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Establishing a national HTA program for medical devices in Italy: Overhauling a fragmented system to ensure value and equal access to new medical technologies

Rosanna Tarricone[a,b,*], Fabio Amatucci[b], Patrizio Armeni[b], Helen Banks[b], Ludovica Borsoi[b], Giuditta Callea[b], Oriana Ciani[b], Francesco Costa[b], Carlo Federici[b], Aleksandra Torbica[a,b], Marcella Marletta[c]

[a] Department of Social and Political Science, Bocconi University, Via Roentgen 1, 20136 Milan (Italy)
[b] Centre for Research on Health and Social Care Management (CERGAS), SDA Bocconi School of Management, Via Sarfatti 10, 20136 Milan (Italy)
[c] Drugs and Medical Devices, Ministry of Health, Via Ribotta 5, 00144 Rome (Italy)

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ABSTRACT

Differing contexts have greatly influenced HTA development in various countries, with considerable effort recently made by international HTA networks (e.g., EUnetHTA) and the European Union (EU) to make HTA a more coherent, equal, and efficient process. Medical devices (MDs) present particular challenges for HTA because of frequent, rapid innovation, outcomes influenced by end-user competence, dynamic pricing and often low-quality scientific evidence. Our objective is to describe the development, structure and governance of a National HTA Program for MDs (PNHTADM) in Italy, a highly participatory, stakeholder-engaged, evidence-based process to reform a fragmented system of appraisal and approval. Based largely on EUnetHTA methods, the resulting process delineates a standardized system for proposing MDs by any stakeholders, accrediting HTA producers, setting criteria for prioritization and appraisals, and innovatively linking recommendations with coverage, reimbursement and procurement of MDs. Expected benefits include reduced disparities in pricing and reimbursement policies and improved access to new technologies across 21 regional healthcare systems in Italy's decentralized, universal system, complete with provisions to require additional evidence collection and centrally monitor diffusion. Though devised for Italy, the design, resources and underlying analysis provide a framework for other nations seeking to consolidate HTA initiatives, particularly in light of new EU regulation.

1. Introduction

Health Technology Assessment (HTA) has evolved over time as a consolidated evidence-based approach to assess the medical, economic, ethical and social aspects of health technologies. Diffusion of HTA has been rapid and widespread since its first applications in the United States (US) in the 1970s [1–3], sweeping through Europe and by now well-entrenched in Asia, South America and Africa [2,4–9]. While some early adopters of HTA (notably, the United Kingdom and Sweden) established centralized processes, in most countries the process has evolved over time in a fragmented manner, where HTA may be carried out in different government agencies and independent entities, at various levels, including national, regional, and even hospital [2,4–9]. The scope of HTA has also expanded considerably, from assessments of the most costly technologies and medicines in a few countries, to include the full gamut of drugs, medical devices (MDs), surgical procedures, diagnostics, public health and even disease management programs and counselling, practiced on a worldwide scale [1,2].

Efforts to build consensus on HTA methodology and reduce redundancy led to the establishment of international networks to help standardize HTA processes, particularly in Europe where the European Network for Health Technology Assessment (EUnetHTA), with 30 countries and over 80 organizations, is the best example of (voluntary) collaboration on HTA by member states [10]. Tools such as the HTA Core Model®, developed through EUnetHTA, provide the basis for standardized applications of HTA [11]. However, duplication and conflicting recommendations have been noted [12,13]. A recent analysis of HTA processes and reimbursement in Europe for new drugs (i.e. innovative cancer drugs) found considerable vari-

* Corresponding author at: Department of Social and political Science, Bocconi University, Via Roentgen 1, 20136 Milan (Italy).
E-mail address: rosanna.tarricone@unibocconi.it (R. Tarricone).

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ation among nations and even evidence of market approvals before HTA reports were completed [14]. As for medical devices, HTA agencies seldom differentiate in terms of methods between drugs and MDs, but often develop dedicated tracks and processes to deal with the evaluation of this type of health technologies [15,16]. A continuing problem with price differentiation among countries [17] – and within countries [18–20] – for the same devices has also underlined the need for transparency in price negotiations and a better understanding of how bargaining ability, centralized purchasing and sharing of HTA at different levels can combat the problem.

Thus, as a result of ex-post evaluations, stakeholder consultations and impact assessments, the European Commission (EC) prepared a proposal in 2018 for a Regulation of the European Parliament (EP) and of the Council on HTA, aimed at improving the functioning of the internal market and overall health protection [21]. Just as the EC is striving to make HTA a more coherent, equal, and efficient process across member states, so has the Italian National Health System (SSN – Sistema Sanitario Nazionale) through its Ministry of Health (MoH) been trying to achieve similar goals on a smaller scale. Considerable harmonization and centralization of HTA at the national level has occurred in order to reduce inefficiencies at the local level, culminating with the most recent initiative for MDs [18].

The objective of this paper is to provide a comprehensive description of the process undertaken in Italy to create a national HTA program for MDs. The main goal of the program is to ensure effective stewardship and guarantee equal access to innovative technologies in all parts of the nation, notwithstanding the decentralized nature of the Italian SSN. The process is notable for its inclusive, bottom-up methodology, transparency and comprehensiveness as a structured system, from coverage to procurement and reimbursement, the result of an exhaustive and evidence-based series of activities that can provide a blueprint - and timesavers - for other nations seeking to similarly order a fragmented system of HTA [5]. Italy represents a compelling example of HTA within a universal coverage health system, where policy, regulation and funding distribution is set nationally, but 21 regional health care systems are responsible for health care planning, budgeting and delivery, carried out through a network of local health authorities (LHAs) within each region [22].

The framework for the program's development refers to the concept of opportunity cost and economic rationality, that is, to the assumption that in times of scarcity, resources need to be allocated efficiently between competing ends to maximize health production [23] and, to a certain extent, to the more recent value-based [24] concept that evaluates the introduction of innovations by considering the whole spectrum of patient care pathways. The Italian case seems also to confirm a higher predisposition by Beveridge-type healthcare systems – such as the SSN - to adopt economic evaluation analysis and HTA approaches to govern technological innovation access [25].

2. Historical overview of HTA development in Italy

The diffusion of HTA in Italy has followed a pattern similar to other nations with a decentralized health system, characterized by early applications of HTA in limited geographic areas (usually a region, LHA, hospital or research institute) for single technologies to assess efficacy and inform coverage and reimbursement decisions [5,18,26]. As in other nations, the proliferation of HTA initiatives led to efforts to consolidate activities and promote the diffusion and sharing of HTA on a wider scale. The first efforts at coordinating HTA centrally in Italy stemmed from the 2006–2008 National Health Plan, when the National Agency for Regional Healthcare Services (AGENAS) was instituted and began providing training and support to the regions in developing HTA [5,26]. Though this certainly had an impact on the diffusion of HTA in Italy, and spawned an Italian network for HTA (RIHTA), the regional focus of HTA activity remained [5,18,26] until 2015, when the Stability Law established the National Program for HTA for MDs (PNHTADM) (Table 1).

3. Why an HTA program just for medical devices?

The reasons behind the Italian MoH's development of an HTA program specifically for MDs are threefold. First, the Italian Medicines Agency (AIFA – Agenzia Italiana del Farmaco) in Italy centrally conducts HTA for drugs and additionally regulates and negotiates pricing for market access and oversees post-marketing surveillance [18]. The MoH, within its General Directorate for Medical Devices and Drugs, regulates MDs, providing oversight; market, adverse effects and clinical trial surveillance; consumption monitoring for publicly funded purchases, and HTA [27]. The MoH also maintains a publicly accessible database of all CE-marked MDs for marketing on national territory as well as annual reports on public expenditure for MDs.

Second, among technologies subject to HTA, MDs warrant particular attention [28–30]. MDs differ from other health technologies in several respects: "(i) they often change rapidly; (ii) clinical outcomes often depend on the training, competence and experience of the end-user; (iii) pricing is typically more dynamic than that of pharmaceuticals; and (iv) costs often comprise both procurement costs (including the associated infrastructure) and running costs (including maintenance and consumables)" [28]. Over time, concerns emerged regarding the adequacy of available HTA methods to meet the challenges posed by the special characteristics of MDs [15,29–33]. An EU-funded project, "MedtecHTA" (2013–2015), investigated the differences between MDs and pharmaceuticals to assess the need for a different HTA framework for MDs. Final recommendations concluded that the methods for HTA for pharmaceuticals cannot be adapted to MDs *tout court* but, instead, should consider MDs as complex interventions; i.e., they require the establishment of high quality registries, should consider an iterative approach to evaluation over time, recognize and allow for the particular characteristics of various MDs, and use appropriate approaches for confounder adjustment in comparative effectiveness studies [30,31].

Third, unlike prescription drugs, clinical evidence regarding safety and clinical effectiveness to support HTA for MDs can be lacking or of low quality, even for high-risk medical technologies; thus, various recommendations have been proposed to address this critical issue in HTA for MDs [33–35]. Recommendations cover in particular the need to follow international guidelines (e.g., EUnetHTA) in conducting HTA, to address specific gaps regarding product lifespan, organizational impact [36], learning curve and potential bias in study designs other than randomized controlled trials, as well as requiring increased collection of data for pre-marketing approval and post-marketing surveillance, using robust statistical methods, and conducting risk analysis using validated tools and standards. Centralized oversight and pooling of skills and resources in conducting HTA were deemed essential to implement the processes required to meet such recommendations.

4. Main features of the national HTA program for medical devices (PNHTADM)

4.1. Governance and methodology

In 2015, the Stability Law [37] established a Steering Committee *(Cabina di Regia)* to address HTA activity for MDs. Composed of representatives from government entities (Fig. 2), the Steering

Table 1
Development of the National HTA Program for Medical Devices (PNHTADM) in Italy.

1980	HTA begins at the NIH for big tickets technologies
1990s	HTA expands as an uncoordinated, experimental, hospital-based approach
2000	Emilia-Romagna, Veneto and Friuli-Venezia -Giulia regions establish their own HTA programs
2006	The National Health Plan sets HTA as a national priority
2007	AGENAS is instituted
2010	RIHTA is established. Campania and Lombardia regions launch their own HTA programs
2012	Calabria, Liguria, Puglia and Sicilia regions launch their own HTA programs
2014	The National Health Plan recommends governing access of MDs based on value generated
2015	Stability Law institutes the PNHTADM
2016	Stability Law sets the governance of the PNHTADM and establishes the Steering Committee (SC). MoH creates 3 working groups (WG) to support the SC and activates WG#2
2017	MoH and Regions sign off the PNHTADM "Strategy Document"
2018	WG#2 concludes its work
2019	MoH establishes the PNHTADM Governance, Method and Process

Abbreviations: HTA – Health Technology Assessment, MDs – Medical devices, ISS - Istituto Superiore di Sanità (National Institute of Health), AGENAS - Agenzia Nazionale per i Servizi Sanitari Regionali (National Agency for Regional Healthcare Services), RiHTA - Italian network for HTA, MoH – Ministry of Health.

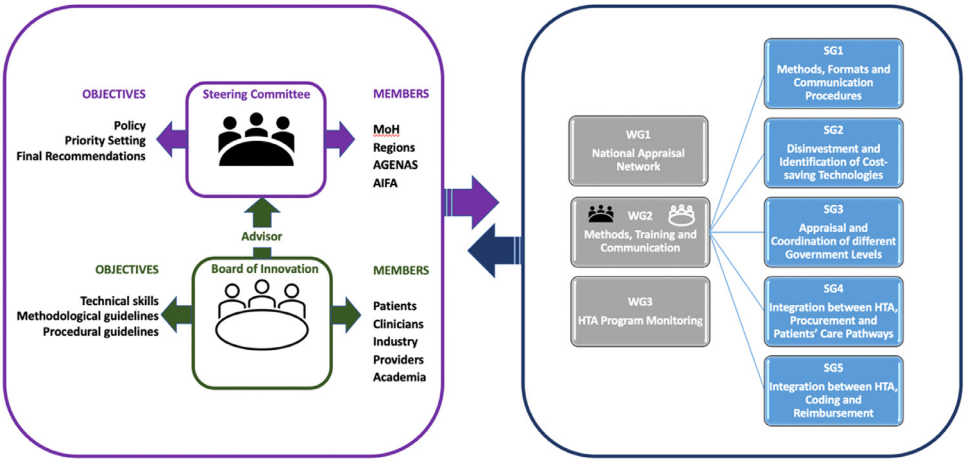

Fig. 1. Governance and Methodology of the Italian National Program of HTA for Medical Devices (PNHTADM).

Committee (SC) launched the PNHTADM to promote the use of HTA tools and the principles of safety, clinical and cost-effectiveness, and social equity in a system of shared evaluation of medical technologies. Recognizing the importance of transparency and inclusiveness, the SC sought advice from a "Board of Innovation" *(Tavolo di Innovazione)* to collaborate on program development, comprised of stakeholders including academia, patients, private and public health care organizations, professional associations, and the MD industry association. Three main work groups and five sub-work groups, composed of members of the SC and the Board of Innovation, were created to address the main objectives of the Program (Fig. 2). The four-year process of developing the PNHTADM was completed in 2019 (Fig. 1), defining recommendations, methods and monitoring of the national program.

Common methodology was used in defining the final PNHTADM structure and documents, based on focus groups or surveys to identify key elements and issues, followed by systematic literature reviews, interviews, in-depth analysis of selected international examples, and subsequent focus groups and internal discussions to formulate recommendations. The recommendations of the five sub-work groups were finally discussed by the SC and consolidated into the official document published on the MoH website, with additional reports from each work and sub-work group, clearly delineating the methods, results, references and associated documents [38]. The final structure and processes that make up the PNHTAMD are defined below.

5. The process and structure of the Italian national HTA program for medical devices (PNHTADM)

Fig. 2 illustrates the processes and structures involved in the PNHTADM, from proposal (signal out) of a technology for HTA through the prioritization, assessment, appraisal, decision and appeal processes, complete with policy recommendations regarding coverage in the nationally-defined guaranteed health basket (LEA), indications regarding procurement and reimbursement policies and how the technology will be delivered throughout the 21 regional health systems.

5.1. Proposals and prioritization

Any technologies can be proposed for assessment, ranging from emergent (i.e., not yet CE-marked) to obsolete (i.e., disinvestment in technologies to be displaced by other available options with superior safety, clinical or cost-effectiveness profiles). An online system for proposing technologies for assessment, developed by the PNHTADM, allows one or more stakeholders to upload the request on the system, starting the process (Fig. 2).

Proposals for technology assessments can be uploaded at any time, but every six months they are evaluated by the SC in order to decide which will be selected. In order to avoid duplications, MDs that have recently been assessed by other agencies - as found for example in the EUnetHTA Planned and Ongoing Projects (POP) Database [39] - are excluded and those that remain are prioritized

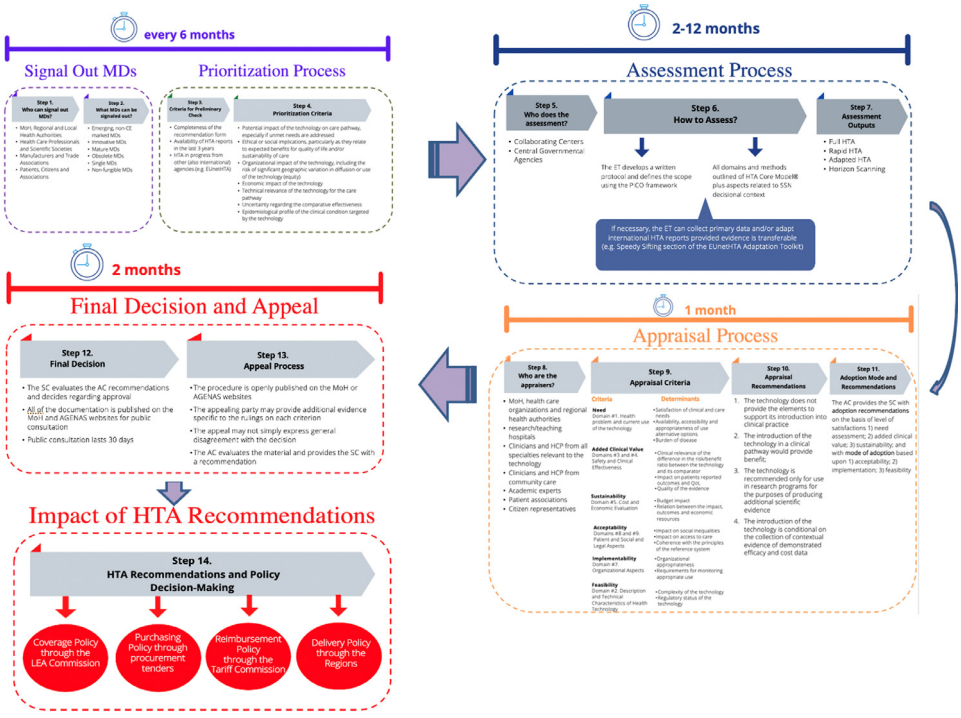

Fig. 2. The process of the Italian National HTA Program for Medical Devices (PNHTADM)
Abbreviations: AC – Appraisal Commission, AGENAS - Agenzia Nazionale per i Servizi Sanitari Regionali (National Agency for Regional Healthcare Services), ET – Evaluation Team, EUNetHTA – European Network for Health Technology Assessment, HCP – health care providers, HTA – Health Technology Assessment, LEA – Livelli essenziali di assistenza (nationally guaranteed health basket), MDs – medical devices, MoH – Ministry of Health, SC – Steering Committee, SSN – Sistema Sanitario Nazionale (Italian National Health System).

according to specific criteria (Fig. 2). Seven criteria have been envisaged to prioritize MDs for further assessment and mainly pertain to the relevant domains of conventional HTA processes (e.g. economic, social, organizational, ethical impacts, epidemiological relevance and uncertainty in clinical evidence).

5.2. Assessments

While a key goal of the PNHTADM is to eliminate redundancy in HTA in the Italian SSN, it also aims to exploit the knowledge, experience and expertise accumulated by past and present Italian HTA producers. Therefore, the SC will accredit "collaborating centres", public or private institutions (mainly regions and academic centres) that meet certain criteria, to collaborate on assessments for the PNHTADM. Once technologies have been prioritized for assessment, the SC decides which are to be assigned to collaborating centres or to central governmental agencies such as AGENAS or the Italian National Institute of Health (Istituto Superiore di Sanità – ISS). Favoring full transparency and inclusiveness, the PNHTADM assessment process is clearly delineated, starting from a written protocol subject to external review to the publication of the evaluation results, open to public consultation for 60 days. For the selected technologies, the evaluation team identifies the scope (research question) in the study protocol using the PICO framework (Population, Intervention, Comparison, Outcome).

Assessment domains are based on the latest version of the HTA Core Model® [11], plus aspects related to SSN coverage decisions at the national or local level (decisional context) (Fig. 2). For each domain, a synthesis is presented of the scientific evidence and its relative quality resulting from the comparative analysis. Where necessary, the Evaluation Team (ET) may collect primary evidence to address areas where the literature provides insufficient information. Where HTA reports produced at the international level are proposed, a tested methodology for such adaptations was developed, based on international and national resources, namely the "HTA network reflection paper – Reuse of joint work in national HTA activities" from the EC [40], the EUnetHTA HTA Adaptation Toolkit [41], and two manuals produced by AGENAS, "HTA Report Adaptation: methodology document" [42] and the "AGENAS Procedural Manual" [43]. An important preliminary phase of the adaptation process involves analysing the information needs for the reference context, or assessing the adaptability of the report for the national health care system. A particularly useful instrument for such adaptability analysis is the Speedy Sifting section of the EUnetHTA Adaptation Toolkit, which provides a rapid screening tool of 8 questions to apply before going on to the main part of the toolkit [41]. According to quality and quantity of evidence, urgency and time constraints, the Evaluation Team (ET) delivers a Full HTA, a rapid or adaptive HTA or a Horizon Scanning (Fig. 2)

5.3. Appraisal

A stated aspiration of the process design was to allow stakeholders to evaluate, point by point, the reasoning and information supporting the validity of the final appraisal decision, even if not in complete agreement. Appointed members of the Appraisal Commission (AC) should be representative of the clinical, economic, organizational and health and social service areas appropriate to the technology under assessment (Fig. 2). All members of the AC must sign statements declaring the absence of potential conflicts of interest.

Based on the HTA report, the appraisal process calls for the AC to evaluate and provide a ruling for each determinant of the evaluation criteria (Need, Added Clinical Value, Sustainability, Acceptability, Implementability and Feasibility, **Error! Reference source not found.** 3): either fully, partially or not satisfied. Four different recommendations can emerge out of the appraisal process: i) rejected; ii) recommended; iii) recommended for research purposes

only; and iv) recommended provided that additional evidence is generated

5.4. Final decision and appeal

The SC evaluates the AC recommendations and comes to a final decision regarding approval. All of the documentation is published on the MoH and AGENAS websites for public consultation, including a formal appeal process. Public consultation lasts 30 days.

5.5. Impact of HTA recommendations

A unique and important characteristic of the PNHTADM is the desire to tie the outcome of the HTA assessment and appraisal process to the most fundamental processes in health policy decision-making: coverage, procurement and reimbursement. In fact, the recommendations of the SC are expressed in relation to four fundamental components of the Italian SSN: the guaranteed health basket (Essential Levels of Assistance, or LEA), the national fee structure for publicly funded health care, the healthcare services delivery through Regional Health Authorities, and the procurement process involved in the purchase of MDs (Fig. 2).

The **National LEA Commission of the MoH** determines coverage policies as they relate to the guaranteed health basket. HTA reports for health and biomedical technologies inform decisions on updating the LEA and provide guidance regarding appropriateness and the conditions under which the benefits will be publicly funded. MDs that have received a positive recommendation from the SC, as well as those healthcare services and procedures containing newly approved devices (e.g. new mini-invasive surgical procedures), need to be discussed within the LEA Commission in order to either upgrade or include them if not present already in the health basket. The **Permanent Tariff Commission of the MoH** then updates the fee structure for all services and procedures that employ MDs that have been incorporated into the LEA. The fee structure would correspond to the value generated by the MD incorporated into the procedure.

While the national government is responsible for national health policy, the LEA and the fee system, as well as levying and distributing taxes to fund health care, the **Regional Health Authorities** are responsible for planning and delivering (through LHAs) health care to their residents based on needs and available funds. Each region may also determine an ad hoc system for regulating procedures involving MDs or medicines, especially when they are particularly expensive or innovative. The distribution system may take the form of a hub & spoke, a system of centers of excellence, setting a minimum number of procedures for approving a center for a particular procedure. In this way, the regions interpret and incorporate the coverage decisions for the approved MDs into the healthcare delivery system and can use HTA reports to inform the resource allocation process within their jurisdiction.

The PNHTADM has also made provisions for the **Procurement** processes **involved in the purchase of MDs**. HTA reports for MDs approved for purchase through the PNHTADM are to be used in procurement as the most recent and authoritative synthesis of the safety and clinical and cost-effectiveness of the MD in question, so to turn the current, mainly price-based purchasing system into a value-based procurement approach.

6. Discussion

The proposed reform of the system of HTA for MDs in Italy described herein illustrates how the MoH has interpreted and incorporated recommendations based on international HTA bodies and studies of critical issues and relevant aspects of MDs, within the conceptual frameworks of economic rationality and value-based healthcare [23,24]. The efforts made so far by public institutions and a large plethora of stakeholders also show that the times are mature to endorse a more transparent, objective and rational process to govern equitable access to technological innovations in healthcare, which is also likely to be the only way forward to keep the SSN abreast of the most cost-effective technologies while maintaining its universalistic architecture and free-of-charge feature at the point of consumption.

The unique challenges presented by MDs in comparison to prescription drugs for HTA [28–30,32] was a main driver of the push to create a dedicated, national program. As one of the latest EU countries to promote a formal, official HTA program, Italy has however had the advantage to benefit from a number of recommendations from international initiatives, professionals and associations (e.g. MedtecHTA, EUnetHTA) [30,31,33] to inform the process and incorporate into the Program. Moreover, the entire development process of the PNHTADM has been conducted through a mixed method approach that has incorporated expert panels, focus groups, systematic literature reviews and case-studies analysis which, all in all, make the Italian HTA program solidly evidence-based.

The Program's centralized process for proposing MDs for HTA also allows for setting priorities and addressing in a comprehensive manner the dearth of quality safety and effectiveness evidence for MDs often cited in the literature [16,31,32,34]. The parties proposing the MDs encompass all relevant stakeholders, from patients to manufacturers, hospitals, clinicians and professional associations, providing that those closest to the technology provide the preliminary information regarding the risk level of the MD, the proposed use and novelty of the device, supporting evidence, related care pathways, and whether it substitutes current technology. The online system allows various stakeholders to start and follow the process and check on progress. All of these measures help to create a system that is accountable not only to government needs and decision-making – a potential drawback of a universal healthcare system [25] – but also those of other stakeholders. The monitoring process also allows for collecting evidence after the MD is approved, which can continue to inform reimbursement and pricing practices [44]. Besides the provision of data, information and evidence, the active participation of stakeholders in the formulation of the most relevant areas of the program (Fig. 2) is likely to be the best predictor of endorsement of the PNHTADM by all relevant parties.

The expected benefits for the 21 regional health systems in Italy include purging redundancy while improving access to innovative technologies in a contemporaneous manner, eliminating differing timeframes for approval for purchase at the regional levels, while aiding centralized, regional purchasing units in evaluating the technical aspects of the MDs. It also addresses disparities in regional resources and abilities to conduct HTA that had been long observed and helps to approach the national process for HTA achieved by AIFA for prescription drugs [5,18,26].

This standardization is expected to also reduce MD price differentiation through increased transparency and a greater ability for centralized purchasing bodies to negotiate based on the added value generated by the new device rather than acquisition prices [17–20]. Clinicians will find HTA an objective tool to support their requests for introducing innovative MDs in routine practice, and Regional Health Authorities, together with LHAs, can organize the delivery of new services or procedures coherent with the regional/local context based upon the final synthesis of evidence stemming from the SC recommendations (e.g., epidemiology, organizational impact). Patients will eventually find no difference in accessing modern technologies across territories, thus reducing patient mobility and all related costs. Finally, manufacturers will benefit from the centralized PNHTADM approval process that will

allow them to streamline regulatory and market access activities for new technologies, erasing the need to negotiate with single regions or even LHAs, especially as these practices relate to evidence and safety requirements for higher-risk MDs, a process already started in anticipation of the new medical device regulation (MDR) ((EU) 2017/745) [45].

7. Future directions

Since 2019 the PNHTADM has remained an orphan program. The one element that did not find agreement was who should fund the program. Although several options were proposed (e.g., publicly funded through Ministries of Health or Finance, co-funding between government and industry) none reached full consensus, and the subsequent succession of MoH leadership and, more recently, the Covid-19 pandemic have shelved the process of introduction and implementation of the PNHTADM in the SSN. In the meantime, technological innovations do continue to enter healthcare markets, and regional disparities do continue to emerge. In this decisional vacuum, some regions have started taking their own initiative as it happened last June 2020 when the Veneto Region instituted a regional Technical Table for MDs and LHA Units for evaluating requests for purchasing new MDs. If the PNHTADM does not take off, the regions – as well as other stakeholders – might lose trust and go back to their regional programs. However, there are (at least) two upcoming opportunities for the launch of the PNHTADM: the proposed EU Regulation on HTA and the Next Generation EU.

Since the vote of the EP in 2018, the EU's proposed Regulation on HTA has gone through several amendments, as requested by the EP, and the position of the European Council is expected in 2021. The Regulation will further harmonize and centralize the comparative clinical assessment of drugs and MDs (mainly class IIb and III) with the aim of reducing disparities across Member States and alleviating their evaluation burden that would, instead, focus on non-clinical domains of HTA. The PNHTADM already addresses adopting and adapting international HTA agency assessments, and the EU Regulation on HTA would therefore fit nicely in the Italian program, which could invest its first energies in contextualizing. More importantly, once EU Regulation has passed, it will be fundamental that each Member State be prepared, structured and organized to receive and process the EU clinical assessments. The PNHTADM is complete, and Italy would find itself ready when the time will come.

The Next Generation EU is the most generous financial aid that the EC has allocated to Member States hit by the COVID-19 pandemic. Out of 750 billion Euro, Italy will receive almost a third (209 billion Euro), and although the percentage allocated to healthcare is still undecided, it will undoubtedly be a unique opportunity to use part of these funds to invest in the future of the SSN. Technological innovation is clearly an important driver of improvement in health outcomes and must be fostered, but – at the same time - access must be governed to keep the entire system financially sustainable. With its conceptual framework rooted in economic rationality and value-based healthcare, the PNHTADM represents an important step in shaping the future of the SSN or, better, to safeguard the current features of universalism, equity and solidarity for the future.

8. Conclusions

Although unique in many aspects, we believe the Italian experience can serve as an example of how HTA can be governed at the national level in order to face the challenges posed by universal coverage in highly decentralized systems. Not only the final result, but also the processes that have been put in place to generate consensus among a number of stakeholders make the Italian PNHTADM an important model that could provide important insights to other jurisdictions faced with similar challenges. Compared to other international HTA programs, the PNHTADM presents distinctive characteristics. The methodology, the governance and the entire process have been specifically developed for MDs and not mediated through pharmaceuticals. Although there are other countries that have developed ad-hoc MD-based HTA programs (e.g., the Netherlands, France, Austria, UK), the PNHTADM is grounded in a comprehensive study of the most up-to-date methodological approaches developed by international organizations and consortia in the field of HTA for MDs. The PNHTADM is highly participatory since all stakeholders have been included in all steps of the process. A few countries can claim a high level of stakeholder participation (e.g., UK), but none can boast such wide-spread participation from a large plethora of stakeholders in the developmental phase of the Program. Third, the PNHTADM is unique in that it rises to all of the most relevant health policies of the SSN (i.e., coverage, procurement and reimbursement), thus setting the trend towards a value-based healthcare approach.

Recent changes in the Italian government - and the Covid-19 pandemic - have temporarily slowed the PNHTADM implementation process. However, we are confident that the repeated emphasis on HTA in the government's "Plan for Health (*Patto per la Salute*) 2020–2021", means that the central government and regional authorities will embrace this singular achievement in governing technological innovation, in short, demonstrating that delivering modern, cost-effective and value-based care to all patients in need is possible, even in a resource-constrained, publicly-funded, universal care system.

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Declaration of Competing Interest

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