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Hospital Management and Patient Safety

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INTRODUCTION

Introduction

Patient safety has been a subject of much research, debate and interest in healthcare services. This topic has become a concern not only for health care providers themselves, but also for patients, managers, and society in general.

The Institute of Medicine (1999) (1) with the “*To Err is Human*” report promoted the discussion of the safety issue in medicine, showing that between 44.000 and 98.000 patients could be dying per year in the United States, from medical errors’ consequences. In Europe, it is estimated that one in ten patients admitted to European Union hospitals will suffer from medical errors during their treatment course (2).

A study published in 2016 by researchers from John’s Hopkins Medical School in Baltimore puts the number much higher, at 250,000 deaths per year (3). A study in 2017 by the OECD estimated that 10% of patients are harmed at some point during their stay in hospital. It also found that unintended or unnecessary harm in a medical setting is the 14th leading cause of ill health globally—a burden akin to malaria (4).

Errors happen, not only under healthcare professionals’ direct responsibility but also as a result of the organizational context in the hospitals’ daily life.

The focus of the problem became "why and how this can happen" and not "who did it."

Non-the-less, patient safety has some peculiarities that make it difficult to approach,

essentially because of the complexity of health care organizations.

The thesis explores prior terminologies of patient safety and errors and clarify their meaning. Building on the notion that learning from errors requires an accurate understanding of their nature, this work also details an in-depth study of error causes.

The main research questions are:

- What are the main errors that produce patient harm?
- What are the causes of these errors?
- What are the possible consequences for the affected patients?

This topic seems to be relevant because, even though some events that compromise patient safety, cannot be totally eliminated or avoided, their consequences can be mitigated, and the last goal is to achieve zero harm and no losses in patient quality of life. A review of specific incidents and near misses remains important, but there is increasing evidence that the damages to patients during care are often due to an accumulation of problems over a long time period across multiple contexts. Therefore, patient safety analysis needs to be expanded.

Answering the main research questions generated several other questions, which we will try to address in the three papers of the thesis.

First, the nature of the issues addressed; and second, the nature of the research method applied.

Initially, we looked for a better understanding of patient safety through a literature review of related concepts (paper I). Then, a framework was identified, and this systematic review led to the development of a theoretical model that analyzed different drivers of patient safety.

After the initial conceptualization, it would be important to analyse a real life situation where errors occur. We chose a healthcare service, more specifically one cardiac surgery service at an European university affiliated hospital. This type of service and medical specialty was found to be of study interest because the patient process is thoroughly detailed, documented and organized.

A qualitative research methodology was used to assess error in this particular setting. This empirical study is presented in paper II, also contributing to a better understanding of error typology, its causes and gravity.

After the empirical study of errors and its causes at the cardiothoracic surgery unit, we postulated a possible relationship between patient safety and postoperative quality of life. Paper III results from the quantitative evaluation of the evolution of the patient quality of life in the first postoperative year.

The thesis will be structured along these three research lines:

The first essay explores how can we improve patient safety by learning from errors. The paper provides a theoretical study of possible mechanisms that promote patient safety monitoring across the different stages of a service process. It explores existent definitions

of patient safety. An integrative framework is conceptually developed, and its application is presented with an illustrative conceptual model, specifically, how the hospital system behaves when an error happens concerning the care of a patient.

The second essay addresses the types of medical errors and its causes. A qualitative methodology was selected in order to fully understand the medical errors that arise in the studied case, using in depth interviews, collection of archival data and observation. The paper describes the types of errors that were found to arise in a cardiothoracic surgery service and considers their possible causes. Based on our findings, this paper develops a new error classification system, with a particular focus on error intensity. This error intensity scale is the study's novelty and contributes further insights into error typologies and their use. Specific recommendations for better error prevention are also provided.

The aim of essay three is to evaluate the evolution of patient quality of life during the first postoperative year and unveil which elements contribute significantly for quality of life after cardiac surgery. Through the use of prospective data, it explores quality of life outcomes at three, six and twelve months post operatively, comparing them to a preoperative baseline. This study also examines how the patients' socio-economic status, past medical history, procedural and surgery characteristics influence the post operative quality of life changes elicited by cardiac surgery.

The paper analyses outcome variations between the three main pathological groups, namely aortic, coronary and mitral disease.

The data were analyzed using a quantitative methodology, using the STATA statistical package, applying to this a paired test (considering a significance level of 5%). Univariate and multivariate regression models have been specified and estimated.

Finally, the last section of the thesis summarises the main conclusions of this work and points out its contributions to theory and management of healthcare organizations, highlighting some practical implications, and proposing routes for further research.

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ESSAY I

How Can We Improve Patient Safety By Learning From Errors?

Abstract

This paper explores the evaluation of a patient safety structure. The study aims to help managers and healthcare providers to analyse possible mechanisms that promote patient safety monitoring across the different stages of a service process.

The research extended the literature in the domains of healthcare services. First, we explore prior terminologies of patient safety and errors and clarify their meaning. Second, an integrative framework is conceptually developed, and its application presented with an illustrative model. The model highlights the importance of analysing different drivers of patient safety.

Finally, the paper discusses the insights that can be derived by applying the integrative framework. This may facilitate service design in healthcare practice by offering new ways to solve and to correct errors.

Keywords: patient safety; healthcare services; models of incidents.

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1. Introduction

Current literature describes service as a process when the service takes place in interactions between the customer, the service employee and or physical resources and systems of the service provider, which are offered as solutions to customer problems (1).

A service organization can only deliver a service after integrating investments in numerous assets, processes, people and materials. A major challenge for service organizations is ensuring that decisions at each of these levels are made consistently, focused on delivering the correct service to targeted customers (2).

In healthcare, the customers are the patients, and for those, healthcare tends to be one of the most important and personal services that they consume. Healthcare is a service that people require but do not necessarily desire as it is mainly sought when people are sick, potentially under anxiety and stress (3).

The evaluation of performance is difficult for patients because of the technical complexity of health services (4,5) and their credence attributes. Patients incur in a certain level of risk when receiving healthcare and their safety can be compromised by several events. This happens for example when procedures go wrong, when patients receive incorrect medication, when they are exposed to other patients with contagious diseases while sitting in the waiting room in hospitals, or when they are exposed to potentially infectious bacteria (6,7).

Safety in healthcare services is difficult to measure. Even after the service being experienced through hospital treatments, there are situations of risk that are difficult to control, and the patient may have to return to the hospital for further treatment (8). The recovery of failures both during the course of treatment and/or after its completion, it demands for extra operational resources, with impact on process and organization efficiency. In that way, safety is a crucial factor for the patient in the same way that patient safety is vital for the healthcare organization. Yet, why is patient safety being jeopardized and avoidable harmful events still remaining unlooked at? What are the challenges that stop healthcare systems from delivering care to its highest level of safety?

A significant percentage of patients are affected by errors and failures. Despite repeated calls to action over the past decade to change this, healthcare has moved slowly in improving performance regarding patient safety (9).

Literature has struggled to analyze if errors are derived not only from humans or from systems, but also if errors are inevitable and incidents unavoidable and if organizations can contribute to the prevention of such.

Considering the awareness to this matter, this paper provides a comprehensive literature review on studies conducted around safety in the healthcare industry and develops a novel framework about the system behavior against an error that happens to a patient.

The purpose is to provide a framework that combines the existing literature in the field, supporting the model of analysis and the study of process design options. This paper is

organized in five main sections. In section two, we articulate a comprehensive list of safety, patient safety and related concepts in healthcare services. In sections three, we build on the existing literature about models of errors and accidents and we present our conceptual model to characterize a dynamic system of errors and failures. In section four and five, we discuss possible future applications of our model. We conclude presenting potential areas that require further research (sections 6,7 and 8).

2. An integrative framework for analyzing patient safety contributions

In this section, we present a framework intended to support patient safety in the healthcare industry. These definitions are taken from several sources such as quality management literature, healthcare services and service operations. Semantics are therefore crucial to provide a precise terminology and mental conception for these constructs.

2.1. Understanding safety

In organizations, safety is generally defined as freedom from accidental injury (10, 11). Parasuraman, Zeithaml and Berry, (1985), (12) present a broader perspective of safety as one of the ten key categories that are labeled “service quality determinants”. Safety, by those authors can be seen as physical, psychological and material safety. The authors advocate that it is the freedom from danger, risk or doubt and involves “physical safety”(12).

Literature in service operations management has, for a long time, explored and recognized the importance of the topic of safety improvement. Most research focuses on the prevention of errors in operations in order to eliminate or reduce safety risks (13). Several studies address safety concerns across multiple sectors such as highway traffic (14) workplace (15) aviation services (16,17,18) and healthcare (19, 20, 21,22).

In healthcare, patient safety is a subject of much debate and concern. A patient is a person who is a beneficiary of healthcare, defined as services received by individuals to promote, maintain or restore health (23).

2.2. Patient safety

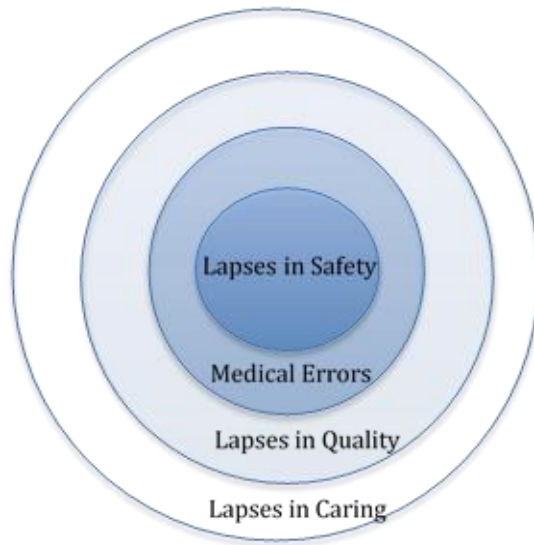
Traditionally, patient safety was considered an assumed byproduct of non-negligent care, rather than a goal to be achieved by the healthcare system (24). Patient safety is also defined as a critical element of service quality together with other components, such as provision of care based on the best available evidence as well as meeting patient preferences by maximal personalization of care (12, 25).

According to Gaba (2000), (26) and Leape, (2002), (27) and The National Patient Safety Foundation (2009), (28) patient safety is the absence of treatment errors and refers to the avoidance and prevention of adverse outcomes or injuries stemming from the processes of healthcare. These events include deviations from normal procedures and directed treatment and accidents such as, injuries related to medical management, events resulting from equipment failures and the insufficiency of a planned action to be completed as

intended (e.g. surgical events, events involving medical devices, patient protection and care) or the choice of an inappropriate plan to achieve a goal.

Woolf, S., (2004), (29) modeled the idea of patient safety in an image of concentric circles representing all deficiencies in healthcare (Figure 1). At the center is the problem of patient safety, in which the attempt to heal has the perverse effect of causing harm. The center blurs into the larger category of mistakes that endanger patients in domains other than “safety”, such as mistakes that create deficiencies in managing chronic disease (30). That circle of medical errors, in turn, blurs into the larger circle of gaps in quality, encompassing not only individual errors, but also organizational causes. These causes included inadequate and restricted access to care, systematic quality defects introduced by insurance and management policies, faulty information systems and flawed system designs. Feinstein, (2001), (31) and Kirsner, (2002), (32) envision a fourth circle, lapses in caring: the extent to which the technical elements of care seem good on the basis of performance indicators, but ultimately fail to be caring because of deficiencies not captured by these measures. The rudeness or insensitivity that patients encounter, or the frustrations they experienced in obtaining information and control over treatment decisions illustrate gaps in quality. These are of deep concern to the public, that often are not measured under normative standards. Figure 1 portrays all these elements and the interrelations between them.

Figure 1. The patient safety deficiencies in healthcare services



Source: Adapted on Woolf (2004) pp. 34

In summary, at the center is the problem of lapses in patient safety, these are mistakes in the provision of healthcare that expose patients to “additive risk” – inducing risks for complications or overt injuries that did not exist before the clinical encounter. In the second circle, medical errors are mistakes that encompass not only lapses in safety but that also include inattention to existant risks that patients bring to the encounter. The third cycle, represents lapses in quality care that does not reach desired standards. First, because of mistakes made by individuals, second because of flaws in the design and operating procedures of systems and organizations (for example, failure to provide care under acceptable waiting times). The fourth and last cycle represents lapses in caring namely, not only unsatisfactory care resulting from failure to meet normative benchmarks for quality, but also from experiences that leave patients feeling uncared for, affecting them in domains that are less easily measured (for example feeling unheard or humiliated or being unable to access desired information).

From the above it appears that patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum (33) and can be considered as one of the most important aspects of healthcare. Nothing is more contrary to the healthcare philosophy and mission than causing injury or harm to the individuals, who search for quality and safety in care.

To the National Patient Safety Foundation (2009), (28) and Charles Vincent (2010), (34), patient safety is the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care. These events include, errors, deviations and accidents. In addition, patient safety emphasizes the reporting analysis and prevention of medical errors that often leads to adverse healthcare events (35).

In this work, we adopted the World Health Organization (2009), patient safety taxonomy definition (universally used). Patient safety is the reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment (36).

The literature review on patient safety allowed and understanding of the elements that put patients at risk or that determine the lack of patient safety. Here we include the more commonly cited: errors, adverse events, near misses, accidents, incidents and sentinel events. Each of these are described in the following sections.

2.3. Errors

We shall here define a comprehensive list of error analysis. We consider several error definitions and error concept variations.

An error may be defined as a not planned act, either of omission or commission (24). Other researchers have proposed that errors are incidents resulting in, or having the potential for physical, emotional or financial liability for the patient (37). It is also understood as an unintended event, no matter how seemingly trivial or commonplace that could have harmed or did harm a patient (38).

Other studies have found that medical errors are also defined as the failure of a planned action to be completed as intended (i.e. an error of execution), or the use of a wrong plan to achieve an aim (i.e. an error of planning), one error is an unconscious deviation of a predefine plan (39). More recently, Slack et al. (2010), (40) found that errors are mistakes in judgment, where a person should have done something different.

An error is a failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase (36).

The literature suggests a distinction between errors and adverse events, near misses, accidents and incidents and sentinel events.

2.4. Adverse events

Adverse events are undesirable occurrences that cause damage for acts committed or for omission in the patient treatment. Adverse events are injuries that result from a medical intervention and are responsible for harm to the patient, namely death, life-threatening illness, disability at the time of discharge and prolongation of the hospital stay. An adverse event is also an injury that was caused by medical management and that prolonged the hospitalization produced a disability at the time of discharge, or both (41). In a typical hospitalization, a patient may have hundreds of encounters with doctors, nurses, hospital staff and equipment. Unexpected results or errors can occur with each encounter, perhaps causing an adverse event (42, 43,44,45).

2.5. Near misses

A near miss is an event or situation that could have resulted in an accident, injury or illness but did not, either by chance or through timely intervention (46). A near miss is an adverse event that either resolves itself spontaneously or is neutralized by voluntary action before the consequences have time to develop. Adverse events may be due to medical errors, in which case they are preventable, or to factors that are not preventable (47). It is also an incident, which did not reach the patient (e.g., a unit of blood being connected to the wrong patient's intravenous line, but the error was detected before the infusion started) (36). Near misses have a fundamental rule because they are easy to report, and they allow knowing accidents ways and prevent them.

2.6. Incidents

Incidents involve damage that is limited to parts of a unit, whether the fail disrupts the system or not (48). Incidents are all unpleasant events that affect the course of a process but do not compromise the final outcome, causing flux disorders or minor damages, without relief consequences, to allow completion of the therapeutic project (49). It is also an incidence resulting in, or having the potential for physical, emotional or financial liability to the patient (50). From the above, the incidents are all undesirable occurrences that affect the course of the process but don't compromise the final result.

2.7. Accidents

An accident is an unexpected event that produces harm to the patient or material damage of any type. They are generally made possible by preexisting hazards that have made the system vulnerable to failure (51). These hazardous conditions are caused by unsafe behaviors carried out by other people.

According to the literature, they are commonly the result of faulty cognitive and attentional processes such as poor selective attention, mental errors and distractions (52,53,54). Unsafe behaviors and accidents tend to occur under familiar conditions in which tasks are automated and a person's attention is externally or internally distracted or preoccupied. Is also an unplanned, unexpected and undesired event usually with adverse consequences (55).

Furthermore, accidents are powerful reminders of the vulnerability of systems in which they occur. Small problems can cascade into accidents if they aren't stopped by preplanned organizational, technical or procedural defenses. Designing such defenses is what system managers do. If they do their work well, nearly all latent catastrophes are prevented before the minor problems become catastrophic (56). Accidents have multiple contributors. They arise out of the same systemic complexity that makes them difficult to investigate in detail. Close study of accidents can reveal many of these contributors.

As Perrow (1999), (48) observed in most organized systems, everything is intertwined, the tighter the intertwining, the more susceptible the system is to disaster if anything goes wrong in any part of the system. According to this, it seems that accidents can be viewed as normal because the interdependencies in a system are so great that one small failure in one place can lead to a large failure somewhere else. Most of the time, the glitch is isolated and fixed before it can mess up something else. However, it's impossible to catch every failure and accidents happening. Problems happen so quickly that the glitches affect something else. Sometimes the unexpected happens before the situations can't be identified and fixed.

In fact, accidents are signals sent from deep within the systems about the sorts of vulnerability and potential for disaster that lie within. Our capacity to make safe systems depends on our ability to connect our experience with accidents to productive work on all the connected elements of the system: people, goals, technology, incentives, rules, knowledge, and expertise (57). In sum, accidents compromise planned processes and final result.

2.8. Hazards

Hazard is a circumstance, agent or action with the potential to cause harm. A circumstance is a situation or factor that may influence an event, agent or person(s). An event is something that happens to or involves a patient and an agent is a substance, object or system that acts to produce change (36).

2.9. Sentinel events

A sentinel event is an unexpected death or serious physical – including loss of limb or function – or psychological injury, or the risk therefore. Any time a sentinel event occurs, the healthcare organization is expected to complete a root cause analysis, make improvements to reduce risk, and monitor the effectiveness of those improvements. The root cause analysis is expected to drill down to underlying organization systems and processes that can be altered to reduce the likelihood of a failure in the future and to protect patients from harm when a failure does occur. A sentinel event can be considered a disaster (58).

In this sense, the accounting of events is comparable to an iceberg: under the water line of our knowledge much more remains than what we perceive above this line. In fact, errors are very frequent, errors recovered without damage are abundant, but incidents, accidents and sentinel events are less frequent.

In summary, patient safety is the avoidance, prevention and improvement of event outcomes stemming from the processes in health care services. The patient safety concept

is always linked with errors. The literature review has highlighted and shows the distinction between these several concepts namely, sentinel and adverse events, accidents, incidents and near misses.

3. Using the framework as a descriptive tool: conceptual models of errors and accidents

Healthcare services literature offers several conceptual models to analyze different process configurations about errors and accidents, which involve different stages in the provision of care process. We compare the different conceptual models and propose a new model.

It is now broadly recognized that errors and accidents in complex systems occur through the concatenation of multiple factors, where each may be necessary but where they are only jointly sufficient to produce the accident. All complex systems contain such potentially multi-causal conditions, but only rarely do they arise thereby creating a possible trajectory for an accident. Often these vulnerabilities are latent, namely present in the organization long before a specific incident is triggered. Furthermore, most of them are a product of the organization itself, as a result of its design, such as staffing, training policy, communication patterns, workflows and hierarchical relationships, or as a result of managerial decisions (59).

We found from the literature that several researchers conceptualized this idea through theoretical models.

3.1. Model of accidents

James Reason (1990), (51) proposes the “swiss cheese” model trying to illustrate how accidents could be seen as the result of interrelations between real time unsafe acts by front line operators and latent conditions.

The “swiss cheese model” (Reason, 1990, appendix 1), describes the human error problem accordingly the person approach and the system approach. Reason (1990), assumes that each of these ways generates different perspectives or approaches philosophies in the management of errors (51).

The person approach is more widespread and traditional. The focus is on actions, errors and processes violations, by those who are at the end of the service provision chain, that are in direct contact with the patient: nurses, physicians, anesthetists, and pharmaceuticals. These errors are the result of mental processes such as, attention disorders and low motivation.

The system approach presumes that errors and accidents are the result of a long chain of causes, latent and active failures that align and causing harm to the patient. Active failures occur at the level of the frontline operator with the effects being felt almost immediately. Active failures are the unsafe acts committed by people who are in direct contact with the patient or system. They take a variety of forms: slips, lapses, fumbles, mistakes and procedural violations. They have a direct and usually short-lived impact on the integrity of the defenses.

Latent failures arise from decisions made by designers, builders, procedure writers and top level management. Latent failures have two kinds of adverse effect. First, they can translate into error provoking conditions within the local workplace (example: time pressure, inadequate equipment, fatigue and inexperience). Second, latent conditions can be identified and remedied before an adverse event occurs.

According to Reason, defenses, barriers and safeguards occupy a key position in the system approach. Moreover, high technological systems have many defensive layers (alarms, physical barriers, automatic shutdowns), other rely on people (surgeons, anesthetists), and yet other depend on procedures and administrative control. Their function is to protect potential victims and assets from local hazards.

Reason (2000), (60) advocates they are more like slices of swiss cheese, having many holes – though unlike in the cheese, these holes are continually opening, shutting and shifting their location. The presence of holes in any one slice does not normally cause a bad outcome. Usually, this can happen only when the holes in many layers momentarily line up to permit a trajectory of accident opportunity – bringing hazards into damaging contact with victims (appendix 1). The “swiss cheese model” postulates that barriers exist to prevent adverse events, but they are like slices of swiss cheese with many holes (errors) in them.

However, we find in the literature several criticisms about the Reason`s model. Shappell and Wiegmann (2000), (61) advocates that in many ways, Reason`s “swiss cheese model” accident causation has revolutionized common views of accident causation.

Unfortunately, however, it is simply a model with a few details on how to apply it in a real-world setting. In other words, the theory never defines what the holes in the cheese really are, at least within the context of everyday operations.

Dekker (2002), (62) adds that, the layers of defense are not static or constant, and not independent of each other either. They can interact, support or erode one another. The “*swiss cheese*” analogy is useful to think about the complexity of failure, and conversely, about the effort it takes to make and keep a system safe. But the analogy does not explain: where the holes are or what they consist of; why the holes are there in the first place; why the holes change over time, both in size and location and how the holes get to line up to produce an accident.

The main external criticism has been that the model is insufficiently specific regarding the nature of the holes in the cheese and their inter-relationships. Thus, it is not easily applicable as an investigation tool. One of the disadvantages of the Reason model is that, it does not account for the detailed interrelationship among casual factors. Without these distinct linkages, the results are too vague to be of significant practical use (63). Furthermore, Nancy Leveson (2004), (64) advocate that the model is no longer adapted to anticipate today`s accidents.

Shorrock et al. (2005), (65) raise that active errors may be the dominant factor: latent conditions are clearly important, but sometimes people really just slip up. The casual link, or even the connection between distant latent conditions and accidents are often tenuous and only visible with the benefit of hindsight and latent conditions can always be

identified with or without an accident. Some latent conditions may be very difficult to control or take many years to address. They also advocate that highlighting management problems may hide very real human factors issues, like the impact of emotion on performance and hamper the research needed to better understand human fallibility.

According to Vincent (2017), (66) a critical challenge for patient safety in earlier years was to develop a more thoughtful approach to both error and harm to patients (67, 68). While a particular action or omission may be the immediate cause of an incident, closer analysis usually reveals a series of events and departures from safe practice, each influenced by the working environment and the wider organizational context (69,70).

Vincent previously extended Reason's organizational accident model and adapted it for use in healthcare, classifying the error producing conditions and organizational factors in a single broad framework of factors affecting clinical practice (67). This gave rise to a method of incident analysis often referred to as ALARM (71) and a later revision and extension in 2004 (Taylor and Adams, 2004), (72) (the 'London Protocol') which has been translated into several languages and can be applied to all areas of healthcare including the acute sector, mental health, and primary care. Similar methods, usually referred to as 'root cause analysis', have been developed and implemented by a number of organizations (68, 73).

The "London Protocol" is the revised and updated version of our original 'Protocol for the Investigation and Analysis of Clinical' outlined, a process of incident investigation and analysis developed in a research context, which was adapted for practical use by risk

managers and others trained in incident investigation. This approach has now been refined and developed in the light of experience and research into incident investigation both within and outside healthcare. The purpose of the protocol is to ensure a comprehensive and thoughtful investigation and analysis of an incident, going beyond the more usual identification of fault and blame.

In summary, the literature shows that errors and accidents come in many sizes, shapes and forms. Some errors are simple and therefore they only need simple explanations and models. Other errors are complex and need comparable models or methods to be analyzed. On this regard, we present in the next section the transformation process model. This is an operational model (instead of Reason's model) that explains the transformation of the processes.

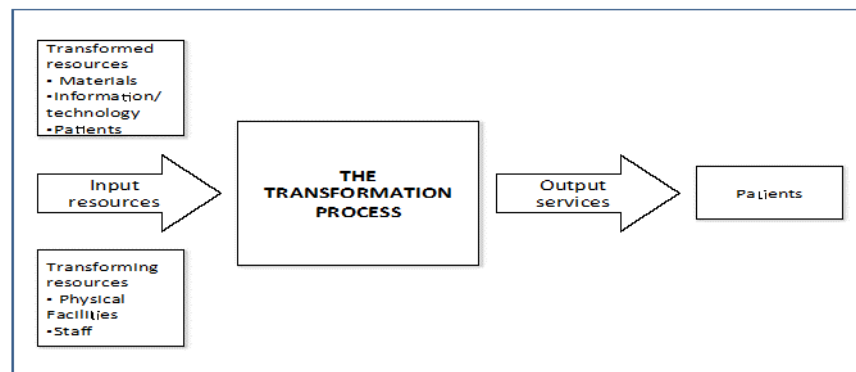
3.2. Transformation processes model

The transformation process model (Figure 2) shows that operations are processes that take in a set of input resources, which are used to transform something or are transformed themselves, into outputs of products and services (40).

Services have been defined as activities, which perform a transformation on some input provided by the customer, in healthcare services by the patient (75, 76,77, 78). Nevertheless, healthcare services differ in the nature of their specific inputs and outputs. For instance, a hospital is a service operation producing services that change the physiological or physical condition of patients. What is inside the operation is patient care

and safety, therapeutic processes and the most important difference is the nature of the input. The hospital transforms the patients themselves. They form part of the input to and the output from the operation (79, 80). This has important implications on how the operation needs to be managed.

Figure 2. Transformation processes model



Adapted from: Slack et al. (2010) page 11

According to this, the inputs can be distinguished as follows:

i) Inputs

- Patients, when the patient is required to be present to perform the service;
- Technology and information: technology when patients commit physical assets; information when service activities handle mainly patients request about immaterial objects, such as in communication;
- Physical facilities and equipment, when the service requires some physical transformation, for example maintenance services;
- Staff, healthcare professionals and their knowledge.

ii) Transformation Processes and Service Process Activities

Service processes can be mapped in a set of activities required to deliver the service. The activities required will be very diverse depending on the service analyzed. To structure mapping we propose to distinguish some common high-level phases of service delivery, where specific activities can be grouped as follows (81):

- (a) Access to the service;
- (b) Check-in and diagnostic;
- (c) Execution of the main service delivery;
- (d) Patient exit;
- (e) Patient follow-up and feedback, which may include quality control.

Depending on the service, the logical sequence of these phases may change.

iii) Service outputs: we shall include here the service outputs building significantly on the extended literature derived from the SERVQUAL model (82). In particular we consider:

- Results quality and safety attributes. We consider here the perceived service, the service delivery and the service quality specifications.

In opposition to Reason`s model, it seems to us that Slack et al. (2010), (40) operations model shows that the service process can be mapped in a set of activities required to deliver the service. The activities will be very diverse depending on the service analyzed. Based on this, our model proposes an integrative framework for analyzing patient safety in healthcare services.

Furthermore, the WHO report (2011), (35) designed the conceptual framework for the International Classification for Patient Safety (ICPS) to provide a much needed method of organizing patient safety data and information so that this data and information could be aggregated and analyzed.

A well-developed conceptual framework for the ICPS could have wider value for advancing the field of patient safety by: facilitating the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care; enabling the categorization of patient safety data and information so it can be used for epidemiological and health policy planning purposes by health care professionals, researchers, patient safety reporting system developers, policy-makers and patient advocacy groups; and providing an outline for developing a patient safety curriculum by setting forth an essential data element set, that describes the current knowledge of the domain of patient safety.

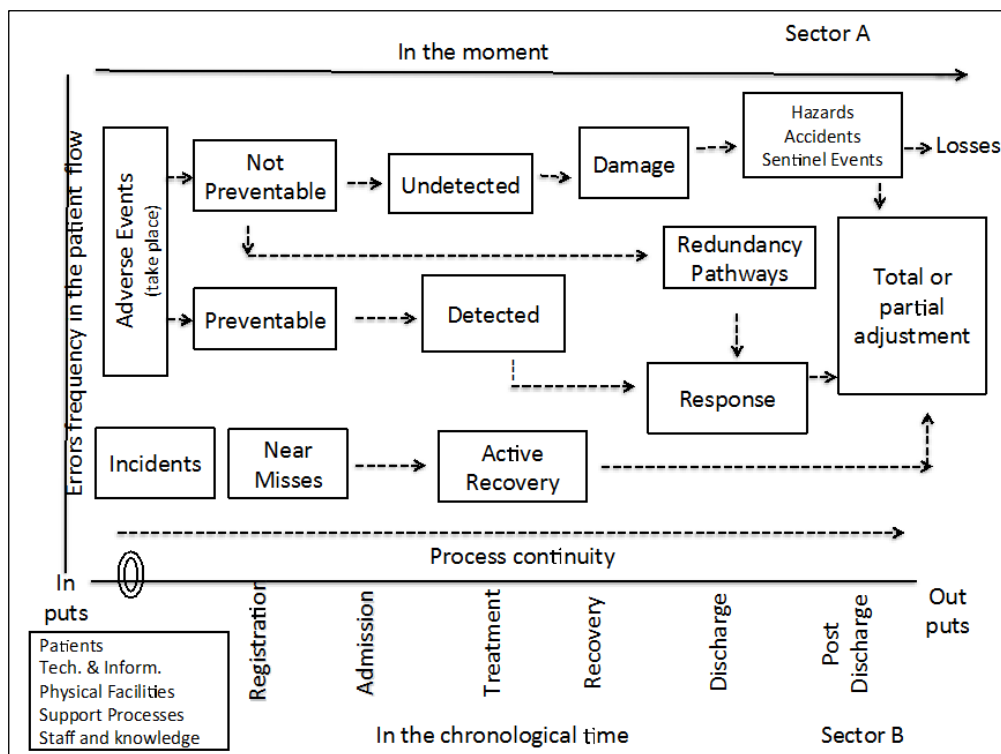
By providing a structure for organizing data and information, a classification is the structural underpinning of a reporting system. A reporting system built upon a well-developed classification comprised of essential data element pertinent to patient safety provides an interface to enable users to collect, store and retrieve relevant data in a reliable and organized fashion. This facilitates learning about the “science of safety” and informs the development of educational and training materials.

4. Using the framework as a descriptive tool: model

In this section we developed a conceptual model displayed in Figure 3. Our model is essentially a simplified representation of something else and is a broad concept containing many potential and employed explanations. It is an artificially created system that represents reality.

Healthcare services differ in the nature of their specific inputs and outputs. For example, a hospital is a service operation producing services that change the physiological or physical condition of patients. What is inside the operation is patient care and safety, therapeutic processes and the most important difference is the nature of the input. The hospital transforms the patients themselves. They form part of the input to and the output from the operation (40). This has important implications on how the operation needs to be managed. The system behavior against an error that happens to a patient model, Figure 3, was created to provide an overview of the patient safety theoretical concepts. The model presents the system behavior against an error that happens to a patient. Our objective is also to show how the concepts are interrelated in the different service moments, namely pre, during and post. In each point of the “sector B” axis, it could also take place every situation of “sector A” (Figure 3).

Figure 3. System behavior against an error that happens to a patient



4.1. The “pre” (inputs) moment of the service process

The first moment of the service process is when the incidents and near misses begin to emerge (refers to an initial stage at each point of process continuity or before the process starts).

One set of inputs to any operation`s processes are transformed resources. These are the resources that are treated, transformed or converted in the process. They are usually patients, technology and information, physical facilities and equipment and support processes (83, 84).

- i) Patients are operations, which process patients, might change their physical properties in a similar way to material processors;
- ii) Technology and information are operations which process information could do so to transform their informational and technological properties;
- iii) Physical facilities and equipment are the buildings, equipment, plant and process operation;
- iv) Support processes are activities carried out by people and units within the hospital, which are not in contact with healthcare providers but that need to happen in order for the service to be delivered;
- v) Staff and knowledge – the people and their knowledge who operate, maintain, plan and manage the operation (note that we use the term staff to describe all the people in the operation, at any level).

Adverse events emerge with the errors frequency within the patient process. In this moment of the process (pre) the errors could be preventable or not. Preventable is being accepted as avoidable in a particular set of circumstances.

The prevention mechanisms emerge in the system adjustment and should work to encourage healthcare professionals to prevent adverse events, especially those that cause medical injury. Organizations that systematically focus on preventing and responding to operational failures, can achieve high levels of reliability (85, 86).

These prevention mechanisms are valid only for adverse events.

The adverse events have always had to happen. Then they can either be prevented or not. The incidents and the near misses were detected in time without compromising the patient's result. Hazards, accidents and losses happen due to late detection and incur in a risk of patient damage.

The classification in adverse events and near misses is retrospective. When the root cause of the incident is retrospectively analyzed and despite the nature of the incident, the conclusion is that the accident could have been prevented – both the error itself (more difficult but possible) and the consequences for the patient. Examples of the first are the physical barriers that exist in anesthesia and which prevent the oxygen cables from plugging into the vacuum inlets and vice versa, or the feed extensions that do not fit into the taps of the central intravenous central catheters; example of the latter is the nurse who detects the physician's prescription error, the anesthesiologist who detects the error of identification of the patient at the entrance of the operation room, the supervisor who detects a calculation error of a dose in the nursing student. There are incidents that cannot be easily prevented, namely a mechanical failure of a device in the block or a ventilator failure during a surgery.

Incident analysis is always retrospective although preventive plans of action can emerge to cope with future incidents. Incident' preventive measures are the management of prospective security with all its instruments: risk assessment, barrier analysis, simulation, failure mode and effects analysis, protocols and training.

We found in the literature several examples of preventing mechanisms. One of the prevention mechanisms is the “safety walk round” (process inspection). It is a process whereby a group of senior leaders visit areas of a health care organization and ask front-line staff about specific events, contributing factors, potential problems, and possible solutions. The leaders then prioritize the events and the patient safety team develops solutions with the physicians. The results are returned as feedback to the staff (87).

The information gleaned in this process often has the solution embedded in the event description. Thus, this process can often result in prompt changes that improve care and safety. It also can lead to culture change, as the concerns of front-line staff are addressed and engaged in continuous observation of solutions for discussion with senior leadership. Leadership walk rounds are a low-cost way to identify errors of concern to front-line staff and make needed changes. They require no additional staff, equipment, nor infrastructure (88).

Another prevention mechanism is screening. This mechanism uses routine data to identify a possible adverse event. It can be performed retrospectively, or in “real” time, either by analysis of traditional paper records or automatically by computer programs if patient clinical and laboratory data is available in electronic form. “Occurrence” screening identifies when a pre-defined event occurs, such as a return to the operating room within

an admission or a readmission for the same problem. Screening criteria is sometimes referred to as “triggers”. When a screening criteria is met, further investigation, usually in person by an expert, is needed to determine whether an event has, in fact, occurred. Another proposed preventing mechanism is periodic training of personnel and upgrading reporting databases. They are necessary, as are systems improvements that depend on error-report analysis. Other contributions have also highlighted the importance of medical record review. It has historically been the major method for oversight of quality. While labor intensive, record review often provides the reviewer with the story and context in which to understand events. In addition, medical record review allows for evaluation of processes as well as outcomes, and can yield information about whether important processes occurred, such as communication, documentation, use of a checklist, or administration of an evidence-based therapy.

Finally, focused reviews are also cited. This prevention mechanism focuses on a specific type of event that can identify critical points of care that represent widespread vulnerabilities. A focused record review might reveal not only the incidence of wrong-site surgery, but also whether a site checklist was executed, and a time-out took place during each operation.

4.2. During the service process (continuity)

During is the moment of the service process that happens between pre and post service and is when the continuance of the service happens.

4.2.1. Detection mechanisms

At “during” stage there are detection mechanisms during the service process. When for example the adverse events were not preventable, they cause damage. If they are undetected they become hazards, accidents and sentinel events. If in turn they are detected, we have total or partial adjustment or system correction.

Detection is an action or circumstance that results in the discovery of an incident, namely by noticing, by a monitor or alarm, by a change in patient condition or by a risk assessment. Detection mechanisms may be part of the system (such as low pressure disconnected alarm in a breathing circuit) and may result from a checking process or from vigilance and situation awareness. Early contributions emphasized that traditional detection mechanisms have used verbal reports and paper-based incident reports to detect significant medical errors. The benefits of these reports are dependent upon the design of the system, how and what information is collected, and whether the information is used to inform a sophisticated investigation of specific errors. The purpose of that is to understand the nature and the magnitude of the problem (89).

Additionally, reports can reflect the clinician’s ability to recognize and willingness to report an error. A consistent finding in the literature is that nurses and physicians can identify error events, but nurses are more likely to submit written reports or use error-reporting systems than are physicians (89).

Furthermore, error reporting may capture only a fraction of the actual errors. Research has approached potential detection errors mechanisms using direct observation, which,

while expensive and not necessarily practical in all practice settings, generates more accurate error reports (90).

More recent approaches have been focusing on increasing and simplifying automation of error detection, including creating web-based forms or adapted standard spreadsheets to reveal patterns of errors (91). Many of these efforts have focused on improving physician participation and emphasize voluntary and confidential reporting (92). Most have encouraged reports of errors and shared occurrences with the risk managers, other agency leaders, and patient safety specialists (91).

Detection mechanisms might improve reporting and ideally would result in safer processes. In addition, patients can also be a source of information to detect and describe occurrences of errors associated with medical interventions. In institutional settings, patients can provide information on new symptoms that may not be readily detected by physicians' observation or testing. From the literature it also seems that verbal, paper-based, electronic, web-based and patient information are all detection and error-reporting mechanisms that have been used to detect, record and communicate errors (89).

4.2.2. Redundancy pathways

Building in redundancy to an operation, means having back-up systems or components in case of failure.

It can be expensive to hospitals and is generally used when the breakdown could have a critical impact. With regards to the process efficiency, it means doubling or even tripling some parts of a process or system just in case of one component fails.

Hospitals have auxiliary systems in case of an emergency, or have back-up staff held in reserve in case of someone does not turn up for work. The reliability of a component together, with its back up, is given by the sum of the reliability of the original component and the likelihood that the back-up component will both be needed and be working (40).

In summary, redundancy pathways are mechanisms installed that double the safety of a process – for example an independent double verification of an account before the administration of a critical drug (adrenaline, dopamine), repeating out loud the oral prescription by the person to whom it was addressed (read back), and UPS's that trigger automatically and prevent a general power failure from having an impact on the operating rooms and medical ventilators.

4.2.3. Response

Following the redundancy pathways, another mechanism to solve errors at this stage is response. Patient safety will improve, when systems effectively assure safety predicated on a culture in which the response mechanisms are considered value, because they present solutions to correct errors.

The literature presents response mechanisms to avert underreporting of errors. The Institute of Medicine, (39) advocate that healthcare professionals need to develop policies

that support response mechanisms and set up the routine of error reporting. This would increase numbers of reports of incidents, near misses and adverse events because this information could be rewarded at the unit basis. Error reporting will most likely increase by eliminating blame and the pressure of a punitive environment (39). Additionally, it seems that healthcare professionals and patients profit from detailed accounts and increased reports, specifically in hospitals that act on unsafe practices identified through analysis of error reports. Systems improvements need to be communicated to all stakeholders, so that they benefit from seeing the feedback loop in action.

Error-reporting systems can also possibly make the time required to report shorter, shorten the time for correcting unsafe conditions, and alert providers to emerging unsafe patterns. Some systems can also facilitate quality improvement initiatives through enhanced error-reporting systems. The benefits of web-based health care reporting systems that physicians find easy to use and see the effects of their reporting in changes to systems, might ultimately reduce the incidence of serious errors, and significantly improve the safety.

However, in this paper context it seems that the item response, is more related with incident analysis and the creation of an action plan that allow error correction or adjustment, or the system failure detected. The response mechanisms objective is to solve and correct the detected failures.

The literature also suggested that focus groups are another example of response mechanisms practices, because it facilitated discussions with staff, physicians and nurses

or with patients and families to elicit insights and perceptions in an open learning environment. Most nurses, for example, are aware of hazards and sentinel events in their daily work, of accidents “waiting to happen”, and are willing to discuss them if given the opportunity (93).

Response mechanism offers an opportunity for a very rich learning environment as members within the group discuss and develop ideas. While this method of information gathering cannot provide trends or benchmarks like a reporting system, it can identify both hazards and potential solutions, and total or partial system correction or adjustment, that otherwise remain hidden.

A response mechanism is the ability to recover from minor and major errors that occur on a daily basis, and this is determinant for a process. The analogy is to keep covering the holes in the “*swiss cheese*” so that they the holes won’t align and lead to a major incident. For instance, doing a blood transfusion as soon as the patient starts bleeding and before detecting any symptoms, to administer an opposite drug to counteract another drug overdose or draining the stomach if the wrong drug is taken.

4.3. Post (outputs) – the moment of the service process

4.3.1. Total or partial error adjustment

In parallel with considering how to prevent, detect or not and respond to errors occurrence, healthcare professionals need to decide what they will do when the errors

occur. Another dimension in our “post” moment in the patient safety model is total or partial adjustment or correction.

Service organizations have the particular interest to work in total or partial errors adjustment, because they can turn system failures around to minimize the effect on patients or even to turn errors into a positive experience.

Healthcare organizations could use science of improvement to develop that. The concept of improvement science emerged to provide a framework for research focused on healthcare improvement. The primary goal of this scientific field is to determine which improvement strategies work as we strive to assure effective and safe patient care.

The conceptual framework that guides the *Improvement Science Research Network* (ISRN) includes all aspects of research that investigates improvement strategies in healthcare, systems, safety, and policy. The science of improvement is a nascent field, emerging along with other fields to answer the call of the IOM Report (39) to improve healthcare quality and safety. Improvement science (IS) is a new field of science. As the science of improvement evolves, the conceptual relationships of organizational systems relevant to IS will be tested, and terminology that is now used in different ways across the new sciences, will emerge and be more precisely demarcated and will drive the science forward (94).

Attempts to achieve optimal care have been expressed via a wide array of approaches, including translational research targets, evidence-based care, accreditation and external

accountability for quality and safety, risk management, error prevention, organizational development, leadership and frontline enhancement, and complex adaptive systems frameworks (95).

The literature shows that many science improvement methods derive from Deming's work (1993) (96). Deming's theory is that improvement will occur through the simultaneous application of methods underpinned by System of Profound Knowledge (SPK) and subject-matter expertise. These methods are often taught to improvement leaders and practitioners to help them to test change concepts locally and are designed to be practical and action-oriented.

Several researchers use this method, for example Dixon-Woods et al. (2011), (97) exploration of reducing bloodstream infections in Michigan suggests that the SPK area of psychology can be expanded to include social science more broadly. Drawing together contributions from rich and developing communities of health services research, implementation science, improvement science, and systems strengthening with the expertise of clinicians and patients will be crucial to these efforts (98). Organizations also need to design appropriate responses to errors, linked to the cost and the inconvenience caused by the error to the patient.

The total or partial errors adjustment techniques need to be a planned process. Such adjustment processes, need to be carried out either by empowered front-line staff or by trained personnel who are available to deal with corrections.

Even when the errors occur, service adjustment or correction - action taken by a service provider after a patient fails to receive the desired service (99) - determines patient satisfaction and retention (100,101), which in turn drive firm profitability (102).

Another way to make errors adjustment is empowering front line healthcare professionals (101,102). Service correction or adjustment strategies, that affect in varying degrees patient satisfaction includes: listening and acknowledgment, apologizing, fixing (replacement), compensation and atonement (101,103,104, 105,106). Patient satisfaction is linked to post-service adjustment and patient contact (101) as well as to the matching of service recovery expectations and perceptions mediated by judgments of fairness (105).

The activity of devising the procedures, which allow the operation to recover from error, is called error planning. The first stage is discovery. The first thing any manager needs to do, when faced with an error is to discover its exact nature: what happen, who will be affected by the error, why did the error occur and what is the action to take. The second stage is act or carrying out: informed and communicate what action is going to happen.

These are the contents of root cause analysis (RCA). Healthcare has several protocols to explain that. RCA is a process widely used by health professionals to learn how and why errors occur. While RCA has been part of health care and patient safety for more than 15 years, success has been variable both within and across institutions. This Institute for Healthcare Improvement (IHI) Virtual Expedition will explore the process of Root Cause Analyses and Actions (RCA2). Expanding on RCA, RCA2 is used to drive improvement

when it comes to reviewing events that cause or may cause serious harm, and in developing and implementing sustainable and measurable actions that prevent future harm to both patients and staff (94). The effects of the error needs to be contained in order to stop the consequences spreading and causing further errors, and follow-up to make sure that the containment actions really have contained the failure. The third stage is learning that it involves revisiting the error to find out its root cause and then engineering out the causes of the error so that it won't happen again. Finally, the healthcare professionals identifying all the possible failures, that might occur and defining the procedures.

In summary, designing appropriate total or partial adjustment mechanisms depends on the type of service, and the target patient segment that are the focus of a service firm. Understanding what patients expect and needs provides the basis for designing service total or partial adjustment processes that meet those needs.

5. Discussion

In this paper, we have presented a framework for the assessment of the patient safety role in the service process. In this context, both the integrative framework for analyzing patient safety contributions and the conceptual model developed, have highlighted and associated different concepts related with errors.

The conceptual model shows the system behavior against an error that happens in the care process of a patient. This model approach shows interactions that deepen the understanding of errors frequency in the patient safety process.

The theoretical model has two parts. The sector A shows the process in an instantaneous or immediate way (the way the system behaves in a specific moment). The section B presents the processes in chronological time; in other words, the errors may be recurrent throughout the time period or in a specific moment (example: different errors could happen in different stages, namely registration, admission, treatment, recovery, discharge and post-discharge).

According to the model, the incidents and near misses are avoidable events. In a near miss an incident happens but its consequences were avoided (by correction, detection or response mechanisms). In an adverse event (preventable or not), the patient harm couldn't be stopped. If it is preventable and detected, then the system could correct the cause and avoid it from happening again. The point is that it can only be called near miss or adverse event after it has happened. This is the problem about our model, when is considered in the chronological time. The scheme doesn't work for adverse events that are preventable because have already harmed the patient. For events that have already occurred, the adjustment can only be done retrospectively.

In summary, our model highlights the system behavior against an error that happens to a patient in an instantaneous or immediate way and in a chronological time scale.

First, there are errors (incidents and near misses) with active recovery and with total or partial correction. Second, there are errors that could be preventable or not. Third, the paper shows that there are errors that might not be detected in the system and the consequence of this are losses. These errors are hazards, accidents and sentinel events. If they are not detected, they will spread. If the system is tightly coupled the failures will rapidly escalate beyond control before anyone understands what is happening and is able to intervene. However, errors might always happen, and it is possible to do a total or partial adjustment or correction.

There are situations that aren't preventable (a sudden unexplainable behavior of a professional, the failure of a flawless material, an earthquake, a terrorist attack).

For that the existence of a recovery plan or redundancy mechanisms are a requirement. The near misses are by definition incidents that occurred (preventable or not), were detected and the patient consequences were avoided (this is the ideal incident to the system improvement). The adverse events (preventable or not) are incidents that emerged, were detected too late because they already caused harm to the patient. They must be the target of a recovery plan, but they have already caused damage. The main point that distinguishes one from another is detection and correction before or after they cause harm to the patient. In other aspects, near misses could have its genesis in the same error of an adverse event.

6. Conclusion

Patient safety is the avoidance, prevention, improvement and risk decrease when errors occur in the system, stemming from the process of health care. The events include errors that are failures of planned actions to be completed as intended, namely error of execution or the use of a wrong plan to achieve an aim.

Errors result from several causes and are different in the moment they occur, in the predictability of the occurrence and in the possibility of prevention or not.

We propose a new theoretical model, which fosters understanding the drivers of patient safety based on the moment and the degree of permissibility and prevention of the patterns that may result in errors. According to the moment in time, the errors may propagate or can be recurrent. Still others can be total or partially adjusted and the complexity of the process may determine the error chain.

The theoretical model shows a global perspective of the “errors frequency in the patient flow”. The model novelty is to explain in a simple way the system behavior regarding an error that happens to a patient. The model also shows that what occurs “in a specific moment”, could also happen in all the moments in the chronological time.

The paper also has a theoretical contribution namely the error taxonomy, which intends to explain and relate the different concepts. None of the previous models presented in this paper (for example, Reason, Vincent) explain the error in this point of view.

It will be useful to healthcare professionals and managers to identify, conduct and connect all the conceptual errors contents. The model helps to practically and visually distinguish the difference between all the concepts.

Furthermore, the model also shows in a perceptive way, the error gravity level and hindmost correction of each other concepts. It could be helpful to target specific harms or specific clinical processes and aims to study the improvement of the underlying work systems.

Finally, it would be crucial analyzing the patient journey, and seeing safety through the eyes of the patient.

7. Contributions

In this study we propose a stepwise approach for addressing the clarification of the moment when the errors may occur during the process. The study also provides a contribution to the potential for the prevention of the occurrence on their elimination. Our work shows that the more complexity of the process, the more the potential for error, and the more simple, the less errors.

In order to make the concepts more understandable to practitioners and researchers, the aim of the research should be to integrate the framework operationally into a conceptual model.

8. Further research

We can think of two main avenues of future research. First, understanding the types of errors and its causes so to explore the prevention, detection, response, redundancy and recovery mechanisms. Second, the study of one or more processes will allow knowing types and causes of errors and the moment of their occurrence.

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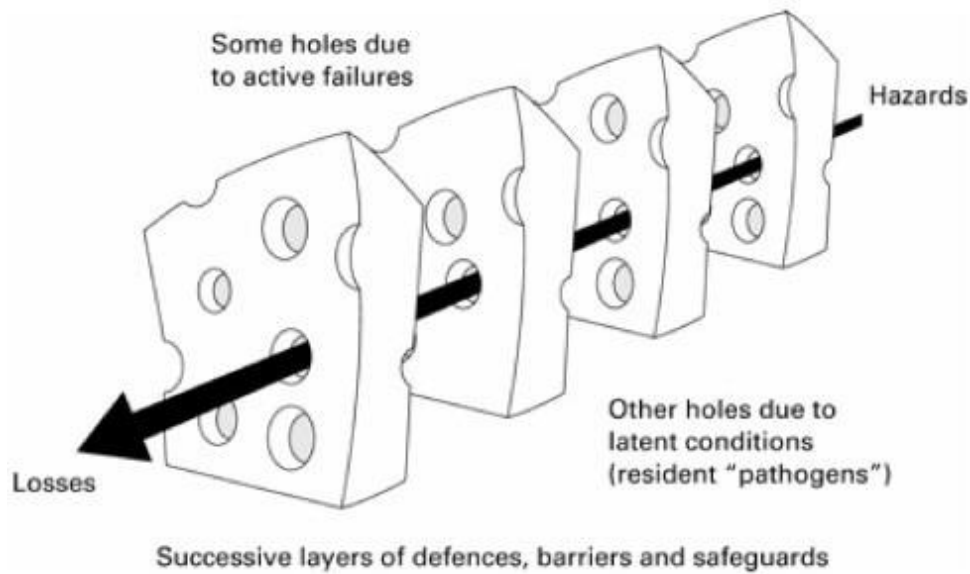
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APPENDIX

Appendix 1. The Swiss Cheese Model - James Reason

Figure A. - Reason, J. (1990), *Human Error*, Cambridge University Press,
Cambridge, England.



ESSAY II

Types, Causes and Intensities of Medical Errors: Lessons From a
Cardiothoracic Surgery Service

Abstract

For many years medical errors have compromised patient safety. Even though physicians, patients and society are aware of this situation, few studies have considered which errors are the most damaging or deadly. Furthermore, those studies that do exist have focused primarily on hospitals in general, rather than on specific departments where these errors might occur.

This article describes the types of error that arise in cardiothoracic surgery services and considers the possible causes of these errors. The relationship between causes and types of error are also explored.

Data collection followed the triangulation principle. First, 45 interviews were undertaken with physicians and nurses. Second, the author spent 199 hours directly observing these staff in their daily activities. Third, the author reviewed archival data from an urban teaching hospital with nine cardiothoracic intensive care beds.

This study develops a new error classification system, with a particular focus on error intensity. The error intensity is the study novelty and brings further insights to error typologies and their use. Specific recommendations for better error prevention are also provided.

Our research identified the presence of several types of error. The most frequently cited errors related to medications. Errors in diagnosis, treatment, communication and the

provision of information were also highlighted, as well as errors arising from the negligence and procrastination of healthcare professionals. Key causes of these errors included equipment failure, miscommunication and looking for alternative routes to solve problems. Staff fatigue and handover failures were also highlighted.

Key words: medical errors; patient safety; healthcare services.

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1. Introduction

Medical errors kill more individuals annually than breast cancer, AIDS, car crashes, or drug overdoses (1), and are the 3rd leading cause of death in the United States (2). Medical errors are also a major problem for European health systems: these errors occur in 8% to 12% of all hospitalizations, and it is estimated that one in ten patients admitted to European Union (EU) hospitals suffers from medical errors during their treatment course (3). A recent survey of EU citizens revealed that almost half of those surveyed felt that they could be harmed by the healthcare system in their country (3). Although the World Health Organization (2017), (4) also reports that 50% to 70% of the harms arising from medical errors could have been prevented.

Although some progress has been made in reducing certain types of error (5), modern healthcare delivery is becoming extraordinarily complex, particularly for patients with difficult or multiple conditions. Avoiding errors in these cases requires a planned, coordinated, and fully integrated approach to care. Complexity is also found elsewhere in the care experience, for example in the number of healthcare professionals and support personnel required and in the multiple venues where care is provided (6).

Learning from errors requires that they are acknowledged, and that their causes are understood. This requires a number of techniques and process-improvement tools, such as engineering to simplify and standardize care and checklists to help teams to focus and improve reliability. According to Morgenthaler and Harper, (2015) (7) human factors science, which studies the relationship between human beings and systems to improve

efficiency, safety, and effectiveness, is now being applied broadly in healthcare in everything from information management to the design of operating rooms and the intensive care units.

This paper presents data which suggests that we cannot regard all errors in the same way because they have different intensities i.e. they differ in terms of their severity and likelihood of detection. A conceptual framework is then developed to analyze how to avoid these errors. As part of the development of this framework, a comprehensive classification system is proposed, the different causes of errors are analyzed, and the relationship between errors is also considered.

We show that the types and causes of error are deeply connected to sequential task fulfillment, and that health care professionals skip certain tasks, breaking the sequence and causing the error. We identify particular issues with checklist procedures and procrastinating tasks, thus making an important contribution to the literature in this area. Our data also show that errors often occur when medical professionals look for alternative routes to solve unexpected problems.

Previous studies have reported that the most common errors are related to medication, followed by diagnostic testing and treatment. We show that the causes of these errors are related to failures in equipment and systems used to support care, miscommunications and staff fatigue. A key conclusion is that a new error classification system is required, and our focus on intensity is one of the novel contributions of this study.

This paper is organized as follows. Section two presents a literature review, which provides an overview of errors, their types, causes and intensities. The literature review presented in this section had to be developed in a limited time period (namely specifically six month's) with ad hoc reviews. In this sense, the papers were chosen according to the researchers most chronologically cited in the literature.

Section three describes the methodology used in our research. Evidence from a cardiothoracic surgery service is presented in section four, and discussed in section five, with a focus on the implications of our findings for hospital managers. Section six reports our conclusions.

2. Previous research on medical errors

Several review papers have considered the subject of medical errors in the past 30 years (8,9,10,11,12,13,14). Broadly speaking, errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in “upstream” systemic factors. These include recurrent error traps in the workplace and the organizational processes that give rise to them (15). However, a key issue across these publications is that there is little agreement on the definition of a medical error. It is therefore important to consider variations in definitions when evaluating the results of these studies.

Errors may be defined as an unintended act or one that does not achieved its intended outcome. Errors can also be understood as unintended events, no matter how seemingly

trivial or commonplace, that could have harmed or did harm a patient, or as mistakes in judgment, where a person should have done something different (6,10). Alternatively, an error could be is an act or omission for which the physician felt responsible and which had serious consequences (8) resulting in or having the potential for physical, emotional or financial liability for the patient (9).

The Institute of Medicine (1999), (16), defines medical errors as “*the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim*”. Errors can include problems in systems, in products, in procedures, and in practices and should be defined in terms of failed processes that are clearly linked to adverse outcomes (17). The term ‘adverse events’ is often defined using words that imply patient harm, such as medical injury and iatrogenic injury (18). Further definitions of medical errors include related terms such as mistakes, close calls, near misses, active and latent errors.

A later study by Tucker and colleagues suggests that an error is a problem in the supply of information, material, equipment or services that interrupts the work of nurses or physicians (11). Van den Bos et al., (2011), (19), state that medical errors are preventable adverse outcomes that result from improper medical management (a mistake of commission), rather than from the progression of an illness resulting from lack of care (a mistake of omission). These errors may or may not result in medical injury. More recently it has been suggested that errors are failures and unintended consequences of medical care that lead to problems for patients (20, 21, 22).

The primary objective of this review is to highlight the need for a clear, comprehensive and universally accepted definition of medical error that explicitly includes the key domains of error causation and captures the faulty processes that cause errors, irrespective of outcome.

Given the above, in this paper we adopt the following definition. An error is the failure of a planned action to be completed as intended (an error of execution) or the use of a wrong plan to achieve an aim (an error of planning) (15). An unintended act (either of omission or commission) or one that does not achieve its intended outcome (23). Deviations from the process of care, which may or may not cause harm to the patient (24).

Given this definition, we next present a comprehensive classification of the different types of error. We then analyze the causes of these errors before evaluating the relationship between these causes and the different types of error. The objective of the following sub-section is to summarize existing knowledge in this field, provide a new typology of errors and add to this typology the notion of error intensity.

2.1. Type of errors

An extensive literature exists regarding the different types of medical error. Many of these studies are associated with multiple medical departments, or hospitals with multiple specialties, although there are some studies, which focus on specific specialties such as primary care or pediatrics.

In this section, we present a framework intended to explore the errors type. In a first step, we specify the types of error that arise in four clinical contexts: hospitals in general, primary care, pediatrics and cardiothoracic surgery. First, we present the contributions by author and then we summarized the contributions by types of errors.

2.1.1. Hospitals in general

Many studies within the medical error literature consider hospitals in general without specifying a particular specialty or department (25). Early contributions, such as Reason (1990) (15), describe two classes of error: planning errors (e.g. mistakes) and execution errors (e.g. cognitive failures). In this case, errors are classified by source, and reflect a breakdown in cognitive functioning that impacts on task execution.

Leape et al., (1991), (6), report the results of a population-based study of iatrogenic (medical examination and treatment) errors experienced by hospitalized patients in New York. Errors are classified by area, and the most common errors fall into five categories:

- 1) Performance errors (e.g. technical errors, inadequate monitoring of patients after procedures);
- 2) Prevention errors (e.g. failure to take precautions to prevent an accidental injury or avoidable delays in treatment);
- 3) Diagnostic errors (e.g. avoidable delays in diagnosis, failure to use indicated tests);
- 4) Medication errors (e.g. errors in dosing, inadequate follow-up of therapy and systems);
- 5) Systematic errors (e.g. inadequate reporting or communications, delays in the provision or scheduling of services).

Leape et al., (1994), (23) characterizes four types of error that result in medical injury, and a later study based only on literature review by Al-Assaf et al., (2003) (26) fall the same categories. These are:

1. Diagnostic errors or delays in diagnosis (e.g. failure to employ indicated tests, use of outmoded tests or therapy, failure to act on test results);
2. Treatment errors (e.g. errors in the performance of an operation, procedure or test, errors in the administration of a treatment, avoidable delays in treatment or in responding to an abnormal test, inappropriate care);
3. Preventive errors (e.g. failure to provide prophylactic treatment);
4. Communication, equipment and system failures.

Braithwaite, (2004) (27) takes a similar line and specifies three categories of error: diagnostic, treatment and prevention.

A study by Tucker (2004), (11) presents more detailed results, identifying 194 operational errors involving different departments. The paper reports on an in-depth study of operational failures encountered by hospital nurses. The majority are system errors. A US study provides additional details on the specific errors that may occur during the course of providing healthcare. These errors include transfusion mistakes, incorrect amputations and hospital acquired or treatment related infections (28).

To describe the characteristics of and factors contributing to trainee errors, Singh et al. (2007) (29), analyzed malpractice claims in which trainees were judged to have played an important role in harmful errors. The researchers propose that poor judgment,

teamwork breakdowns and lack of technical competence are the most prevalent failures. Lack of supervision and handoff problems are the most frequent teamwork problems. Both are disproportionately more common among trainees. The most common tasks during which failures of technical competence occur are diagnostic decision making and monitoring of patients or situations. In addition to problems with handoffs, healthcare professionals are particularly vulnerable to medical errors owing to teamwork failures, especially lack of supervision.

A further study conducted retrospective case record reviews of patients who died in English hospitals. The principal problems associated with preventable deaths were poor clinical monitoring, diagnostic errors and errors relating to medication or fluid management (30).

The literature approaches the context of studies over errors in hospitals in a miscellaneous fashion. We concluded that the studies above have different settings namely errors that are experienced by hospitalized patients, medical injury, operations management and processes and patient treatment.

Furthermore, a wide range of different types of errors have been reported in past studies, including errors relating to planning and execution, medication, performance, preventative activities, diagnostics, communication, treatment, delays, equipment, systems, material delivery, judgment, team work breakdowns, lack of competence and poor supervision.

2.1.2. Primary care

Several studies have considered the types of error reported in primary care settings (8,31,10,32,33,34,35,36). Early study contributions, (8), note that the types of error most frequently observed are related to diagnosis, delayed treatment, physical stressors, the process of care, patient related factors and physician characteristics.

Similar arguments (31) identify errors in three categories: diagnostics, preventive activities and treatment. Other studies (10) note that type of error is related to system and process failures, and errors in workflow (e.g. preparing a patient for transfer and then finding out that the transfer is cancelled, or preparing medication and finding that it is discontinued).

Elder et al., (2002), (34) describe errors identified by family physicians in primary care during office-based clinical encounters. Office administration errors were most frequently noted, particularly related to charting (e.g. part of a chart is not present, is in the wrong place or the entire chart is missing). Errors relating to general office administration, staffing problems, missing or incorrect forms or paperwork, and laboratory and radiograph processing errors were also described. Physicians also reported errors related to skill problems, poor time management and communication between patients and physicians. Appointment, triage and errors related to misdiagnosis, diagnostic delays and incorrect treatment are also cited.

Nancy et al., (2002), (37), have showed other proposals. They outline several factors, such as, classification of preventable adverse events in primary care, namely:

- Diagnosis- Related to symptoms;

Misdiagnosis: missed diagnosis and delayed diagnosis;

Related to prevention: Misdiagnosis and missed diagnosis and delayed diagnosis;

- Treatment- Drug: incorrect drug, incorrect dose, delayed administration, omitted administration; Non-drug: inappropriate, delayed, omitted and procedural complication;
- Preventive services – inappropriate, delayed, omitted and procedural complication.

Another factor is the classification of process errors in primary care, namely:

- Clinician factors: clinical judgment and procedural skills error;
- Communication factors, clinician-patient; clinician-clinician or healthcare system personnel;
- Administration factors: clinician; pharmacy; physical therapy; occupational therapy and office setting;
- Blunt end factors: personal and family issues of clinicians and staff; insurance company regulations; government regulations, funding and employees; physical size and location of practice and general health care system.

In this case, it seems that the error classification is according to the agent involved.

Other authors have suggested a preliminary taxonomy of medical errors, describing two general categories: errors in the process of delivering healthcare and errors relating to knowledge and skills (38). Process errors arise:

1. When conducting an administrative task (e.g. information field in wrong place or wrong time);

2. When investigating a patient`s condition (e.g. errors in the process of laboratory investigations);
3. During diagnostic imaging investigations (e.g. wrong test ordered or test not ordered when appropriate);
4. When treating a patient (e.g. medication errors);
5. During communication (e.g. between physicians and patients, when obtaining informed consent;
6. During payment, errors in the process of healthcare payment systems.

The second type of error arises due to a lack of clinical knowledge or skills during the performance of a clinical task. These errors can include incorrect or missed diagnoses and incorrect treatment decisions. Overall, this study appears to classify errors according to their source.

In a group of studies about errors in family medicine, a later study by Dovey (2003), (38) describes the five error types most often observed and reported by US family physicians.

These errors relate to:

1. Prescribing medications;
2. Getting the right laboratory test done for the right patient at the right time;
3. Filing system errors;
4. Dispensing medications;
5. Responding to abnormal laboratory test results.

Other researchers reported similar findings (35) and highlighted errors related to prescriptions, particularly errors in dosage. Wolf et al. (2004), (36) report that errors are related to treatment, diagnosis, and communication. For example, communication breakdowns occur among colleagues and between clinicians and patients, errors are made in the handling of patient requests and messages, medical records may be inaccessible, and reminder systems may be inadequate.

The Joint Commission (2013), (39) advances similar arguments. This institution is an independent, not-for-profit organization and accredits and certifies nearly 21,000 health care organizations and programs in the United States. (Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards). Joint Commission state that failures are the leading cause of inadvertent patient harm. Analysis of sentinel events revealed that the primary cause of errors in primary care was communication failure. Many factors contribute to this. First, physicians and nurses are trained to communicate differently. Nurses are taught to be very broad and narrative in their descriptions of clinical situations ("paint the big picture"), whereas physicians learn to be very concise, and get to the "headlines" quite quickly. Nurses are often told in training that they "don't make diagnoses". This leads to nurses telephoning physicians and being very broad and narrative in their descriptions, with the physicians impatiently "waiting to find out what they want". The fact that nurses interpret the speech in their own way can lead to errors.

In summary, the key errors identified in primary care relate to administration, diagnostic tests, treatment, preventative activities, systems and process failures, office administration, the prescription and preparation of medications, hierarchy or power distance, and clinical and physical stressors.

2.1.3. Pediatrics

With regard to errors in pediatrics, early contributions report that incorrect dosing is the most common error (40, 6, 41, 42;). However, a later study by Flores et al., (2003), (43) instead notes that errors in interpretation (in this case interpretation is related to a medical interpreter between the limited English proficiency and the healthcare provider) are most common. Within this category, the most common error type is omission. Errors committed by ad hoc interpreters were significantly more likely to be errors of potential clinical consequence, compared to those committed by hospital interpreters. Such errors included:

1. Omitting questions about drug allergies;
2. Omitting instructions on the dose, frequency, and duration of antibiotics and rehydration fluids;
3. Stating that hydrocortisone cream should be applied to the entire body, instead of only to a facial rash;
4. Instructing a mother not to answer personal questions;
5. Failing to state that a child had already been swabbed for a stool culture;
6. Instructing a mother to put amoxicillin in both ears for treatment of otitis media.

Shah, (2009) ,(44) also identified errors in hospital admissions. Most were deficiencies in charting or record-keeping and multiple errors occurred in every inpatient pediatric admission. The data reported also suggest that the presence of small errors may be associated with a risk of adverse events.

The literature also emphasize that errors are often linked to handover moments e.g. patient transitions from the operating room to the intensive care unit. Handovers are a further important cause of medical errors in cardiothoracic surgery, particularly when information or responsibility are transferred between staff. Two further studies describe how information transition failures can contribute to errors in healthcare provision (20,21). Finally, Starmer et al. (2014), (22) demonstrate that miscommunication is a leading cause of errors.

In summary, the main errors identified in pediatrics related to medications, medical interpretation, information transition and communication.

2.1.4. Cardiothoracic surgery and intensive care units

Several studies have explored and described errors in cardiothoracic surgery services.

The studies highlight in this section are likely reporting primary research and describe the study findings not literature review themselves.

Ever since the 60's the literature has explored errors but it seems that the same classification has not always been used. Researchers started to look into this issue and his paper is related to "hazards of hospitalization" (22). This investigation was planned as a

prospective study of the type and frequency of hospital errors and complications occurring in the patients of a university medical service.

Donchin et al. (1995), (46) for example presents an article about the main outcomes and conclusions of a two year research effort directed to study the causes of human errors in an Intensive Care Unit. In the course of the study, doctors and nurses recorded errors in treatment routines that were committed during their daily work. Over a period of 4 months we collected 554 errors, which were independently judged for their criticality. In addition, 46, twenty-four hour, observations were conducted, of all activities at a patient bed. A total of 8178 activities were recorded over the 46 observations. They also performed: a detailed human factors analysis of the patient bed as a work station.

Wright (1999), (47) presents a study undertaken in an intensive care unit in Scotland over a ten year period. The author found that although some errors in this clinical context were caused by equipment failure, most are motivated by human error, in particular negligence of nurses and the failure of physicians to perform tasks adequately.

Carthey et al. (2001), (48) discuss human factors research in cardiac surgery and other medical domains. The paper describes a systems approach to understand human factors in cardiac surgery and summarize the lessons that have been learned about errors, critical incident and near-miss reporting in other high technology industries that are pertinent to this field.

Landrigan et al. (2004), (49) conducted a prospective, randomized study comparing the rates of serious medical errors made by interns while they were working according to a traditional schedule with extended (24 hours or more) work shifts every other shift (an “every third night” call schedule) and while they were working according to an intervention schedule that eliminated extended work shifts and reduced the number of hours worked per week. Incidents were identified by means of a multidisciplinary, four-pronged approach that included direct, continuous observation. Two physicians who were unaware of the interns' schedule assignments independently rated each incident. Interns made substantially more serious medical errors when they worked frequent shifts of 24 hours or more than when they worked shorter shifts.

Suresh, et al. (2004), (50) describe the types of error arising in an intensive care unit. Most errors related to incorrect medications or dosing, administration of treatments, patient misidentification and system failures. Delays in diagnosis and errors in the performance of procedures were also cited.

Wiegmann et al. (2007), (51) develop a study about surgical errors and their relationship to surgical flow disruptions in cardiovascular surgery prospectively to understand better, the effect of these disruptions on surgical errors and ultimately patient safety. A trained observer recorded surgical errors and flow disruptions during 31 cardiac surgery operations over a 3-week period and categorized them by a classification system of human factors. Flow disruptions were then reviewed and analyzed by an interdisciplinary team of experts in operative and human factors.

The results show that flow disruptions consisted of teamwork/communication failures, equipment and technology problems, extraneous interruptions, training-related distractions, and issues in resource accessibility. Surgical errors increased significantly with increases in flow disruptions. Teamwork/communication failures were the strongest predictor of surgical errors. These findings provide preliminary data to develop evidence-based error management and patient safety programs within cardiac surgery with implications to other related surgical programs.

Martinez et al. (2011), (52) reveal that most cardiac surgery errors occur in the operating room. This is not surprising considering the complexity of procedures and surgical team dynamics in the operating room. The researchers also find that the use of new technology, team member personalities, communication failures, and high workload and competing tasks, all affected team performance and jeopardized patient safety. Furthermore, they suggest that surgical staff may perceive that deviating from safe practices is admissible because there are safety nets to catch errors. Although the majority of errors in this analysis did not result in reported harm, these incidents provide important information. It has been shown that an increase in the number of minor events (i.e. anything that disrupts surgical flow, but in isolation is not expected to impact on the safety of the patient) decreases the ability of the cardiac surgery team to compensate for a future major event in the same case. Thus, no-harm incidents may reflect latent failures in the system that, under different circumstances, could result in patient harm or reduce the ability of a system to compensate for major errors.

Spiess (2011) (53) analyzes cardiothoracic surgery services and identifies surgical errors

that result in patient injury. In most cases, 75% (in 100%) of errors occurred in intraoperative care, 25% in preoperative care and 35% in postoperative care. System factors contributed to errors in 82% of cases. The leading system factors were inexperience or lack of technical competence and communication breakdown. Cases with technical errors were more likely than those without technical errors to involve errors in multiple phases of care, multiple personnel, lack of technical competence and knowledge and patient-related factors. System factors play a critical role in most surgical errors, including technical.

Zeggwagh et al., (2014) (54) note that the types of errors that cause harm are primarily diagnostic errors (e.g. failure to make a diagnosis), inappropriate technical procedures, errors in the medication process, or therapeutic and treatment errors (e.g. a diagnosis has been made but an appropriate therapeutic has not been delivered).

In summary, the key errors found in cardiothoracic surgery related to equipment, negligence, medications, treatment, systems, diagnostics, performance (performance, procedures and tests, technology, miscommunication; errors in the patient pathway, lack of technical competence, team member personalities, high workload, and inappropriate technical procedures and interpretation.

2.1.5. A summary of errors in the four specialties

The previous four sub-sections have provided a review of the existing literature on types of medical error. These findings are summarized in Table I.

Table I. Categorization of errors in the literature, by clinical specialty

	Hospitals in General	Primary care	Pediatrics	Cardiothoracic Surgery
Medication	X		X	X
Prescription		X		
Preparation		X		
Incorrect dosing			X	
Dosing interval			X	
Diagnostic	X	X		X
Treatment	X	X		X
System	X	X		X
Thecnology problems				X
Process failures		X		
Communication	X	X	X	X
Medical interpretation			X	
Information transition			X	
Communication omission			X	
Substitution			X	
Editorialization			X	
Record keeping deficiencies			X	
Equipment	X	X		X
Material deliver	X			
Clinical	X	X		X
Judgment	X			
Teamwork breakdowns	X			
Hierarchy or power distance		X		
Lack of compeance and supervision	X			
Competence	X			
Supervision	X			
Delays	X			
Planning and execution	X			
Planning	X			
Execution	X			
Performance	X			X
Prevention	X			
Administrative		X		
Staffing problems		X		
Team member personalities				X
Missing or incorrect forms of paper work		X		
Radiographic processing errors		X		
Follow the work and breakdowns		X		
Knowledge and skills		X		
Time management		X		
High workload				X
Inapropriate technical procedures				X
Procedure tests				X
Problems in the patient pathway				X

The majority of usual errors in all medical areas are related to medication, diagnostic, treatment and communication. Some authors also suggest that some errors emerge in task execution processes and system breakdowns. It also seems that are differences in the categorization of errors by the four different areas. For example, the errors in the hospitals

in general are connected with planning and execution, primary care with administrative errors, pediatrics with interpretation problems and cardiothoracic surgery with specific errors in the patient pathway.

All these studies attempted to categorize errors, although several different typologies were presented. We propose that errors can be classified as follows:

- By the moment of the error (e.g. planning, execution, process, knowledge and skills, systems);
- By the area of occurrence (e.g. medication, diagnostics; performance; prevention; treatment; guidelines, inadequate reporting, delays in the provision or scheduling of a service);
- By a combination of the two previous systems (e.g. diagnosis, surgical and medical treatment mishaps);
- By the agent involved (e.g. clinician factors, communication and administration).

In order to better understand errors in Intensive Care Units, we propose a diagram of the physicians and nurses (**appendix 1**) process with the different types of errors. This diagram clarifies the moment of the area, of the occurrence of the error as well as the intervenient more related to it.

In summary, this section has clarified and highlighted the types of error in the literature as well as the broad categories used for classification. A key insight which emerged from the literature analysis is that different types of errors could have different intensities.

Although the literature on this topic is relatively sparse, the following section describes the concept of error intensity in greater detail.

2.2. Error intensity

According to the literature review the errors may have several degrees of harmship to the patient, in which the minimum equals to no patient harm and the maximum equals severe harm on the patient or even death. In physics, intensity is the power transferred per unit area, where the area is an imagined surface that is perpendicular to the direction of propagation of the energy. As in physics we called it intensity because as the error spreads it's severity also increases.

In this paper error intensity is broadly defined as the level that reflects information about both severity and likelihood of detection. We propose to distinguish between different error intensities as follows.

2.2.1. Maximum intensity

Medical errors in this category are serious errors that cause harm or injury or have the potential to impact on patient mortality. For example, inappropriate use of tacrolimus in chronic myelogenous leukemia patients with graft-versus-host disease following bone marrow transplantation can lead to acute renal failure and then death. Another example of a potentially life-threatening error is when a transfusion-related acute lung injury occurs following a red blood cell transfusion in a patient with anemia and coronary artery disease. A third example is the provision of an incorrect dose of antibiotics (imipenem)

following a tonic-clonic seizure in a patient with pseudomonas pneumonia. When correct antibiotic was provided, the seizures resolved (55).

2.2.2. Medium intensity

Errors in this category include serious errors that are intercepted before reaching the patient. Such errors include skill-based slip medication errors, where the wrong dosage of a drug is provided because of the presence of an extra zero in the prescription. For example, an order for IV octreotide at 500 ug/hr for a patient with an acute upper GI hemorrhage from esophageal varices was intercepted by a pharmacy and corrected to 50 ug/hr (11).

2.2.3. Minimum intensity

These errors (also known as ‘near misses’ or ‘the happiest errors’) are not detected and are not a danger to patients. For example, a patient with an acute myocardial infarction (AMI) inadvertently began receiving subcutaneous heparin immediately after coronary artery stenting instead of full-dose IV heparin. Although the error was not recognized for 12 hours, no adverse event occurred. Such errors are known as knowledge-based medication error (56). It is clear from this section that intensity is an important consideration when distinguishing between different types of error. Indeed, all the types of errors described in Table I could have the three intensity levels described above. In the next section we consider the causes of these errors in more detail.

2.3. Causes of errors

There are a wide range of reasons why errors arise in healthcare provision. In this section we explore the causes of medical errors in more depth. We first consider the causes of errors in hospitals and medicine in general, before turning to cardiothoracic surgery services and intensive care units, which are the focus of this study.

2.3.1. Hospitals and medicine in general

Several studies have classified the causes of errors in hospitals and medicine in general. Two studies (57,58) were among the first to analyze the process of data integration among physicians. They identified four common causes of errors: incorrect synthesis (lack of knowledge about a disease leading to an incorrect conclusion); premature closure (not all disease processes were either discovered or considered); inadequate synthesis (data do not support a clinician's conclusions), and omission (important information that could have led to a correct diagnosis was not obtained).

Several authors concur that many medical errors arise due to issues surrounding the operational management of healthcare systems (59,60,61). Such issues include high workload, speedy organizational change, inadequate supervision and a faulty chain of command. Others suggest that errors arise due to equipment failure (62). Leape et al., (1995) (63) focus instead on medication errors such as lack of drug knowledge, lack of information about the patient, rule violations, slips and memory lapses, transcription errors, issues surrounding drug identification or dose checking, faulty interactions with other services, inadequate monitoring and a lack of standardization.

Blendon (2002) suggests that the top four causes of errors are: insufficient time spent by clinicians with patients; overwork; stress or fatigue on the part of health professionals and failures of health professionals to work together or communicate as a team, and understaffing of nurses in hospitals. Teamwork breakdowns and lack of technical competence were the most prevalent contributing factors. Furthermore, issues surrounding handoff and a lack of supervision were disproportionately more common among trainees (64).

Benner et al., (2002) focused on nursing errors, identifying eight categories of error: lack of attentiveness; lack of agency and fiduciary concerns; inappropriate judgment; lack of intervention on the patient's behalf; medication errors; lack of prevention; missed or mistaken healthcare provider's orders and documentation errors. Causes of errors at the system and practice responsibility levels were also identified (65).

As Al-Assaf, et al., (2003) observed that errors are caused by the execution of a task that is either unnecessary or incorrectly carried out and that could have been avoided with appropriate distribution or pre-existing information (26).

Further studies also suggest that the majority of errors stem from system and process failures (66,67,11). Specifically, the authors state that errors emerge during normal workflow and during preparation for care delivery, resulting from breakdowns in the supply of materials or information across organization boundaries (11).

McFadden and Stock, (2006) take a different approach, describing external and internal causes of errors in healthcare provision in hospital settings. External causes relate to equipment failure, infrastructure breakdowns and disruptions in communication systems. Internal causes relate to unplanned shortages in capacity, scheduling of fatigued staff and unexpected demand for personnel in a specific area (68).

Studies have also shown that physicians and nurses are particularly vulnerable to medical errors due to teamwork failures, especially lack of supervision. Singh et al. (2007) suggest that graduate medical education reform should focus on strengthening these aspects of training (69).

A study by Hilligoss et al., (2011) covered similar ground, noting that a formal, structured handover process for pediatric patients transitioning to the intensive care unit after cardiac surgery can reduce the medical errors that arise during the admission process, and also improve teamwork among caregivers (70). Two further studies suggest that the omission of critical information and the transfer of erroneous information during handoffs also causes errors in healthcare provision (20, 21). Finally, Starmer et al. (2014) note that communication failures, including miscommunications during handoffs of patient care from one resident to another are a leading cause of errors (22).

In summary, errors in hospitals and in medicine in general arise for a wide variety of reasons. Table II summarizes the key causes in this clinical context.

2.3.2. Cardiothoracic surgery services and intensive care units

This study focuses specifically on cardiothoracic surgery services and intensive care units. Medical errors also arise for a wide variety of reasons in these two clinical contexts. A key early study by Donchin et al., (1995) advanced that lack of standardization and the congestion of instruments, monitors, wires, and intravenous catheters around a patient's bed are important causes of medical error (46). These factors complicate access to a patient's bed and lead to issues with identification and status assessment. Tubes, fluid bags and drugs may also be insufficiently marked or have labels that are hard to read.

O'Connor et al., (2004) suggest that errors in this context may be caused by a failure to follow policies or protocols, inattention, communication problems, errors in charting or documentation, distraction, inexperience, labeling errors and poor teamwork (71).

Nast et al., (2005) state that the most frequent causes are related to human and organizational factors, and in fact events often have multiple causal factors. They go on to propose that the application of a causal classification model for patient safety event coding in the intensive care and preoperative and postoperative care units would facilitate the communication of important event-related information (72).

The main aim of a study by Sanghera et al., (2007), was to explore the attitudes and beliefs of healthcare professionals relating to the causes of errors in an intensive care unit. Staff identified many contributing factors, including miscommunications, frequent interruptions, and issues surrounding medications (73). Organizational factors included a lack of clarity on the responsibility of nurses, a lack of feedback on medication errors,

and a common and accepted practice of administering medication without a complete medication order. Barriers to reporting included administrative paperwork and lack of encouragement by management.

Finally, a recent study by Zeggwagh et al. (2014), classified causes of errors according to: defective or unavailable equipment, inadequate communications, inadequate training or supervision of clinical staff, delays in investigations, inadequate staffing, and inadequate functioning of hospital departments (54).

In summary the main causes of errors in this specific clinical context are a lack of standardization and congestion of instruments, a failure to follow policy or to implement a protocol, communication problems, errors in charting or documentation, inadequate training or supervision of clinical staff, poor teamwork and medication problems. These causes are summarized in Table II.

Table II. Summary of the causes of errors that were investigated in different studies

Causes	Hospitals in General	Cardiothoracic Surgery
Wrong synthesis (lack of knowledge about a disease leading to an incorrect conclusion);	x	
Premature closure (not all disease processes were either discovered or considered);	x	
Physicians not having enough time with patients (overwork, stress or fatigue);	x	x
Understaffing of nurses; teamwork breakdowns; lack of technical competence;	x	
Lack of attentiveness; lack of agency and fiduciary concern; inappropriate judgment;	x	
Lack of intervention on the patient's behalf; lack of prevention; missed or mistaken healthcare provider's orders and documentation system and practice responsibility levels;	x	
Execution of tasks that are unnecessary or incorrectly carried out;	x	
Unplanned shortage of capacity, scheduling fatigued staff and unexpected demand for personnel in a specific area;		
Teamwork failures, especially lack of supervision; Faulty chain of command;		
Omission of critical information and the transfer of erroneous information during handoffs;		
Communication failures, including miscommunication during handoffs of patient care from one resident to another;	x	x
Lack of standardization and congestion of instruments, monitors, wires and intravenous catheters around the patient's bed;		x
Delay in investigations (laboratory tests, X. ray);		x
Failure to follow policy or to implement the protocol;		x
Inattention; communications problems; error in charting or documentation;		x
Inadequate training or supervision of clinical staff; poor teamwork;		x
Medication problems: lack of clarity on the responsibility of the second nurse's check for medication administration, lack of feedback on medication errors; accepted practice of administering medication without a complete medication order		x

According to the literature review, it seems that there aren't clear differences in terms of the causes of errors in cardiothoracic surgery/ICUs and hospitals in general. However lack of standardization and congestion of instruments around the patient's bed and delay in investigations (laboratory testes) are only mentioned in cardiothoracic surgery/ICUs.

2.3.3. Summary and next steps

To date, much of the existing knowledge of the causes of medical errors has been generated in studies in hospitals in general. Few studies have addressed the causes of errors in specific departments and few studies have explored the relationship between errors and causes. To better understand these issues, it would be useful to study a specific department in a hospital where the patient flow is thoroughly programmed. The remainder of this chapter presents such a study. We focus on a cardiothoracic surgery service where

only open-heart surgeries take place. In this service department all activities are tightly scheduled from patient arrival at hospital to surgery and then discharge. We conduct a detailed study of hospital nursing and clinical care processes to explore the types of error that arise in this area of surgery and to investigate the possible causes of these errors.

From all data collection it was possible to design the follow diagram that represents the analyzed processes (**appendix 1**).

The following section describes the methodological approach that underpins this study.

3. Methodology

A qualitative methodology was selected in order to fully understand the medical errors that arise in our case study: cardiothoracic surgery services. Such an approach “*allows the researcher to study and codify the social realities under analysis, described through verbal reports, written records or visual data*” (74). This approach is also consistent with the advice of grounded theorists (75) who emphasize the importance of gaining a solid base of observed events and descriptions as precursors for theory building (11).

The research objective is to study types and causes of errors in one cardiothoracic surgery service. Hence, attention is draw to the specific cardiothoracic surgery unit, which is the study`s unit of analysis.

3.1. Case selection

In the following section we present the results of the analyzed data followed by a discussion of the main types of error and its causes against the existing literature.

3.2. Data collection

Data collection was guided by a protocol that we developed comprising a list of the research variables to be addressed, indicative questions to be asked, and potential sources of information and field procedures. Prior to the main study a pilot study was undertaken to refine the data collection plans with respect to both the content of the data and the procedures to be followed (76). Three approaches were ultimately used to collect data for this study: face to face interviews, direct observation, and analysis of archival data. These approaches are described in the following sub-sections. In all cases, data were collected between May 2014 and March 2015.

3.2.1. Face to face interviews

Data were first collected via face to face interviews with consenting physicians, nurses, administrative staff and technicians at the hospital. The interviews with administrative staff and technicians were conducted in order to obtain in depth knowledge of hospital operations and daily administrative procedures. The interviewees were volunteers who met key criteria (e.g. masculine and feminine gender; ages between 18 to 64; they had to work on all shifts; they want to talk about medical errors; 5 years of experience in cardiothoracic surgery services). All interviews were conducted and recorded by the author. Using a grounded theory approach, interviews were then transcribed verbatim and

imported to Nvivo (77) for analysis. An inductive process was then used to open-code the transcripts for themes relating to interviewee opinions (77). **Appendix 2** presents the field procedures and the interview question guide. However the main research questions are: What types of errors exist in cardiothoracic surgery activities? Which are the possible causes of those errors? What causes lead to those errors?

Semi-structured interviews (45 interviews) were conducted with healthcare professionals: 17 physicians, 20 nurses and eight administrative staff and technicians. The characteristics of these interviewees are described in Table III.

Table III. Interviews' characteristics

Group	Gender		Ages				Total
	M	F	18-29	30-39	40-49	50-64	
Administratives and Thecniques	2	6	0	5	3	0	8
Nurses	3	17	0	5	8	7	20
Physicians	13	4	0	3	4	10	17
Total							45

3.2.2. Direct observation

This interview data was supplemented by data collected during 930 hours of direct observation of staff in the cardiothoracic surgery service: medical check and patient admission: 25 hours; preoperative: 140 hours; intraoperative: 140 hours; operating room 140; intensive care unit: 320; infirmary: 140 hours and patient discharge: 25 hours.

Physicians and nurses working in the cardiothoracic surgery service were directly

observed. The observation style was observer-as-participant (78), with detailed information recorded on the daily tasks of the healthcare professionals in this service. Observations ranged from 2 to 5 hours in duration and included all three shift changes to ensure that variation in the physicians and nurses tasks were captured. Observations were also carried out on all five days of the working week (observations on a Monday also included a review of the weekend). After the observations had been collected, the author wrote a detailed transcript of the day's events.

3.2.3. Archival data

In addition, a wide range of materials were evaluated as part of the review of archival data. The origin and content of these documents is summarized in **appendix 3**. In the following two sub-sections we describe the types of error that arise in cardiothoracic surgery services, and the causes of these errors.

These materials included both internal process documents and other forms of communication such as audio recordings and institutional websites. These documents were analyzed to evaluate factors, undertake comparisons, note apparent contradictions and similarities, make inferences and gain insight (79).

3.2.4. Data analysis

The data that was extracted was organized and coded following the usual guidelines for qualitative research (80). It has been noted previously that the implementation of a strong data coding mechanism is an important component of the methodological process (75).

Coding is deep reflection about and thus, deep analysis and interpretation of the data's meanings. Codes are primarily used to retrieve and categorize similar data chunks so the researcher can quickly find, pull out and cluster the segments relating to a particular research question, hypothesis, construct or theme. The codes that we identified via our analysis of archival data fall into two broad categories, which were reviewed during data analysis and updated as required when new information emerged. The structure and the unity in code lists are summarized in **appendix 4**.

These categories were:

- Types of error (e.g. performance, prevention, diagnostic, medication, system, treatment, knowledge and skills, process errors);
- Causes of errors: (e.g. structural, flawed systems, task execution, miscommunications).

In the following section we describe the data that was collected via these three approaches, summarize the main types of error that were identified and discuss these findings, relating them to the existing literature.

4. Results

4.1. Types of errors in cardiothoracic surgery services

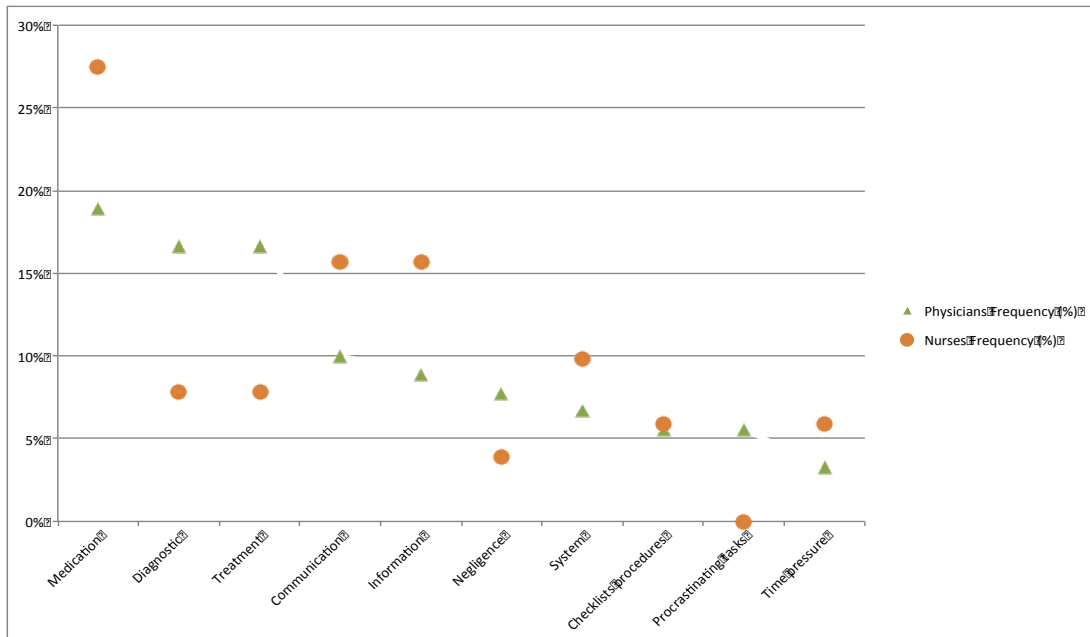
The types of errors that arise in this clinical context fall into a number of different categories. Table IV describes how frequently each type of error was identified in interviews with physicians and nurses. Figure 1 presents this information graphically.

Errors in eight broad categories are described in the following sub-sections. Quotations from the interviews with healthcare professionals are provided in appendix 5.

Table IV. Error frequencies in interviews with physicians and nurses

Type of Errors	Physicians			Nurses		
	Frequency (#)	Sequence	Frequency (%)	Frequency (#)	Sequence	Frequency (%)
Medication	17	1	19%	14	1	27%
Diagnostic	15	2	17%	4	5	8%
Treatment	15	3	17%	4	6	8%
Communication	9	4	10%	8	2	16%
Information	8	5	9%	8	3	16%
Negligence	7	6	8%	2	9	4%
System	6	7	7%	5	4	10%
Checklists procedures	5	8	6%	3	7	6%
Procrastinating tasks	5	9	6%	0	10	0%
Time pressure	3	10	3%	3	8	6%
	90		100%	51		100%

Figure 1. A comparison of error frequencies in interviews with physicians and nurses



4.1.1. Medication errors

Both physicians and nurses reported experiencing several types of error in this category. A majority of participants in both groups believed that these were the most frequently occurring errors in this context. These errors occurred at various stages of the medication process. At the start of the process, the interviewees observed both duplication of prescriptions and also incomplete prescriptions. They also reported erasure that compromised reading in the medication transcription. Observations and interviews also suggest prescription problems in the medication distribution.

"the situation's gravity depends on the medicine. For instance, I know of a case where ameadarona was mistaken for paracetamol. Ameadarona slows cardiac rhythm and paracetamol is for pains...and so, by swapping these two medicines, I might have caused a bracidardia to a patient because I gave him "ameadorona instead of paracetamol" (Physician, Female, aged, 50-64).

Further along the medication process physicians and nurses noted instances whereby the incorrect dosage of a drug was provided, or the correct dosage was provided at the wrong time or incorrect length of treatment was specified. The interviewees also observed daily failures in dose adjustment.

"I went through a situation when I changed ampoules...calcium ampoules specifically because the package was identical, however one ampoule was to compensate the calcium deficit, the other calcium chloride was an emergency drug." (Nurse - Female, aged 40-49).

“A patch of fetamil was given to a patient (for chronic pain) and prescription was 50 but we gave 25 because that was all left in stock and that meant that the patient remained with pain” (Nurse, Male, aged 30-39).

In addition, the interviews revealed that medication errors emerged more frequently when patients were recovering, either in the intensive care unit or the infirmary. In the intensive care unit, these failures are mostly related to the provision of the incorrect medication at the wrong dose. In the infirmary the failures are related to the provision of medication at the wrong time, and nurses reported that a common error was that medications are not adjusted to the patient.

Through the flowchart we concluded that medication problems emerged in the patient treatment, namely in the transition times of medication strategy to medication therapy, and in the patient monitoring to patient recovery.

4.1.2. Diagnostic and treatment errors

The opinions of physicians and nurses differed in terms of which were the next most frequent errors. Physicians stated that the second and third most frequent errors were in diagnosis and treatment whereas nurses felt that communication and information errors were more common.

A key error identified by physicians was that they sometimes diagnose one disease and treat another (e.g. diagnose flu and treat pneumonia). One consequence of this type of error could be that a patient receives inadequate prophylactic treatment. Both physicians

and nurses thought that diagnostic errors happened most frequently at the preoperative stage of the patient pathway.

“When things go wrong in the hospital, physicians tend to be focused on doing what they do best: conveying medical information and treating the patient ... We are in the preoperative stadium before you treat, you have to diagnose and understand what’s going on... and the problem was that it’s not checked if the patient had or not a pre-respiratory insufficiency and if the patient needed respiratory optimization before the surgery” (Physician, Male, aged 50-64).

“One of our patients has a coronary and a moderate aortic disease. It is important to diagnose all kinds of diseases for which no problems occur in the post-operative” (Physician, Male, aged 40-49).

In terms of treatment errors, physicians noted that these can arise when treatment is delayed due to an abnormal test result. These errors emerge most frequently in the postoperative and recovery phases of the patient pathway, particularly in the intensive care unit, the infirmary and during patient discharge.

“When the patient has a cardiac arrest, we often have to reanimate the patient and make decisions quickly. At that time, there are many questions that had to be dealt with: “why did the heart stopped?” Were the potassium levels that caused it? (Physician, Male, aged 50-64).

Through the flowchart, it seems that the diagnostic errors emerged in the transition time of patient assessment and monitoring.

4.1.3. Communication and information errors

Communication is the second most frequently mentioned error by nurses. Healthcare professionals reported issues surrounding miscommunications between residents, noting that vague non-specific communications were common. This is less of an issue if healthcare professionals frequently work with the same team. In this situation, non-verbal communication is more common and reduces the need for verbal communication to, for example, confirm procedures. Most of the physicians who were interviewed also felt that implementation of oral and written communication procedures is not standardized, which leads to errors.

“Disruptions in communication between nurses and physicians are also an error cause... it seems that to improve this, patients would receive faster and more efficient care if nurses were authorized to make decisions such as, when it is necessary to remove a catheter or change of a medication dosage” (Nurse, Male, 50-65).

“a patient has been in an observation room and a physician and a nurse observed him. The physician asked the nurse for heparin (anticoagulant – stops the blood from clot). The nurse didn’t notice understand the word, did not question the command and gave adrenaline instead, we know that it increases

the heart rate frequency and the amount of blood pumped in each heart beat, yes, can kill the patient..."(Physician, Male, aged 40-49).

The third most frequently mentioned error by nurses relates to the recording, checking, processing and interpretation of information. Nurses expressed particular concern that routines can become so ingrained that when checks are performed, some of the items are forgotten. A further issue is that healthcare professionals often have to record a lot of information in a short period of time. In such a situation, they state that they have to turn to their memory instead of registering information, which leads to errors. Both nurses and physicians suggested that shift-changes help to reduce these errors, as nurses can become overwhelmed with information during longer shifts, leading to more errors.

Some nurses noted that when information is provided by physicians the enunciation is sometimes not explicit. As nurses are often reluctant to ask physicians to repeat information, this can lead to processing errors. Errors in the provision of data on blood pressure and urine flow were noted.

The transmission of the patient` allergies as an error related with information passage.

"This information was transmitted orally and has not been recorded in the patient process, but this kind of data has to be very visible in the patient's file, because it could cause problems to the patient." (Nurse, Female, aged 30-39).

“In a shift change, a nurse didn’t pass the necessary information to his colleague so that the patient would remain without eating because he would go thru a CT Scan (Axial Tomography Computerized) first thing in the morning (Nurse, Female, aged 40-49).”

Further issues are related to the omission of critical information. This can happen if, for example, the night shift receives a patient with an arrhythmia that was not accounted for but they don’t pass this information on to the day shift because they don’t consider that it is relevant. Finally, it was noted that interpretation of information can vary quite widely between healthcare professionals.

“one patient must take a drug of 60 mg one pill but one pill it’s in another document, nurses can only read the first page and not read the remaining lines eventually take a pill and not one and a half” (Physician, Male, 40-49).

“we also have the case of the information that is not passed thru to the next level or shift change and become unknowned and is also a mistake (Physician, Male, 40-49).

Through the flowchart it seems that these two types of errors occur in the largest part of the processes, namely in patient assessment and control; and patient treatment (non medication and medication therapy and strategy).

4.1.4. Negligence related errors

Errors relating to negligence were the sixth most frequently cited error by physicians and the ninth most frequently cited error by nurses. Both physicians and nurses stated that this type of error is associated with ignorance and exhaustion. Some physicians noted that the cardiothoracic surgery department has specific care requirements, and that patients require careful monitoring following surgery. This requires that a clear and structured plan is put in place for patient recovery in the intensive care unit. However, other staff often fail to follow this plan. Nurses reported that support is required to avoid such errors.

However, other healthcare professionals described how these patient plans can be volatile, in part because patient symptoms can change every few hours. This makes this variable difficult to control. In the analysis of archival data, negligence errors were observed due to a lack of implementation rules, which often leads to delays in surgeries. Through the flowchart it seems that this type of errors occur in patient monitoring and treatment.

4.1.5. Systematic errors

Both physicians and nurses also highlighted systematic errors. For nurses, this was the fourth most frequently cited error. Such errors can arise when equipment is not working (e.g. because of a system break), or when equipment is out of place and it takes time for it to be located. Another cause of these errors is when healthcare professionals do not correctly insert full details of all procedures in the computer system.

“Today there are a lot of generics, and heparina is frequently used to prevented the blood to coagulate. If it doesn't work surgery is the only option. We have witnessed that a specific type of heparina coagulates and forces the patient to receive higher dosage to make it feasible. A number of questions arise: are we ministering the right drug? It is working as predicted? (Physician, Male, 40-49).

"if 48 hours have passed since surgery and the patient remains on hepatic diet due to anesthesia and the body's evolution, the type of food that the patient can eat had to be inserted in the system but the physicians don't comply consistently" (Nurse, Male, 40-49).

“Drugs prescription is not up to date in the system. Often, the patient has to go thru draining after a surgery and some of the times physicians have to be warned by the nurses... On other occasions while going thru draining the antibiotic is suspended and we are ones who call out" (Nurse, Female, 30-39).

According to the flowchart it seems that system errors increase in patient monitoring, namely control and inside parameters verification and in patient treatment, non medication and medication therapy.

4.1.6. Checklist procedure errors

The sixth broad category of errors relates to checklist procedures. Such errors often arise because checklists in this clinical context can be extensive, with up to three pages of

unstructured information, and are sometimes performed from memory. As a consequence, nurses and physicians do not register some events, or do not even execute the checklist.

“The most frequent failure is not to follow everything that is in the checklists. In a majority of cases the professionals check the options without even checking. The same physician’s state that checklists are extensive and comprehensive but are not thought out to be particle. Sometimes they are redundant”.(Physician, Male, 50-64).

“The patient’s potassium was corrected instead of the sodium or he was given x grams of an antibiotic instead of y grams – the professional changes an ventilator parameter or even a medication and doesn’t check for changes in the condition after an hour” (Physician, Male, 50-64).

"On Friday, a patient left the ICU for the infirmary with a urinary catheter. The doctor in charge left a written instruction so that the urinary catheter would be removed on Sunday morning. On Tuesday, the physician received a phone call from a nurse asking if she could remove the urinary catheter from the patient" (Nurse, Female, aged 40-49).

According to the flowchart it seems that check-lists errors increase in patient assessment and in patient treatment, namely non medication.

4.1.7. Time pressure errors

These errors were mentioned infrequently by physicians and nurses and relate to a lack of time and a hurry to leave following a shift. Physicians stated that sometimes they have less time to study patients than is required, and that this can lead to either inadequate surgical strategies or excessive workloads and prolonged surgeries. A further issue highlighted in this category is that time pressures, combined with a sense of responsibility towards patients, can make it difficult for nurses to verbalize concerns about errors. Indeed, some nurses were resigned to the fact that daily failures are a part of providing health services.

"Sometimes we have shorter time than required to study the patients, that can lead to inadequate surgical strategy or excessive workload and prolonged surgeries"(Physician, Male, 50-64).

"Time pressure, specifically lack of time to study the patients, can lead to inadequate surgical strategy" (Physician, Male, aged 50-64).

"Often, they have to change the patient to the infirmary from the intensive care unit but sometimes they don't have physical space" (Nurse, Female, aged 30-39).

"An example it's the fact of distributing beds in the intensive care unit; "when beds are constantly being given to different patients according to number our

clinical state, there will also be a need to put in a bed all who left the surgery.

Planning is essential" (Nurse, Male, aged 50-64).

Through the flowchart, it seems that time pressure is more present in patient monitoring and in transition times namely operating room to intensive care unit and intensive care unit infirmary.

4.1.8. Procrastination related errors

Finally, physicians noted that procrastination-related errors can delay the start or the completion of tasks. For example, we observe that the process is defined based on hierarchical needs and not on the current patient needs. Observations showed that individuals are overwhelmed by ever-growing incoming information and requests for their attention in their private as well as their work environment. In fact, individuals have to decide on how to prioritize tasks.

Half of the physicians interviewed mentioned that they procrastinate tasks across a variety of daily tasks. The interviews also identified situations where something is postponed constantly for several reasons. For example, if the workload is excessive or if they have emergency situations there is no way to be effective and that causes task procrastinating. One physician stated that he had to spend an hour with each patient looking into several items but, if he had nine patients in a ICU it is clear that he won't spend 9 hours with his routes.

"If the work load is excessive, there is no way to be effective and that causes task procrastinating... a physician has to spend an hour with each patient

looking into several items but, if he has nine patients in a ICU it is clear that he won't spend 9 hours with his routes" (Physician, Female, aged 40-49).

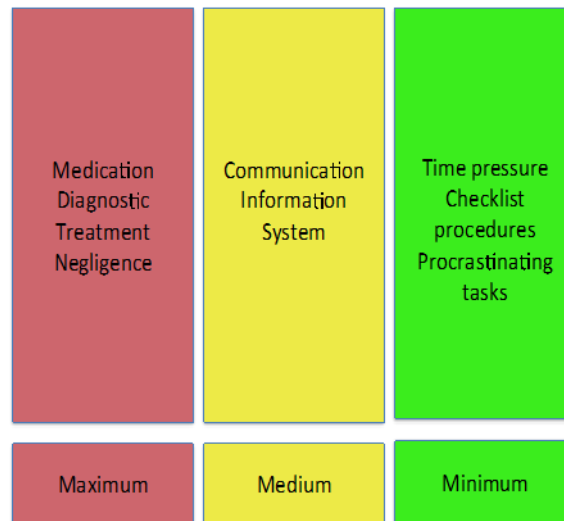
"The process is defined based on the hierarquical needs and not on the actual patient needs. Some tasks are postponed and will lead to errors in the ICU but also on other points of the patient pathway" (Nurse, Female, aged 40-49).

Through the flowchart, it seems that procrastinating tasks occur more frequently in patient assessment, namely verification of patient condition every three hours during two days.

4.1.9. Intensity of errors

The errors identified in the previous seven sub-sections can be categorized according to their intensity. This categorization was deduced not only from the literature review as also from the interviews and the observation process. Figure 2 summarizes this information. The errors that fall into the maximum intensity category are those related to medication, diagnostics, treatment and negligence because this type of errors could cause harm to the patient. Medium intensity errors are those from which the patient might recover. These include errors related to miscommunication, information and systems. Minimum intensity errors do not place patients in danger. In this context, these errors are related to checklist procedures, procrastinating tasks and time pressure.

Figure 2. Types of error arising in cardiothoracic surgery services, by intensity



4.2. Physicians and nurses' views on the causes of errors

The causes of the errors identified by physicians and nurses fell into five categories: staff fatigue, handover failures, equipment failures, miscommunications and other causes. Table V describes how frequently each cause was identified in interviews with physicians and nurses. These categories are described in more detail in the following sub-sections.

Table V. Cause frequencies in interviews with physicians and nurses

Causes of Errors	Physicians			Nurses		
	Frequency (#)	Sequence	Frequency (%)	Frequency (#)	Sequence	Frequency (%)
Staff Fatigue	15	1	28%	18	1	29%
Handovers - information and responsibility	13	2	24%	13	3	21%
Miscommunication	12	3	22%	15	2	24%
Equipment failures	10	4	19%	9	4	15%
Lack of performance	4	5	7%	0	6	0%
Lack of availability	0	6	0%	7	5	11%

4.2.1. Staff fatigue

Both physicians and nurses identified fatigue and sleepiness as two of the key causes of medical errors, noting that 24 hour long shifts were not uncommon. Physicians also stated that they made many more serious errors when they worked frequent shifts of 24 hours or more. Nurses commented that staff fatigue was associated with work pressure and stress. A high weekly workload, insufficient financial compensation and daily exposure to a stressful workplace (with constant requests and emergencies) were also mentioned.

4.2.2. Handover failures

As patient care becomes more complex, the number of handovers required between healthcare professionals is increasing, and both physicians and nurses increasingly depend on receiving critical information from each other in a timely manner. However, these handovers can fail, causing errors. Key handover points where errors occur include care transitions. At these times it is particularly important that insights are shared, treatments are coordinated, and decisions are collaborative (Sutcliffe et al., 2004). Information failures can also occur at shift changes, when daily rounds are organized, and patient pathways are reviewed.

With regard to responsibility, most physicians stated that they pass responsibility on to nurses daily. For example, physicians prepare prescriptions but in the intensive care unit it is nurses who administer the prescribed medication to patients. In some cases (e.g. use of potassium) administration by nurses is done empirically without any input from physicians, which can lead to errors due to a lack of clinical knowledge. Responsibility handover from physician to physician can also cause errors. One physician described how

a senior physician performing heart surgery was called away urgently to perform another surgery. A junior surgeon replaced him to perform the original surgery and several processes then went wrong (e.g. an oversized vent was used, a laceration to the lower left pulmonary vein occurred, and the patient eventually died).

4.2.3. Equipment failures

The third category of causes of errors related to equipment failures. Errors can be caused by equipment that has not been connected, causing a process delay, or equipment that is not functioning as expected. For example, we observe a patient who stayed in the intensive care unit waiting for a specific equipment that would have to come from another hospital. Issues also sometimes arise with software which is not updated due to the high costs of doing so. Finally, the more widespread adoption and use of electronic health records was said to be problematic, as these tools are not focused on improving patient safety.

4.2.4. Miscommunication

Both physicians and nurses reported that miscommunication cause errors in cardiothoracic surgery. According to physicians, the lack of language structure and the misinterpretation of speech devalue the relevance of medical notes cause medical errors. Other potential causes of errors included the transmission of information orally (i.e. not by writing), the fact that information is not communicated at the weekend and the fact that surgical protocols were rarely discussed. For example we observed that nurses have fear of ridicule or punishment when they need to interrupt the physicians. ‘The Gap’ exists between work as perceived by managers and work as performed by front line staff.

This gap is endemic to top down safety approaches.

4.2.5. Other causes

Two further causes were highlighted that fell outside of these four categories. First, nurses stated that the medical errors that are commonly ascribed to their actions are sometimes caused by the limited availability of physicians to respond to questions from nurses, and also the fact that procedures are not applied consistently. Second, some physicians noted that errors could be caused by deficiencies in performance due to the limited personal consequences arising from medical errors (e.g. not acting in good time or overacting).

5. Discussion

In this chapter, we have provided an overview of medical errors, their types, causes and intensities. We have also presented the methods and results of a study which investigated the types and causes of errors in a cardiothoracic surgery service. In this section we discuss the findings from the previous four sections of the chapter and consider the implications of our findings for managers.

A number of publications were identified which considered the topic of medical errors. Furthermore, the World Health Organization (2009) has developed an error classification typology with twenty-nine different error types (81). This clearly indicates that there has been a relevant shift in the importance of this topic. However, past studies have focused on only the most common types of error, related to medications, miscommunications and systematic errors. Our study adds to this literature by proposing an updated error

classification typology, which now includes information failures, ignorance; checklist failures; errors related to time pressure and errors related to procrastination.

From this study comes the knowledge of a new classification that can be used in future studies. As there is service knowledge, it seemed important to group errors into the following tipification:

- By the source of the error (e.g. planning, execution, process, knowledge and skills, systems);
- By the area of occurrence (e.g. medication, diagnostics; performance; prevention; treatment; guidelines, inadequate reporting, delays in the provision or scheduling of a service);
- By a combination of the two previous systems (e.g. diagnosis, surgical and medical treatment mishaps);
- By the agent involved (e.g. clinician factors, communication and administration).

A key insight from our review of the literature was that errors can also be classified according to their intensity. We therefore proposed a classification relating intensity with impact. For example, maximum intensity errors can lead to patient death, whereas medium intensity errors are those from which a patient might recover. Minimum intensity errors do not constitute a danger to patients.

This classification system helps to determine error intensity which can assist to determine the previous phases on the process that need to be reviewed and which could lead to error reduction.

Our study shows that the most frequent errors occur in medication, diagnoses and treatment and these should be the focus of the process review.

Furthermore, our research suggests that the causes of errors are not the errors themselves but problems with changes, confusion, lack of action, concentration, information confirmation or procedures that have gone wrong. It seems that the central elements to all these problems is amplification and error propagation.

Data also suggests that there are errors that are “easy” to deal with, specifically communication. There are also “main errors” that are the most quoted, namely medication, diagnostic, treatment and negligence. Finally there different errors in terms of being a novelty that is not mentioned in the literature and are one if this study conclusions, which are checklists procedures and procrastinating tasks.

Our study of a cardiothoracic surgery service built on these findings by interviewing physicians and nurses who noted that daily errors are an inevitable consequence of providing healthcare services. The interviewees identified several key causes of errors in this context, including staff fatigue, miscommunications and handover failures. Our analysis of the results of these interviews was then able to explicitly link some of these causes to common medical errors. For example, miscommunication of information among physicians or between physicians and nurses can lead to diagnostic errors. Such miscommunication is driven by a culture that discourages transparency and disclosure, and which impedes attempts to learn from these events and improve diagnoses.

Furthermore, looking for alternative routes to solve such problems can lead to negligence, which can also cause errors.

A further finding from our case study work was that staff fatigue leads to treatment errors. Staff are becoming tired as a result of working 24 hour shifts (due to budget cuts and unapproved requests to hire new personnel) and this has a knock-on effect on patient safety. Finally, handovers are another cause of medical errors, particularly when information or responsibility are transferred between staff.

5.1. Implications for managers

Although this study focuses on hospital nurses and physicians in a cardiothoracic surgery service, the lessons learned have implications for managers as well. In this sub-section we propose a framework to assist managers, healthcare professionals and teams to efficiently handle medical errors. These are implications to the medical organizations but also to the cardiothoracic surgery service.

a). Work-flow improvement

A number of general points hold true. If tasks are scheduled and well oriented, this helps to reduce errors. Even though tasks must be structured and implemented, the professionals need to be prepared to handle unpredicted occurrences. So, teams need to be structured like an organizational workflow to better handle the unexpected.

For example, healthcare professionals should avoid procrastinating tasks and should apply the solutions of which they are already aware. Whenever tasks are postponed that is due to the lack of ability do prioritize them. For instance, when a nurse is changing a bandage, it should not be noticeable to the patient that he is concerned about put everything in the computer, but if he does not do that, he will be penalized.

b). Human resources management adapted

There has to be an adequate human resources management. This implies team's training and increasing awareness to alert mechanisms and error prevention. It is then necessary to evaluate individual performance, team's fatigue management and a positive acknowledgment of effort.

For example, teams should be motivated with financial compensations, rest extra hours, and by promoting their development as a professional by participating in congresses and courses. All the same, the emotional side of the professional needs to be nourished so that he knows that his work is of value.

A solution to staff fatigue if the budget allows, is to hire additional staff so that the team can rest more and then put extra effort into their work, while also limiting staff exiting the team. We also propose that two or three different hierarchical levels of nurses and physicians should do information and process supervision, so that every process data and all information will be more accurate.

c). Error detection culture and error correction

Accountability, a systematic review of the clinical processes and error detection needs to be implemented. There should also be a structured process of gathering, evaluating and implementation of those proposals.

For example, the most frequent type of error relate to medication. A key first step in solving these errors is for hospitals to analyze which products are most often associated with medication errors in cardiothoracic surgery services, possibly in collaboration with other hospitals. This could challenge pharmaceutical companies to resolve problems such as those associated with packaging formats and similarities between medications. Another issue will be the hospital improving the logistics of medication distribution. Medication comes from the hospital's drug store but there should be a thorough double-check in the receiving department.

External auditing needs to exist and whenever there is a recurrent error it should be reported to the supervising authority. There should be internal audits to the service quality (these are currently done by nurses and it shouldn't be so). A multi-department team that ensures every department participation should be responsible for this internal supervision and reports production.

New processes should also be implemented to avoid errors related to miscommunications.

A systematic review of communication should also take place and the teams that look

into the errors should also propose new communications solutions. There is a deficit of standardization on the doctor/nurse language. As in aviation, there must be an information validation done by specific codes/codification. For instance, a specific code should exist to prevent errors such as the following: the physician writes down a dosage of 300 for amedrona and assumes that everyone will interpret it in milligrams, but some of the times the nurse doesn't double-check and it could lead to error.

Finally, we also propose implementing a culture of safety in healthcare organizations, placing the responsibility for safety on everybody within an organization. This cultural change should be implemented at an early stage in the career pathway of nurses and physicians e.g. at medical school.

5.2. Strengths and weaknesses of this study

Our study has a number of strengths and limitations.

One of the strengths is related to literature review. Based on literature review, we developed a new error classification typology, namely the errors can be classified by the source of error; by the area of occurrence; by a combination of the two previous systems and by the agent involved.

Another key strength is that qualitative data on the subject of medical errors was collected directly from physicians and nurses in a specific clinical context.

In terms of the limitations of our study, our focus on a single case study limits our ability to generalize to a broad range of settings. Furthermore, observational studies can change the behavior of participants, for example by motivating high levels of performance (81). This might have introduced biases into our results.

A third issue relates to data collection, which was undertaken by a researcher who was not a medical specialist. This hampered our understanding of some of the events that were witnessed (11). Furthermore, observation is subjective: the beliefs of observers may influence what is recorded, hence data may not accurately reflect the dynamics of the situation (80).

Finally, whilst staff were encouraged to speak openly, it is possible the consequences of speaking up (i.e. fear of retribution) might have presented a barrier to complete disclosure (83).

5.3. Limitations

Our methodology had several limitations. Collecting data through observation presented several difficulties. The fact that the author was not a medical care provider hindered her ability to understand some events. Observation is subjective, observers` beliefs influence what is recorded and therefore data may not accurately reflect dynamics of the situation (80).

The results of this study are based on the analysis of types and causes of errors. The research work was based on the observation of the service process and interviews. Further replication of this work would therefore be necessary to generalize the ideas suggest by our results.

In this study, only the researcher had access to the data collected. An assessment also done by the managers or by other researchers would have increased the internal validity of the study.

5.4. Testable hypotheses for future research

Insights from this exploratory study can benefit future research by beginning to develop theory and propositions that can be tested using rationalist research methods such us survey analysis (79). Future studies should examine comparable units and have a performance measure that is linked to service preparation fail.

6. Conclusion

A systematization of the types and causes of errors can be drawn from the literature. However, this doesn't allow management to know how and where to implement improvements that will avoid and stop those flaws from happening.

In order to do that, we explored the actual process by observing it. We discovered that a part of the literature of errors classification overlaps itself if we consider the moment

when the flaw happens and the accountability for it. The moment in which the flaws are noticed, registered and in which most of them actual occur is whenever there is more than one professional involved and passing of responsibility occurs, that is, whenever there is judgement, decision and in transition times. That's where the potential for flaw occurs and the professionals are not fully aware of the relevance of this stage.

Concerning intensity, the importance of defining error intensity emerged. From the data analysis it became clear that some errors occur along the process or operation but have their origin in other areas or stages, namely planning and execution of earlier stages. In fact, a lot should be transposed to planning and execution so that all the actions assure the planned result.

We also concluded that when error accountability is implemented, it is easier to prevent errors from happening.

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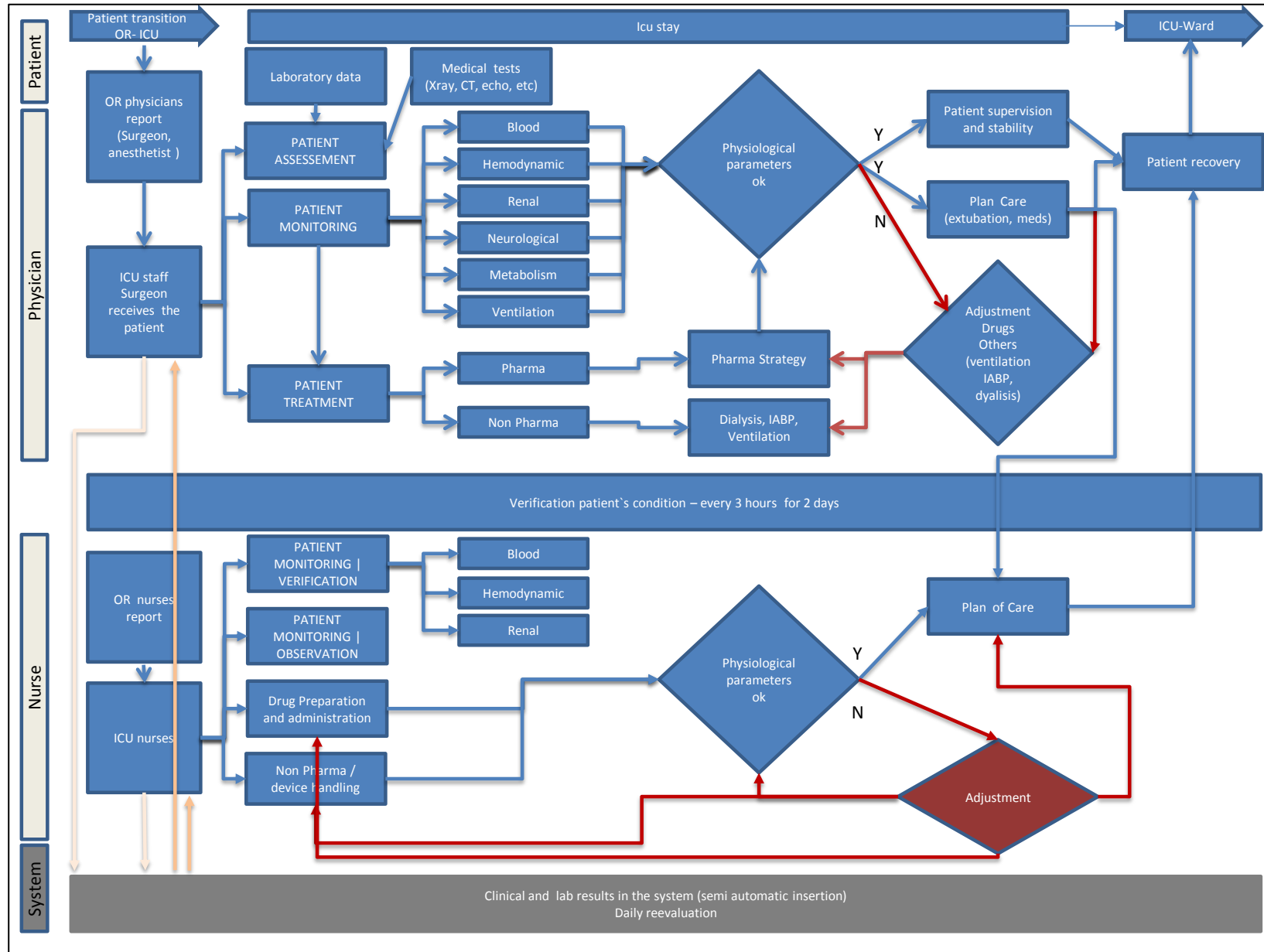
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APPENDIX

Appendix 1. Process mapping in the intensive care unit



Appendix 2. Field procedures and interview question guide

1. Pre-visit to the Hospital

- (a) In the organization is identified a research representative (nurse) who acts as main coordinating link between the researcher and the hospital;
- (b) Archival resources are investigated to provide background information on the hospital site. This may include the software platform of errors reporting; protocols, annual reports, databases and general information about the healthcare portuguese service system.

2. On site procedures

- (a) Formal presentation of myself and of the research project;
- (b) Confidentiality (term signed by the researcher);
- (c) Tape record policy – ask for permission to tape record the interview guaranteeing the confidentiality of the data and that it only be used to dispense the researcher of being so worried in taking notes. No recorded information will be used without authorization.

In the second meeting with the hospital research representative, the research tries to identify the physicians and nurses knowledgeable about the areas addressed by the study with which semi-structured interviews will be conducted.

3. Case Study Protocol, Questions and Interviews

The goal of this paper is to understand types and causes of medical errors: lessons from a cardiothoracic surgery service.

This study can be divided in two main research questions:

1. Types of error that arise in cardiothoracic surgery services;
2. The possible causes of these errors.

The relationship between causes and types of error are also explored.

The next table detail the questions that the researcher kept in mind and that were answered about each topic, namely types and causes of errors and the potential sources of information for answering the questions.

Appendix 2. The Interview Question Guide

Context Areas	Patient Pathways	Questions	Interviews
<p>Type of Errors</p> <p>Causes of Errors</p>	<p>Patient Admission</p> <p>Preoperative</p> <p>Intraoperative</p> <p>Intensive Care Unit</p> <p>Infirmery</p> <p>Patient Discharge</p>	<ul style="list-style-type: none"> •What is your understanding of what an error/medical error is? •What is your knowledge of what types of errors/failures exit in hospitals, or in cardiothoracic surgery services? •Can you describe us some error examples that happen with you daily, Or with your colleagues and teams? •What are the most critical to the patients and to patient safety? •What are the possible causes for them? •Which are the primary causes of these failures? •To the best of your knowledge, can you describe us incidents /errors in your own words and comment possible causes? 	<p>Administratives</p> <p>Thecnicians</p> <p>Physicians</p> <p>Nurses</p>

Appendix 3. Summary of the materials evaluated in the review of archival data

Hospital Stages	Document Topic	Content
External Consultation	Examples of Patient identification forms Outpatient sheet registration	General procedures, for the employees doing the patient registration
Patient Admission	Nursing data collection form	detailed Steps and descriptions for process analysis
Preoperative	Anesthesia form Preoperative ID form Surgical check-list form	Detailed information about general procedures and tasks
Intraoperative	Patient security surgical check Operative room check list Nursing protocol between OR and ICU Surgical Ccheck list	Detailed information about general procedures and tasks
Intensive Care Unit	ICU protocol reception Pre bypass checklist ICU Checklist	Procedures, steps and descriptions to processes analysis
Infirmary	Infirmary transference form Nursing Diary Infirmary form (infirmary diary)	Procedures, steps and descriptions to processes analysis
Patient Discharge	Program of Patient medication form Nursing discharge note	Details defined to analysed the patient discharge process
Risk Office	Joint Comission international - Patient Identification Informative document - Patient safety Mecanisms and procedures of identification in healthcare institutions Policy (definitons about: patient safety; error; incident; damage; adverse event) Clinical Governance Policy Political risk management - policies and procedures Annual plan of internal quality audits Reporting incidents form Shift change information Healthcare professionals training plan seminars Clinical audit plan Internal audit quality program Pacient safety policy manual World Health organization - research policy	Mechanisms and patient identification procedures Procedures to solve specific problems for patient safety policy

Appendix 4. Structure and Unity in Code Lists

1. Description

Codes are labels that assign symbolic meaning to the descriptive or inferential information compiled during a study. Codes usually are attached to data “chunks” of varying size and can take the form of straightforward, descriptive label or a more evocative and complex one. Saldaña (2013) defines a code as most often a word or short phrase that symbolically assigns a summative, salient, essence-capturing, and/or evocative attribute for a portion of language based or visual data.

Our data can consist in interview transcripts. The portion of data to be coded during first cycle coding processes can range in magnitude from a single word to a full paragraph to an entire page of text. In second cycle coding processes, the portions coded can be the exact same units longer passages of text, analytic memos about the data and even the reconfiguration of the codes themselves developed so far. In qualitative data analysis a code is a researcher generate construct that symbolizes and thus attributes interpreted meaning to each individual datum for later purposes of pattern detection, categorization, theory building and other analytic processes (Miles and Huberman, p.72).

Display 1.1. is our structured code list: a star list of codes, keyed to research questions (in this case).

Display 1.1. Illustration of a start list of codes

Category: Types of Errors – ErrTyp

Abbreviation: ErrTyp

Type of Errors (ErrTyp)	Abbreviation
ErrTyp: Performance	Pe
ErrTyp: Prevention	Pn
ErrTyp: Diagnostic	Dc
ErrTyp: Medication	Mn
ErrTyp: System	Sm
ErrTyp: Treatment	Tt
ErrTyp: Knowledge	Ke
ErrTyp: Skills	Ss
ErrTyp: Planning	Pg
ErrTyp: Execution	En
ErrTyp: Equipment	Et
ErrTyp: Clinical	Cl
ErrTyp: Communication	Cn
ErrTyp: Administrative	Ae
ErrTyp: Payment	Pt

Category: Causes of Errors –ErrCau

Abrevitation: ErrCau

Causes of Errors (ErrCau)	Abrevitation
ErrCau- Structural	Sl
ErrCau- Formal dimension	Fd
ErrCau- Informal dimension	Id
ErrCau-Technology dimension	Td
ErrCau- Physical dimension	Phd
ErrCau- Flawed systems	Fs
ErrCau- Task execution	Te
ErrCau- External reasons	Er
ErrCau- Internal reasons	Ir

Appendix 5. Selected quotations from the interviews with physicians and nurses

Types of errors	Physicians quotations	Nurses quotations
Medication	<p>"the situations gravity depends on the medicine. For instance, I know of a case where ameadarona was mistaken for paracetamol, Ameadarona slows cardiac rhythm and paracetamol is for pains...and so, by swapping these two medicines, I might have caused a bradycardia to a patient because I gave him "ameadorona instead of paracetamol" (Physician, Female, aged, 50-64).</p>	<p>"I went through a situation when I changed ampoules...calcium ampoules specifically because the package was identical, however one ampoule was to compensate the calcium deficit, the other calcium chloride was an emergency drug." (Nurse - Female, aged 40-49).</p> <p>"A patch of fetamil was given to a patient (for chronic pain) and prescription was 50 but we gave 25 because that was all left in stock and that meant that the patient remained with pain"(Nurse, Male, aged 30-39).</p> <p>"Sometimes nurses got the prescription wrong because the patient was not sitting on the bed but on a couch and that implied a swap in medication...it is always necessary to call out the patient's first and last name"(Nurse, Female, aged, 40-49).</p>
Diagnostic	<p>"We are in the preoperative stadium before you treat, you have to diagnose and understand what's going on... and the problem was that it's not checked if the patient had or not a pre-respiratory insufficiency and if the patient needed respiratory optimization before the surgery"(Physician, Male, aged 50-64).</p> <p>"One of our patients has a coronary and a moderate aortic disease. It is important to diagnose all kinds of diseases for which no problems occur in the post-operative" (Physician, Male, aged 40-49).</p>	
Treatment	<p>"when the patient has a cardiac arrest, we often have to reanimate the patient and make decisions quickly. At that time, there are many questions that had to be dealt with: "why did the heart stopped?" Were the potassium levels that caused it? (Physician, Male, aged 50-64).</p>	
Communication	<p>"a patient was been in an observation room and a physician and a nurse observed him. The physician asked the nurse for heparin (anticoagulant – stops the blood from clot). The nurse didn't notice understand the word, did not question the command and gave adrenaline instead, we know that it increases the heart rate frequency and the amount of blood pumped in each heart beat, yes, can kill the patient..."(Physician, Male, aged 40-49).</p> <p>"oral and written communication and implementing communication procedures is not standardized and this leads to errors. There was the need to define the possible process flows across the patient pathway activity" (Physician, Female, aged, 30-39)</p>	<p>"Disruptions in communication between nurses and physicians are also an error cause... it seems that to improve this, patients would receive faster and more efficient care if nurses were authorized to make decisions such as, when it is necessary to remove a catheter or change of a medication dosage" (Nurse, Male, 50-65).</p>
Information	<p>"one patient must take a drug of 60 mg one pill but one pill it's in another document, nurses can only read the first page and not read the remaining lines eventually take a pill and not one and a half" (Physician, Male, 40-49).</p> <p>"we also have the case of the information that is not passed thru to the next level or shift change and become unknown and is also a mistake (Physician, Male, 40-49).</p>	<p>The transmission of the patient` allergies as an error related with information passage. "This information was transmitted orally and has not been recorded in the patient process, but this kind of data has to be very visible in the patient's file, because it could cause problems to the patient." (Nurse, Female, aged 30-39).</p> <p>In a shift change, a nurse didn't pass the necessary information to his colleague so that the patient would remain without eating because he would go thru a CT Scan (Axial Tomography Computerized) first thing in the morning (Nurse, Female, aged 40-49).</p> <p>"when a patient is discharged, he leaves with a lot of information, with the phone number for our consultation, we follow-up on information, we detect several mistakes because we give the patient a lot of information all at once and there is a lot of misunderstanding" (Nurse, Female, 50-64).</p>
Ignorance and Default	<p>"Physicians are always required to report this situations... one patient had an arrhythmia during the night and an health professional decided to ignore this symptom. Furthermore the information was not passed in the shift change. The professional that witnessed the symptoms may not know the patient's history record, thus disregarding its importance" (Physician, Male aged, 40-49).</p>	

Types of Errors	Physicians quotations	Nurses quotations
System	<p>"Today there are a lot of generics, and heparina is frequently used to prevented the blood to coagulate. If it doesn't work surgery is the only option. We have witnessed that a specific type of heparina coagulates and forces the patient to receive higher dosage to make it feasible. A number of questions arise: are we ministering the right drug? It is working as predicted? (Physician, Male, 40-49).</p>	<p>"if 48 hours have passed since surgery and the patient remains on hepatic diet due to anesthesia and the body's evolution, the type of food that the patient can eat had to be inserted in the system but the physicians don't comply consistently" (Nurse, Male, 40-49).</p> <p>"Drugs prescription is not up to date in the system. Often, the patient has to go thru draining after a surgery and some of the times physicians have to be warned by the nurses... On other occasions while going thru draining the antibiotic is suspended and we are ones who call out" (Nurse, Female, 30-39).</p>
Don't follow the procedures	<p>"The most frequent failure is not to follow everything that is in the checklists. In a majority of cases the professionals check the options without even checking. The same physician's state that checklists are extensive and comprehensive but are not thought out to be particule. Sometimes they are even redundant" (Physician, Male, 50-64).</p> <p>"The patient's potassium was corrected instead of the sodium or he was given x grams of an antibiotic instead of y grams – the professional changes an ventilatory paramether or even a medication and doesn't check for changes in the condition after an hour" (Physician, Male, 50-64).</p>	<p>"On Friday, a patient left the ICU for the infirmary with a urinary catheter. The doctor in charge left a written instruction so that the urinary catheter would be removed on Sunday morning. On Tuesday, the physician received a phone call from a nurse asking if she could remove the urinary catheter from the patient" (Nurse, Female, aged 40-49).</p>
Procrastinating tasks	<p>"If the work load is excessive, there is no way to be effective and that causes task procrastinating... a physician has to spend an hour with each patient looking into several items but, if he has nine patients in a ICU it is clear that he won't spend 9 hours with his routes" (Physician, Female, aged 40-49).</p>	<p>"The process is defined based on the hierarquical needs and not on the actual patient needs. Some tasks are postponed and will lead to errors in the ICU but also on other points of the patient pathway" (Nurse, Female, aged 40-49).</p>
Time pressure	<p>"Sometimes we have shorter time than required to study the patients and that can lead to inadequate surgical strategy or excessive workload and prolonged surgeries" (Physician, Male, 50-64).</p> <p>"Time pressure, specifically lack of time to study the patients, can lead to inadequate surgical strategy" (Physician, Male, aged 50-64).</p>	<p>"Often they have to change the patient to the infirmary from the intensive care unit but sometimes they don't have physical space" (Nurse, Female, aged 30-39).</p> <p>"An example it's the fact of distributing beds in the intensive care unit; "when beds are constantly being given to different patients according to number our clinical state, there will also be a need to put in a bed all who left the surgery. Planning is essential" (Nurse, Male, aged 50-64).</p>

ESSAY III

The Year After: Patient Quality of Life After Cardiac Surgery

Abstract

Cardiac disease remains a leading cause of global mortality and morbidity, frequently treated by cardiac surgery. Patient postoperative quality of life is very important in deciding whether or not surgery should be performed. However, there are few studies addressing the issue of quality of life post cardiac surgery.

In this study, we aim to evaluate the evolution of postoperative quality of life (at 3,6, and 12 months) of patients undergoing cardiac surgery, comparing to a baseline preoperative evaluation. Patients were grouped by main diagnosis in aortic, coronary artery or mitral disease groups.

Our data suggest that the underlying diagnosis is a major component of pre-operative quality of life being worse for mitral disease patients.

Surgery increased quality of life in all diagnostic groups, albeit with differences in relevance and timing: at 3 months, mitral patients' disease showed higher benefit. The mitral disease patient's group showed higher benefit than the other groups. Aortic patients showed higher benefits at 6 months postoperative but at 12 months, mitral disease patients were, again, the group that showed most benefit. These differences, albeit small, are significant statistically.

Key words: patient quality of life; cardiac surgery; cardiac diseases.

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1. Introduction

Cardiac disease (CD) is one of the most prevalent health conditions in modern societies, being an important cause of absenteeism, disability and death.

Cardiovascular disease (CVD) is the global leading cause of death (1) according to the World Health Organization and is projected to cause more than 23.6 million deaths by the year 2030 (2,3).

In Europe, CVD is responsible for a huge part of the total mortality burden and of premature mortality, with a total 0.4 million human losses per year. Males are more likely to die prematurely from CVD than females (4).

Over the past years, quality of life (QoL) has become an increasingly important aspect in healthcare and social sciences. Evidence based medicine now attributes importance not only to the direct physical impact of the disease and the results of treatment, but also to a patient's QoL (5).

For these reasons, it would be helpful to have a clearer picture regarding cardiac surgery patients' pre and postoperative QoL.

Prior studies have found that physicians need more information on the real health impact of cardiac interventions (both surgical and percutaneous) their effects on the resulting patient quality of life. Post procedural expected QoL is, therefore, a vital aspect to be considered when proposing a specific form of treatment. (6).

According to Cassar et al. (2009), this information treatment method is important to follow patients after cardiac surgery (6).

Postoperative QoL studies in cardiac surgery patients are scarce and highly variable in design and evaluation methods. Therefore, there is a specific need to address this issue in more detail.

The main objective of this study is to explore if and how quality of life improves after cardiac surgery. Through the use of prospective data, we explore the evolution of QoL outcomes at three, six and twelve months after cardiac surgery, compared to a baseline preoperative evaluation. The study also examines how patient clinical characteristics influence QoL changes associated with cardiac surgery.

2. Understanding cardiac diseases

Cardiac disease is one of the most prevalent health conditions in modern societies. Whereas coronary artery disease is one paradigmatic example of “lifestyle originated” diseases, in which unhealthy habits are a major factor in generating the atherosclerotic process and subsequent disease, degenerative valvular disease is associated with senescence and is becoming a major problem as life expectancy continues to increase.

Deaths by communicable disease have reduced steadily as health conditions improved in most countries, whereas the death rate from non-communicable diseases (NCDs) (also known as chronic diseases, tend to be of long duration and are the result of a combination

of genetic, physiological, environmental and behaviors' factors) has increased steadily from 1980 to 2015, with total deaths increasing by 14,1% in 2015 (7).

In 2015, the leading causes of NCD deaths were cardiovascular disease (17,9 million), cancers (8,8 million), and chronic respiratory diseases (3,8 million). Global cardiovascular disease deaths rose by 12,5% between 2005 and 2015, whereas age-standardized rates of death due to cardiovascular disease fell 15,6%. These reductions were largely driven by declining mortality rates due to cerebrovascular disease (ie, stroke; decreased by 21,0%) since 2005. Globally, deaths due to ischemic heart disease between 2005 to 2015, increased by 16,6% to 8,9 million deaths, whereas age-standardized mortality rates for ischemic heart disease decreased at a more moderate pace (falling by 12,8%). Ischemic heart disease and stroke accounted for 15,2 million deaths in 2015, equating to 85,1% of all deaths due to cardiovascular disease that year. (GBD 2013 Mortality and Causes of Death Collaborators & Collaborators GBD 2013 Mortality and, 2015) (7).

Despite significant geographical differences, the burden of CVD is major in Europe. More than 4 million Europeans die of CVD every year, and many more are hospitalized after acute episodes or treated for chronic cardiovascular ill health (8,9).

Figure 1: Age standardized death rates by sex (1990-2015).

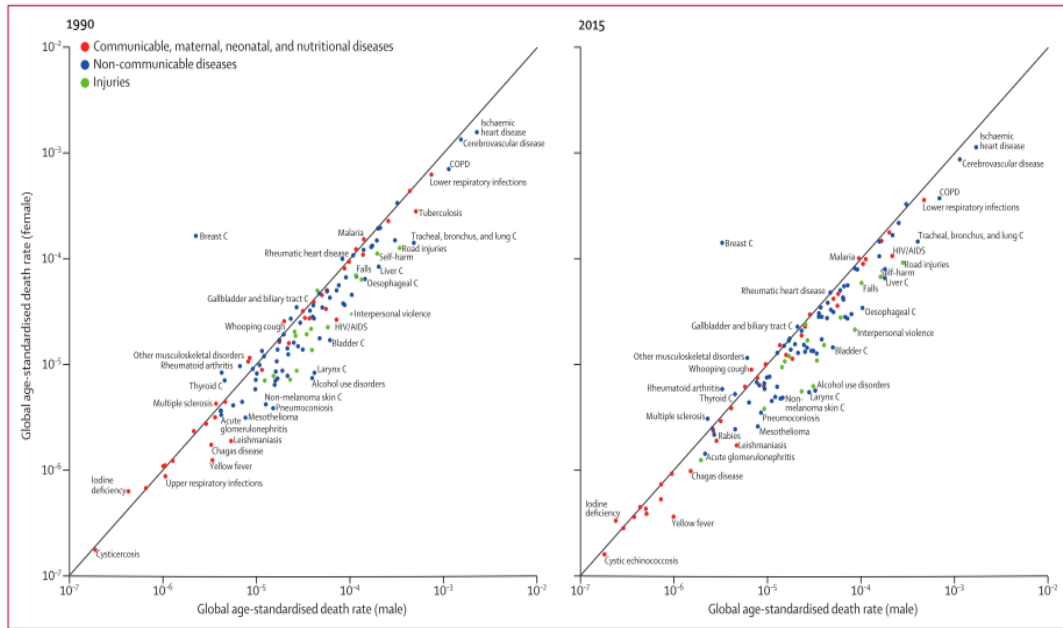


Figure 12: Global age-standardised death rates for males versus females, by GBD cause level 3, 1990 and 2015. The y-axis and x-axis are shown on a log scale to enable comparisons between males and females spanning a wide range of values. Black lines show where death rates are identical for males and females. Causes that only affect one sex, including maternal disorders, chlamydia, cervical, uterine, ovarian, prostate, testicular cancers, and gynaecological diseases are not shown. GBD=Global Burden of Disease. COPD=chronic obstructive pulmonary disease. C=cancer.

Source: GBD (2015) Mortality and Causes of Death Collaborators, The Lancet (7)

Heart failure (HF), a state in which the heart is unable to adequately provide adequate cardiac output, is the common and final stage of longstanding heart disease. This condition is responsible for important physical limitations that range from diminished exercise capacity to total dependence. It has been estimated that there are currently 6.5 million HF patients in Europe (9,10). Ischemic heart disease is the main cause of heart failure (68% cases), followed by valvular disease in 29% of the cases and idiopathic dilated cardiomyopathy in 6% (11).

2.1. Cardiovascular disease

Cardiovascular disease (CVD) is a broad term used to designate degenerative arterial disease, characterized by atherosclerosis and atheromatous plaque deposition in large or medium sized arterial vessels.

A common pathological pathway and risk factors (hypertension, diabetes, dyslipidemia, smoking, and genetic factors) define this entity as a generalized macro vascular disease, with variable anatomical manifestations. The disease is multifocal, involving multiple vascular beds in a given patient, and relies heavily on risk factor optimization for optimal control. It is evidenced by a variety of ischemic symptoms according to the vascular territory affected. These symptoms reflect chronic, longstanding and recurrent ischemia or acute vascular occlusion and tissue necrosis. Thus, the involvement of cerebral arteries will lead to cerebrovascular disease (CVD) as a chronic form and stroke (acute presentation), whereas involvement of the coronary vessels will lead to coronary artery disease (CAD) and acute myocardial infarction (AMI) and lower aortic and limb vessel disease will lead to peripheral arterial disease (PAD) and acute limb ischemia, respectively. The most prevalent forms of presentation are chronic cardiac ischemia (angina), or acute coronary syndromes in the heart or cognitive dysfunction and stroke.

Furthermore, coronary artery disease (CAD) can be associated with valvular disease, whether as a direct consequence of the ischemic process (ischemic mitral disease) or unrelated to the main disease (e.g.: aortic stenosis or mixomatous mitral disease). In the Euro-Heart Survey, 4.8% (11) of patients had significant concomitant valve disease.

These patients were older, more likely female and with serious comorbidities such as diabetes and chronic renal failure; they were more likely to have had episodes of heart failure (HF), left ventricular (LV) dysfunction, previous cardiac ischemic events or revascularization. This increased severity has a direct impact in the hospital and 30-day mortality of the patients with valve disease (13.4% and 15.5% with versus 6.4% and 7.7% without valvular disease) (12).

2.1.1. Treatment of coronary artery disease

Coronary Artery Disease (CAD) is highly dependent on lifestyle and risk factors. Therefore, disease progression and prevention of ischemic events rely heavily on promoting lifestyle changes as well as pharmacological interventions such as use of cholesterol lowering drugs, beta-blockers, nitroglycerin, and medical control of diabetes and hypertension.

However, effective relief of ischemia can only be achieved by revascularization of the diseased vessels. Revascularization aims to resolve the coronary blood flow blockages created by the atheromatous plaque deposition in the vessel walls. This can be achieved either by percutaneous therapy (balloon dilatation or insertion of a metallic stent in the coronary artery through a catheter (Percutaneous Coronary Intervention- PCI) or surgical revascularization (Coronary Artery Bypass Grafting- CABG).

These approaches differ widely in terms of cost, accessibility and results. Although PCI is widely available, less invasive and putatively less costly, long term results are suboptimal when compared to surgery in some subsets of patients as clearly demonstrated by some pivotal studies, especially the Syntax (13,14).

As a result of the body of evidence collected in many studies, indications for each of these procedures have been determined and guidelines for treatment have been published. CABG is the therapy of choice in subsets of CAD patients: those with one, two or three vessel diseases with proximal left anterior descending artery (LAD) disease, especially if diabetes and depressed ventricular function are present (15).

2.1.2. Coronary artery bypass grafting

In the last decades, most cardiac surgeries performed were revascularization procedures (coronary artery bypass grafting- CABG), with treatment of degenerative valvular disease presenting an increasing number of procedures. Coronary artery bypass grafting is the most prevalent type of cardiac surgery performed in the world, comprising from 50 to 66% of surgical cases in most western countries (16) CTS Blue Book Online - Cardiac Surgery Audit Data, 2014). Furthermore, treatment of degenerative valvular disease has been steadily growing and will become more important in the coming decades. Surgical treatment is an important tool in caring for these patients and most procedures are done with Cardio Pulmonary Bypass (CPB). According to Eurostat numbers published in 2016, in 2013, 241,570 cases of CABG were performed in the European Union member states. The Eurostat data are incomplete since they measure only CABG and do not account for other procedures performed under CPB (17).

More accurate European data are difficult to obtain, due to reporting inequalities among countries, but some national numbers are available: data published by the British Heart

Foundation in 2015 for the year 2012, state that 16,791 cases of CABG and 10,738 cases of valvular surgery¹ were performed in the United Kingdom (18).

2.2. Valvular heart disease

Valvular heart disease (VHD) is any disease process involving one or more of the four heart valves (the aortic and mitral on the left side, and the pulmonary and tricuspid on the right). These conditions occur largely as a consequence of aging, (19) but may also be the result of congenital (inborn) abnormalities or specific disease processes such as endocarditis and rheumatic heart disease.

During most of human history, excepting a few surviving cases of congenital disease and degenerative disease, cardiac valvular disease was closely related with streptococcal infection and rheumatic fever. This almost exclusivity for rheumatic origin began only to be changed with the widespread use of antibiotics to treat streptococcal infection from the 1950's onward. Only in recent decades, the health benefits of this approach began to be noticeable, with rheumatic valve disease becoming the exceptional case. In the 1980's and early 1990's, most valvular disease was performed in rheumatic fever patients, with a prevalence of mitral valve replacement procedures.² Nowadays, rheumatic valvular disease occupies a negligible place in the overall number of valvular surgical cases. This

¹ British Heart Foundation (*bbf-cvd-statistics-2015-final.pdf*)

Isolated aortic valve replacement: 4,561

Aortic valve replacement and coronary artery bypass graft (CABG): 3,263

Isolated mitral repair: 1,456

Mitral repair and coronary artery bypass graft (CABG): 588 Isolated mitral replacement: 638 Mitral replacement and coronary artery bypass graft (CABG): 232

² Personal analysis, service's records for patients operated since 1960 to 2017.

paradigm shift had several important consequences. First, the practical disappearance of a disease that created a huge burden on personal and public health, (as rheumatic patients survived for years with significant morbidity and disability and died prematurely), allowed for a healthier population that lives longer and in better physical conditions. Secondly, the increased life expectancy and the elimination of a premature “killer” allowed for the appearance of degenerative forms of valvular disease that had, hitherto, been rare.

These types of disease appear associated with the aging process and are, in some cases, associated to specific metabolic disturbances (such as, mitral valve myxomatous degeneration) or chronic inflammatory processes akin to atherosclerotic disease such as calcific degenerative aortic disease.

2.3. Aortic valve disease

Degenerative calcific aortic valvular disease (AVD) is associated with aging and senescence. AS is but a dynamic process of inflammation, lipid accumulation, and calcification, that shares clinical risk factors with atherosclerosis, such as advanced age, hypertension (HTN), hyperlipidemia, smoking, and diabetes. Association with chromosome 16q22.1-q22.3 and lipoprotein(a) gene polymorphisms have recently been identified, suggesting that some patients may have a genetic predisposition to degenerative aortic valve disease (20).

The progressive stenosis will pose a significant burden on the ventricular muscle (pressure overload), which leads to myocardial hypertrophy and dysfunction. Clinical manifestations derive from the structural myocardial changes and loss of cardiac output due to the physical obstacle to ventricular ejection and range from angina, fatigue and syncope to sudden death, myocardial infarction, ventricular dysfunction and heart failure.

The change from rheumatic to degenerative etiology in AS, was clearly demonstrated by Passik et al., (1987). In this study analyzing pure AS patients in a 5-year period, the relative frequency of rheumatic disease decreased from 30% to 18% whereas the relative frequency of degenerative-calcific aortic stenosis increased from 30% to 46%. The frequency of bicuspid valve disease was relatively constant (37% to 33%), which is consistent with a genetically determined disease occurring in a relatively constant rate (21).

2.3.1. Epidemiology of aortic valve disease

Degenerative aortic valve stenosis (AVS) is a disease closely associated with aging and varying degrees of aortic valve degeneration can be found in population studies. In a Mediterranean population, Ferreira-Gonzales et al. (2013), found, in a random sampling of people over the age of 65 years, that mild aortic calcific degeneration (ASC) was present in 45,4% of individuals at age 65 but increased to 73.5% in people over 85 years. However, clinically significant AS prevalence was 3% for the total cohort and 7.4% in people over 85 years (22). These study's data indicate a definite correlation with age and suggest an association with pro atherosclerotic risk factors in the development of AVS. Stewart et al. (1997), showed that clinical factors associated with aortic valve sclerosis

and stenosis are similar to risk factors for atherosclerosis: age, male gender, height (inverse relation), smoking, history of hypertension, elevated serum levels of Lipoprotein (a), and LDL-cholesterol (23). Although the progression rate from aortic valve sclerosis to full aortic stenosis is rather low, its high prevalence associated with age has serious clinical consequences, as demonstrated by Coffey et al. (2014) (24). These authors, in a meta-analysis of several studies, demonstrated that in total, 1.8% to 1.9% of participants with ASC had progression to clinical aortic stenosis per year.

Furthermore, increased risk for cardiovascular events, cardiovascular and overall mortality were demonstrated: 68% increased risk of coronary events (hazard ratio [HR]: 1.68; 95% confidence interval [CI]: 1.31 to 2.15), 27% increased risk of stroke (HR: 1.27; 95% CI: 1.01 to 1.60), a 69% increased risk of cardiovascular mortality (HR: 1.69; 95% CI: 1.32 to 2.15), and a 36% increased risk of all-cause mortality (HR: 1.36; 95% CI: 1.17 to 1.59) (24).

According to Faggiano et al., (2006), aortic stenosis occurs in 2 to 9% of the population, which was corroborated by other studies (25). In the Helsinki Ageing Study, 53% of 75–86 year old subjects showed some degree of aortic valve calcification and moderate to severe aortic stenosis from 2.5% in the 75–76 years old group to 8.1% in the 85–86 years old group (26). In the Cardiovascular Health Study (subjects older than 65 years), aortic sclerosis was present in 29% of the overall population and aortic stenosis in 2% (23).

2.3.2. Treatment of aortic stenosis

Since Braunwald and Ross' (1968), classical autopsy data report (27), the onset of symptoms was considered the turning point for mortality in AS. However, several later studies confirmed a high cardiac mortality even in asymptomatic patients. Otto et al. (2014), showed that the probability of event-free survival (death or aortic valve replacement) at 2 years was only 21%.

Similarly, Rosenhek et al. (2000), demonstrated that event-free survival (death or symptomatic AVR) was 56% at 2 years (29). Pellikka et al. (2005) and Malouf et al. (2002) corroborated the high cardiac mortality in AS patients, thus contributing to the surgical treatment rationale even in asymptomatic patients (30,31).

Even in mild and moderate AS, several studies also showed an excess mortality and major adverse effects: Rosenhek et al. (2000), demonstrated a mortality rate 1.8 times greater than expected and the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) study demonstrated the need for AVR in 10% of patients with mild AS within 5 years compared to 38% of those with moderate AS (29). There was also a high incidence of ischemic CV events in the SEAS study even in milder forms of disease (12% of patients with mild AS and 22% of those with moderate AS) (32).

Due to the non-existence of medical alternatives to a “mechanical” disease, most patients with AS will need aortic valve replacement (AVR), resulting in improvement in LVH, systolic and diastolic function, symptoms, and survival. Given the poor natural history of untreated symptomatic AS, any symptomatic patient with severe AS should be considered

for AVR. European Vahanian et al., (2012) and US Nishimura et al., (2014), guidelines were established in order to propose the best therapeutic alternatives (33,34). Nonetheless, despite the recommendations, multiple studies have shown inappropriate denial of AVR in 30%–50% of patients with severe symptomatic AS. The most common reasons are age, HF, neurologic concerns, or other morbidities, as well as overestimation of the risk of AVR (35).

As an alternative to surgical AVR (SAVR), trans catheter AVR (TAVR) is gaining popularity. This type of therapy, allowing to forgo sternotomy and cardiopulmonary bypass was initially proposed for inoperable or high risk patients, with improved survival and acceptable risk as shown in the Partner 1 study (Smith et al., 2011), but its use in medium risk patients has been proposed and its feasibility and safety demonstrated, both in the Partner 2 (36) and the Surtavi (37) trials. These studies revealed non-inferiority of TAVR compared to SAVR and, as expected, different patterns of complications.

Surgical AVR is associated with an operative mortality of 1%–3% in patients aged <70 years, and 3%–5% in those who are older, but individual risk varies widely based on age, morbidities, and concomitant procedures. Validated models to estimate surgical risk in an individual patient include the STS risk score and the Euro SCORE. Among co-morbidities (e.g., renal failure, diabetes), clinical factors for increased surgical risk include age (>80 years), emergency operation, reoperation after previous bypass surgery, depressed left ventricular ejection fraction (LVEF) and limited contractile reserve (34).

2.4. Mitral valve disease

Rheumatic valve disease has been a human companion since the beginning of humanity. Although congenital and degenerative forms might occur, the most prevalent form of mitral disease, historically, was rheumatic stenosis as a consequence of streptococcal throat infections.

As penicillin and its derivatives became increasingly available, adequate treatment was offered to the majority of the population and, in modern societies, rheumatic valvular disease is almost extinct.

The decrease in rheumatic valve disease and the increase in life expectancy brought the appearance of a “new” type of mitral valve disease. The degenerative forms of mitral disease, hitherto unapparent by the early mortality, became the most prevalent mitral valvular disease in the developed countries.

Mitral regurgitation (MR) is presently, the most prevalent forms of mitral valve disease in high and medium income countries.

MR can be further separated in functional disease as a consequence of ventricular dysfunction (as in ischemic disease or aortic regurgitation) or as “organic” disease as a result of degenerative, genetically determined alterations of the valve leaflets.

2.4.1. Mitral stenosis and rheumatic fever

Rheumatic heart disease is a direct consequence of streptococcal throat infection. It mostly affects the mitral valve and, in decreasing order of involvement, the aortic, tricuspid and pulmonary valves. The most common lesion is mitral stenosis. It was a common occurrence in the preantibiotic era and, even when antibiotics became available, lack of adequate treatment was responsible for a significant incidence and prevalence of the disease. In a seminal study, Olesen, (1962), reported the natural history of patients with untreated rheumatic mitral stenosis in an historical cohort (diagnosed from 1939 to 1949 and reevaluated in 1951-53 and in 1959) (38). The patients were relatively predominantly female (2-5: 1), young (average age 41 years old) and the prognosis was dismal: 70% of patients at the first follow up and 83% at the last were dead at an average age of 46 to 48 years of age.

2.4.2. Non-rheumatic forms of mitral disease and mitral regurgitation

Mitral valve prolapses (MVP) is the most frequent form of mitral degenerative disease. It is characterized by typical fibromyxomatous changes in the mitral leaflet tissue with superior displacement of one or both leaflets into the left atrium. It can be associated with significant mitral regurgitation (MR), bacterial endocarditis, congestive heart failure, and even sudden death.

MVP may be familial or sporadic. Despite being the most common cause of isolated MR requiring surgical repair, little is known about the genetic mechanisms underlying the pathogenesis and progression of MVP. A majority of data favors an autosomal dominant pattern of inheritance in a large proportion of individuals with MVP. MVP can be

distinguished into primary or “non-syndromic” MVP, and secondary or “syndromic” MVP. In the latter case, MVP occurs in the presence of connective tissue disorders. MVP has also been observed in hypertrophic cardiomyopathy and may contribute the pathophysiology of obstruction typical of this myopathy.

MVP is a progressive disease affecting predominantly middle-aged individuals (39).

There are two major phenotypes of the degenerative mitral valve disease/prolapse:

- a) Fibroelastic deficiency;
- b) Barlow’s disease.

Fibroelastic deficiency is usually seen in individuals older than 60 years, is characterized by single chordal rupture and prolapse of an isolated scallop, most commonly the P2. Barlow’s disease is typically seen in younger patients, 40–60 years old, and is characterized by excess leaflet tissue throughout. The leaflets and the chordae appear thickened, redundant and elongated. Multiple scallops of both anterior and posterior leaflets prolapse or may flail into the left atrium during systole.

The common physiological consequence is mitral regurgitation.

These forms of mitral valve prolapse represent a severity spectrum with MVP representing the mildest and Barlow’s disease the worst scenarios. In clinical practice, most patients fall between these two extremes (40).

The natural history for MR is of a serious disease: Early series reported widely variable mortality rates, ranging from 27% to 97% at 5-year follow-up. In a series from Ling et al., medically treated patients with severe regurgitation had a mortality rate significantly higher than the expected (6.3% yearly mortality, $p=0.016$, when compared with the expected rate in the US population according to the 1990 census). Death or need for surgery was almost unavoidable within 10 years of diagnosis and surgical correction improved long-term survival (40).

In patients with clinically less severe regurgitation (asymptomatic and with normal left ventricular function), Enriquez-Sarano et al. (1993), showed that the 5-year mortality from any cause was 22% and the cardiac mortality was 14% in medically managed patients (41). Cardiac surgery was associated with improved survival. Rosenhek et al. (2004), showed a better survival than earlier series without the need of surgery: 92% at 2 years, 78% at 4 years and 65% at 6 years (40).

2.4.3. Epidemiology of mitral valve disease

Rheumatic heart disease is still one of the major health problems globally: about 33 million people are affected globally by rheumatic heart disease with an additional 47 million having asymptomatic damage to their heart valves (42). As of 2010, rheumatic heart disease resulted in 345,000 deaths worldwide, down from 463,000 in 1990 (43). In countries in Southeast-Asia, sub Saharan Africa and Oceania, the prevalence of children with rheumatic heart disease detected by auscultation was 2.9 per 1000 children and by echocardiography it was 12.9 per 1000 children (44,45,46,47).

Non-Rheumatic mitral disease encompasses a spectrum of alterations ranging from mitral valve prolapse to Barlow's disease. Mitral valve prolapses (MVP) is one of the most frequent forms of degenerative mitral disease. It affects 2 to 3% of the population in US studies. Based on a prevalence of 2-3%, MVP would be expected to affect approximately 7.8 million individuals in the United States and over 176 million people worldwide.

In the Framingham study, there was an estimated overall prevalence of 2.4%. The prevalence of MVP was fairly evenly distributed among individuals in each decade of age from ages 30 to 80 years. With respect to gender, MVP was equally distributed between men and women (48). This prevalence data was confirmed in different ethnic backgrounds in several studies: The Strong Heart Study (native Americans), the SHARE study (Canadians of South Asian, European and Chinese descent). However, there is a lack of information on the prevalence in African American and Hispanic population cohorts (48).

Tricuspid valve prolapse has been observed in up to 40 to 50% of patients with primary or 'non-syndromic' MVP, but isolated tricuspid prolapse has been rarely reported (39).

According to Maslow et al. 2017 (40), MR is the most common valve disorder in the United States, affecting more than 2 million individuals, with a striking increase in prevalence with advanced age. According to these authors, the prevalence of mitral regurgitation is greater than 10% in adults older than 75 years, with no significant difference in age-adjusted rates between men and women.

In Europe, as shown in the Euro Heart Survey, moderate or severe mitral regurgitation requiring surgical intervention was the second most common form of valve abnormality, behind only aortic stenosis (mitral regurgitation 31.5% versus aortic stenosis 43.1%) (11, 40).

2.4.4. Secondary - ischemic mitral disease

Secondary mitral regurgitation is a term used to describe a type of mitral regurgitation due to changes in the left ventricle and papillary muscles that affect the motion of the valvular leaflets or that cause anatomical disturbances that enlarge the mitral annulus. Therefore, the valvular disease is a consequence of myocardial disease and not valvular disease. The most common etiologies for ventricular dysfunction are ischemic, valvular and myopathy.

2.4.5. Treatment of mitral valve disease

Mitral valve disease depends on surgical treatment for adequate treatment. Medical management of heart failure of associated arrhythmias is important but will not, per se, alter the natural history of the disease. Virtually all patients with MS will need surgery at some point and most mitral regurgitation patients will need surgery.

Surgical alternatives include valvular repair or replacement.

Mitral valve repair is the preferred treatment for patients with primary mitral regurgitation as it is associated with better outcomes than mitral valve replacement. Repair, however, is not always feasible or indicated, especially in older patients with calcified deformed valves, rheumatic heart disease or severe sub-valvular thickening. These cases are usually

treated with mitral valve replacement. However, mitral replacement has disadvantages as it leads inevitably to deterioration of left ventricular function and ejection fraction, the need for anticoagulation with the use of mechanical prosthesis and late structural deterioration and need for repeat intervention with bioprosthesis, contributing to early and late morbidity and mortality (40).

Treatment of secondary mitral disease is challenging, as this particular set of conditions requires a tailored approach combining mitral valve repair or replacement with coronary revascularization and/or ventricular restoration techniques. Despite the fast progression of percutaneous techniques, valvular surgery has maintained a steady number of procedures and the tendency will be to the increase of valve procedures over CABG, as shown in figure two (49).

Figure 2: Temporal evolution of valvular heart surgery incidence rates

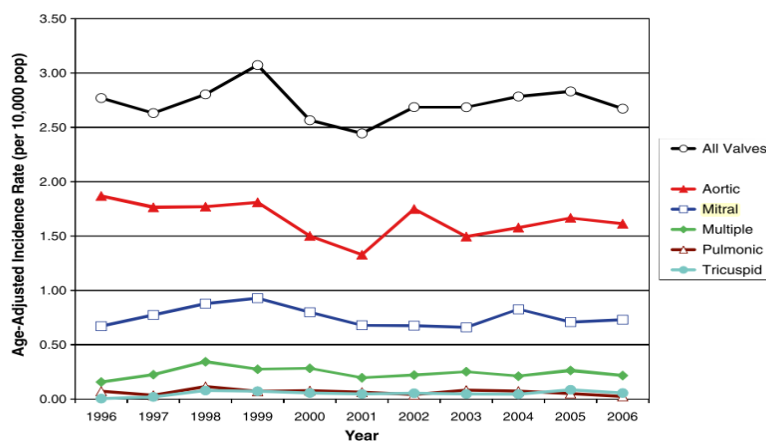


Fig.2.9 Incidence rates for open heart valve operations (from The National Hospital Discharge Survey (NHDS), available at <http://www.cdc.gov/nchs/nhds.htm>)

Source: Katlic, M. Edition (2011), Cardiothoracic Surgery in the Elderly, Springer.

2.4.6. Surgical treatment of heart disease

Despite the fast progression of percutaneous techniques, cardiac surgery is an invaluable tool in the treatment of heart disease and is still the main therapeutic option in a series of conditions.

Surgical treatment of CAD has maintained a steady number of procedures, despite the increase in PCI and valve procedures have been slowly but steadily rising. Coronary artery bypass grafting is the most prevalent type of cardiac surgery performed in the world, comprising from 50 to 66% of surgical cases in most western countries (16).

According to Eurostat numbers published in 2016, in 2013, 241,570 cases of CABG were performed in the European Union member states. The Eurostat data are incomplete since they measure only CABG and do not account for other procedures performed under CPB (23). More accurate European data are difficult to obtain, due to reporting inequalities among countries, but numbers are available: data published by the British Heart Foundation in 2015 for the year 2012, state that 16,791 cases of CABG and 10,738 cases of valvular surgery, were performed in the United Kingdom (23).

3. Quality of life after cardiac surgery

3.1. Definition of quality of life

WHO (2011) defines Quality of Life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their

goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment (50).

The recognition of the importance of health related QoL has led to the growing inclusion of QoL measures as endpoints in most clinical studies, complementing more traditional endpoints such as morbidity and mortality. From 1978 to 1980, there were approximately 200 publications with QoL in the title (51), whereas in the years 1988 to 1989, over 1,400 publications considered QoL (52).

Several factors can be related to the growing interest in QoL (53,54). Advances in medical care have made available an array of therapeutic options, with QoL often being the only in outcome influencing treatment choice. QoL issues are becoming central in the treatment of chronic conditions that accompany the growth of an aging population. Quality of life is important to everyone. Although the World Health Organization (WHO) defined health very broadly as long as a half century ago, health in the European Union has traditionally been measured narrowly and from a deficit perspective, often using measures of morbidity or mortality.

However, and getting closer to the WHO's definition, health is increasingly recognized as a multidimensional construct including physical, mental and social domains (50).

Although no universal definition of QoL exists, there is an emerging consensus that two main dimensions, physical and mental functioning, can represent QoL. Physical function, physical development, corporal pain and health in general are analyzed in the physical

component and the mental component comprises mental functioning mental health, emotional development, social function and vitality (55). Thus, QoL can be viewed as a multidimensional concept best approached empirically through multi attribute measurement techniques.

A review of the literature on quality of life after cardiac surgery in patients with coronary and valvular disease was performed (MEDLINE and PUBMED), with the following keywords: "Coronary Artery Disease"[Mesh] OR "Heart Valve Diseases"[Mesh]) OR (("coronary disease"[Title/Abstract]) OR "valvular disease"[Title/Abstract]))* AND "Quality of Life"[Mesh]. Forty-five papers were found and analyzed with 75 exclusions.

3.2. Quality of life in cardiac surgery

Although improved quality of life is a major objective of cardiac surgery, there are few reports concerning QoL after cardiac surgery (5). QoL relates to more than just the presence of symptoms of disease or the side effects of a treatment or surgery. It is based on how patients perceive and experience these manifestations in their daily life.

Hollandsworth et al., (1988), investigated the effect of medical care on QoL in patients with various medical diagnoses over a 5-year period (1980-1984). The findings were compared with a similar study reporting data during the years 1975 to 1979 (56).

Several shortcomings were identified: absence of subjective indicators of QoL, reliance on one-time evaluations, and lack of a comprehensive assessment model for determining QoL. With time, a substantial increase in both the quantity and quality of studies was noted. (5).

Fletcher, Hunt and Bulpitt (1987), analysed and selected cardiovascular trials in which QoL had been addressed as an outcome variable (57). These authors found a number of problems in the design of the study and analysis that greatly influence QoL evaluation. The researchers emphasized the importance of matching measurement tools with the outcomes of interest, taking into account the period of time required for their manifestation. This is illustrated by four examples: evaluation of anti-hypertensive drug therapy, coronary artery bypass graft surgery, treatment of angina, and heart failure. Several important outcome measures were suggested, including psychological wellbeing, physical function and activity, degree of disruption caused by treatment of the disease and side effects of therapy.

O' Young and McPeck (1987), reviewed reports of surgical trials to evaluate the inclusion of QoL as an outcome variable. In analyzing cardiac surgery processes in particular, these investigators found that only a few studies included subjective indicators of QoL, whereas most focused on objective indicators, such as return to work or physical functioning (58).

Beto and Bansal (1992), analyzed nine published trials of QoL in the pharmacologic treatment of hypertension in which patients served as their own controls (59). Five specific constructs representing quality of life—sexual function, sleep, psychomotor

function, general wellbeing, and mood—were used as grouping factors. Three constructs—life satisfaction, work performance, and social participation—were dropped from analysis because of insufficient data. No negative effect of treatment for any of the five constructs, six drug groups, or construct-drug group combination was found. These analyses revealed the need for greater specificity of QoL constructs to guide prescription choices.

Srivastava et al., (2017), analysed the impact of mental health on HRQoL in patients with coronary artery disease: patients in the panic disease group had a worse QoL than those in the CAD and healthy control group. This highlights the importance of mental status as a relevant factor QoL (60).

3.3. Gaps in the literature on cardiothoracic surgery quality of life

The literature review shows that information about QoL after cardiac surgery is limited, not only because the number of studies is scarce, but also because the design of the studies differs widely. QoL assesses several domains, each one affecting the others. Furthermore, there is a pronounced variability in the clinical and mental state of patients, as are their expectations regarding the surgery. Most QoL studies do not start with preoperative QoL data. Instead, QoL is used to compare the effect of-different therapeutic techniques (5). Some studies explore preoperative QoL data and compare these with the postoperative data (61, 62, 63, 64, 65, 66, 67, 68).

These studies have, follow-up time from three months to one year, and frequently only make one post-operative evaluation. Only in six of the nine studies, present information about the number of patients included (61,66,67,68).

Koch et al. (2008), stated the need for good clinical trials concerning QoL after cardiac surgery in order to address the physician's need for information on the HR QoL impact of cardiac interventions and surgery (69). Postoperative QoL data are vital to justify the decision to propose surgical treatment and to be able to inform patients about the pros and cons of surgical therapy. The authors also stress the lack of patient information regarding post cardiac surgery QoL.

Noyez *et al.* (2011), studied the basic requirements needed to increase the value of studies concerning quality of life after cardiac surgery (5). Among the most relevant is the number of patients included. This means defining not only the patient population, but also a clear definition of inclusion and exclusion criteria. The second requirement is information consistency both for preoperative and postoperative QoL. Complete QoL information is required in both evaluations.

Finally, the authors also suggest that studies missing preoperative QoL data and comparison of demographics, co-morbidities, cardiac data and risk stratification should be considered lacking and incomplete.

The amount and level of evidence for HRQoL in cardiac surgery, the natural history of HRQoL in these patients, the outcome comparison between different surgical techniques

and patient populations, the personal, and economic impact are aspects that need further investigation.

To this date, much quality of life research has been developed. Even though there are several interesting contributions addressing quality of life in general, most research in cardiac surgery has focused on specific pathologies.

Our study aims to contribute to a better knowledge of HRQoL in cardiac surgery patients by comprehensively analyzing a large population of patients at several time intervals.

4. Methods

4.1 Statistical analysis

The primary objective of this paper is to describe patient quality of life after-cardiac surgery.

Included in the study were consecutive adult patients who had undergone major cardiac surgery at a cardiothoracic service, successfully discharged and followed in outpatient medical and nursing consultations. In each, a standard questionnaire was made (**appendix 1**) including clinical and QoL data. Exclusion criteria were death, transference and subsequent discharge from another hospital.

Data was based on the patient`s last known status at the latest known time point: at the time of the preoperative, at one month, six months and twelve months. All the individuals that do not have one of the pathologies aortic, coronary or mitral, were excluded to the sample. A sensitivity analysis was performed to account for missing data, including the patients who were lost to follow-up or withdrew from the study.

Data analysis was developed using SF36 that was converted in the score analysis SF6D, using the conversion algorithm provided by Sheffield University. A license is available free of charge for all non-commercial applications including work funded by research councils, Government agencies and charities. (The SF-36 is the questionnaire, the SF-6D is a measure that is obtained from the answers from the questionnaire) (70).

This conversion tool estimates the SF-6D score from SF-36 using a set of non-parametric Bayesian preference weights.

All SF-36 data from operated patients were collected and grouped according to the main diagnosis. Questionnaires from patients outside the three main diagnostic groups were excluded from the analysis. This conversion tool estimates the SF-6D score from SF-36 using a set of non-parametric Bayesian preference weights (**appendix 2**).

However, the statistical analysis has two different aspects, the SF36 questions are used to generate the SF-6D Score.

The second point is that the statistical analysis is determined by the questions that we

have to answer which gave rise to tests.

To assess differences in mean quality of life between pre and post operation scores and between scores after operation at different dates, we use statistical tests of the differences of means.

The analysis was made with the OLS estimator. Univariate analysis of quality of life factors was performed, and factors found to trend toward significance ($p\text{-value}<0.05$) were entered into multivariable analysis. A stepwise multivariable Cox regression model was then constructed with those factors to determine independent predictors of quality of life ($p\text{-value}<0.05$). The Friedman nonparametric test for differences in mean was used to compare the preoperative and postoperative functional class. A value of $p\text{-value}<0.05$ was considered significant for all statistical calculations. The STATA system for statistics was used for all data analyses (Version 15 for Mac).

This research set out to explore patient quality of life evolution after cardiac surgery, the main research questions being:

H1. What are there differences between patient quality of life between the preoperative and postoperative periods? H2. What is the temporal evolution of postoperative quality of life? H3. Is postoperative quality of life influenced by diagnosis? H4. Which are the most significant factors that influence postoperative patient quality of life?

5. Data collection

The data collection was performed in a cardiac surgery hospital at a cardiothoracic service. Preoperative demographic information and postoperative events were retrieved from the hospital databases (**appendix 3**).

Systematic collection of clinical data, from the pre and postoperative period, was made through the application of standard questionnaires. All clinical variables and events in the patient survey were defined according to the European Society of Cardiology. Diagnostic groups were defined according to the ICD-9 codes. (ICD-9 codes contain a list of codes corresponding to diagnoses and procedures).

The follow up information was obtained through personal and/or telephonic interviews with the patients at preoperatory, one, three, six and twelve months. Patient quality of life was assessed with the Short Form-36 (SF-36) tool.

The 36-Item Short Form Health Survey questionnaire (SF-36) is a very popular instrument for evaluating Health-Related Quality of Life (71).

The SF-36 consists of eight domains:

- i. limitations in physical activities, because of health problems;
- ii. limitations in social activities because of physical or emotional problems;
- iii. limitations in usual role activities because of physical health problems;
- iv. bodily pain;

- v. general mental health (psychological distress and well-being);
- vi. limitations in usual role activities because of emotional problems;
- vii. vitality (energy and fatigue) and
- viii. general health perceptions.

Each of these eight domains consists of different items ranging from two in the social functioning domain to ten in the physical functioning one, with each item containing a different number of levels.

The SF 36 permits scoring the eight domains, being each scored from 0 to 100. The eight domain scores can be further summarized into two measures: the physical and mental component summary (72).

However, these two components do not produce a single quality of life estimate. For that reason, a method was developed to derive a single quality of life estimate from the SF36, known as the Short-Form 6D (73,74). The SF6D consists of 11 items from the SF36, divided into 6 attributes (physical functioning, role limitations, social functioning, pain, mental health and vitality), with 4 to 6 levels each, generating a total of 18,000 different health states.

Researchers developed this algorithm to translate the SF-36 results into health state utilities. A valuation survey was carried out in the United Kingdom to obtain values to a sample of 249 health states defined for the SF-6D. A representative sample of the general UK population valued these health states, by using the standard gamble method. Econometric models were estimated by using the data collected to predict utility scores

for all health states defined by the SF-6D (73,74). These health state values constitute the SF-6D index, which can be seen as a continuous value ranging from 0.35 to 1.00.

With the SF36 being the most widely used generic health outcome measure globally (122) the SF-6D offers the possibility of evaluating quality in a way that enables QoL construction. Due to the large number of health states, the SF-6D has been shown to be more responsive to health changes than the EQ-5D (76).

However, the SF-6D has some limitations: it takes longer to complete which increases the likelihood of non-completion and although the SF-6D has been translated into other languages, validations are only available for the UK. This program is available for all non-commercial applications, including work funded by research councils and Government Agencies, although a license is required.

6. Data analysis and results

Between January 1, 2011 and December 31, 2015, 1614 patients with an average age of 66, (61,34% male and 38,66 female) underwent cardiac surgery at an European, university affiliate cardiac surgery hospital service. The main three diagnoses, representing 73% of the total, were: aortic valve disease (AVD) n=521; coronary artery disease (CAD), n= 477 and mitral valve disease (MVD), n=180 (see table I).

Due to the fact that these three diagnostic groups comprised most of the patients, we selected these groups for analysis. The clinical and socio-economic baseline demographics are described in table I.

The clinical variables considered were age, sex, relevant symptoms at presentation and comorbidities.

The socio-economic variables analyzed were education, work situation, family support and monthly income.

We also considered in the data analysis the time of the first consultation, the patient discharge, the surgery waiting time, time discharge consultation and time admission.

The **appendix 4** shows the mean difference tests between intervention pairs. Nevertheless, data show that they're no differences between the different diagnostic groups (aortic, coronary and mitral).

Table I. Baseline and socio-economic characteristics

Baseline characteristics				
	Aortic		Coronary	Mitral
Number	1178	521	477	180
Age	69.36		65.88	63.91
Sex				
Female	254 (48.75%)		93 (19.50%)	93(51.67%)
Male	267 (51.25%)		384 (80.50%)	87(48.33%)
Past medical history				
	Aortic		Coronary	Mitral
Hypertension	43,95		47.71%	42.33%
Hypercholesterolemia	30.40%		31.49%	28.11%
Diabetes	10.64%		10.90%	9.11%
Previous AMI			3,52%	
Chronic Afib				16,89%
Smoking	1.65%			
Others	13.36%		6,38%	3,56%
Presentation				
	Aortic		Coronary	Mitral
New York Heart Association (NYHA) classification				
Class I	32		70	9
Class II	239		220	78
Class III	192		140	66
Class IV	44		33	19
-	14		14	8
Angina				
No	284(54.51)		236(49.48)	104(57.78)
Yes	237(45.49)		241(50.52)	76(42.22)
Socio-economic characteristics				
	Aortic		Coronary	Mitral
Education				
None	60(11.52)		53(11.11)	19(10.56)
Primary	295(56.62)		237(49.69)	98(54.44)
High School	124(23.80)		154(32.29)	46(25.56)
Graduation	25(4.80)		20(4.19)	10(5.56)
-	17(3.26)		13(2.73)	7(3.89)
Working Status				
Unemployed	15(2.88)		18(3.77)	11(6.11)
Employed	81(15.55)		101(21.17)	36(20)
Incapacity	10(1.92)		22(4.61)	7(3.89)
Retired	387(74.28)		315(66.04)	116(64.44)
House Work	8(1.54)		3(0.63)	4(2.22)
-	20(3.84)		18(3.77)	6(3.33)
Family Support				
Live with someone	399(76.58)		399(83.65)	139(77.22)
Live alone	104(19.96)		62(13.00)	32(17.78)
-	18(3.45)		16(3.35)	9(5.00)
Monthly Income				
Less than 350 Eur	58(11.13)		44(9.22)	19(10.56)
350-900 Eur	170(32.63)		156(32.70)	50(27.78)
901-2000 Eur	61(11.71)		78(16.35)	32(17.78)
More than 3500 Eur	5(0.96)		0	0
No answer	104(19.96)		98(20.55)	37(20.56)
-	110(21.11)		92(19.29)	37(20.56)

6.1. Population characteristics

The population in this analysis had a mean age of 66 years. Consistent with the published literature, there were no significant differences between the ages between the diagnostic groups (aortic, coronary and mitral).

Noticeably, 47% of patients were older than 70 years and 27% had more than 75 years. According to Martinsson et al. (2015), the gender distribution of patients with aortic stenosis was 54,7% men and 45,3% women, which is also confirmed by our data. But, there is a difference in terms of age per gender between their study and ours, because in theirs' men were in average 74 and women 79.

According to the Euro Heart survey, the patients that were submitted to the valvular aortic substitution, 54,3% had more than 70 years old and 85% had symptoms of cardiac insufficiency, according to the NY Art Class II to IV, (25), which is in the line with our study.

In what regards gender distribution, 61,34% of patients were male and 38,66 were female. We observed a clear gender distribution asymmetry with statistical significance in the patients with CAD as is epidemiologically described.

Significant comorbidities such as hypertension in 42 to 48% of cases and diabetes (9-10%) did not show significant differences between gender.

According to the European Society of Cardiology Report on Cardiovascular Statistics (2017), the prevalence of hypertension in Europe is 25% in women and 35% in men. Hypercholesterolemia is almost the same for men and women, namely between 16% to 17%. The diabetes prevalence in Portugal is 9,6% (European Society of Cardiology Report, page 72, 2017) (77).

Regarding risk factors, and comparing with the European statistics published, the prevalence of hypertension and dyslipidemia are higher than in the general European population. This is consistent with the peculiarities of the Portuguese population and also to taking into account the patients characteristics that we are analyzing.

Chronic atrial fibrillation (AFib) was the only comorbidity with significant difference between diagnostic groups, being more prevalent in the MVD group, which is consistent with the clinical disease characteristics.

In what concerns to the functional limitation (fatigue), the vast majority (80% of total) are in classes II (46%) and III (34%) of the New York Heart Association (NYHA).

These patients had moderate to severe limitations of their functional capacity. Patients with extreme functional limitations (NYHA class IV) are relatively few but are more usual in patients with valvular pathology.

According to the Euro Heart survey, 85% of patients undergoing aortic replacement, had symptoms of heart failure, NYHA Class II to IV, (25), which is in the line with our study.

6.2. Past medical history and prescribed medication

There is a significant statistical difference in the preoperative period in what concerns the use of anticoagulation between patients with mitral disease and the other diagnostic groups namely, aortic and coronary.

Table II. Past Medical History

Past Medical History	Aortic (N=521)	Coronary (N=477)	Mitral (N=180)
Smoking Habits			
No	493(94.63%)	404(84.70%)	169(93.89%)
Yes	28(5.37%)	73(15.39%)	11(6.11%)
Medication			
Vasodilator			
No	466 (89.44%)	294 (61.64%)	168 (93.33%)
Yes	55 (10.56%)	183 (38.36%)	12 (6.67%)
Antiarrhythmic			
No	462 (88.68%)	429 (89.94%)	121 (67.22%)
Yes	59 (11.32%)	48 (10.06%)	59 (32.78%)
Antihypertensive			
No	151 (28.98%)	140 (29.35%)	45 (25.00%)
Yes	370 (71.02%)	337 (70.65%)	135 (75.00%)
Anticoagulation			
No	473 (90.79%)	445 (93.29%)	94 (52.22%)
Yes	48 (9.21%)	32 (6.71%)	86 (47.78%)

The **appendix 5** shows the pairwise comparisons of adjusted predictions.

6.3. Procedural and surgery characteristics

Table III shows the procedural characteristics from 1st consult with a cardiac surgeon to first outpatient postoperative follow up, as well as surgical characteristics. The data show an extensive waiting period between 1st consult and surgery, well over 100 days. This waiting time is especially grievous in mitral disease patients who wait, in average, for than 200 days for surgery (1st consult to surgery).

Data shows that the time between 1st consult and insertion in the waiting list being 23,8 days for AO patients, 15,2 days for CAD and 67,5 days for MV patients. However, after insertion in the waiting list (surgery waiting time) the differences are less significant, with a slighter higher time for mitral disease patients. This discrepancy between mitral valve disease patients and other diagnostic groups might be related to the need of further diagnostic testing previous to acceptance for surgery and result in a considerable delay for surgery.

Waiting times after acceptance for surgery and insertion in the waiting list (surgery waiting) are also elevated, exceeding 100 days in all cases, with special relevance in MV patients. These delays directly impact preoperative QoL.

Table III. Procedural Characteristics

Procedural Characteristics	Aortic	Coronary	Mitral
	(N=521)	(N=477)	(N=180)
1st consult to surgery time	166.4823	123.2977	218.6095
Surgery waiting time	109.3278	108.0549	151.142
Surgery-patient discharge	7.204593	6.630058	8.076923
Patient discharge- First medical check post-surgery	35.08977	36.04913	35.89941
Patient admission-hospitalization	107.9311	106.4133	149.7811
Patient admission-discharge	116.5324	114.685	159.2189
	42	131	11

Table IV. Surgery Characteristics

Surgery Characteristics (hours)	Aortic	Coronary	Mitral
	(N=521)	(N=477)	(N=180)
Operating room time (mean)	04:27:59	04:40:20	04:53:45
Surgery time (mean)	03:05:48	03:15:16	03:28:37

In what concerns surgical times and operating room utilisation times there were no significant differences between diagnostic groups.

7. Discussion

Data shows that preoperative QoL in cardiac surgery patients differs significantly with the underlying diagnosis, being worse for MV patients.

All diagnostic groups benefit from surgery: the present study identifies that the post operative QoL improves significantly in all analyzed pathologies up until twelve months postoperative (p-value=0,000), but with a special importance between surgery and the 3rd postoperative month.

The higher increases in QoL occur until the third postoperative month, and a small consolidation occurs up to the sixth postoperative month. Between 6th and 12th months, although there is further improvement, it is much less expressive, and loses statistical significance (p-value=0.0135 to p-value<0.0001) (however, there was a significant improvement between 6th and 12th months).

In the analysis by diagnostic groups, the general pattern of postoperative improvement is maintained. However, the improvement is not uniform for all diagnostic groups nor is evenly distributed in time.

Some diagnostic groups benefited more in terms of QoL improvement: regarding differences between preoperative assessment and 3rd post operative assessment, the patients that showed higher benefit were mitral valve disease patients. Aortic patients showed higher benefits at 6 months post op but at 12 months mitral valve disease patients were the group with most benefit. These differences, albeit small, are significant.

The next table presents the quality of life evolution from preoperative to 12 months post operative ascertained by SF-6D.

Table V. Quality of life evolution

SF-6D (mean & std)	Pre operative	Post operative		
		3 months	6 months	12 months
Coronary	.614 (.148)	.747 (.109)	.760 (.107)	.775(.110)
Aortic	.605 (.149)	.727 (.107)	.758 (.114)	.761(.123)
Mitral	.591 (.143)	.724 (.109)	.737 (.112)	.751(.113)

The **appendix 6 to 9**, shows the histograms and the distribution of scores in preoperative,

before surgery, and in postoperative namely in three, six and twelve months after the surgery.

These data show that there are significant differences between the preoperative and the postoperative (3,6, and 12-month postop) periods in what concerns quality of life. Quality of life improves significantly with surgical therapy in all diagnostic groups ($p=0,000$).

The aortic group showed significant improvement occurring in the first six post operative months, most especially in the first three months. Between six and twelve months, the small improvement verified does not reach statistical significance.

In CAD patients, the most significant improvement in quality of life emerges until the 3rd postoperative month, with a slight and sustaining increase from that time. As with aortic patients, the results between six and twelve months are not significantly different.

As for temporal evolution, the main QoL gains are obtained in the first three postoperative months, with little gain afterwards.

The multivariable analysis shows statistical relevance of the diagnosis of the patient quality of life in preoperative period. However, when we introduced the administrative variables there was a loss of the analysis discrimination between 1 to 0,48.

In this analysis the diagnostic group loses meaning, the only significative factor being the presence of pain; namely, to the all of factors analyzed, the item pain is the only item that

influences patient quality of life between preoperative and three months after surgery. This situation is replicated when we analyse the preoperative and the six months and also the preoperative and the twelve months. Pain characteristics are very different in the pre and postoperative periods but the presence of pain of any etiology (disease vs surgical) plays a very significant role in patient QoL.

Table VI. Improvement among pathologies

Time Point	Aortic	Coronary	Mitral	All Sample
Pre_O - 3 Months	0,126	0,1393	0,1424***	0,1338
Pre_O - 6 Months	0,1621	0,1583	0,1555***	0,1596
Pre_O - 12 Months	0,1647	0,1688	0,171***	0,1673
3 Months - 6 Months	0,0348	0,01627	0,01	0,0236
3 Months - 1 Year	0,0396	0,0261	0,023	0,0315
6 Months - 1 Year	0,0034	0,0095	0,016	0,0079

Variation of the score and *p* values are reported

*, **, *** denote, respectively statistical significance at 10%, 5% and 1%

This table presents the variation and the *p* value for each one of the pathologies. The main objective was to determine if there were significant improvements between pathologies.

7.1. Procedural and surgery characteristics

Analyzing procedural data characteristics for the different pathologies, (aortic, coronary and mitral), data shows that the time of the first consultation to surgery has significant impact in the patient quality of life (less waiting time for the surgery means best quality

of life). CAD patients were the most significantly and negatively affected group in terms of QoL, especially by the presence of associated pain.

Table VII. Waiting time between the first consultation and the surgery relevance

Dependent Variable	Coef.	Std. Err.	t	P>t	95% Conf. Interval	
Dif_preop_1 Year_OHS						
Aortic	.1168564	.0215972	5.41	0.000	.0744682	.1592446
Coronary	.1265264	.0227549	5.56	0.000	.0818661	.1711868
Mitral	.0960586	.0250498	3.83	0.000	.0468939	.1452232
Antecedents	-.0020199	.004895	-0.41	0.680	-.0116271	.0075874
Presence Pain	.0416834	.0106829	3.90	0.000	.0207163	.0626504
*Time_pc_c_coronary	-.0001221	.0000589	-2.07	0.038	-.0002377	-6.53e-06
*Time_pc_c_aortic	-.0000286	.0000397	-0.72	0.472	-.0001066	.0000494
*Time_pc_c_mitral	.0000756	.000048	1.57	0.116	-.0000187	.0001699

*quality of life increment with “time”

(gen t pc c mitral=time_firstcons_surgery*mitral; gen t pc c aortic=time firstcons_surgery*coronary; gen t pc c coronary=time_firstcons_surgery*coronary-

In the table VII, the dependent variable is the difference between the preoperative and one year (dif-preo-Y-OHS). The demographics variables were tested but they aren't significant.

In what regards to the dummies for each one of the interventions and to the category omitted, none was omitted because we didn't have an independent term. We removed the incident term and we could include the three, specifically, aortic, coronary and mitral.

Data show that the coronary disease is the only that make the difference in the patient waiting time.

Of all time intervals analyzed, only the time between 1st consultation and surgery were relevant (**appendix 10**).

8. Conclusions

This study describes the evolution in QoL of a population of patients undergoing cardiac surgery from a preoperative state to one year post at 3 months intervals.

The population was elderly and did not presented significant age and gender distribution differences to the published literature.

As for comorbidities there was a huger incidence of hypertension, which is different from published literature.

The only significance difference in medication was anticoagulation use in mitral valve patients.

Most patients presented in class NYHA II or III.

Data shows that preoperative Qol in cardiac surgery patients differs significantly with the underlying diagnosis, being worse for MV patients.

Surgery increases QoL in all diagnostic groups, albeit with differences in relevance and timing: at 3 months, MV patients showed higher benefit. Aortic patients showed higher benefits at 6 months post op but, at 12 months, mitral valve disease patients were the group with most benefit. These differences, albeit small, are significant.

As for temporal evolution, the main QoL gains are obtained in the first 3 postoperative months, with little gain afterwards.

In view of this data, the preoperative quality of life is worse in patients with mitral valve disease, and that these patients show the greatest increase in post operative QoL.

According to this, we postulate that mitral disease patients, notwithstanding the clinical peculiarities of this disease, are offered surgery at a later stage in which quality of life is significantly impaired and chances of full recovery are lessened. In this sense it would be necessary to investigate to what extent an earlier surgical therapy in mitral patients could lead to significant improvements on the patient quality of life.

The multivariable analysis shows statistical relevance of the diagnosis of the patient quality of life in preoperative period. However, when we introduced the administrative variables, there was a loss of the analysis discrimination between 1 to 0,48.

In this analysis the diagnostic group loses meaning, the only significative factor being the presence of pain; namely, from all the analyzed factors, pain is the only item that influences patient quality of life between pre-operative and three months after surgery.

This situation is replicated when we analyse the pre-operative period versus and the six and twelve post operative months.

Pain characteristics are very different in the pre and postoperative periods but, nonetheless, the presence of pain of any etiology (disease vs surgical) plays a very significant role in patient QoL.

The time of the first consultation has significant impact in the patient quality of life (less waiting time for the surgery means best quality of life). CAD patients were the most significantly and negatively affected group in terms of QoL, especially by the presence of associated pain.

9. Recommendations

The data show a consistent increase in QoL after cardiac surgery in all main diagnostic groups, in spite of the trauma of surgery. This evidence suggests that QoL is an important factor and should be taken into account and discussed with the patient when proposing surgical therapy.

1. Our data reveal that mitral disease patients have the worst preoperative QoL of all diagnostic groups. This can be related not only to clinical factors such as the nature of the disease or the need for anticoagulation, but also to procedural factors, since they wait significantly longer for surgery. Research also demonstrated that these are the patients who show the most QoL benefits post surgery. We would suggest that, in the case of mitral

disease patients, the timing for proposing surgical therapy should be reviewed and optimized and that improving the pathways for patients awaiting mitral valve surgery would bring significant clinical advantages.

2. The time awaiting surgery is significant and this delay was demonstrated to be an important factor in the decrease in QoL. Also, the delay from consult to surgery may be a cause of errors or significant clinical consequences: disease evolution might change the clinical scenario while waiting and the information available can be rendered inaccurate. The need to repeat tests, unexpected operative findings, difficulties in the recovery process and serious complications can ensue. Therefore, improving clinical pathways and organizational inefficiencies can be a valuable tool in improving patient safety and quality of life.

3. Pain was a major determinant of pre and postoperative QoL. Although preoperative pain is mostly disease related and postoperative pain is mostly procedure related, the impact of this symptom is huge. As such, access improvement by reducing waiting time between consult and surgery and optimized pain control strategies can be valuable tools for QoL improvement.

4. Data have also shown that postoperative QoL improvement occurs in the first post operative trimester, with little gains afterwards. As such, efforts to improve post operative QoL should be focused in this time interval. Optimization of the recovery process, by rehabilitation, pain management, adequate referrals, as well as resource optimization,

should thus be concentrated on the first trimester, allowing for improved results and resource allocation.

This information could also be important when assessing a patient's chances for recovery and in determining the amount of resources and clinical investment allocated to a specific patient.

10. Study Limitations

Like any research, this study also has limitations. Time and thesis length constraints have imposed a limit to the study of only one hospital. The study of different hospitals with the same specialty could have allowed more richness or even different findings.

Physicians and psychologists developed the SF36 questionnaire applied in this study. Furthermore, only the nurses fill in the survey. Using this questionnaire methodology does not allow access to rich interaction to the patients.

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APPENDIX

Appendix 1. Patient Survey – Preoperative

PATIENT SURVEY PRE-OPERATIVE			
Filling out date: ____/____/201__			
VINHETA DE IDENTIFICAÇÃO			
Preencher com um (X) a resposta correspondente			
PHYSICAL ACTIVITY			
1. PRESENCE OF FATIGUE			
+	+		
<input type="checkbox"/> I – Absent (absence of <u>fatigue</u> , even during physical activity)	<input type="checkbox"/> II – Moderate activity (ex: more than 2 flights of stairs)	<input type="checkbox"/> III – Mild activity (ex: less than 2 flights of stairs, bathing, etc)	<input type="checkbox"/> IV – Rest (presence of fatigue with minimum exertion)
2. NURSING INTERVENTION			
<input type="checkbox"/> Autonomous orientation in daily routine			
<input type="checkbox"/> Orientation to progressive increase in physical activity, according to exertion tolerance			
<input type="checkbox"/> Orientation to rest between activities			
<input type="checkbox"/> Other _____			
PROFESSIONAL ACTIVITY			
3. DEGREE OF EDUCATION			
<input type="checkbox"/> None			
<input type="checkbox"/> None, but know how to read and write			
<input type="checkbox"/> Primary Schooling			
<input type="checkbox"/> Completed high school			
<input type="checkbox"/> Technical course/ Bachelor			
<input type="checkbox"/> Superior course/ graduation degree			
<input type="checkbox"/> Post Graduate / Master's degree / PhD			

4. WORKING STATUS (choose the most adequate option)

- Retired
- House work
- Farming
- Student
- Incapacity (mild)
- Unemployed
- Profession _____

5. MONTHLY INCOME

- Less than 350 €
- 350 – 900 €
- 901 – 2000 €
- 2001 – 3500 €
- More than 3500 €
- No answer

PAIN ASSESSMENT

6. PRESENCE OF PAIN

- Yes
Where _____
- No (skip to question 8)

Pain Scale

1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	----

7. TYPE OF PAIN

- Pre-cordial pain
- Osteo-muscular pain
- Other _____

8. ACTION

- Pain therapy
- Comfortable position
- Massage
- Other
- Which? _____
- Absent

9. NURSING INTERVENTION

- Instruction to do pain therapy
- Stimulus to do pain therapy
- Teaching of non pharmacological measures of pain relief
- Other _____

EATING

10. EATING HABITS

	Always	Sometimes	Never
Five or more meals a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consumes at least 2 pieces of fruit a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consumes at least 2 portions of vegetables a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diverse nourishment (white meat/fish), mainly grilled and baked meals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cut down on salt when preparing food and don't add salt at the table	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consume 1L-1,5L of water a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't drink more than 2dl of red wine during meals or a beer a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Actual weight: _____Kg

Height: _____m

11. NURSING INTERVENTION

- Teaching balanced meal consumption
- Teaching water ingestion
- Teaching alcohol consumption
- Other _____

SMOKING

12. Smoking Habits

- Yes
N° cig/day ? _____
- No (skip to question 14)

13. TRYING TO QUIT SMOKING

- Yes. How?
 - Smoking counsel
 - Family physician
 - Alone
- No

TERAPÉUTICA

14. PRESCRIBED MEDICATION

- Vasodilator medication (anti-angina) _____
- Antiarrhythmic medication _____
- Antihypertensive medication _____
- Antithrombotic agents _____
- Hypocoagulante agents _____
- Anti -cholesterol medication _____
- Other _____

FAMILY SUPPORT

15. FAMILY SURROUNDING

- Live alone
- Live with a someone (skip to question 33)
With whom? Partner
 Children
 Other _____

16. FAMILY SUPPORT OR OTHER (if living alone)

- Yes
 - Formal care-taker
 - Informal care-taker
- No

FOLLOW UP

17. FOLLOW UP

- Yes, which?
 - Social worker
 - Dietetic appointment
 - Smoker appointment
 - Physician
 - Other _____

Preenchido por:
Rubrica _____
Nº da Ordem _____

ESCALA SF-36 V2

Place a cross in the corresponding square, which best describes your health

1 – In general, would you describe your health as:

- | | | |
|----------------------|--------------------------|---|
| Excellent | <input type="checkbox"/> | 1 |
| Very good | <input type="checkbox"/> | 2 |
| Good | <input type="checkbox"/> | 3 |
| Reasonable | <input type="checkbox"/> | 4 |
| Weak | <input type="checkbox"/> | 5 |

+

2 – In comparison to a year ago, how would you classify your current health status

- | | | |
|---------------------------------|--------------------------|---|
| Much better than a year ago | <input type="checkbox"/> | 1 |
| A little better than a year ago | <input type="checkbox"/> | 2 |
| Same as a year ago | <input type="checkbox"/> | 3 |
| A little worse than a year ago | <input type="checkbox"/> | 4 |
| Much worse than a year ago | <input type="checkbox"/> | 5 |

3 – The following questions are about your daily routine. Does your current health limit your daily activity? If yes, how?

(Place a cross in the corresponding square)

	Yes, greatly limited	Yes, a little limited	No, no limitation
Vigorous activity, such as running, lifting weights, sport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Moderate activity, such as lift a table, vacuum the house, ride a bicycle or swim	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carry groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climb several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climb one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tilt, kneel, lower yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk more than a Km	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk several hundred meters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk a hundred meters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bath and dress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4 – In the last four weeks, how long did the following problems, related do your physical health, bother your work or daily activities?

	Always	Most of the time	Some of the time	Hardly ever	Never
Reduced the time you spent working or on daily activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Got less done, than you wished	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt limited in work or other activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Had difficulty in doing your Job or other activities.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

5 – In the last four weeks, how long did the following problems, related do your emotional health, (depression/anxiety) bother your work or daily activities?

	Always	Most of the time	Some of the time	Hardly ever	Never
Reduced the time you spent working or on daily activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Got less done, than you wished	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Carried out your work and daily activities with less care than usual	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

6 – In the last four weeks, to what extent did your physical health or emotional problems interfere with your normal social relationship with your family, friends, neighbours or other people?

Absolutely nothing	A little	Moderately	A lot	Immensely
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

7 –, In the last four weeks, how much pain did you feel?

None	Very mild	Mild	Moderate	Intense	Very Intense
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

8 – In the last four weeks, in what way did the pain interfere with your work (work and house work)?

Nothing	A little	Moderately	A lot	Immensely
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

9 – The following questions, are aimed at assessing how you felt and how things worked out in the past four weeks. For each question, please give the answer that best describes how you felt.

	Always	Most of the time	Some of the time	Mostly never	Never
Felt full of vitality?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt very nervous	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt so depressed that nothing cheered you up	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt calm and peaceful	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Had lots of energy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt sad and depressed	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt very tired	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt happy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt tired	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5


10 – In the last four weeks, to what extent did your physical health or emotional problems interfere with your social activity (visiting family, friends)

Always	Most of the time	Some of the time	Hardly ever	Never
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

11 – Which of the following affirmations are true or false in your opinion.


	Absolutely true	Very true	Not sure	False	Absolutely false
Seems I fall ill more often than others	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I'm as healthy as the next person	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I'm convinced that my health is going to worsen	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
My health is excellent	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Appendix 1. Patient Survey – 1 Year after surgery



CENTRO HOSPITALAR DE LISBOA CENTRAL

SERVIÇO DE CIRURGIA CARDIOTORÁCICA
PERCURSO INTEGRADO DO UTENTE NA CONSULTA DE FOLLOW-UP



HOSPITAL DE SANTA MARIA

**PATIENT SURVEY
1 YEAR AFTER SURGERY**

Filling out date: ____/____/201__

VINHETA DE IDENTIFICAÇÃO

TYPE OF FILLING OUT

IN PERSON

ON THE PHONE

PHYSICAL ACTIVITY

1. PRESENCE OF FATIGUE

<p>I – Absent (absence of fatigue, even during physical activity) <input type="checkbox"/></p>	<p>II – Moderate activity (ex: more than 2 flights of stairs) <input type="checkbox"/></p>	<p>III – Mild activity (ex: less than 2 flights of stairs, bathing, etc) <input type="checkbox"/></p>	<p>IV – Rest (presence of fatigue with minimum exertion) <input type="checkbox"/></p>
--	--	---	---

2. NURSING INTERVENTION

- Autonomous orientation in daily routine
- Orientation to progressive increase in physical activity, according to exertion tolerance
- Orientation to rest between activities
- Other _____

PROFESSIONAL ACTIVITY

3. WORKING STATUS (choose the most adequate option)

- Retired
- House work
- Farming
- Student
- Incapacity (mild)
- Unemployed
- Profession _____

DATE 15-07-2010	DONE BY Enfermeira Helena Lima	HEAD NURSE
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1

PAIN ASSESSMENT

4. PRESENCE OF PAIN

- Yes
Where? _____
- No (skip to question 8)

Pain Scale

1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	----

5. TYPE OF PAIN

- Pre-cordial pain
- ~~Cardio~~-muscular pain
- Other _____

6. ACTION

- ~~Pain therapy~~
- ~~Comfortable position~~
- ~~Massage~~
- Other
Which? _____
- ~~Absent~~

7. NURSING INTERVENTION

- Instruction to do pain therapy
- Stimulus to do pain therapy
- Teaching of non pharmacological measures of pain relief
- Other _____

SURGICAL SUTURES

8. PROTECTION OF SURGICAL SCAR IN THE SUN

- Always
- Sometimes
- Never Why?
 - Lack of Knowledge
 - False belief in health
 - Other _____

DATE 15-07-2010	DONE BY Enfermeira Helena Lima	HEAD NURSE
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9. NURSING INTERVENTION

- Instructions relative to the care of surgical suture/scar
- Teaching of inflammatory signs
- Caring for colloid scars
- Instructions relative to operative scar moisturizing
- Instructions relative to operative scar sun protection
- Teaching of the importance of leg elevation
- Teaching of the importance of not crossing your legs
- Other _____

EATING



10. EATING HABITS

	Always	Sometimes	Never
Five or more meals a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consumes at least 2 pieces of fruit a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consumes at least 2 portions of vegetables a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diverse nourishment (white meat/fish), mainly grilled and baked meals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cut down on salt when preparing food and don't add salt at the table	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consume 1L-1,5L of water a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't drink more than 2dl of red wine during meals or a beer a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Actual weight: _____Kg Height: _____m

11. NURSING INTERVENTION

- Teaching balanced meal consumption
- Teaching water ingestion
- Teaching alcohol consumption
- Other _____

SMOKING

12. SMOKING HABITS

- Yes
Nº cig/day ? _____
- No (skip to question 14)

13. TRYING TO QUIT SMOKING

- Yes. How?
 - Smoking counsel
 - Family physician
 - Alone
- No

DATE	DONE BY	HEAD NURSE
15-07-2010	Estefanía Helena Lima	

MEDICATION

14. PRESCRIBED MEDICATION (see discharge form)

- Vasodilator medication (anti-angina) _____
- Antiarrhythmic medication _____
- Antihypertensive medication _____
- Antithrombotic agents _____
- ~~Hypocoagulants~~ agents _____
- Anti -cholesterol medication _____
- Other _____

15. MEDICATION ADHESION

In the last four weeks, relative to any of the following medication: Statins, B-Blockers; ACE inhibitors; e Anti-thrombotic/ Anticoagulantes (mention the medication names, commercial/generic, in accordance to patient prescription)



	Always 1	Frequently 2	Sometimes 3	Never 4
1. Did you ever forget to take your medication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you ever careless with the time you should take your medication?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you ever not taken your medication because you feel better?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you ever decided not to take your medication, because you felt it made you feel worse?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Have you ever decided to take one or several pills, after feeling worse?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Have you ever stopped taking your <u>medication</u> , because you let your pills finish?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Have you ever stopped taking your medication for any other reason, other than, your doctors indication?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.1 If the answer was "always", "Frequently" or "sometimes" in the previous question (7), state the reasons:

- Break in routine/life changes (ex: weekend outing/busy at home/arrived home late from work, meeting/parties with friends/on a trip)
- Because they too expensive
- Due to side effects
- too many pills
- don't know what they for
- Not having anyone to remind me
- Allowing medication to finish without renewing my prescription
- Pharmacy too far
- Don't trust the doctor
- Didn't want to
- Other reasons. which? _____

DATE 15-07-2010	DONE BY Enfermeira Helena Lima	HEAD NURSE
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16. ADHESION TO HYPOCOAGULANT THERAPY

- Schedule
- Dose (pink book)
- INR test
- Where?
 - Laboratory
 - Pharmacy
 - Hospital
 - Health center
 - Other _____
- General care (medication interaction, other)

17. NURSING INTERVENTION

- Instructions on taking hypocoagulant medication
- Teaching concerning general precautions related to taking hypocoagulant medication
- Teaching concerning prescribed medication:
 - Name
 - Indication/action
 - Dosage
 - Eside effects
 - Other _____
- Teaching concerning the benefits of adhering to the prescribed medication
- Other _____

CONTROL

18. MEASURING ARTERIAL PRESSURE

- Always (\geq once a week)
- Sometimes (< once a week)
- Never Why?
 - Don't have the means
 - Lack of knowledge
 - Believe I'm healthy
 - Other _____

19. MEASURING HEART RATE

- Always (\geq once a week)
- Sometimes (< once a week)
- Never Why?
 - Don't have the means
 - Lack of knowledge
 - Believe I'm healthy
 - Other _____

20. MEASURING GLYCAEMIA (clinical indication)

- Always (\geq 3 times a week)
- Sometimes (once-twice a week)
- Never Why?
 - Not applicable
 - Don't have the means
 - Lack of knowledge
 - Believe I'm healthy
 - Other _____

DATE	DONE BY	HEAD NURSE
15-07-2010	Infenoreira Helena Lima	

21. NURSING INTERVENTION

- Teaching about the importance of taking care of your health
- Instructions concerning the reading of a blood pressure, pulse rate and/or glycaemia
- Other _____

SCHEDULED APPOINTMENTS

22. CONFIRMATION OF SCHEDULES APPOINTMENTS (confirm knowledge of appointment)

- Cardiothoracic Surgeon (next)
- Cardiologist (follow up)
- Physician (follow up)
- Telephone nursing appointment, if necessary (teaching)
- Other ~~appointments~~ _____

23. FOLLOW UP

- Yes, which?
 - Social worker
 - Cardiology appointment
 - Cardiac Surgery appointment
 - Dietetic appointment
 - Smoker appointment
 - Physician
 - Other _____
- No

Preenchido por:

Rubrica _____

Nº da Ordem _____

DATE	DONE BY	HEAD NURSE
15-07-2010	Infante Helena Lima	

ESCALA SF-36 V2

Place a cross in the corresponding square, which best describes your health

1 – In general, would you describe your health as:

- | | | |
|----------------------|--------------------------|---|
| Excelent | <input type="checkbox"/> | 1 |
| Very good | <input type="checkbox"/> | 2 |
| Good | <input type="checkbox"/> | 3 |
| Reasonable | <input type="checkbox"/> | 4 |
| Weak | <input type="checkbox"/> | 5 |

+

2 – In comparison to a year ago, how would you classify your current health status

- | | | |
|---------------------------------|--------------------------|---|
| Much better than a year ago | <input type="checkbox"/> | 1 |
| A little better than a year ago | <input type="checkbox"/> | 2 |
| Same as a year ago | <input type="checkbox"/> | 3 |
| A little worse than a year ago | <input type="checkbox"/> | 4 |
| Much worse than a year ago | <input type="checkbox"/> | 5 |

3 – The following questions are about your daily routine. Does your current health limit your daily activity? If yes, how?

(Place a cross in the corresponding square)

	Yes, greatly limited	Yes, a little limited	No, no limitation
Vigorous activity, such as running, lifting weights, sport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Moderate activity, such as lift a table, vacuum the house, ride a bicycle or swim	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carry groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climb several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climb one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tilt, kneel, lower yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk more than a Km	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk several hundred meters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk a hundred meters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bath and dress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DATE 15-07-2010	DONE BY Enfermeira Helena Lima	HEAD NURSE
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4 – In the last four weeks, how long did the following problems, related do your physical health, bother your work or daily activities?

	Always	Most of the time	Some of the time	Hardly ever	Never
Reduced the time you spent working or on daily activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Got less done, than you wished	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt limited in work or other activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Had difficulty in doing your Job or other activities.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

5 – In the last four weeks, how long did the following problems, related do your emotional health, (depression/anxiety) bother your work or daily activities?

	Always	Most of the time	Some of the time	Hardly ever	Never
Reduced the time you spent working or on daily activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Got less done, than you wished	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Carried out your work and daily activities with less care than usual	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

6 – In the last four weeks, to what extent did your physical health or emotional problems interfere with your normal social relationship with your family, friends, neighbours or other people?

Absolutely nothing	A little	Moderately	A lot	Immensely
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

7 –, In the last four weeks, how much pain did you feel?

None	Very mild	Mild	Moderate	Intense	Very Intense
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

8 – In the last four weeks, in what way did the pain interfere with your work (work and house work)?

Nothing	A little	Moderately	A lot	Immensely
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

DATE	DONE BY	HEAD NURSE
15-07-2010	Rebeca Helena Lima	

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9 – The following questions, are aimed at assessing how you felt and how things worked out in the past four weeks. For each question, please give the answer that best describes how you felt.

	Always	Most of the time	Some of the time	Mostly never	Never
Felt full of vitality?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt very nervous	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt so depressed that nothing cheered you up	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt calm and peaceful	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Had lots of energy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt sad and depressed	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt very tired	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt happy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Felt tired	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

10 – In the last four weeks, to what extent did your physical health or emotional problems interfere with your social activity (visiting family, friends)

Always	Most of the time	Some of the time	Hardly ever	Never
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

11 – Which of the following affirmations are true or false in your opinion.

	Absolutely true	Very true	Not sure	False	Absolutely false
Seems I fall ill more often than others	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I'm as healthy as the next person	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I'm convinced that my health is going to worsen	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
My health is excellent	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

DATE	DONE BY	HEAD NURSE
12-07-2010	Infanteiros Helena Lima	

Appendix 2. SF6D Programmes and Licence

NON-COMMERCIAL END USER LICENCE AGREEMENT

PLEASE READ THE FOLLOWING TERMS AND CONDITIONS BEFORE PROCEEDING. . IF YOU DO NOT AGREE TO BE BOUND BY THE TERMS AND CONDITIONS BELOW DO NOT COMPLETE THE REGISTRATION FORM. IF YOU ARE OUTSIDE THE CATEGORY OF LICENSEE TO WHICH THESE TERMS APPLY AND WISH TO USE THE PROGRAM PLEASE CONTACT THE UNIVERSITY. THE ACCEPTANCE OF THESE TERMS AND CONDITIONS BY THE LICENSEE DOES NOT CREATE ANY OBLIGATION UPON THE UNIVERSITY TO PROVIDE THE LICENSEE WITH A COPY OF THE PROGRAM. YOUR LICENCE TO USE THE PROGRAM UPON THESE TERMS COMMENCES WHEN YOU RECEIVE A COPY OF THE PROGRAM.

THE UNIVERSITY RESERVES THE RIGHT TO REFUSE TO PROVIDE THE LICENSEE WITH A COPY OF THE SOFTWARE AND TO WITHDRAW AND/OR AMEND THESE TERMS AND CONDITIONS AT ANY TIME AT ITS ABSOLUTE DISCRETION

1. **GRANT OF LICENCE**

Sheffield grants to the Licensee, a non-exclusive non-transferable licence to use the Program (in object code form) and accompanying written materials and to display one copy of the Program on a single computer (i.e. with a single CPU) at a single location for research and teaching purposes. For the avoidance of doubt

the Licensee shall not use the Program nor allow any third party to use the Program for consultancy work, commercial projects, sponsored research projects or for any purpose which results in commercial gain for the Licensee or any third party. The Licensee is granted no rights other than as expressly granted under this Agreement.

2. **OWNERSHIP OF PROGRAM**

The Licensee acknowledges that as between it and Sheffield the Program and all rights in and to the Program (including without limitation all copyright, patent rights and other intellectual property rights) are the exclusive property of Sheffield.

3. **RESTRICTIONS**

3.1 The Licensee may physically transfer the Program from one computer to another provided that the Program is deleted from the computer from the Program is transferred and therefore is installed only on a single computer at any one time.

3.2 The Licensee may not

3.2.1 electronically transfer the Program from one computer to another over a network.

3.2.2 make the Program available over a network or allow remote access to the Program.

3.2.3 distribute copies of the Program or the accompanying written materials to any third party.

3.2.4 modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Program except to the extent permitted by and in accordance with applicable law.

3.2.5 sub-licence or assign the benefit or burden of this Licence in whole or part, or allow the Program to become the subject of any charge, lien or encumbrance without the prior written consent of Sheffield.

3.3 The Licensee shall effect and maintain adequate security measures to safeguard the Program from access or use by an unauthorised user.

3.4 In the event that the results of the project are published, the user shall cite the following in the references:-

Brazier, JE, Roberts, JR,. The estimation of a preference-based index from the SF-12. Medical Care, 2004;42(9):851-859.

Kharroubi, S, Brazier, JE, Roberts, JR, et al. Modelling SF-6D health state preference data using a nonparametric Bayesian method. Journal of Health Economics, 2007;26(3):597-612.

McCabe, C, Brazier, JE, Gilks, P, et al. Using rank data to estimate health state utility models. *Journal of Health Economics*, 2006;25(3):418-431.

4. **TERMINATION**

4.1 Unless terminated in accordance with this clause 4 this Agreement shall be effective for a period of 1 year commencing on the date the Licensee receives a copy of the Program which shall be deemed to be two days after a copy of the Program is posted to the Licensee by Sheffield. Sheffield may terminate this Agreement at any time on written notice to the Licensee if the Licensee:

- a) is in material or persistent breach of any of the terms of this Agreement and either that breach is incapable of remedy, or the Licensee fails to remedy that breach within 30 days after receiving written notice requiring it to remedy that breach; or
- b) is unable to pay its debts (within the meaning of section 123 of the Insolvency Act 1986), or becomes insolvent, or is subject to an order or a resolution for its liquidation, administration, winding-up or dissolution (otherwise than for the purposes of a solvent amalgamation or reconstruction), or has an administrative or other receiver, manager, trustee, liquidator, administrator or similar officer appointed over all or any substantial part of its assets, or enters into or proposes any

composition or arrangement with its creditors generally, or is subject to any analogous event or proceeding in any applicable jurisdiction.

4.2 Sheffield may terminate this Agreement at any time by giving the Licensee 30 days notice in writing.

4.3 Termination by Sheffield in accordance with the rights contained in this clause 4 shall be without prejudice to any other rights or remedies of either party accrued prior to termination.

4.4 On termination for any reason:

- a) all rights granted to the Licensee under this Agreement shall cease;
- b) the Licensee shall cease all activities authorised by this Agreement;
- c) the Licensee shall immediately destroy or return to Sheffield (at Sheffield's option) all copies of the Program and the accompanying written material then in its possession, custody or control and, in the case of destruction, certify to Vulcan Solutions that it has done so and delete all copies of the Program from any computer. .

5. **WARRANTY AND LIABILITY**

5.1 Sheffield makes no representation and gives no warranty or undertaking with regard to the Program and accompanying written materials. All conditions warranties or other terms which might have effect between the parties or be implied or incorporated into this Licence or any collateral contract, whether by statute, common law or otherwise, are hereby excluded, including without limitation, the implied conditions, warranties or other terms as to satisfactory quality, fitness for purpose or the use of reasonable skill and care. Sheffield does not warrant that the use of the Program will be uninterrupted or error-free. The Licensee accepts responsibility for the selection of the Program to achieve its intended results. The entire risk as to the quality and performance of the Program is with the Licensee. Should the Program prove defective, the Licensee assumes the cost of all necessary servicing, repair or correction.

5.2 Except as expressly stated in clause 5.5

- a) Sheffield hereby excludes all liability for negligence.

- b) Sheffield shall have no liability for any losses or damages which may be suffered by the Licensee (or any person claiming under or through the Licensee), whether the same are suffered directly or indirectly or are immediate or consequential, which fall within the following categories:
 - (i) special damage even though Sheffield was aware of the circumstances in which such special damage could arise;

- (ii) loss of profits, anticipated savings, business opportunity or goodwill; and
- (iii) loss of data;

c) The Licensee acknowledges that no representations were made prior to entering into this Agreement. The Licensee agrees that, in entering into this Agreement, it did not rely on any representations (whether written or oral) of any kind or of any person other than those expressly set out in this Agreement. The Licensee shall have no remedy in respect of any representation (whether written or oral) made to it on which it relied in entering into this Agreement and Sheffield shall have no liability otherwise than pursuant to the express terms of this Agreement.

5.5 The exclusions in this clause 5 shall apply to the fullest extent permissible at law, but Sheffield does not exclude liability for death or personal injury caused by the negligence of Sheffield its officers, employees, contractors or agents for fraud, breach of the obligations implied by section 12 Sale of Goods Act 1979 or section 2 Supply of Goods and Services Act 1982, or any other liability which may not be excluded by law.

5.6 Sheffield shall be under no obligation to provide further copies of the Program to the Licensee.

7. **UPDATE AND MAINTENANCE POLICY**

7.1 Sheffield accepts no responsibility for maintenance of the Program once delivered to the Licensee and is under no obligation to provide:

a) Enhancements, updates and improvements to the Licensees version of the Program

b) Written or telephone consultations

c) Correction of errors and deficiencies in the software

d) Revised or additional supporting documentation

8 **CONFIDENTIALITY**

8.1 Each party shall, during the term of this Agreement and thereafter, keep confidential all, and shall not use for its own purposes nor without the prior written consent of the other disclose to any third party any, information of a confidential nature (including, without limitation, trade secrets and information of commercial value) which may become known to such party from the other party, unless such information is public knowledge or already known to such party at the time of disclosure, or subsequently becomes public knowledge other than by breach of this Agreement, or subsequently comes lawfully into the possession of such party from a third party.

The provisions of this Clause 8.1 shall remain in full force and effect notwithstanding termination of this Agreement for any reason.

9. **GENERAL**

9.1 Notices

Any notice to be given to under this Agreement shall be in writing and shall be sent by recorded delivery first class mail to (in the case of notices to the University) to the address of Sheffield University Enterprises Ltd, 217 Portobello, Sheffield S1 2DP and in the case of notices to the Licensee to the address completed on the Registration Form.

9.2 Complete Agreement

This Agreement supersedes and cancels all previous agreements and working arrangements whether oral or written, express or implied between the parties in respect of the licensing of the Program.

9.3 Variation

Any variation of any of the terms and conditions of this Agreement shall not be effective unless in writing signed by both parties (in the case of Sheffield being signed by a duly authorised representative of Company).

9.4 Headings

Clause and sub-clause headings are inserted in this Agreement for ease of reference only and accordingly neither the headings nor the layout form part of this Agreement for the purposes of interpretation or construction.

9.5 Waiver

No forbearance or delay by either party in enforcing its rights shall prejudice or restrict the rights of that party, and no waiver of any such rights or of any breach of any contractual terms shall be deemed to be a waiver of any other right or of any later breach.

9.6 Severability

If any provision of this Agreement is judged to be illegal or unenforceable, the continuation in full force and effect of the remainder of the provisions shall not be prejudiced.

9.7 Third Party Rights

No term of this Agreement is intended to confer a benefit on, or to be enforceable by, any person who is not a party to this Agreement.

9.5 Governing Law and Jurisdiction

The construction, validity and performance of this Agreement shall be governed in all respects by English law and the parties hereby agree to submit to the non-exclusive jurisdiction of the English Courts.

10. **ACKNOWLEDGMENT**

You acknowledge that you have read this Agreement, understand it and agree to be bound by its terms and conditions.

Appendix 3. Healthcare Ethics Committee Approval



ACM
19 JUL. 2017
Armando Sousa Guerreiro
Diretor
COMISSÃO DE ÉTICA PARA A SAÚDE

Parecer

Data: 15.07.2017
Processo n.º 465/2017

Título: "Errors and Patient safety: wich ones matter most?"

Relator: Sandrina Bento

Investigadores: Dra. Filipa Breia da Fonseca (Doutoramento em Gestão da Faculdade de Economia e Gestão da Universidade Nova de Lisboa), sob orientação do Prof. Dr. Pedro Pita Barros

Local: Serviço de Cirurgia Cardiorábrica do Hospital de Santa Marta

Apreciação:

O 3º paper científico do estudo " Erros médicos e segurança do paciente", submetido a apreciação por esta Comissão, tem como objetivo determinar como é que a adesão à terapêutica influencia a qualidade de vida do paciente submetido a cirurgia cardíaca ao primeiro, terceiro, sexto e décimo segundo mês pós-operatórios. O desenvolvimento do estudo prevê o acesso da investigadora a uma base de dados do Serviço de Cirurgia Cardiorábrica, cuja consulta e análise foram autorizadas pelo Diretor da Área, o Exmo. Professor Doutor José Fragata que, após pedido de esclarecimentos por parte desta CES, assegura tratar-se de uma base de dados anónima.

Não estão previstos quaisquer encargos financeiros para o Centro Hospitalar de Lisboa Central.

Está prevista a divulgação dos resultados sob a forma de artigos científicos publicados em revistas académicas nacionais e internacionais.

Conclusão:

Assim sendo, o estudo em análise não levanta questões do ponto de vista ético, respeitando os princípios da Declaração de Helsínquia pelo que esta Comissão entende emitir parecer favorável à sua realização.

O Presidente da Comissão de Ética

(Gonçalo Cordeiro Ferreira)

CENTRO HOSPITALAR DE LISBOA CENTRAL, EPE	
Secretariado CA	
Nº:	465/2017
Entrada:	15.07.2017
Saída:	24 JUL. 2017


```

      mitral |   .1424353   .0126325   11.28   0.000   .1176468
.1672238
-----

```

--

```

( 1) aortic - mitral = 0
( 2) aortic - coronary = 0

      F( 2, 1023) =   1.07
      Prob > F =   0.3449

```

```

( 1) aortic - mitral = 0

      F( 1, 1023) =   1.27
      Prob > F =   0.2607

```

```

( 1) aortic - coronary = 0

      F( 1, 1023) =   1.59
      Prob > F =   0.2077

```

```

( 1) - coronary + mitral = 0

      F( 1, 1023) =   0.04
      Prob > F =   0.8360

```

```

      Source |          SS          df          MS      Number of obs =
1,050
-----+-----
363.43                                F(3, 1047) =

```

```

Model | 26.7659937          3  8.92199789  Prob > F      =  0.0000
Residual | 25.7032373      1,047  .024549415  R-squared     =
0.5101
-----+-----
0.5087                                Adj R-squared =
Total | 52.469231      1,050  .049970696  Root MSE     =
.15668

```

--

```

dif_p~6M_OHS |          Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-----+-----

```

--

```

      aortic |   .1621282   .0072195   22.46   0.000   .1479618
.1762947
      coronary |   .1583856   .0076092   20.82   0.000   .1434546
.1733166
      mitral |   .1555226   .012585   12.36   0.000   .1308278
.1802174
-----

```

--

```

( 1) aortic - mitral = 0
( 2) aortic - coronary = 0

      F( 2, 1047) =   0.13
      Prob > F =   0.8812

```

```

( 1) aortic - mitral = 0

      F( 1, 1047) =   0.21
      Prob > F =   0.6490

```

```

( 1) aortic - coronary = 0

```

```

F( 1, 1047) = 0.13
  Prob > F = 0.7213

( 1) - coronary + mitral = 0

F( 1, 1047) = 0.04
  Prob > F = 0.8457

Source |          SS          df          MS      Number of obs   =
-----+-----
1,042
384.10
Model | 29.1777117          3  9.72590392   F(3, 1039)      =
0.0000
Residual | 26.3084786      1,039  .025320961   Prob > F         =
0.5259
-----+-----
0.5245
Total | 55.4861904      1,042  .053249703   R-squared        =
.15913
Adj R-squared =
Root MSE =

-----
--
dif_pr~Y_OHS |      Coef.   Std. Err.    t    P>|t|    [95% Conf.
Interval]
-----+-----
--
aortic | .1647312   .0074032   22.25  0.000   .1502043
.1792581
coronary | .1687918   .0077187   21.87  0.000   .1536457
.1839378
mitral | .1709968   .0127813   13.38  0.000   .1459167
.1960768
-----
--

( 1) aortic - mitral = 0
( 2) aortic - coronary = 0

F( 2, 1039) = 0.12
  Prob > F = 0.8863

( 1) aortic - mitral = 0

F( 1, 1039) = 0.18
  Prob > F = 0.6715

( 1) aortic - coronary = 0

F( 1, 1039) = 0.14
  Prob > F = 0.7043

( 1) - coronary + mitral = 0

F( 1, 1039) = 0.02

  Prob > F = 0.8826

```

Appendix 5. Pairwise comparisons of adjusted predictions

Model VCE : OLS

Expression : Linear prediction, predict()

```
-----
--
--
--          |          Delta-method          Unadjusted
--          |          Contrast      Std. Err.      [95% Conf.
Interval]  +-----+-----+-----+-----+
--
--          |          DIAGNOSTICS_I |
aortic vs coronary | -.099297   .018362   -.1353229  -.0632711
mitral vs coronary | -.0919287  .0253466  -.1416583  -
.0421991
mitral vs aortic   |  .0073683  .0250516  -.0417826
.0565192
-----
```

Pairwise comparisons of adjusted predictions

Model VCE : OLS

Expression : Linear prediction, predict()

```
-----
--
--
--          |          Delta-method          Unadjusted
--          |          Contrast      Std. Err.      [95% Conf.
Interval]  +-----+-----+-----+-----+
--
--          |          DIAGNOSTICS_I |
aortic vs coronary | -.2780816  .024329   -.3258148  -.2303484
mitral vs coronary | -.3169811  .0335834  -.3828713  -
.2510909
mitral vs aortic   | -.0388996  .0331926  -.104023
.0262239
-----
```

Pairwise comparisons of adjusted predictions

Model VCE : OLS

Expression : Linear prediction, predict()

```
-----
--
--
--          |          Delta-method          Unadjusted
--          |          Contrast      Std. Err.      [95% Conf.
Interval]  +-----+-----+-----+-----+
--
--          |          DIAGNOSTICS_I |
aortic vs coronary |  .0126148  .0214919   -.029552   .0547817
mitral vs coronary |  .2271488  .0296671   .1689424
.2853553
-----
```

```

    mitral vs aortic |    .214534    .0293219    .1570049
.2720632
-----

```

--

Pairwise comparisons of adjusted predictions

Model VCE : OLS

Expression : Linear prediction, predict()

--

```

Interval]          |          Contrast      Delta-method      Unadjusted
                   |          Std. Err.      [95% Conf.
-----+-----
    DIAGNOSTICS_I |
aortic vs coronary |    .0036738    .0286338    -.0525054    .059853
mitral vs coronary |    .043501    .0395257    -.0340478
.1210499
    mitral vs aortic |    .0398273    .0390658    -.0368192
.1164737
-----

```

--

Pairwise comparisons of adjusted predictions

Model VCE : OLS

Expression : Linear prediction, predict()

--

```

Interval]          |          Contrast      Delta-method      Unadjusted
                   |          Std. Err.      [95% Conf.
-----+-----
    DIAGNOSTICS_I |
aortic vs coronary |   -.2637164    .0296345    -.3218589   -.2055739
mitral vs coronary |   -.4559748    .040907    -.5362338    -
.3757158
    mitral vs aortic |   -.1922585    .040431    -.2715835    -
.1129334
-----

```

--

Pairwise comparisons of adjusted predictions

Model VCE : OLS

Expression : Linear prediction, predict()

--

```

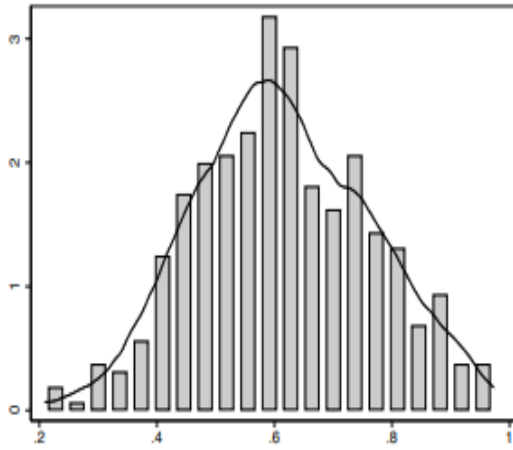
Interval]          |          Contrast      Delta-method      Unadjusted
                   |          Std. Err.      [95% Conf.
-----+-----
    DIAGNOSTICS_I |
aortic vs coronary |    .0250446    .0201112    -.0144133    .0645024

```

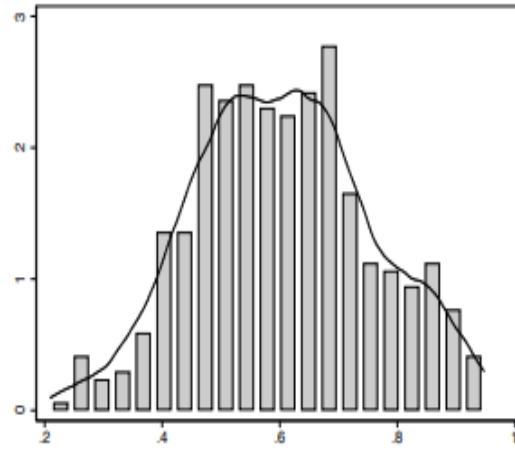
mitral vs coronary	.4106918	.0277612	.3562248
.4651588			
mitral vs aortic	.3856473	.0274381	.3318141
.4394805			

Appendix 6. Histograms - Distribution of Scores – Preoperative

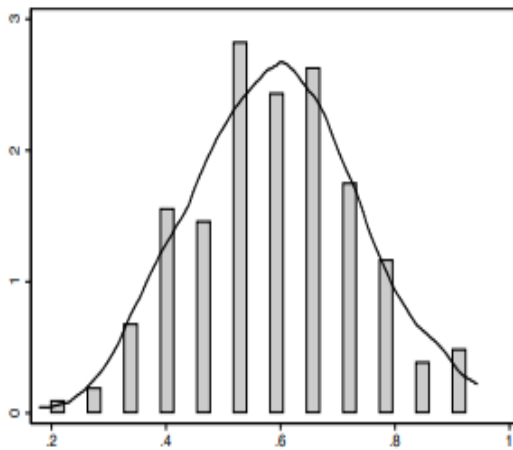
(a) Coronaria: before surgery



(b) Aortica: before surgery

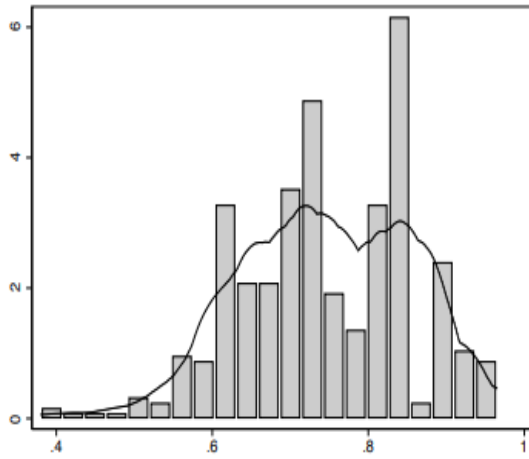


(c) Mitral: before surgery

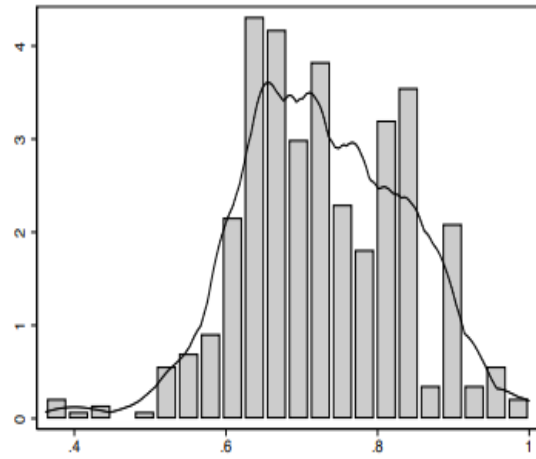


Appendix 7. Histograms - Distribution of Scores – 3 Months

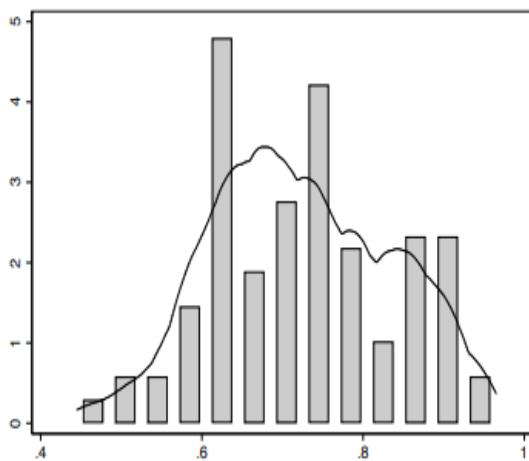
(a) Coronaria: 3 Months



(b) Aortica: 3 Months

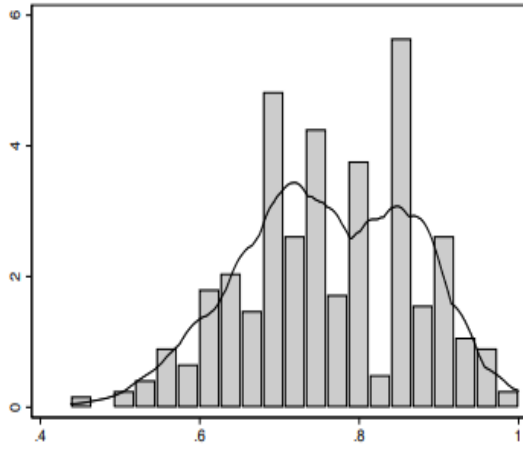


(c) Mitral: 3 Months

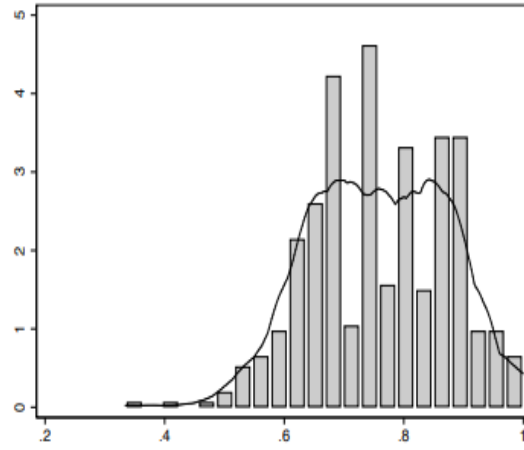


Appendix 8. Histograms - Distribution of Scores – 6 Months

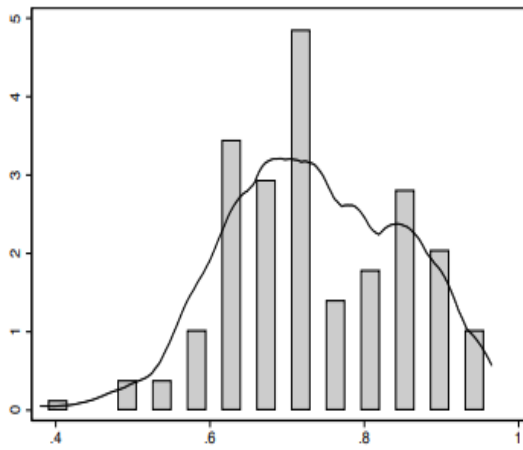
(a) Coronaria: 6 Months



(b) Aortica: 6 Months

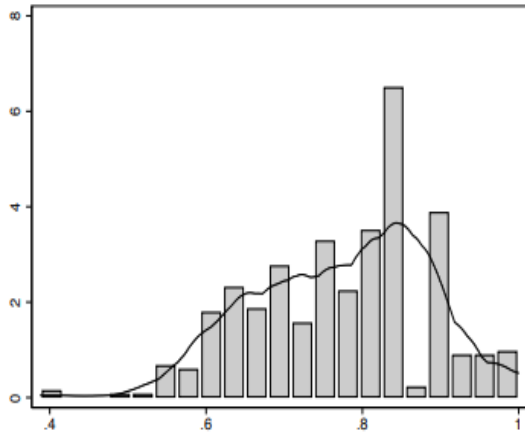


(c) Mitral: 6 Months

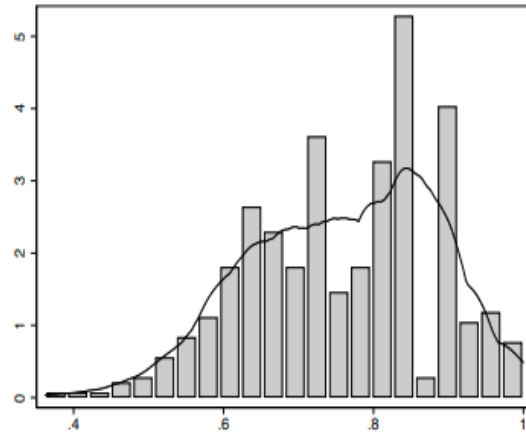


Appendix 9. Histograms - Distribution of Scores – 12 Months

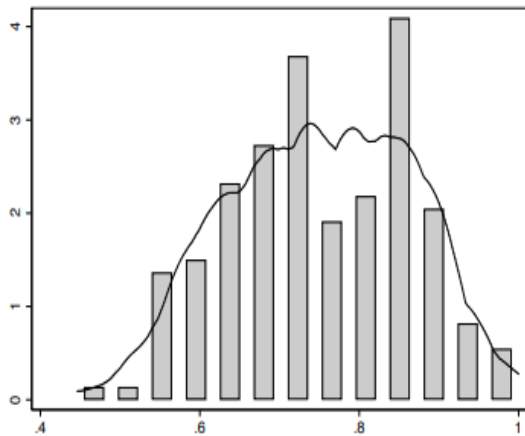
(a) Coronaria: 12 Months



(b) Aortica: 12 Months



(c) Mitral: 12 Months



Appendix 10. Time Intervals Analysis

```

-----
-----
dif_preop_~Y_OHS |      Coef.   Std. Err.      t    P>|t|      [95% Conf.
Interval]
-----+-----
-----
      aortica |   .1163268   .0209856    5.54   0.000    .0751392
.1575145
      coronaria |   .1152832   .0222005    5.19   0.000    .0717111
.1588553
      mitral |   .1178335   .0234556    5.02   0.000    .0717979
.163869
tempo_primeira~a |  -.0000152   .0000273   -0.56   0.577   -.0000688
.0000384
      nantecedentes |  -.0022455   .0049074   -0.46   0.647   -.0118772
.0073861
PRESENCA_DOR_P~A |   .0409699   .0107006    3.83   0.000    .0199683
.0619715
-----
-----

```

```

( 1) aortica - mitral = 0
( 2) aortica - coronaria = 0

      F( 2, 879) = 0.01
      Prob > F = 0.9875

( 1) aortica - mitral = 0

      F( 1, 879) = 0.01
      Prob > F = 0.9217

( 1) aortica - coronaria = 0

      F( 1, 879) = 0.01
      Prob > F = 0.9300

( 1) - coronaria + mitral = 0

      F( 1, 879) = 0.02
      Prob > F = 0.8753

```

CONCLUSIONS

Conclusions

The primary aim of this thesis was to contribute to the study of patient safety.

We started by exploring medical errors. What are the main errors in medical care, its causes and possible consequences for the patients. We then developed the main research idea into several questions: How can we improve patient safety by learning from errors? This study was based in a theoretical review thus allowing for the development of an integrative conceptual model. One case study was performed in a cardiothoracic surgery service to explore the questions about types and causes of medical errors. We chose to develop this research in a particular cardiothoracic surgery service because processes and patient pathways are thoroughly detailed, recorded and organized, thus reducing the occurrence of errors to a possible minimum. Error reduction is a major factor in improving patient safety, specially in such complex systems as cardiac surgery.

We then sought to analyse the evolution of postcardiac surgery quality of life and to ascertain if surgery is a reliable and safe option to improve patient's quality of life. As before, we used real data from the cardiothoracic service we had previously studied.

In the first paper, existent terminologies and concepts of patient safety and error were reviewed and clarified. The literature review highlighted the importance of the distinction between several concepts, namely: sentinel and adverse events, accidents, incidents and near misses. An integrative framework was conceptually developed and its application

presented with an illustrative model. The model's novelty is ability to explain the system behaviour in the occurrence of an error.

This new theoretical model further understanding on the drivers of patient safety based on the moment of the occurrence of failures or errors. According to the moment in time, the errors may propagate or can be recurrent. Still others can be total or partially adjusted and the complexity of the process may determine the error chain.

The model enables the identification of different types of error. It will be useful for healthcare professionals and managers to identify and connect all the conceptual errors contents. The model also shows, in a perceptive way, the error gravity level and hindmost correction of each other concepts. Therefore it could be helpful to target specific harms or specific clinical processes to study the improvement of the underlying work systems.

This paper provides an important new direction for research in service failure and healthcare organization. Past research has, for the most part, neglected to explain the error taxonomy. This lapse precludes the clarification and interconnection between the different error concepts. This model is, therefore, an original contribution, since none of the previous models and research presented in this paper (Reason J. 1990, Vincent, 2003) explained the error in this approach.

In the second paper, a qualitative empirical study was conducted, involving physicians and nurses, in order to explore the types and causes of medical errors in the cardiothoracic surgery service. In this, we identified the most frequent types of errors.

Furthermore, from this study also comes the knowledge of a new classification that can be used in future studies. It seemed important to group errors into the following typification:

- By the source of the error (e.g. planning, execution, process, knowledge and skills, systems);
- By the area of occurrence (e.g. medication, diagnostics; performance; prevention; treatment; guidelines, inadequate reporting, delays in the provision or scheduling of a service);
- By a combination of the two see before (previous systems) (e.g. diagnosis, surgical and medical treatment mishaps);
- By the agent involved (e.g. clinician factors, communication and administration).

We also noticed that a part of the literature on error classification overlaps itself when we consider the moment when the flaw happens and the accountability for it. The moment in which the flaws are noticed, registered and in which most of them actual occur is whenever there is more than one professional involved and passing of responsibility occurs, that is, whenever there is judgement, decision and in transition times. That's where the potential for flaw occurs and the professionals are not fully aware of the relevance of this stage.

A key insight from our review was the importance of defining error intensity in error classification. We therefore proposed a classification relating intensity with clinical impact. Maximum intensity errors can lead to a patient's death, whereas medium intensity

errors can lead to an array of clinical consequences from which the patient may recover with or without definitive sequel. Minimum intensity errors do not constitute a danger to patients.

From the data analysis it became clear that some errors occur along the process or operation but have their origin in other areas or stages, namely at planning in earlier stages. Managers need to ensure that functions are adequately trained and staffed to perform their function's efficiently. Staff also be prepared to eliminate redundant steps and get evolved in the communication and in solutions to error resolution.

We also concluded that, when error accountability is implemented, it is easier to prevent errors.

The causes of errors were also explored. The research suggests that errors are related to problems with changes, confusion, lack of action, concentration, information confirmation or procedures that have gone wrong. It seems that the central element is error amplification, propagation and handoffs. Therefore, the errors that patients suffer are sometimes an accumulation of problems in the system, over long periods of time and encompassing multiple contexts.

In the third paper we tried to investigate a possible link between patient safety and patient quality of life. This connection seems very important to us because once we are studying a cardiothoracic surgery service, we were able to follow whole the patient pathway process namely before, during and after cardiac surgery.

To do that, we developed a quantitative study on the evolution quality of life of patients who had undergone cardiac surgery. Cardiac surgeries included in the analysis relate to the main three diagnoses of heart disease: aortic valve disease, coronary artery disease and mitral valve disease. We developed a quantitative study focusing on the evolution of quality of life during the first year post cardiac surgery.

It was concluded that surgery increases quality of life in all diagnostic groups, albeit with differences in relevance and timing: we concluded that at three months, mitral valve patients showed higher benefit. Aortic patients showed higher benefits at six months post op but, at twelve months, mitral valve disease patients were the group with most benefit. These differences, albeit small, are significant.

As for temporal evolution, the main QoL gains are obtained in the first three postoperative months, with little gain afterwards.

In view of this data, the preoperative quality of life is worse in patients with mitral valve disease and these patients showed the greatest increase in postoperative quality of life. Data showed that patients with mitral valve disease had significantly worse pre operative quality of life than any other groups. However, they were the patient group that showed a greater increase in postoperative quality of life.

Pain characteristics are very different in the pre and postoperative periods but, nonetheless, the presence of pain of any etiology (disease vs surgical) plays a very significant role in patient quality of life. Multivariate analysis showed that the presence

of pain was the only factor that most affected quality of life, whether pre or postoperatively. Although the pain characteristics are fundamentally different, the presence of this symptom had a very significant role in the patient's quality of life.

Timing of first consult had a significant impact in the patient quality of life (less waiting time for the surgery means best quality of life). Coronary artery disease patients were the most significantly and negatively affected group in terms of QoL, especially by the presence of associated pain.

It would be good to refer that procedural variables such as 1st consult to surgery waiting time and others were analyzed and that only one variable showed significant impact on patients' quality of life.

Finally, the research provides evidence that if we know in detail what are the items that influence the procedural and surgery characteristics, we could contribute to a better patient quality of life.

a) Implications

a.1) Implications for literature and researchers

The research provides a relevant new direction in medical errors and healthcare management research. The conclusions point out to the need of further investigation on error intensity.

The theoretical model shows a global perspective of the errors' frequency in the patient flow. The model's novelty is to explain, in a simple way, the system's behavior regarding an error that happens to a patient. The theoretical model also shows that what occurs "in a specific moment" could also happen in all the moments in the chronological time.

It will be useful to healthcare professionals and managers to identify and connect all the errors taxonomy and contents. The model helps to practically and visually distinguish the difference between all the types of errors.

a.2) Implications for managers

Our findings also have implications for managers who seek to recover errors and improve patient safety and patient quality of life. Managers could enforce procedures to provide process improvement that are making hospitals less dangerous for patients. Solution efforts are likely to involve mechanisms used to request and provide information and services among the different healthcare groups (Spear and Bowen, 1999).

First, organizations will need teams to do daily meetings to review errors reported overnight. It is also important to debrief the relevant staff, and sometimes, for example in the case of the botched chest drain, recommend changes to procedures or eliminate unnecessary steps. Managers can also provide problem solving assistance for front-line workers (for example in tasks interdependence, namely information passage or in work systems problems solving).

During interviews, some surgeons felt that using a checklist infantilizes them and undermines their expertise. According to this, we advocate about the importance of having better and verifiable procedures.

The research highlighted some failures in the patient pathway process. We propose that managers, physicians and nurses should study the workflow process and improve the individual tasks. If tasks are scheduled and well oriented, ineffectiveness can be spotted and reduced. Any member of staff should be encouraged to halt a procedure deemed unsafe. The action should be “go and see for yourself”, a standardized way for executives to visit wards and speak to staff about safety risks.

Managers can also provide some sort of signal to notify nurses and physicians when missing medicines are delivered to a unit (for example in intensive care unit or infirmary).

Perhaps the greatest potential for reducing medical errors, however, lies in new technology. The use of mobile phone apps and alerts could provide a fast and secure way of providing information and aid swift and accurate clinical decision making. One significant problem with this approach would be how to tackle alarm fatigue.

As we observed nursing work, we found that nurses are interrupted every five to six minutes. Constant interruptions are a source of distraction and possible error. Little wonder, perhaps, that staff can ignore alerts, with sometimes fatal consequences.

In summary, medical technology is saving ever more lives, but by expanding the range of what medicine and technology can do, progress also brings with it new routes for harm.

Another important finding refers to waiting time between 1st consult and surgery. This time had a significant impact in the patient quality of life (less waiting time for the surgery means best quality of life).

To improve this, managers could design and adopt a strategy, which analyzes data about the events that lead to inordinate delays. The goal would be to identify the causes of delays such as, inadequacy of resource allocation, procedural or administrative causes. This program might use machine learning to detect patterns and thus help to pinpoint problems and propose adequate solutions.

There are many ways to improve safety - regulations settings, changes to training, identification of operational failures - but it might also help to remember that, for all health care's dazzling progress, healthcare professional are humans.

b) Further Research

This section ends the thesis pointing out directions for future research. Some of them are motivated by the research findings.

Further research studies might pursue a single type of error, such as medication, through the system to find the error source. The conceptual model could be used to tested this.

Future studies should examine comparable cardiothoracic units. The study could be replicated in a different context (another country with a different culture). The findings of paper II could be further tested in the same or in a different medicine specialization through quantitative research methods.

Further study possibility is to explore and support the cardiothoracic hospital service to know what went wrong in the patient pathway service process, signal that and related this results with the patients that didn't recover in the postoperative, namely after the surgery. If nothing will be significant, it is a sign that the processes and procedures are correct.