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Fast-track health technology assessment for in vitro diagnostics—a design thinking case study

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ABSTRACT

The evolution of diagnostic technologies, combined with the urgent need for efficient healthcare delivery in challenging public health contexts, calls for agile and empathetic innovation. This is particularly relevant in the context of in vitro diagnostics (IVDs), which significantly impact patients, healthcare providers and the overall healthcare system. This broad reach depends on specific health technology assessment (HTA) frameworks for IVD, which are still underdeveloped. As a response to this challenge, our study seeks to document the inspiration, ideation and implementation of a fast-track HTA project for IVDs, employing a design thinking (DT) methodology. We report an iterative process encompassing different methodologies including a narrative literature review, in-depth semistructured interviews and interdisciplinary workshops. Our results confirmed the value of IVDs for different healthcare dimensions, including clinical outcomes, economic impact, operational efficiency in healthcare delivery, patient outcomes and healthcare innovation. Stakeholders proposed innovative IVD solutions, which were assessed based on their feasibility, impact and potential for commercialisation. As a result, a fast-track HTA for IVDs was selected for implementation. Following the identification of contextual challenges, specific suggestions for idea implementation were prioritised. By applying a comprehensive and multidisciplinary approach, our study offers insights into how HTA processes can be adapted to rapid healthcare innovation cycles and provides a practical roadmap for policymakers and stakeholders in

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The rapid evolution of in vitro diagnostics (IVDs) and their critical role in preventive medicine, early disease detection and treatment highlight the need for an optimised health technology assessment (HTA) framework to ensure timely patient access and efficient healthcare delivery.

WHAT THIS STUDY ADDS

⇒ This design thinking study incorporates the perspectives of different healthcare stakeholders to assess the value of IVDs in healthcare, including their impact on clinical outcomes, cost-effectiveness and operational efficiency.

⇒ Through an ideation and implementation process, this study also proposes an innovative fast-track HTA system for IVDs, tailored to their unique innovation cycle, with the potential to improve IVD evaluation and adoption in clinical practice.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study demonstrates how a design thinking approach can drive innovation by engaging diverse stakeholders to develop a fast-track HTA framework for IVDs, by addressing current gaps in health technology evaluation and adoption processes.

⇒ The proposed HTA framework has the potential to enhance IVD evaluation, support policy development and promote more efficient use of healthcare resources while highlighting the effectiveness of design thinking in advancing innovation within the diagnostic technologies field.

the health technology sector, which is particularly relevant in an era where healthcare innovation is a key driver of economic growth and global strategic advantage.

INTRODUCTION

The rapid evolution of diagnostic technologies, combined with the urgent need for efficient healthcare delivery in challenging public health contexts, calls for agile and empathetic innovation. In parallel, the potential impact of in vitro diagnostics (IVDs) reflects on patients but also on healthcare providers (at the level of workflow benefits, for example) and the overall healthcare system.[1] IVDs can be applied in screening, early detection, diagnosis, prognosis and therapeutic monitoring. IVD healthcare innovations can address public health emergencies, such as pandemics (eg, PCR tests for emerging pathogens), focus on areas with a high disease burden (eg, natriuretic peptides for early diagnosis of heart failure or pTAU/beta-amyloid testing to rule out Alzheimer's disease in patients with mild cognitive impairment), or target areas with high relative costs, such as sequencing (eg, tests to interpret liquid biopsies for determining cancer patients' eligibility for targeted therapies). As IVDs are fundamental tools in preventive medicine and early disease detection (enabling prevention, treatment or an extension of quality-adjusted life years) most interventions using innovative IVD solutions could potentially be cost-effective. Therefore, a specific, rigorous and streamlined assessment framework for IVDs could enhance patient access to healthcare, improve patient outcomes, achieve operational efficiencies and generate significant cost savings. This depends on robust health technology assessment (HTA) frameworks that ensure that scientific and technology advancements follow rigorous standards of efficacy, safety, cost-effectiveness and social responsibility, ultimately enhancing patient care and system efficiency.[2] HTA of IVDs faces a unique set of challenges and opportunities. Unlike medicines, where the HTA frameworks and processes are well established across most European countries, a specific pathway for IVD HTA is still underdeveloped.[2] This gap in HTA is particularly limiting given the fundamental role that IVDs play in the healthcare continuum, specifically in the prediction, early detection, diagnosis, treatment, monitoring and management of diseases, which may lead to improved patient outcomes and healthcare resource allocation.[1]

Importantly, the innovation cycle of IVDs is inherently more dynamic than the conventional innovation cycle for medicines. This may be due to different factors, including the quicker pace of scientific advancements, the less burdensome nature of regulation in some jurisdictions partly due to a focus on analytical and clinical validity rather than on clinical efficacy, a demand for continuous innovation in diagnostic technologies that feed precision medicine initiatives and a high degree of digital health integration, which aligns with a rapid pace of software development compared with traditional pharmaceutical research and development.[3] Furthermore, the demonstration of utility and cost-effectiveness can be more straightforward for IVDs in comparison to medicines, which can accelerate the healthcare system's adoption of new diagnostics tools, particularly if these address unmet clinical needs without requiring significant changes to existing treatment protocols and whose adoption is relatively cost-neutral. Finally, the increasing complexity of technologies in the IVD environment (resulting from a combination of IVD with digital solutions like AI scores and algorithms) calls for HTA frameworks which are flexible and fit-for-purpose. Consequently, traditional HTA methodologies and processes, characterised by being time-consuming, may not be optimised for the fast-paced environment of IVD development.[2] This inadequacy is compounded by the different nature of evidence required in the IVD space as well. These factors may constitute barriers to the adequate and timely introduction of innovative diagnostic tools into clinical practice, potentially delaying access to healthcare and reducing the efficacy of health systems.

As a response to this challenge, our study seeks to document the inspiration, ideation and implementation of a fast-track HTA project for IVDs, employing a design thinking (DT) methodology. DT has a significant potential for the ideation and implementation of innovative solutions in different contexts, including healthcare.[4] Characterised by its human-centred approach that prioritises the needs and experiences of users in the development of new products and services, DT consists in an iterative process involving three key stages: inspire, ideate and implement. DT facilitates the understanding of user needs, a dynamic ideation of possible solutions to meet those needs and continuous feedback integration leading to effective innovation.[5] In healthcare, where complex challenges intersect with sometimes conflicting stakeholder needs, DT offers a framework for innovation that is both adaptable and wide-ranging, enabling the development of accessible, usable and real-world impactful solutions.[4] Specifically, in the IVD sector, DT-driven innovation allows the introduction of positive change in a complex landscape of patient care, regulatory compliance and technological advancement by considering contextual-specific challenges of HTA.

Specifically, our study aims to offer insights into how HTA processes can be optimised to better align with the rapid innovation cycles characteristic of the IVD sector. This work also aims to provide a practical roadmap for policymakers and stakeholders in the health technology sector to design a more innovative, responsive and efficient HTA system for IVDs.

METHODS

This study encompassed three phases, corresponding to the DT core activities: inspire, ideate and implement.

Inspiration phase

This phase included a narrative literature review and a series of in-depth interviews, offering insights and contextual understanding of stakeholders' perspectives.

The narrative literature review consisted in an initial literature search using electronic platforms PubMed, Scopus, Web of Science and Google Scholar, using the following search keys and MeSH (Medical Subject Headings) terms: (*diagnostics*; *test diagnostics*; *early diagnostics*, *screening*, *value/added value*, *cost-effectiveness*, *precision medicine* and *IVD*). Additional references were identified by backward and forward citation chaining. Finally, articles from scholars known to the authors and relevant grey literature, including reports, white papers and policy documents, were also analysed to complement the analysis. General eligibility criteria included date of publication (from 1990 to 2021); language of the article (English, Spanish and Portuguese) and article type (peer-review original research articles published in indexed scientific journals; grey literature; full-text access to manuscript).

Overall, 111 studies were identified and 47 were comprehensively reviewed.

The semistructured in-depth interviews were conducted among a sample of interest composed of one hospital manager, four health professionals, five health policy experts and decision makers and two members of patient associations. Interviewees originated from the following organisations: Portuguese Ministry of Health, Portuguese National Health Service, Portuguese Association of Medical Colleges and Portuguese Association of Patient Associations. Interviews were conducted between April and May 2021. Our interview script was developed based on the results from the systematic review, which provided an evidence-based framework for the thematic structure, ensuring that key insights from published literature were translated into semiopen questions. Our interview script was pretested in a convenience sample of one health policy expert, one health professional and one healthcare decision maker. As a result of this test, changes were introduced to clarify definitions, expressions and concepts included in the questions. The interviews consisted of 13 semiopen questions, divided by three areas: Decision Making and Value for Health; Innovation and the Patient at the Centre of Care and The Value of Diagnosis. Interviewees had the freedom to discuss other topics they found important for the future of healthcare.

Ideation phase

This phase consisted in a workshop/think tank held in Lisbon, Portugal, in July 2022, where nine participants from various healthcare sectors and institutions, including healthcare professionals, patients, regulators, policymakers and industry representatives, gathered to actively participate in the ideation process. Participants were purposively selected aiming to include different stakeholder perspectives and considering expertise, experience and established credibility as selection criteria. We also aimed at including broad institutional representation, from the public, private and social sectors. During the workshop, participants engaged in a structured sequence of methods aimed at fostering empathy, generating ideas and evaluating potential solutions for improving IVD testing. Participants initially conducted mutual interviews to understand each other's experiences with IVD testing and uncover needs for future solutions. This exchange preceded the ideation phase, where, following the presentation of topics derived from the inspiration phase (in-depth interviews), participants engaged in a brainstorming session to generate and organise ideas. This included an initial unstructured idea generation phase using post-it notes, followed by a phase of grouping ideas on an A3 grid according to overall coherence. In the subsequent storyboarding phase, participants used visual aids such as sketches, diagrams and flowcharts to outline the main components of their ideas, illustrating potential workflows, stakeholder involvement and expected outcomes, which helped refine and communicate the key aspects of each concept more effectively. Ideas were then qualitatively assessed by each participant according to feasibility (considering workflow integration and potential obstacles to adoption), impact (considering the broader importance and relevance of the idea for the health sector, along with its ethical, legal and social implications) and implementation potential (considering alignment with best practices and the entities that should be involved). Participants were then asked to rank the ideas from first to third based on their overall evaluations. These individual rankings were aggregated, and the idea with the highest overall ranking was selected. This structured process facilitated collaborative identification of promising solutions for further development in IVD testing.

Implementation phase

This phase consisted in a workshop conducted in March 2023 aiming to provide a structured platform for collaborative problem-solving and consensus building. Eight participants with established credibility and recognised expertise from different healthcare sectors and institutions, including healthcare professionals, regulators, policymakers, members from academia and industry representatives participated in this workshop. The workshop execution involved two rounds: round 1 was dedicated to the identification of contextual implementation challenges, round 2 was dedicated to models of implementation. Each round was composed of three fundamental steps: (1)

Table 1 Value of IVDs for patients, health professionals and the health system

Value of IVDs	Studies	Specific examples
Patients		
Reduced mortality	6–9	The use of HPV tests reduces the annual incidence (30%) and the annual mortality from cervical cancer (70%).[9] HPV tests have substantially higher sensitivity and negative predictive value in the detection of high-grade disease and 60%–70% better protection against invasive cervical cancer in women over the age of 30 when compared with cytology.[10] The introduction of the sFlt-1/PlGF ratio makes it possible to exclude the development of pre-eclampsia in the subsequent week with a negative predictive value of 99.3%.[11] Which may avoid the pregnant women's unnecessary hospital admission and stay.[12]
Increased in QALYS	13 14	
Higher life expectancy	15	
Increased survival rates for different diseases	16	
Empowerment for efficient disease management	9 17	
Reduced costs	18 19	
More time and well-being	9	
Healthcare professionals		
More diagnostic accuracy	20	The detection of LAM in urine samples from HIV patients has proven to be a fast, safe, available and useful tool for controlling tuberculosis, especially for those who are unable to spit, severely ill, with low CD4 or multisystemic disease.[21] The superior accuracy of non-invasive prenatal testing compared with conventional methods for first trimester screening has led to significant decreases in the number of invasive diagnostic procedures, in addition to a concomitant decrease in the number of procedure-related fetal losses.[22] High-sensitivity cardiac troponin assays may allow rapid rule out of myocardial infarction and avoid unnecessary hospital admissions.[23 24] Liquid biopsy targeting cfDNA frequently reveals strong level-of-evidence actionable alterations in Cancers of Unkown Primary, and high degrees of matching to therapy correlates with better patient outcomes.[25]
Less invasive recommendations	11	
More effective treatment recommendations	26	
Less delays in implementing the right intervention	27	
Reduced adverse effects	21	
Better patient stratification and monitoring	28	
Better patient prognosis	29	
Reduced costs	27	
Healthcare system		
Better patient risk stratification	30 31	In Portugal, HPV testing with HPV16/18 genotyping and cytology screening generates annual cost savings of €9.16 million and HPV testing with cytology screening generates cost savings of €9.36 million per year.[31] In the context of Trisomy 13, 18 and 21 screening in the first trimester of pregnancy, the introduction of the fetal free DNA test in a contingent screening strategy for high/intermediate risk pregnant women (>1:1000) has an incremental cost ratio of €16/per pregnant woman for the Portuguese Healthcare System.[31] The use of NT-proBNP for the differential diagnosis of heart failure in primary care corresponds to savings of €500 283/year for the Portuguese health system.[32] The determination of NT-proBNP in point-of-care devices can generate significant savings (2 547 069€/year).[31]
Early diagnosis of chronic diseases	33	
Early diagnosis of acute illness	34	
Reduced mortality	35	
Reduced morbidity	36	
Reduced costs	6 13 19 31 32 35–45	
Cross-cutting		
More active and productive individuals	39	Clinical use of rapid tests to detect infection from Strep A can help limit antibiotic prescriptions to children presenting with pharyngitis, thus limiting the spread of Antibiotic Resistance.[46] ESMO recommends that clinical research centres develop multigene sequencing as a tool to screen patients eligible for clinical trials and to accelerate drug development, and prospectively capture the data that could further inform how to optimise the use of this technology.[47] Digital pathology research, driven by the integration of artificial intelligence, allows the use of computational technologies to manage data, presenting an opportunity to improve the efficiency of diagnosis and treatment.[48]
Reduced absenteeism	39	
Increased efficiency	39	
Better resource allocation	39	
Reduced uncertainty	39	
Deeper knowledge about health and disease	39 49	
Scientific spill-over, innovation and opportunity expansion	39 49	

IVDs, in vitro diagnostics; LAM, lipoarabinomannan; PlGF, placental growth factor; QALY, quality adjusted life year; sFlt-1, soluble fms-like tyrosine kinase 1.

concept generation—participants wrote up to three ideas in short sentences; (2) concept discussion—ideas were collectively discussed to determine their clarity and importance and (3) concept registration—clarified ideas deemed important were registered.

Prior to the session, all members of the workshop received a support document outlining the session's structure, topic introduction and issues to be discussed.

Informed consent for participation and data collection was obtained from all participants at all stages of the study.

RESULTS

Inspiration phase

The results from our literature review are summarised in table 1. Overall, our analysis highlighted the value of IVDs for different healthcare dimensions, including clinical outcomes, economic impact, operational efficiency in healthcare delivery, patient empowerment and quality of life and healthcare innovation and practice improvement. These interconnected dimensions capture the benefits associated with the use of IVDs for different stakeholders, highlighting the fundamental role of IVDs for healthcare advancement.

Overall, our review has shown that IVDs contribute significantly to healthcare by improving diagnostic accuracy, reducing costs and enhancing clinical outcomes. Table 1 illustrates how IVDs support better patient management through reduced mortality, increased life expectancy and improved quality of life. Additionally, the examples provided illustrate the impact of IVDs on healthcare professionals, such as enabling more accurate diagnosis and faster treatment decisions, and on the healthcare system by generating cost savings and improving resource allocation. These findings informed subsequent interviews with key stakeholders regarding the value of IVDs and the associated challenges, providing a basis for understanding the multifaceted role of IVDs in healthcare.

Table 2 Stakeholders' perspectives on the value of IVDs and associated challenges

Area of interest	Specific quotes
Decision making and value for health	
Relevance of diagnostics for the health system	Today, diagnostic tests are essential, they're fundamental to clinical practice, whether it's for the most mundane routine or for more defined situations, particularly when they're well applied, they can help us make diagnoses that are so precise that we wouldn't be able to reach them otherwise, without a doubt. (Healthcare Professional) The results of the methodologies we apply are not measured, so it is impossible to understand the impact of the decisions, making it difficult to analyse their effectiveness and efficiency. **Member of patient association** There is not a parallel with the pharmaceutical industry where the incentives are well stipulated according to their added value. **Healthcare decision maker**
The model for measuring the impact of the technologies is associated with a barrier to innovation	
Difficulty in measuring the impact of the decisions with implications for effectiveness and efficiency consequences	
Contrasting reality to pharmaceutical industry, where the incentives for innovation are correctly legislated and regulated, and the added value is recognised	
Innovation and the patient at the centre of care	
Relative dissatisfaction with lack of patient-centred innovation	The big winner is the patient. If we forget about the patient, it's like forgetting that a bicycle has wheels (…) But I think that a chain of value developed and aimed at diagnostic tests makes perfect sense and will develop healthcare aimed at the patient (…), improving results, improving morbidity and mortality rates. If not, there's no point, is there? **Healthcare professional** These contributions, in essence our agreements, between State and industry, whether it's Medical Devices or Pharmaceuticals, are very much related to the question of the sustainability of the system. **Health policy expert** If it adds value to life, evaluation must naturally be prioritized. I think here it's more of a learning curve, an experience curve and the organization of national agencies so that this evaluation is faster. **Healthcare decision maker**
Personalised medicine and prevention will be the way forward to improve the sustainability of the healthcare system, reducing costs in the long term	
Lack of across-the-board knowledge of the implications of the financing methods for IVDs, particularly regarding the extraordinary contribution made by suppliers to the NHS medical devices industry.	
The value of diagnosis	
Lack of specific recognition by policymakers.	'In the vast majority of cases, political decision-makers don't realize the value of diagnosis. They don't understand how it's done or its importance. **Healthcare professional** All clinical processes start with a diagnosis. (…) IVD is a very promising area. Defining its most important aspects is fundamental for policymakers, but unless they have very specialized training, they won't be aware of the particular relevance of IVD. What is really important is defining a strategy. Hospital Administrators are usually aware of the role of IVD, and therefore have an important role to play. **Healthcare decision maker** Training people is important. New doctors need to be well-trained (…). Predictive medicine will help us manage resources better. **Member of medical association** Policy looks at what science says. **Healthcare decision maker** The medical profession should have an overview of health spending in order to take action on a daily basis (patient management, management of diagnostic tests). The NHS should organize itself to provide a favourable framework for such decision-making. **Healthcare professional** Currently, we have a model focused on acute care and little investment in prevention. There should be greater intervention in the community and the implementation of surveillance programmed. Investment models of monitoring healthy people. **Health policy expert**
Requirement for raising policymakers' and hospital administrators' awareness about diagnostics and prevention	
Specialised training about IVDs required	
Clear communication of up-to-date scientific information is required	
Requirement for higher integration among different health professionals and stakeholders	
Fundamental to reduce costs in the long term (population-based screening) and to make diagnoses with greater autonomy at the point of care.	

IVDs, in vitro diagnostics; NHS, National Health Service.

The main results from our in-depth interviews are summarised in table 2. Overall, stakeholders expressed the need for education and awareness efforts that align with the potential of innovative IVD solutions. Furthermore, the importance of developing and communicating relevant metrics for the impact and value of IVDs was also noted. Regulatory barriers, reimbursement issues were identified as key challenges to the adoption of innovative IVD solutions. Specifically, a need for innovative partnerships between government, industry and academia to address these challenges was highlighted. Additionally, interviewees emphasised the lack of specific recognition by policymakers regarding the value of IVDs, with many stakeholders noting that diagnostic tools are not as clearly prioritised as pharmaceuticals. There was also a call for increased investment in training healthcare professionals and raising awareness among hospital administrators to ensure a broader understanding of the role of IVDs in clinical practice and their potential to support preventive care.

Ideation phase

Our study resulted in the development of different of innovative IVD solutions, which are summarised in table 3. One idea was the creation of a Fast-track HTA system for IVDs, which involves a multistep

Table 3 Stakeholders' ideas for IVD innovation in healthcare and respective assessment

Ranking	Ideas for IVD innovation	Features
First	Fast-track health technology assessment for IVDs	Creation of a multistep fast-track system to support IVD HTA: 1. The organisation providing the innovation follows a submission process including technical, clinical and economic components, as is the case for innovative medicines. 2. An assessment phase led by a standing committee assesses the submission in light of predefined assessment criteria and issues an opinion. 3. A process of negotiating an agreement begins followed by a funding decision. 4. A monitoring phase collects real-world data in order to (re)assess the level of confidence in the technology.
Second	IVD innovation project incubator	Development of innovation hubs as social communities, workspaces or research centres that provide expertise on technological trends, knowledge and strategic innovation management, as well as industry-specific knowledge. IVD innovation hubs would allow researchers and industry professionals to actively share knowledge with those working in business, government and academia. Here, decision-makers can network with scientists and industry experts and pool ideas for solutions that could be decisive for difficult business problems.
Third	Innovative IVD technology assessment department and governance model	Creation of a IVD technology assessment department, independent of the Ministry of Health, whose main objectives are the formalisation of lobbying practices, the development of an independent evaluation of quality and results of IVDs and health literacy promotion in the context of IVDs.

HTA, health technology assessment; IVDs, in vitro diagnostics.

evaluation process including technical, clinical and economic assessments similar to the procedures used for innovative medicines. Another proposed idea was the establishment of IVD innovation project incubators, imagined as dedicated hubs where researchers, industry professionals and decision-makers can collaborate. A third idea was the creation of an independent IVD technology assessment departments, which would formalise lobbying practices, conduct independent evaluations and promote health literacy related to IVDs. Following an assessment of the different ideas based on their feasibility, impact and potential for commercialisation, participants selected the Fast-track HTA for IVDs as the preferred idea for implementation. Participants noted that this system could streamline the evaluation and funding processes for IVDs, reduce adoption delays and make sure that robust evidence was generated to support decision-making and sustainability in healthcare.

Subsequently, participants identified innovation enablers and barriers in the context of the selected idea. These results are indicated in table 4. Enabling factors included robust clinical research, the conduction of economic evaluations and cost-effectiveness analyses and the establishment of networks between hospitals. Participants also highlighted that a mindset adaptable to innovation and the availability of real-world evidence demonstrating the value of IVDs are crucial for successful implementation. Alternatively, identified barriers included the lack of awareness among policymakers regarding the value of IVDs, unclear guidelines and insufficient funding. Moreover, the postponement of HTA processes, the complexity of IVD terminologies and the misalignment of stakeholder expectations were also viewed as significant obstacles. Together, these factors were considered as critical context for the subsequent implementation phase of the study.

Table 4 Stakeholders' perspectives on elements that enable and hinder innovation in HTA in the context of a fast-track process for IVDs

Enabling factors	Hindering factors
Robust clinical research	Reduced knowledge of policy makers in the different diagnostic areas
Conduction of economic evaluation and cost-effectiveness analysis	IVD tests not seen as a priority by stakeholders
Easy introduction to market	Complexity of adopted IVD terminologies
Having a mindset that adapts to innovation	Lack of calibration of expectations of different stakeholders
Network between different hospitals (recently fostered by the COVID-19 pandemic)	Unawareness of the value of IVDs
Real-world evidence of how certain interventions bring value to healthcare (recently demonstrated by the COVID-19 pandemic)	Lack of specific and clear guidelines
	IVD frameworks not sufficiently comprehensive
	Accessing to IVD results
	Accelerated pace of innovation
	Postponement of HTA processes and evaluation
	Lack of funding

HTA, health technology assessment; IVDs, in vitro diagnostics.

Box 1 Perspectives regarding contextual relevance and challenges to implementation of a HTA fast-track process for IVDs

A. Contextual relevance

Medical devices are gaining relevance in relation to medicines. This fast-track HTA process will have to exist.

Member of Public Healthcare Institution

Hospitals are facing increasing problems in evaluating IVDs. It's a concern related with what to use and how to use it. If there is a prior IVD evaluation process, it will be easier.

Member of Public Healthcare Institution

We need to create a methodology of IVD HTA because the existing ones are very focused on medicines. And one of the big challenges is data and the information that the pharmaceutical industry has available to provide for technology assessment.

Director of Public Healthcare Institution

Current technology validation is imperfect, there is budget pressure from Precision Medicine leading to healthcare access disparities; there is a lack of NHS trained teams for specific technologies and the need for working groups dedicated to resource management.

Representative of Professional Healthcare Association.

B. Contextual challenges to implementation

1. Conducting horizon scans
2. Designing methodology/evaluation procedures and defining metrics
3. Establishing priorities/developing guidelines
4. Increasing the installed capacity
5. Reducing the resistance to change
6. Forming multidisciplinary teams
7. Setting prices and guaranteeing sustainability

IVDs, in vitro diagnostics; HTA, health technology assessment.

Implementation phase

In this phase of the study, participants addressed the relevance of and respective contextual challenges to implementation of the fast-track HTA process for IVDs (box 1). Stakeholders highlighted the growing importance of medical devices in relation to medicines and the need for a dedicated HTA methodology tailored to IVDs. They noted that hospitals currently struggle with evaluating IVDs due to a lack of standardised assessment processes and expressed concern about disparities in healthcare access stemming from the lack of validated methodologies. Contextual challenges identified included conducting horizon scans, establishing evaluation metrics and reducing resistance to change, which were viewed as critical steps for the successful adoption of the fast-track process.

Subsequently, participants refined the idea by presenting suggestions for implementation (table 5). In a technological and scientific dimension, participants recommended a validation process focused on analytical and clinical validity, clinical utility, safety, efficacy

Table 5 Perspectives on the implementation model of an HTA fast-track for IVDs

Technological and scientific	Socioeconomic	User value	Organisations to involve
▲ Validation focused on analytical and clinical validity, clinical utility, clinical safety, efficacy and effectiveness. ▲ Validation according to clear submission guidelines (who, what, when) and transparent criteria (clinical, pathological target) ▲ Assessment conducted by multidisciplinary teams. ▲ Identification using horizon scanning tools or available data	▲ Rigorous evaluation of cost-effectiveness ratios, budget impact and health gains ▲ Clear priority setting according to cost-opportunity and cost- effectiveness rationales. ▲ Ponder ethical issues. ▲ Required definition of evaluation priorities (which IVDs to evaluate first) ▲ Evidence-based definition of funding priorities.	▲ Healthcare access with quality and safety. ▲ Standardisation of higher healthcare standards. ▲ Clearer identification of opportunities and challenges to guide ways forward. ▲ Improved communication and patient-engagement.	Public Health Authorities; National Authority of Medicines and Health Products; Independent Health Regulators; National Scientific and Public Health Laboratories; Central Health Administration; Health Data Authorities; Academia; Industry, Professional Associations; Patient Associations; European Health Authorities; Scientific Societies.

HTA, HTA, health technology assessment.; IVDs, IVDs, in vitro diagnostics.

and effectiveness, supported by clear submission guidelines and transparent assessment criteria. From a socioeconomic perspective, participants suggested that priorities should be set based on cost-effectiveness ratios, budget impact and health gains, while also considering ethical issues and evidence-based funding priorities. In terms of user value, participants highlighted the need to promote healthcare access with quality and safety, improve patient engagement and standardise higher healthcare standards. Finally, participants identified key organisations to involve in the implementation process, such as public health authorities, regulatory agencies, scientific societies and patient associations, to ensure a comprehensive and well-aligned implementation process.

Overall, our results demonstrate that IVDs play a fundamental and comprehensive role in healthcare. We conducted an iterative DT process leading to impactful positive change for the IVD sector, by generating different innovative ideas, including a fast-track HTA of IVDs. We identified a clear contextual relevance for this idea and identified different informative cues for its implementation.

DISCUSSION

Following an inspiration phase which clearly established the relevance of IVDs for healthcare from a professional, patient and organisational perspective, our DT case study has focused on ideating and cueing the implementation of a fast-track HTA for this technology. As a result, it become clear that the development of IVD innovation depends on the establishment of scientifically rigorous, clear, transparent and clear-cut HTA metrics and procedures.

Currently, the lack of standardised assessment of IVDs on the HTA context poses a significant challenge, which may hinder the adoption of these beneficial technologies.[2] Furthermore, establishing a harmonised framework for a multistep IVD assessment would facilitate the comparison between different IVD solutions, aiding healthcare professionals, decision makers and authorities in making informed decisions regarding their adoption and use.[3] Our study also highlighted different enabling and hindering factors to HTA innovation in the context of a fast-track process for IVDs, including those related with scientific research, market introduction and healthcare practice. Importantly, maintaining trust in the HTA of IVD among all stakeholders, including developers, healthcare providers and patients depends on the perception of a fair and objective process while fostering an environment of accountability, leading to improved decisions regarding the funding, reimbursement and implementation of IVDs. As our case study demonstrates, such decisions can only result from a multidisciplinary analysis based on collaborative efforts among literate professionals, regulatory bodies, healthcare institutions and industry members. Therefore, as our study and others demonstrate, raising awareness about the merits of innovative IVD is imperative for their adoption and integration into healthcare systems.[1 3] In particular, health professionals must understand advancements in IVD technologies to make informed decisions regarding their use in patient care. This requires ongoing education and training programmes that highlight the clinical, operational and economic advantages of IVD. Similarly, patients should be informed about the potential benefits (and risks) of IVDs, including improved diagnostic accuracy, personalised treatment options and enhanced disease management, to increase their acceptance and demand for these technologies. Finally, as policymakers play a crucial role in the adoption of innovative IVD solutions, by understanding the value proposition of IVDs, policymakers can define supportive regulations and policies that facilitate the development, evaluation and integration of these technologies into healthcare systems. This includes the design and implementation of a fast-track HTA of IVDs such as the one described in this study, which can accelerate the technology assessment process in this context and expand quality healthcare access for populations. In conclusion, enhanced awareness among all stakeholders is essential for creating an environment that supports innovation in the IVD sector by integrating educational initiatives and public campaigns.

In parallel, establishing effective funding and reimbursement mechanisms for innovative IVD solutions constitutes a significant challenge for innovation in this sector.[3] In particular, the integration of HTA of IVDs with reimbursement schemes, especially in the context of primary healthcare settings is not optimised.[1–3] This challenge is compounded by the need to balance cost-effectiveness with the clinical value of new IVD solutions. Reimbursement policies must consider the specificity of innovative IVDs, while also ensuring sustainability within healthcare budgets. This requires a comprehensive understanding of the socioeconomic impact of IVDs, including the estimation of their potential to reduce overall healthcare costs through early diagnosis and precision treatment strategies. Addressing these challenges requires a multidisciplinary approach that includes input from health economists, clinical experts and policy makers, as our study has aimed to prototype. Collaborations between the IVD industry and academic institutions are a cornerstone for innovation in the IVD sector.[1 3] Furthermore, other stakeholders with expertise in regulatory affairs and market dynamics, can navigate the path to commercialisation, ensuring that innovative IVD reach the market efficiently. Such cross-disciplinary collaborations ensure that IVD solutions are scientifically robust and aligned with market needs. Moreover, collaborative projects in this context can catalyse further healthcare innovation and address challenges to IVD innovation adoption, including regulatory and reimbursement challenges. In particular, regulatory challenges, such as

the complexity and variability of approval processes across different jurisdictions, can be addressed through partnerships involving regulators, industry experts and academic institutions. These collaborative initiatives can promote the harmonisation of regulatory frameworks and assist in streamlining regulatory processes by developing robust risk-assessment and weight-of-evidence methodologies and shared evaluation criteria to support the approval of innovative IVD. Similarly, reimbursement challenges, particularly the misalignment between the value of IVDs, existing reimbursement mechanisms and HTA, can be effectively addressed through collaborative partnerships between healthcare providers, payers, health economists and policymakers, including government agencies. For example, outcome-based reimbursement models, developed through diverse stakeholder collaboration, could incentivise the adoption of IVDs that demonstrate both clinical and economic benefits leading to specific, evidence-based reimbursement policies. Such collaborative efforts also assist in identifying and establishing international best-practices for possible incorporation at the national level.

Finally, our study has identified the absence of a widely adopted fast-track HTA pathway for IVDs in most European countries as an opportunity for innovation in this sector. The idea put forward in this case study could serve as an initial concept for the design and establishment of a pan-European comprehensive framework for the HTA of IVDs which could accelerate the assessment and adoption of IVD in the European Union (EU) and elsewhere. A pan-European approach to IVD HTA would strengthen consistency in evaluation standards, facilitating cross-border adoption of validated IVD. Such an approach could also potentiate expertise and resources, reducing redundancies and increasing the efficiency of the HTA process in the EU.

The fast-track HTA framework proposed in this study aligns with current EU HTA practices by incorporating core principles such as rigorous evaluation of clinical effectiveness, safety and cost-effectiveness, which are fundamental across member states. The framework also reflects the EU's emphasis on evidence-based and multidisciplinary evaluation, aligning with initiatives like EUnetHTA—European Network for Health Technology Assessment (https://www.eunethta.eu) that promote collaboration and standardisation among member states. Furthermore, it also aligns with the recent HTA EU Regulation (Regulation (EU) 2021/2282), which aims to enhance collaboration, harmonise methodologies and improve the quality and transparency of HTA reports across member states, while reducing duplication and ensuring long-term sustainability through a permanent framework. The proposed fast-track HTA framework seeks to involve national organisations, making it tailored to the specific country context while remaining aligned with ongoing EU efforts to reduce redundancy and promote harmonisation. In the future, capacity building, such as specific involvement and training for national HTA agents, engaging stakeholders through continuous communication and pilot programmes in different countries could help refine the framework proposed in this study and ensure its applicability, paving the way for implementation and wider adoption, in particular across the EU. By aligning IVD-specific HTA methods and criteria across EU countries, stakeholders could simultaneously promote data-driven health innovation while ensuring rigorous standards of efficacy, safety and cost-effectiveness. This too would require significant collaborative efforts among different experts in different countries. Nonetheless, such an effort could contribute to strengthen European competitiveness in the global healthcare market while promoting equitable access to healthcare innovation.

Overall, by prioritising the development of a fast track HTA process for IVD such as the one ideated in this case study, the healthcare sector could maximise the potential of innovative IVD to improve patient outcomes, enhance diagnostic accuracy and optimise healthcare resource utilisation.

CONCLUSIONS

This article presents a case study that utilises the DT methodology to inspire, ideate and implement innovative solutions that improve the HTA framework for IVD by identifying and aligning the needs and perspectives of diverse stakeholders.

IVD are relevant for healthcare in the perspective of professionals, patients and organisations. Innovative IVD tools can help healthcare providers to better understand the needs of their patients and to develop more effective interventions. They can also help policymakers to develop more informed public health policies. Overall, innovation on the IVD sector can enable earlier diagnosis, more personalised treatments, and improved outcomes for patients and healthcare systems.

In this study, experts from different disciplinary backgrounds and health sectors designed different ideas to improve the IVD field and subsequently decided to focus on innovation of HTA. Specifically, the idea to fast-track HTA for IVD was selected for development. In the DT implementation stage, different implementation cues were identified (according to a technoscientific dimension, a socioeconomic one, the user value and the organisations to involve).

The innovation cycle of IVD calls for a corresponding tailored evolution in HTA practices and frameworks. A fast-track HTA framework for IVD is potentially significant to reconcile the need for thorough evaluation of these technologies—considering their ongoing evolution, such as their integration with AI—with the imperative of speed and incorporation into funding and reimbursement schemes, ultimately contributing to healthcare budget sustainability. Such a framework,

aligned with current HTA practices by incorporating core principles such as rigorous multidisciplinary evaluation of clinical effectiveness, safety and cost-effectiveness and emphasising specific evidence-based decision-making would not only facilitate timely access to innovative diagnostic solutions but also enhance the competitiveness of the European IVD industry in the global market. This is particularly relevant in an era where health innovation is a key driver of economic growth and global strategic advantage.

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REFERENCES

1 Rohr U-P, Binder C, Dieterle T, *et al*. The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. *PLoS One* 2016;11:e0149856.
2 Trowman R, Migliore A, Ollendorf DA. The value and impact of health technology assessment: discussions and recommendations from the 2023 Health Technology Assessment International Global Policy Forum. *Int J Technol Assess Health Care* 2023;39:e75.
3 Salama JS, Lee A, Afshin A. Innovating in healthcare delivery: a systematic review and a preference-based framework of patient and provider needs. *BMJ Innov* 2019;5:92–100.
4 Altman M, Huang TTK, Breland JY. Design Thinking in Health Care. *Prev Chronic Dis* 2018;15:E117E117.
5 Baker FW, Moukhliss S. Concretising Design Thinking: A Content Analysis of Systematic and Extended Literature Reviews on Design Thinking and Human-Centred Design. *Rev Educ* 2020;8:305–33.
6 Bilir SP, Ferrufino CP, Pfaller MA, *et al*. The economic impact of rapid Candida species identification by T2Candida among high-risk patients. *Future Microbiol* 2015;10:1133–44.
7 Hardcastle JD, Chamberlain JO, Robinson MH, *et al*. Randomised controlled trial of faecal-occult-blood screening for colorectal cancer. *The Lancet* 1996;348:1472–7.
8 Mandel JS, Bond JH, Church TR, *et al*. Reducing Mortality from Colorectal Cancer by Screening for Fecal Occult Blood. *N Engl J Med* 1993;328:1365–71.
9 Tjalma WAA, Kim E, Vandeweyer K. The impact on women's health and the cervical cancer screening budget of primary HPV screening with dual-stain cytology triage in Belgium. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2017;212:171–81.
10 Kyrgiou M, Arbyn M, Bergeron C, *et al*. Cervical screening: ESGO-EFC position paper of the European Society of Gynaecologic Oncology (ESGO) and the European Federation of Colposcopy (EFC). *Br J Cancer* 2020;123:510–7.
11 Zeisler H, Llurba E, Chantraine F, *et al*. Predictive Value of the sFlt-1:PlGF Ratio in Women with Suspected Preeclampsia. *N Engl J Med* 2016;374:13–22.
12 Verlohren S, Brennecke SP, Galindo A, *et al*. Clinical interpretation and implementation of the sFlt-1/PlGF ratio in the prediction, diagnosis and management of preeclampsia. *Pregnancy Hypertens* 2022;27:42–50.
13 Chugh Y, Premkumar M, Grover GS, *et al*. Cost-effectiveness and budget impact analysis of facility-based screening and treatment of hepatitis C in Punjab state of India. *BMJ Open* 2021;11:e042280.
14 Jafari A, Rezapour A, Hajahmadi M. Cost-effectiveness of B-type natriuretic peptide-guided care in patients with heart failure: a systematic review. *Heart Fail Rev* 2018;23:693–700.
15 Reddy KP, Gupta-Wright A, Fielding KL, *et al*. Cost-effectiveness of urine-based tuberculosis screening in hospitalised patients with HIV in Africa: a microsimulation modelling study. *Lancet Glob Health* 2019;7:e200–8.
16 Rozenblum AB, Ilouze M, Dudnik E, *et al*. Clinical Impact of Hybrid Capture-Based Next-Generation Sequencing on Changes in Treatment Decisions in Lung Cancer. *J Thorac Oncol* 2017;12:258–68.
17 Lim SM, Kim EY, Kim HR, *et al*. Genomic profiling of lung adenocarcinoma patients reveals therapeutic targets and confers clinical benefit when standard molecular testing is negative. *Oncotarget* 2016;7:24172–8.
18 Dreyer G, Maske C, Stander M. Clinical evaluation and budget impact analysis of cervical cancer screening using cobas 4800 HPV screening technology in the public sector of South Africa. *PLoS One* 2019;14:e0221495.
19 Pliakos EE, Andreatos N, Shehadeh F, *et al*. The Cost-Effectiveness of Rapid Diagnostic Testing for the Diagnosis of Bloodstream Infections with or without Antimicrobial Stewardship. *Clin Microbiol Rev* 2018;31:e00095-17.
20 Maisel AS, Krishnaswamy P, Nowak RM, *et al*. Rapid measurement of B-type natriuretic peptide in the emergency diagnosis of heart failure. *N Engl J Med* 2002;347:161–7.
21 Elhalawany N, Shalaby N, Fathy A, *et al*. Role of detection of lipoarabinomannan (LAM) in urine for diagnosis of pulmonary tuberculosis in HIV patients: Egyptian experience. *Egypt J Bronchol* 2021;15:20.

22 Warsof SL, Larion S, Abuhamad AZ. Overview of the impact of noninvasive prenatal testing on diagnostic procedures. *Prenat Diagn* 2015;35:972–9.
23 Westwood M, Ramaekers B, Grimm S, *et al*. High-sensitivity troponin assays for early rule-out of acute myocardial infarction in people with acute chest pain: a systematic review and economic evaluation. *Health Technol Assess* 2021;25:1–276.
24 Sandoval Y, Apple FS, Mahler SA, *et al*. High-Sensitivity Cardiac Troponin and the 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guidelines for the Evaluation and Diagnosis of Acute Chest Pain. *Circulation* 2022;146:569–81.
25 Kato S, Weipert C, Gumas S, *et al*. Therapeutic Actionability of Circulating Cell-Free DNA Alterations in Carcinoma of Unknown Primary. *JCO Precis Oncol* 2021;5:PO.21.00011:1687–98:.
26 Tan O, Shrestha R, Cunich M, *et al*. Application of next-generation sequencing to improve cancer management: A review of the clinical effectiveness and cost-effectiveness. *Clin Genet* 2018;93:533–44.
27 Tan AC, Lai GGY, Tan GS, *et al*. Utility of incorporating next-generation sequencing (NGS) in an Asian non-small cell lung cancer (NSCLC) population: Incremental yield of actionable alterations and cost-effectiveness analysis. *Lung Cancer (Auckl)* 2020;139:207–15.
28 Byeon S, Lee B, Park W-Y, *et al*. Benefit of Targeted DNA Sequencing in Advanced Non-Small-Cell Lung Cancer Patients Without EGFR and ALK Alterations on Conventional Tests. *Clin Lung Cancer* 2020;21:e182–90.
29 Schächinger V, Britten MB, Zeiher AM. Prognostic impact of coronary vasodilator dysfunction on adverse long-term outcome of coronary heart disease. *Circulation* 2000;101:1899–906.
30 Quinlan TAG, Schroeder B, Kwon S, *et al*. Economic Impact of Coverage Expansion for Non-invasive Prenatal Testing Through a Performance-Based Risk-Sharing Agreement. *Pharmacoecon Open* 2021;5:449–58.
31 Matias A, Cohen A, Sousa MJ, *et al*. Testes Pré-Natais Não Invasivos no rastreio de aneuploidias: avaliação económica de um modelo de rastreio primário e contingente. *Reun Cient SPOMM* 2017.
32 Genovez V, Brito D, Bettencourt P, *et al*. PCV48 Budget Impact of NT-proBNP for Diagnosing Suspected Chronic Heart Failure Patients in Portuguese Primary Care. *Value Health* 2020;23:S495.
33 RothJA, deVosT, RamseySD. Clinical and Budget Impact of Increasing Colorectal Cancer Screening by Blood- and Stool-Based Testing. *Am Health Drug Benefits* 2019;12:256–62.
34 Termrungruanglert W, Khemapech N, Tantitamit T, *et al*. Cost effectiveness analysis of HPV primary screening and dual stain cytology triage compared with cervical cytology. *J Gynecol Oncol* 2019;30:e17.
35 Pista A, Costa C, Saldanha C, *et al*. Budget impact analysis of cervical cancer screening in Portugal: comparison of cytology and primary HPV screening strategies. *BMC Public Health* 2019;19:235.
36 Paolini D, Tiseo M, Demma F, *et al*. Ventana ALK (D5F3) in the Detection of Patients Affected by Anaplastic Lymphoma Kinase-positive Non-Small-cell Lung Cancer: Clinical and Budget Effect. *Clin Lung Cancer* 2018;19:e735–43.
37 Berdugo MA, Kirson NY, Zimmer L, *et al*. Economic and clinical benefits of early identification of acute kidney injury using a urinary biomarker. *J Med Econ* 2019;22:1281–9.
38 Campos A, Machado AP, Martins H, *et al*. sFlt-1/PlGF ratio for the predictive diagnosis of preeclampsia: budget impact analysis from the public healthcare perspective in Portugal sFlt-1/PIGF no diagnóstico preditivo de pré-eclâmpsia: estudo de impacto económico em Portugal. *Acta Obstet Ginecol Port* 2019;13:82–90.
39 Garrison L, Mestre-Ferrandiz J, Zamora B. The value of knowing and knowing the value: improving the health technology assessment of complementary diagnostics. 2016. Available: https://www.epemed.org/online/www/content2/104/105/5115/pagecontent2/5170/866/ENG/WP_EpemedOHE_final.pdf [Accessed 14 May 2023].
40 MacIntyre AT, Hirst A, Duttagupta R, *et al*. Budget Impact of Microbial Cell-Free DNA Testing Using the Karius® Test as an Alternative to Invasive Procedures in Immunocompromised Patients with Suspected Invasive Fungal Infections. *Appl Health Econ Health Policy* 2021;19:231–41.
41 Manchanda R, Sun L, Patel S, *et al*. Economic Evaluation of Population-Based *BRCA1*/*BRCA2* Mutation Testing across Multiple Countries and Health Systems. *Cancers (Basel)* 2020;12:1929.
42 Nshimyumukiza L, Beaumont JA, Rousseau F, *et al*. Introducing cell-free DNA noninvasive testing in a Down syndrome public health screening program: a budget impact analysis. *Cost Eff Resour Alloc* 2020;18:49.
43 León-Justel A, Mangas MA, Fontán RI, *et al*. Budget impact of using midnight salivary cortisol in the diagnosis of hypercortisolism. *Clin Chim Acta* 2011;412:2248–53.
44 Petry KU, Barth C, Wasem J, *et al*. A model to evaluate the costs and clinical effectiveness of human papilloma virus screening compared with annual papanicolaou cytology in Germany. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2017;212:132–9.
45 Voermans AM, Mewes JC, Broyles MR, *et al*. Cost-Effectiveness Analysis of a Procalcitonin-Guided Decision Algorithm for Antibiotic Stewardship Using Real-World U.S. Hospital Data. *OMICS* 2019;23:508–15.
46 Hendi SB, Malik ZA, Khamis AH, *et al*. High diagnostic accuracy of automated rapid Strep A test reduces antibiotic prescriptions for children in the United Arab Emirates. *BMC Pediatr* 2021;21:52.
47 Mosele F, Remon J, Mateo J, *et al*. Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancers: a report from the ESMO Precision Medicine Working Group. *Ann Oncol* 2020;31:1491–505.
48 Qiao Y, Zhao L, Luo C, *et al*. Multi-modality artificial intelligence in digital pathology. *Brief Bioinform* 2022;23:bbac367.
49 Wurcel V, Cicchetti A, Garrison L, *et al*. The Value of Diagnostic Information in Personalised Healthcare: A Comprehensive Concept to Facilitate Bringing This Technology into Healthcare Systems. *Public Health Genomics* 2019;22:8–15.