizations.

Further research is needed to explore and clarify why and how failures on effective and sustainable management systems to promote HAIs prevention and control systems are occurring. If it is not due to the lack of pertinent programmes, systems and related organizational options and solutions, it must be due to how these are being implemented.

Appendix

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ANNEXE III – National Framework for HAI Prevention and Control systems, applied to Hospitals.

Table 74 – National framework for HAI prevention and control systems, applied to hospitals - National level.

YEAR	LEGAL/REGULATION FRAMEWORK
1996	*Despacho n.º 242/96, de 05 de Julho do Ministério da Saúde - Gabinete da Ministra: triagem e tratamento de resíduos hospitalares. Diário da República; Ministério da Saúde.*
1999	*Despacho de 14/05/1999 - Criação do Programa Nacional de Controlo da Infecção. Direcção Geral de Saúde; Ministério da Saúde.*
2005	*Despacho nº 23455/2005 de 15/11/2005 - Criação da Comissão para a formulação do Programa Nacional de Prevenção de Infecções Nosocomiais, Diário da República nº 219, 2ª Série: 16012; Ministério da Saúde.*
2006	*Despacho nº 256/2006 de 10/10/2006 - Transferência do Programa Nacional de Prevenção das Infecções Nosocomiais do Instituto Nacional Dr. Ricardo Jorge para a Direcção Geral de Saúde. Gabinete do Ministro da Saúde; Ministério da Saúde.*
2007	*Despacho nº 14178/2007 de 04/07/2007 - Aprovação do Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde. Gabinete do Ministro da Saúde; Ministério da Saúde.*
2007	*Despacho nº 18052/2007 de 14/08/2007 - Reestruturação das Comissões de Controlo de Infecção; Ministério da Saúde.*
2008	*Despacho do Director Geral da Saúde de 19/05/2008 - Reorganização do Grupo Coordenador do Programa Nacional de Control da Infeção. Direcção Geral da Saúde; Ministério da Saúde.*
2008	*Circular Normativa nº 27/DSQC/DSC de 03/01/2008 - Programa Nacional de Prevenção e Controlo das Infecções Associadas aos Cuidados de Saúde: Regulamento interno do grupo coordenador. Direcção Geral da Saúde; Ministério da Saúde.*
2008	*Despacho n.º 20729/2008 de 29/07/2008 - Criação da comissão técnica responsável pelo desenvolvimento, implementação, monitorização e avaliação do Programa Nacional de Prevenção das Resistências aos antimicrobianos; Ministério da Saúde.*
2013	*Despacho n.º 2902/2013 de 22/02/2013 - Atribuições em relação ao Programa de Prevenção e Controlo da Infeções e de Resistência aos Antimicrobianos, Gabinete do Secretário de Estado Adjunto do Ministro da Saúde; Ministério da Saúde.*
2013	*Despacho n.º 3635/2013 de 27/02/2013 - Estabelecimento pelas entidades prestadoras de cuidados de saúde de um plano de ação anual de acordo com a Estratégia Nacional para a Qualidade na Saúde, segundo um modelo definido pelo Departamento da Qualidade na Saúde; Ministério da Saúde.*

Table 75 – National framework for HAI prevention and control systems, applied to hospitals - Regional level.

YEAR	LEGAL/REGULATION FRAMEWORK
2007	*Circular Normativa nº 24/DSQC/DSC de 17/12/2007 - Grupos coordenadores regionais de prevenção e controlo de infecção. Direcção Geral da Saúde; Ministério da Saúde.*

Table 76 – National framework for HAI prevention and control systems, applied to hospitals - Hospital level.

YEAR	LEGAL/REGULATION FRAMEWORK
1979	*Circular Informativa nº6/79 de 09/02/1979 – Infecção hospitalar. Direcção Geral dos Hospitais.*
1988	*Circular Informativa nº 8/86 de 25/03/1986 - Prevenção das Infecções Hospitalares. Lisboa, Direcção Geral dos Hospitais.*
1993	*Circular Normativa nº 4/93 de 10/02/1993 - Necessidade de Institucionalização das Comissões de Controlo da Infecção nos Hospitais. Direcção Geral dos Hospitais.*
1997	*Ofício Circular de nº 01996 da DSPGQ de 5/02/1997: Comissão de Controlo da Infecção: Regulamento-tipo, Direcção Geral de Saúde.*
1999	*Circular Informativa nº 20/GAB/DG de 30/07/1999 - Criação do Programa Nacional de Controlo da Infecção. Direção Geral da Saúde; Ministério da Saúde.*
2007	*Circular Normativa nº 18/DSQC/DSC de 15/10/2007 - Constituição e Operacionalização das Comissões de Controlo da Infecção. Divisão de Serviços da Qualidade Clínica. Direcção Geral de Saúde; Ministério da Saúde.*
2010	*Circular Normativa Nº: 13/DQS/DSD de 14/06/2010 - Orientação de Boa Prática para a Higiene das Mãos nas Unidades de Saúde. Direção Geral de Saúde; Ministério da Saúde.*
2011	*Orientação nº 025/2011 de 28/06/2011 - Utilização de Ampicilina, Amoxicilina e Amoxicilina/Ácido Clavulânico. Resistência aos Antimicrobianos. Departamento da Qualidade na Saúde. Direção Geral de Saúde; Ministério da Saúde.*
2011	*Orientação nº 028/2011 de 15/07/2011. Comissões de Antimicrobianos para serviços prestadores de cuidados do Sistema Nacional de Saúde. Departamento da Qualidade na Saúde, Direção Geral da Saúde; Ministério da Saúde.*
2012	*Orientação nº008/2012 de 04/06/2012 - Reprocessamento em Endoscopia Digestiva. Departamento da Qualidade na Saúde. Direção Geral da Saúde; Ministério da Saúde.*
2012	*Orientação nº 011/2012 de 30/07/2012 - Análise de Incidentes e de Eventos Adversos. Lisboa, Departamento da Qualidade na Saúde. Direção Geral da Saúde; Ministério da Saúde.*
2012	*Norma nº029/2012 de 28/12/2012 - Precauções Básicas do Controlo da Infeção. Departamento da Qualidade na Saúde. Direção Geral da Saúde; Ministério da Saúde.*
2013	*Norma 02/2013 de 12/02/2013 - Cirurgia Segura, Salva Vidas. Departamento da Qualidade na Saúde, Direção Geral da Saúde; Ministério da Saúde.*
2013	*Norma 004/2013 de 21/02/2013 - Vigilância Epidemiológica das Resistências aos Antimicrobianos. Departamento da Qualidade na Saúde. Direção Geral da Saúde; Ministério da Saúde.*

Table 77 - National programmes for HAI prevention and control and AMR prevention systems – National level.

YEAR	NATIONAL PROGRAMMES
2007	*Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde. Direção Geral da Saúde; Ministério da Saúde.*
2009	*Programa Nacional de Prevenção das Resistências aos Antimicrobianos, Departamento da Qualidade na Saúde. Direção Geral da Saúde; Ministério da saúde.*
2013	*Programa de Prevenção e Controlo das Infeções e Resistências aos Antimicrobianos. Departamento da Qualidade na Saúde. Direção Geral de Saúde; Ministério da Saúde.*

Table 78 – Technical recommendations for HAI prevention and control and AMR prevention systems– Hospital level.

YEAR	TECHNICAL RECOMMENDATIONS
2002	*Prevenção de Infecções Adquiridas no Hospital - Guia Prático WHO/CDS/CSR/EPH/2002.12. Programa Nacional de Controlo da Infecção. Direcção Geral da Saúde; Ministério da Saúde.*
2004	*Recomendações para a Prevenção da Infecção do Local Cirúrgico, Instituto Nacional de Saúde Dr. Ricardo Jorge; Ministério da Saúde.*
2004	*Recomendações para a prevenção da infecção do trato urinário. Algaliação de curta duração. Programa Nacional de Controlo da Infecção. Instituto Nacional de Saúde Dr. Ricardo Jorge; Ministério da Saúde.*
2004	*Recomendações para a Prevenção da Infecção Respiratória em Doente Ventilado; Ministério da Saúde.*
2005	*Orientações para a elaboração de um manual para as boas práticas em Bacteriologia. Instituto Nacional de Saúde Dr. Ricardo Jorge; Ministério da Saúde.*
2006	*Recomendações para a Prevenção da Infecção Associada aos Dispositivos Intravasculares; Ministério da Saúde.*
2007	*Recomendações para as precauções de isolamento. Precauções básicas e dependentes das vias de transmissão. Direcção Geral da Saúde; Ministério da Saúde.*
2007	*Plano de intervenção na possibilidade ou suspeita de surto. Programa Nacional de Controlo da Infecção. Instituto Nacional de Saúde Dr; Ricardo Jorge. Ministério da Saúde.*
2007	*Recomendações para o Controlo do Ambiente - Princípios Básicos. Direcção Geral da Saúde; Ministério da Saúde.*
2007	*Higienização do Ambiente nas Unidades de Saúde - Recomendações de Boa Prática. Direcção Geral da Saúde; Ministério da Saúde.*
2008	*Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde: Manual de Operacionalização; Direcção Geral da Saúde. Ministério da Saúde.*
2009	*Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde. Vigilância Epidemiológica das Infecções Associadas aos Cuidados de Saúde. Critérios para a Definição de Infecções nos Cuidados de Saúde de Agudos. Programa Nacional de Controlo da Infecção. Direção Geral de Saúde; Ministério da Saúde.*
2009	*Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde. Inquérito de Prevalência de Infecção. Protocolo Programa Nacional de Controlo da infecção. Departamento da Qualidade na Saúde - Direcção Geral da Saúde; Ministério da Saúde.*

Table 79 – Reports from HAI prevention and control and AMR prevention systems – National level

YEAR	REPORTS
2005	*Relatório - Inquérito de Prevalência da Infecção 2003. Estudo Nacional de Prevalência de Infecção Nosocomial. Direcção Geral de Saúde; Ministério da Saúde.*
2009	*Inquérito Nacional de Prevalência de Infecção - Relatório. Departamento da Qualidade na Saúde - Direcção Geral da Saúde; Ministério da Saúde.*
2011	*Relatório IGAS nº280/2011 - Avaliação da Implementação do Programa Nacional de Prevenção e Controlo da Infecção Associada aos Cuidados de Saúde nas Unidades de Saúde Públicas e Privadas, com Internamento. Inspeção-Geral das Atividades de Saúde.*
2011	*Relatório Departamento da Qualidade na Saúde. Campanha Nacional de Higiene das Mãos 2010-2011. Departamento da Qualidade na Saúde. Direção Geral de Saúde; Ministério da Saúde.*
2011	*Relatório - Inquérito de Prevalência de Infecção 2010. Departamento da Qualidade em Saúde - Direcção Geral de Saúde; Ministério da Saúde.*
2013	*Relatório de Prevalência de Infeção Adquirida no Hospital e do Uso e Antimicrobianos nos Hospitais Portugueses 2012. Departamento da Qualidade em Saúde - Direção Geral da Saúde; Ministério da Saúde.*

ANNEXE IV – Interview guidelines

In this section will be presented two versions of the interview guidelines used in the interviews,

- Portuguese version (Original and used during the interview process);
- English version (This is a translated version, without validation).

Interview guidelines – Portuguese version

As perguntas que se seguem têm como principal objetivo identificar a perceção em relação:

- *Às ferramentas de gestão/melhoria da qualidade existentes (ou não) na organização e sua interação como o sistema de prevenção e controlo da infeção;*
- *Ao processo desenvolvimento e implementação do sistema de prevenção e controlo da infeção na organização;*
- *À "cadeia de valor" do processo de implementação de uma norma/regulamento associado ao sistema de prevenção e controlo da infeção;*
- *Barreiras existentes no processo organizacional.*

Processos/serviços organizacionais - interação com Sistema de Prevenção e Controlo da Infeção

1 – Qual é o seu papel no sistema de prevenção e controlo da infeção?

2 – Como é que o seu serviço interage com o sistema de prevenção e controlo da infeção?

3 – Como perceciona a relação entre "clínico-gestor"?

4 – Como perceciona a relação "gestão de topo – serviço/departamento"?

Processos de acreditação/certificação – Interação com Sistema de Prevenção e Controlo da Infeção

5 – Há interação (documentação, processos, sistemas de monitorização e avaliação, outros) entre os sistemas de acreditação e o sistema de prevenção e controlo da infeção implementado segundo a regulamentação nacional (quando aplicável)?

6 – A existência da acreditação hospitalar traz alguma vantagem/desvantagem para o sistema de prevenção e controlo da infeção que deverá cumprir com a regulamentação nacional?

Outras ferramentas/metodologias de gestão

7 – Qual(ais) o(s) sistema(s) de monitorização e avaliação que se encontra(m) implementado(s)? Qual o âmbito?

8 – O Hospital procede à avaliação do risco associado ao sistema de prevenção e controlo da infeção implementado? Se sim qual(ais) as ferramentas/metodologias utilizadas?

9 – O Hospital utiliza mais alguma ferramenta/metodologia de gestão para apoiar o sistema de prevenção e controlo da infeção implementado segundo a regulamentação nacional? Se sim qual(ais) as ferramenta(s)/metodologia(s) utilizada(s)? (por exemplo: diagramas de causa-efeito, histogramas, brainstorming, planos, árvore de decisão, PDCA, cartas de controlo, checklist, ...)

10 – A aplicação das ferramentas/metodologias de gestão apresentadas traz alguma vantagem/ desvantagem para o sistema de prevenção e controlo de infeção implementado segundo a regulamentação nacional?

Sistema de Prevenção e Controlo da Infeção

11 – Como está estabelecido o processo de implementação/adoção de normas associadas ao sistema de prevenção e controlo da infeção na sua organização? (onde entram na organização e depois qual a "cadeia de valor" desde que há a tomada de consciência até que fica devidamente implementada e é operacionalizada? (Sugestões: Descreva o processo de implementação/adoção de uma norma/legislação/regulamentação, desde o momento em que dá "entrada" na organização, passando pelo planeamento da sua adaptação/adequação (quem, onde, quando, como, com quê), e pela implementação no terreno (quem, onde, quando, como, com quê) e posterior a avaliação (quem, onde, quando, como, com quê)).

12 – Como acha que deveria ser o processo de implementação/adoção de normas associadas ao sistema de prevenção e controlo da infeção na sua organização?

13 – Como é efetuada a avaliação do sistema de prevenção e controlo da infeção? Quais as entidades que procedem à avaliação (internas e externas)?

14 – Quais são as prioridades do sistema de controlo da prevenção instalado?

15 – Quais as principais barreiras identificadas na sua implementação e operacionalização?

16 – Como "vê" a interação entre o sistema de prevenção e controlo da infeção e os serviços/departamentos do hospital? (aceitam as sugestões e implementam, fazem feedback de informação dos serviços para o controlo da infeção e vice-versa, pedem apoio, há facilidade de comunicação,...)

17 – Estão estabelecidos os canais de comunicação entre os serviços/departamentos e o sistema de controlo da infeção?

18 – Qual a capacidade de reação do sistema implementado?

19 – Como interage o sistema da qualidade no sistema de controlo da infeção?

20 – Qual é a sua perceção global do sistema de gestão da prevenção e controlo da infecção em termos de gestão da sua organização (estrutura, processos e resultados)? Se possível identifique as oportunidades de melhoria.

Perguntas específicas para os elementos da gestão da qualidade

<u>Modelo KF-CHKS</u>

- *De que forma o modelo KF-CHKS dá resposta às exigências atuais do controlo da infecção?*
  - *Vai de encontro ao estipulado pela Tutela?*
  - *Vai para além do estipulado pela Tutela?*
- *Quais as normas do manual que, para além da norma 13, estão relacionadas com o controlo da infeção?*
  - *Diretamente*
  - *Indiretamente*

Norma 13- Controlo da infeção:

- *Como se cumpre (há legix/reg/recomend/orientações/normas; está relacionado com alguma outra norma do manual KF;*

13.11	There are dated, documented infection control procedures for disposal of clinical and non-clinical waste. The procedures have been written/reviewed within the last three years. (*norma 15 – gestão de resíduos*)
13.12	There is a dated, documented procedure for handling outbreaks of infection, written/reviewed within the last three years. (*norma 7 – Risco Geral,...)*
13.9	There is a dated, documented procedure for aseptic techniques. The document has been written or reviewed within the last three years.
13.24	The infection control policies and procedures are distributed throughout the hospital.
13.25	The Infection control policies and procedures are centrally indexed and compiled into a policy manual that includes details of the circulation of each policy and procedure.
13.34	Large outbreaks of infection are classified as incident and reported through the incident reporting system used by the organisation

13.36 Results from the audit programme are reported to the appropriate group. There is evidence that results are acted on.

- *Há alguma norma geral associada ao controlo de documentos/controlo de registos?*
- *Como são enquadradas, na ótica do controlo da infeção, as restantes normas (há mais algum cruzamento)? (Há interação entre as normas tipo: serviço de alimentação/serviço de limpeza; aquisição de bens e serviços; gestão de risco, segurança e saúde do doente, gestão de medicamentos, serviços de esterilização, gestão de resíduos, gestão de registos clínicos; serviços de transporte; gestão de edifícios e instalações; serviços mortuários)*
  - *Processo de implementação*
  - *Envolvimento do departamento de gestão da qualidade*
  - *Processo de avaliação: auditorias internas e externas*
- *Quem responde pela implementação das normas/procedimentos associadas ao controlo da infeção? Cada área de atuação?*
- *O departamento de gestão da qualidade acompanha todo o processo de auditoria da KF-CHKS?*
- *Como é que se processa o controlo da legislação: este é exigido pelo modelo KF-CHKS? Se sim qual a norma?*
- *O Programa Nacional de Controlo da Infeção salienta a necessidade estabelecimento de um manual de Controlo de infeção. Existe?*
- *O departamento de Gestão da qualidade foi incluído no processo de elaboração desse manual ou apenas foi elaborado pela Comissão de Controlo da Infeção?*

Modelo JCI

- *De que forma o modelo ISO dá resposta às exigências atuais do controlo da infecção?*
  - *Vai de encontro ao estipulado pela Tutela?*
  - *Vai para além do estipulado pela Tutela?*
- *O controlo de infeção está identificado como um processo organizacional?*
- *Quem responde por ele? Qual a sua ligação/relação com a Gestão de topo?*
- *Como está desenhado no que diz respeito a:*
  - *Exigências da tutela;*
  - *Exigências dos requisitos normativos;*

- *Como são enquadradas, na ótica do controlo da infeção, as restantes normas (há mais algum cruzamento)? (Há interação entre as normas tipo: serviço de alimentação/serviço de limpeza; aquisição de bens e serviços; gestão de risco, segurança e saúde do doente, gestão de medicamentos, serviços de esterilização, gestão de resíduos, gestão de registos clínicos; serviços de transporte; gestão de edifícios e instalações; serviços mortuários)*
  - *Processo de implementação*
  - *Envolvimento do departamento de gestão da qualidade*
  - *Processo de avaliação: auditorias internas e externas*
- *Quem responde pela implementação das normas/procedimentos associadas ao controlo da infeção? Cada área de atuação?*
- *Há algum processo associado ao controlo de documentos/controlo de registos?*
- *Como estão estabelecidos os sistemas de monitorização, avaliação e atuação?*
- *Quem responde pelo processo/sistema em sede de auditoria?*
- *Como é que se processa o controlo da legislação/regulamentação associada com o controlo da infeção?*
- *O Programa Nacional de Controlo da Infeção salienta a necessidade estabelecimento de um manual de controlo de infeção. Existe?*
- *O departamento de gestão da qualidade foi incluído no processo de elaboração desse manual ou apenas foi elaborado pela Comissão de Controlo da Infeção?*

Modelo ISO

- *De que forma o modelo ISO dá resposta às exigências atuais do controlo da infecção?*
  - *Vai de encontro ao estipulado pela Tutela?*
  - *Vai para além do estipulado pela Tutela?*
- *O controlo de infeção está identificado como um processo organizacional? Se sim de que tipo?*
- *Quem responde pelo controlo da infeção em termos organizacionais? Qual a sua ligação/relação com a Gestão de topo?*
- *Como está desenhado no que diz respeito a:*
  - *Exigências da tutela;*
  - *Exigências dos requisitos normativos;*
- *Como são enquadradas, na ótica do controlo da infeção, as restantes normas (há mais algum cruzamento)? (Há interação entre as normas tipo: serviço de alimentação/serviço de limpeza; aquisição de bens e serviços; gestão de risco,*

segurança e saúde do doente, gestão de medicamentos, serviços de esterilização, gestão de resíduos, gestão de registos clínicos; serviços de transporte; gestão de edifícios e instalações; serviços mortuários)

  - *Processo de implementação*
  - *Envolvimento do departamento de gestão da qualidade*
  - *Processo de avaliação: auditorias internas e externas*

- *Quem responde pela implementação das normas/procedimentos associadas ao controlo da infeção? Cada área de atuação?*
- *Como estão estabelecidos os sistemas de monitorização, avaliação e atuação?*
- *Quem responde pelo processo/sistema em sede de auditoria?*
- *Como é que se processa o controlo da legislação/regulamentação associada com o Controlo da Infeção?*
- *O Programa Nacional de Controlo da Infeção salienta a necessidade estabelecimento de um manual de Controlo de Infeção. Existe?*
- *O departamento de gestão da qualidade foi incluído no processo de elaboração desse manual ou apenas foi elaborado pela Comissão de Controlo da Infeção?*

Interview guidelines – English version

The following questions have the main objective to identify the perception regarding:

- Quality Management/improvement tools implemented in the organisation and their interaction with HAI prevention and control system;
- HAI prevention and control system development and implementation in the organization;
- HAI prevention and control standard implementation "value chain";
- Existing Barriers in the organisational process.

Organisational Processes – Interaction with HAI prevention and control system

1 – What is your role in HAI prevention and control system?

2 – How your service/department interacts with HAI prevention and control system?

3 – What is your perception about to "clinical – manager" relationship?

4 – What is your perception about "Board-to-ward" relationship?

Accreditation/Certification processes – Interaction with HAi prevention and control system

5 – There is interaction (documentation, processes, monitoring and evaluation systems, and others) between accredited system HAI prevention and control system developed as defined by national legal/regulation framework (when applicable)?

6 – Hospital accreditation brings any advantage/disadvantage to HAI prevention and control system developed as defined by national legal/regulation framework?

Management tools/methodologies

7 – Which are the monitoring and evaluation systems implemented? What is the scope?

8 – The hospital develops risk analysis related with HAI prevention and control system? If yes, which tools/methodologies are used?

9 – The hospital uses any management tool/methodology to support HAI prevention and control system developed as defined by national legal/regulation framework? If yes, which management tools/ methodologies are used? (For example: cause-effect diagram, histograms, barnstorming, plans, decision tree, PDCA cycle, control charts, checklists…)

10 – The application of these tools brings any advantage/disadvantage to HAI prevention and control system developed as defined by national legal/regulation framework?

HAI prevention and control system developed

11 – How is defined the implementation/adoption process of a standard related with HAI prevention and control? (For example: how a standard is introduced in the organisation and then which is its "value chain" since that moment till it is totally implemented and applied. Suggestion: Describe the implementation process for a standard/law/ regulation, taking into account, for example "Who, Why, What, When, Where, With What and How")

12 – How it should be? (Suggestions)

13 – How is monitoring and evaluate the HAI prevention and control system developed as defined by national legal/regulation framework? Which entities are able to do it (internal and external)?

14 – Which are the priorities for HAI prevention and control system developed as defined by national legal/regulation framework?

15 – Which are the barriers to its implementation and operation?

16 – How do you see the interaction between HAI prevention and control system (structures and processes) and other hospital services/departments? (For example: suggestions acceptance, information feedback, ask for support…)

17 –There are established communication channels between HAI prevention and control system and hospital services/departments?

18 – What is the responsiveness of HAI prevention and control system implemented?

19 – How quality management system interacts with HAI prevention and control system?

20 – What is your global perception about HAI prevention and control system implemented in your hospital (structures, processes and results)? If possible, identify improvement suggestions.

(Questions for quality management department)

KF-CHKS Model

- How KF-CHKS model "answers" to HAI prevention and control system demands?
  - Does as defined by national legal/regulation framework?
  - Does more than defined by national legal/regulation framework?

- In addition to Standard 13 – Control of infection, which standards are related with HAI prevention and control?
  - Directly?
  - Indirectly?

Standard 13- Control of infection:

- How the hospital "answers" to these criteria? (There is legal/regulation/standards/ recommendations)

13.11	There are dated, documented infection control procedures for disposal of clinical and non-clinical waste. The procedures have been written/reviewed within the last three years. (Standard 15 – Waste management)
13.12	There is a dated, documented procedure for handling outbreaks of infection, written/reviewed within the last three years. (Standard 7 – risk management,...)
13.9	There is a dated, documented procedure for aseptic techniques. The document has been written or reviewed within the last three years.
13.24	The infection control policies and procedures are distributed throughout the hospital.
13.25	The Infection control policies and procedures are centrally indexed and compiled into a policy manual that includes details of the circulation of each policy and procedure.
13.34	Large outbreaks of infection are classified as incident and reported through the incident reporting system used by the organisation
13.36	Results from the audit programme are reported to the appropriate group. There is evidence that results are acted on.

- There is any standard related with document control and records control?
- How other standards interact with HAI prevention and control system/standard? (For example: Food service, Cleaning/Housekeeping service, Provision service, Risk Management department, Medication management, Sterilisation service, Waste management, Record management, Transportation services; Facilities and equipment management; Post-mortem Services)
  - Implementation process
  - Quality involvement

    - Evaluation process: internal and external audit
- Who is the responsible for those standards? Each service?
- Who is res
- Quality management department is present during all KF-CHKS audit process?
- How legislation and regulation (acquisition, knowledge about their publication) is controlled? This is a criterion of KF-CHKS model? If yes, in which standard?
- The NPIPC highlights the importance of infection control manual development. Quality management department helped to do it?

JCI Model

- How JCI model "answers" to HAI prevention and control system demands?
    - Does as defined by national legal/regulation framework?
    - Does more than defined by national legal/regulation framework?
- HAI prevention and control is identified as an organisational "process"?
- Who is its responsible for HAI prevention and control system? What is the relation between the responsible and Top management?
- How it is design?
    - According to national legal/regulation framework;
    - According to standards requirements.
- How other processes/services interact with HAI prevention and control system/process? (For example: Food service, Cleaning/Housekeeping service, Provision service, Risk Management department, Medication management, Sterilisation service, Waste management, Record management, Transportation services; Facilities and equipment management; Post-mortem Services)
    - Implementation process
    - Quality management involvement
    - Evaluation process: internal and external audit
- Who is responsible for the implementation of standards/procedures in those services? Each service?
- How are defined the monitoring and evaluation process?
- Who is the responsible for HAI prevention and control system/process evaluation system? (For example. Audit process)
- How legislation and regulation (acquisition, knowledge about their publication) is controlled?
- The NPIPC highlights the importance of infection control manual development. Quality management department helped to do it?

ISO based Model

- How ISO model “answers” to HAI prevention and control system demands?
  - Does as defined by national legal/regulation framework?
  - Does more than defined by national legal/regulation framework?
- HAI prevention and control is identified as an organisational “process”?
- Who is its responsible for HAI prevention and control system? What is the relation between the responsible and Top management?
- How it is design?
  - According to national legal/regulation framework;
  - According to standards requirements.
- How other processes/services interact with HAI prevention and control system/process? (For example: Food service, Cleaning/Housekeeping service, Provision service, Risk Management department, Medication management, Sterilisation service, Waste management, Record management, Transportation services; Facilities and equipment management; Post-mortem Services)
  - Implementation process
  - Quality management involvement
  - Evaluation process: internal and external audit
- Who is responsible for the implementation of standards/procedures in those services? Each service?
- How are defined the monitoring and evaluation process?
- Who is the responsible for HAI prevention and control system/process evaluation system? (For example. Audit process)
- How legislation and regulation (acquisition, knowledge about their publication) is controlled?
- The NPIPC highlights the importance of infection control manual development. Quality management department helped to do it?

ANNEXE V – Barriers and Suggestions: Comparative Analysis

All barriers and suggestions are compiled in the following tables. Identical barriers and suggestions are with a grey shadow. The presentation is organised by dimensions previously defined.

Barriers

In following tables are presented the barriers identified in the multi-case study and in literature review.

Table 80 – "Who we are" barriers analysis for the three hospitals and comparison with international literature review.

SUB-DIMENSION	CONTENT	KF	JCI	ISO	INTERNATIONAL LITERATURE REVIEW
RESOURCES	TIME	Not enough allocated time (or nothing at all) for some ICC members (such as facilitators) for the implementation of HAI prevention and control activities	Not enough allocated time (or nothing at all) for some ICC members (such as facilitators) for the implementation of HAI prevention and control activities	Not enough allocated time (or nothing at all) for some ICC members (such as facilitators) for the implementation of HAI prevention and control activities	Time consumed by surveillance
	COSTS		HAI prevention and control costs	Acquisition of material not adequate (associated with HAI prevention and control costs)	Costs and Under-resourced infection prevention programmes
CULTURE AND VALUES	COMPLIANCE	No compliance with culture and policies associated with HAI prevention and control (more doctors than nurses)	No compliance with culture and policies associated with HAI prevention and control (more doctors than nurses)	No compliance with culture and policies associated with HAI prevention and control (more doctors than nurses)	No compliance with infection control culture, policies, and social norms
	CAREERS RELATION	Some career conflict between doctors and nurses	Some career conflict between doctors and nurses	Some careers conflict between clinical and nonclinical professionals	(Not identified)
	CULTURE ISSUES	Although the real name of ICC is "HAI prevention and control committee", the name used is "Infection control team" and "control" is seen as pejorative and negative, like inspection	Although the real name of ICC is "HAI prevention and control committee", the name used is "Infection control team" and "control" is seen as pejorative and negative, like inspection	Although the real name of ICC is "HAI prevention and control committee", the name used is "Infection control team" and "control" is seen as pejorative and negative, like inspection	(Not identified)
			The ICC name is not adequate for marketing	The ICC name is not adequate for marketing	Not identified

Table 81 – "How we do" barriers analysis for the three hospitals and comparison with international literature review.

SUB-DIMENSION	CONTENT	KF	JCI	ISO	INTERN. LITERATURE REVIEW
	CLINICAL PRACTICES	No compliance (or less than expected) with clinical best practices associated with HAI prevention and control (more doctors than nurses)	No compliance (or less than expected) with clinical best practices associated with HAI prevention and control (more doctors than nurses)	No compliance (or less than expected) with clinical best practices associated with HAI prevention and control (more doctors than nurses)	Poor/Lack on infection control practices
		The most representative type of sample for HAI identification to avoid report errors are not defined			Poor infection control practices and biological factors
				Lack on HAI prevention and control best practices and recommendations from DGH apply to primary care and continuous care.	Poor/Lack on infection control practices
	THERAPY	Some difficulties to promote therapeutic evidence-based decision instead empirical-based decision	Some difficulties to promote therapeutic evidence-based decision instead empirical-based decision	Some difficulties to promote therapeutic evidence-based decision instead empirical-based decision	Therapy
MANAGEMENT PROCESSES	LEADERSHIP	Absence of penalties or incentives for compliance with HAI prevention and control recommendations;	Absence of penalties or incentives for compliance with HAI prevention and control recommendations;	Absence of penalties or incentives for compliance with HAI prevention and control recommendations;	Lack on leadership
		Absence of top management leadership	Absence of top management leadership	Top management makes short-term plans and it is difficult to demonstrate some advantages associated with HAI prevention and control activities in short term.	Lack on leadership
		No top-down definition of strategies for HAI prevention and control systems	No top-down definition of strategies for HAI prevention and control systems		Lack on leadership
		No decision-making tools to support department/services directors management	The ICC recommendation are not mandatory		Lack on leadership
			Change resistance promoted by top management noncompliance		Lack on leadership
			The organisational vision into functional departments hinders the implementation of a transversal process		Lack on leadership

(Cont.)

SUB-DIMENSION	CONTENT	KF	JCI	ISO	INTERN. LITERATURE REVIEW
MANAGEMENT PROCESSES	TEAM MANAGEMENT AND RELATIONSHIP	General lack of motivation and Lack on professional involvement	General lack of motivation and professional involvement promoted by the economic crisis	Meetings with all national ICC are not established	Team management and relationship
		No expected interaction between ICC and other nonclinical services (such as facilities management department), or other nonclinical services as define in HAI prevention and control programme and in the accreditation programme	The rotation of cleaning teams	The roles and responsibilities for national programme for HAI prevention and control coordinator group and for regional coordinator group are not so well defined as done to hospital ICC	Team management and relationship; responsibilities definition
		No expected interaction between quality department and ICC because of conflicts caused by the redundancy of activities and overlapping roles (such as occupational health and safety)	Therapeutic committee doesn´t exist and, when created, ICC must be part of it	ICC doesn't participate on material provision commission	Team management and relationship
				Inadequate conflict management	Team management and relationship
	KNOWLEDGE, EDUCATION AND TRAINING	The relation between clinical and manager can be difficult due to differences in language, knowledge and way of thinking	The relation between clinical and manager can be difficult due to differences in language, knowledge and way of thinking	The relation between clinical and manager can be difficult due to differences in language, knowledge and way of thinking	Not identified
		The "sensitivity" for HAI issues is related with lack of knowledge.	The "sensitivity" for HAI issues is related with lack of knowledge.	The "sensitivity" for HAI issues is related with lack of knowledge.	Not identified
		No training related with audit process .The hospital solved this problem because is has the quality accreditation	Gap associated with clinical knowledge and competence of nurse professionals that can not validate imaging results		Knowledge, education and training
		Lack of knowledge related with HAI prevention and control at all levels			Not identified
	AWARENESS, AND INDIVIDUAL BEHAVIOUR	Application of "has always been like this" or " its good enough" to justify not acting	Application of "has always been like this" or " its good enough" to justify not acting		Not identified
		Most professionals assume that control of infection is done by ICC and not by each one in their daily work	Most professionals assume that control of infection is done by ICC and not by each one in their daily work	Most professionals assume that control of infection is done by ICC and not by each one in their daily work	Awareness, perceived risk, individual attitude, individual behaviour
		General lack of motivation and lack in professional involvement	General lack of motivation and lack in professional involvement		

(Cont.)

SUB-DIMENSION	CONTENT	KF	JCI	ISO	INTERN. LITERATURE REVIEW
MANAGEMENT PROCESSES	COMMUNICATION	Inexistence of a well-defined communication system, between services (internal) and with interested parties	Inexistence of a well-defined communication system, between services (internal) and with interested parties	Inexistence of a well-defined communication system, between services (internal) and with interested parties	Not identified
		The communication at regional level and national level is not as expected (with delays or inexistent)	The communication at regional level and national level is not as expected (with delays or inexistent)	The communication at regional level and national level is not as expected (with delays or inexistent)	Not identified
		Lack on information flow	Lack on the definition of information and communication policies and flow	Lack of information about operation recommendations and standards	Not identified
	MONITORING /EVALUATION	Inexistence of evidence between a programme/activity implementation and its outcomes	The level of evidence of ICC service in terms of costs / gains is very low and cannot be used as a negotiating weapon	The level of evidence of ICC service in terms of costs / gains is very low and cannot be used as a negotiating weapon	Lack on assessment/evaluation (business case, cost-effectiveness analysis
				Some difficulties in indicators definition	Not identified
				Monitoring and evaluation tools, such as audit process, are seen as "witch-hunt"	Not identified

Table 82 - "What we get" barriers analysis for the three hospitals and comparison with international literature review.

SUB-DIMENSION	CONTENT	KF	JCI	ISO	INTERN. LITERATURE REVIEW
DATA	DATA TREATMENT	Some difficulties in data treatment because of absence of IT system	Data susceptible of error	No sufficient data information from DHG in IT platforms	Lack of data; Data treatment/analysis limitations
	ANALYSIS LIMITATIONS	Some difficulties from services to analyse the information from ICC (knowledge, time)	Some limitations to ICC nurses related with data analysis from patient clinical records analysis		Analysis limitations
		HAI prevention and control data are not used to promote better management (No internal service data analysis)			Analysis limitations
REPORTING	FEEDBACK	No feedback from some services	No feedback from some services		Lack on reporting systems
		Not all data related with control of infection are reported to ICC (such as reporting from HELICS survey, adverse events notification, occupational incidents)			Lack on reporting systems
		Existence of a significant delay on reporting system from State to hospital	Existence of a significant delay on reporting system from State to hospital	Existence of a significant delay on reporting system from State to hospital	Lack on reporting systems
	REPORTING SYSTEM	The reporting system doesn't allow comparative analysis between services/departments because each service has access to global data report and to its individual data report	The reporting system doesn't allow comparative analysis between services/departments because each service has access to global data report and to its individual data report	The reporting system doesn't allow comparative analysis between services/departments because each service has access to global data report and to its individual data report	Lack on reporting systems
		The reporting system sometimes is limited to service / department director (not share with other professionals from that service/department)			Lack on reporting systems

Suggestions

In following tables are presented the suggestions from the three hospitals

Table 83 - "Who we are" improvement suggestions analysis for the three hospitals.

Sub-dimension	Content	KF	JCI	ISO
RESOURCES	HUMAN RESOURCES	Inclusion of an epidemiologist in ICC	Inclusion of an epidemiologist in ICC	Inclusion of an epidemiologist in ICC
CULTURE AND VALUES	COMPLIANCE	Must be introduced an incentive system to promote compliance with recommendations	Must be introduced an incentive system to promote compliance with recommendations	Must be introduced an incentive system to promote compliance with recommendations
		Must be introduced a penalisation system for noncompliance with recommendations and best practices	Must be introduced a penalisation system for noncompliance with recommendations and best practices	
	CULTURE ISSUES	Change the name of "infection control committee" to "infection prevention team".	Change the name of "infection control committee" to "infection prevention team".	Change the name of "infection control committee" to "infection prevention team".

Table 84 - "How we do" improvement suggestions analysis for the three hospitals.

Sub-dimension	Content	KF	JCI	ISO
CLINICAL PROCESSES	THERAPY	Introduce internal indicator to monitor medication prescription and its relation with usual service ecology	Promotion of discussion and analysis of therapeutic issues in a more frequent and systematic basis	Promotion of discussion and analysis of therapeutic issues in a more frequent and systematic basis
				Promotion of research about more adequate therapy associated with gender and age
	SURVEILLANCE	It is important to implement CAUTI surveillance at national level and hospital level	It is important to implement CAUTI surveillance at national level	It is important to implement CAUTI surveillance at national level and hospital level
MANAGEMENT PROCESSES	LEADERSHIP	All standards and recommendations from top management (internal and external) must start with "must do" instead "must do". HAI prevention and control requirements must be implemented on a mandatory basis instead on a voluntary basis.	All standards and recommendations from top management (internal and external) must start with "must do" instead "must do". HAI prevention and control requirements must be implemented on a mandatory basis instead on a voluntary basis.	
		The HAI prevention and control coordinator must be the president of administration or a member of this board to ensure top management commitment.		HAI prevention and control requirements must be implemented on a mandatory basis instead on a voluntary basis.

(Cont.)

Sub-dimension	Content	KF	JCI	ISO
MANAGEMENT PROCESSES	EDUCATION AND TRAINING	To promote better knowledge about HAI prevention and control it is important to include in basic education learning programmes (all the areas) and in higher education (health areas) specific content related with HAI prevention and control	To promote better knowledge about HAI prevention and control it was important to include in basic education learning programmes (all the areas) and in higher education (health areas) specific content related with HAI prevention and control	To promote better knowledge about HAI prevention and control it was important to include in basic education learning programmes (all the areas) and in higher education (health areas) specific content related with HAI prevention and control
		Education and training by promoting internal and external benchmarking	Promotion of education and training related with risk management	Introduction of benchmarking tools (internal and external)
		The incorporation in the hospital of a new professional must take into account HAI prevention and control knowledge (a clinical auxiliary must be introduced into a service with less susceptibility of infection)	Promote training by exchange experiences with other sectors (risk management in industry, objective-based management in banking sector, and others)	Promote training by exchange experiences with other sectors (risk management in industry, objective-based management in banking sector, and others)
				Introduction of collaborative tools to promote education and training.
				Promote some education and training about indicators definition and development
	TEAMS MANAGEMENT AND RELATIONSHIP	Definition of roles and responsibilities for multidisciplinary teams working on HAI prevention and control issues (such as risk management, occupational health management, ICC and quality management	Promotion of interaction with primary care centres	
	AWARENESS AND INDIVIDUAL BEHAVIOUR	It is important to introduce in ICC competences not only "know-how" and "know how to do", but also "know how to be"	It is important to introduce in ICC competences not only "know-how" and "know how to do", but also "know how to be"	It is important to introduce in ICC competences not only "know-how" and "know how to do", but also "know how to be"
	COMMUNICATION	It must be established better information channels internal (between services) and external this could be developed based on 5W methodology (why, when, where, who, what).	It must be established better information channels internal (between services) and external this could be developed based on 5W methodology (why, when, where, who, what).	It is important to establish better communication channels (internal and external)
		Laboratory information included in patient clinical record must have an alert system related with information updates.		It is important to promote HAI prevention and control image through marketing techniques. It is important to innovate in this area
		ICC must have more information about clinical process (patient records) to promote a better work (ICC information is based on laboratory information). It must be an IT tool to do this.		
	MONITORING AND EVALUATION	It must be introduce again HAI prevention and control indicators in the hospital contracting process with Regional Health Administration	It must be introduce again HAI prevention and control indicators in the hospital contracting process with Regional Health Administration	Establishment of ranking/rating systems to promote internal and external evaluation and to promote competitiveness between services and hospitals
		Introduce comparative analysis between productivity indicators and effectiveness indicators (not only enhance the high occupancy rate of operating room – a productivity indicator, but analysed together with HAI rate – an effectiveness indicator.)		

Table 85 - “What we get” improvement suggestions analysis for the three hospitals.

Sub-dimension	Content	KF	JCI	ISO
DATA	DATA TREATMENT AND ANALYSIS	It must be developed an IT tool to help ICC on data treatment and analysis	It must be developed an IT tool to help ICC on data treatment and analysis	It must be developed an IT tool to help ICC on data treatment and analysis
REPORTING	REPORTING SYSTEM	All nonconformities must be reported in the same platform and coordinated by one department that ensures the effectiveness of the reporting system for all services/departments involved The Administration Board must participate in the meetings promote by ICC to validate results and to understand better ICC work (monthly or quarterly)		