

# IMPLEMENTATION OF EUNETHTA CORE MODEL<sup>®</sup> IN LOMBARDIA: THE VTS FRAMEWORK

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**Objectives:** This study describes the health technology assessment (HTA) framework introduced by Regione Lombardia to regulate the introduction of new technologies. The study outlines the process and dimensions adopted to prioritize, assess and appraise the requests of new technologies.

**Methods:** The HTA framework incorporates and adapts elements from the EUnetHTA Core Model and the EVIDEM framework. It includes dimensions, topics, and issues provided by EUnetHTA Core Model to collect data and process the assessment. Decision making is instead supported by the criteria and Multi-Criteria Decision Analysis technique from the EVIDEM consortium.

**Results:** The HTA framework moves along three process stages: (i) prioritization of requests, (ii) assessment of prioritized technology, (iii) appraisal of technology in support of decision making. Requests received by Regione Lombardia are first prioritized according to their relevance along eight dimensions (e.g., costs, efficiency and efficacy, organizational impact, safety). Evidence about the impacts of the prioritized technologies is then collected following the issues and topics provided by EUnetHTA Core Model. Finally, the Multi-Criteria Decision Analysis technique is used to appraise the novel technology and support Regione Lombardia decision making.

**Conclusions:** The VTS (*Valutazione delle Tecnologie Sanitarie*) framework has been successfully implemented at the end of 2011. From its inception, twenty-six technologies have been processed.

**Keywords:** EUnetHTA, EVIDEM, Regional Framework, Multi-Criteria Decision Analysis, Prioritization

The present study describes the health technology assessment (HTA) framework implemented in 2008 by Regione Lombardia (RL) to decide on the introduction and delisting of health technologies. The framework (named VTS, *Valutazione delle Tecnologie Sanitarie*) applies the EUnetHTA Core Model<sup>®</sup> (1;2) to define the procedures, responsibilities, and criteria that the Health General Directorate follows for evidence-based and legitimate decisions.

The introduction of a formal HTA framework stemmed from a strive to balance goals of continuous innovation with needs of steady cost containments. While introducing state-of-art technologies is crucial for higher standards of care, their expenditures are critical factors for the increase of healthcare costs (3–5). Policy makers have thus emphasized the introduction of tools that manage which, why, and how technologies get in or out the system (6).

RL targeted these concerns by using the EUnetHTA Core Model to legitimize a structured approach in the adoption and delisting of technologies. Specifically, the Core Model is not used as a generic guideline for HTA, but formalized in three regional laws that *compel* RL into following a standard procedure.

The Core Model in the VTS framework supports the entire decision-making process of RL, i.e. prioritizing technology requests; assessing the impacts of the technology; apprais-

ing the decision to invest in the technology (6). Two changes were introduced to fulfill this purpose. First, the framework makes explicit the implementation of a cost-opportunity logic according to which the adoption of new technologies *must* be balanced by the delisting of obsolete ones. Second, the framework incorporates tools and techniques for Multi-Criteria Decision Analysis (MCDA) (7). The Core Model concentrates on data collection and technology assessment, but does not endorse explicit tools to translate the latter into decisions. MCDA served this purpose, and its inclusion required a few changes to the Core Model, that is, (i) map EUnetHTA domains into *dimensions* that RL set up to legitimize the prioritization of technologies and (ii) include *criteria* from an open source framework (EVIDEM) that could best support the systematic appraisal of the assessment report into a final decision (7). Both “dimensions” and “criteria” are consistent with the Core Model as they do not distort its logic, structure, and contents.

The present study will describe the VTS framework in all its components. The study is structured as follows. In section one, we outline the context of RL, in which the framework takes place. Then, we describe the key principle of *cost-opportunity* that grounds the framework. Next, we outline the elements composing the VTS architecture, and the process of its functioning.

Last, we discuss current experiences with framework implementation.

## CONTEXT OF APPLICATION

Under the Italian Constitution, the primary responsibility for Healthcare is granted to Regions, which are autonomous in the organization of services and can independently choose the nature and quantity of technological investments (8). The regional nature of the Italian Healthcare System leads to the lack of a national agency that could mandate and control the implementation of a shared HTA framework. Responsibility to assert HTA frameworks is delegated to each Region, with the result of having twenty-one distinct HTA applications in Italy (9).

RL represents one of the leading systems in terms of technology investments and quality of care. RL includes almost 10 million residents and 30,000 beds; and employs 150,000 healthcare professionals, 8,000 general practitioners. RL is organized as a quasi-market system (8), with a neat distinction between purchasers (fifteen Local Health Authorities) and providers (twenty-nine hospitals, four research institutes, and almost 200 other healthcare organizations). Public healthcare-related expenditures amass to 17,000 mil € in 2012, which represent the vast majority of RL budget. The need to monitor local expenditures on the budget triggered the formalization of a HTA framework to decide over the introduction/delisting of technologies.

## COST-OPPORTUNITY AND THE VTS FRAMEWORK

The VTS framework aims at supporting the continuous refurbishment of technologies under the constraints of fixed budgets. Such constraints magnify the role of *opportunity costs* associated with new investments, because the resources spent in a new technology might prevent investments somewhere else. RL conceived the VTS framework as a structured tool to identify obsolete technologies whose disinvestments could clear financial space for new investments. The VTS framework is thus structured to provide knowledge on (i) the comprehensive improvements associated with new technologies, vis-à-vis established ones; (ii) the possibility and extent of *substituting* obsolete technologies with the new ones.

Traditional cost-effectiveness analyses (CEA) fall short in both regards. The attention on costs and effectiveness is significantly less informative for policy makers than HTA methods that assume a multidimensional perspective. Also, CEA stimulate the accumulation, rather than the substitution, of technologies because they provide a rationale for investment, but not for disinvestment (10–12).

The VTS framework adopts instead a principle of *cost-opportunity* which considers how new technologies substitute established technologies and, thus, push disinvestments. The

VTS framework incorporates this principle by explicitly requiring proponents of new technologies to indicate which set of established technologies would become obsolete after the investment and, thus, candidates for disinvestment. This approach is applied at its best when a new technology replaces established ones. In this case, resources necessary to cover the new investment can be found from the disinvestment. The approach can be also applied when the new technology does not replace, but adds, to established ones. In this case, while no obsolete technology is fully disinvested, it is still possible to identify activities, processes, and resources that would become redundant or unnecessary with the new technology. Removing them, it is then possible to reduce the budget costs necessary for the new investment.

## ELEMENTS OF THE VTS FRAMEWORK

The cost-opportunity analysis is performed through a structured model for (i) the collection and assessment of scientific evidence about technology impacts and (ii) the appraisal of results in ways that can be promptly communicated to and understood by decision makers.

### VTS Framework Combines EUnetHTA and EVIDEM Models for These Purposes

The EUnetHTA Core Model represents an important European reference for technology assessment because it is the result of joint work from multiple agencies (1). It delineates a nested structure of *issues*, *topics*, and *domains* that organizes the collection and assessment of evidence. At top level, the model outlines nine *domains* (Table 1). Each domain represents “a wide framework within which technology is considered. It provides an angle of viewing the use, consequences and implications of technology” (EUnetHTA, 2011). Domains reflect the fact that data for technology impacts should be managed by experts in different disciplinary areas. Each domain is populated with several *topics*, representing the specific areas in which different impacts can be expected. For instance, the domain “clinical effectiveness” includes topics such as mortality, morbidity, and quality of life. Each topic includes several *issues* which represent the questions that experts should answer to assess technology impacts. For instance, to assess the impact on quality of life, an expert should answer to issue D0012: “What is the effect of the technology on health-related quality of life?” and D0016: “How does the use of technology affect activities of daily living?”

The EUnetHTA Model was adopted with two changes. First, the nine EUnetHTA domains were re-elaborated into eight *dimensions* (cf. Table 1). The changes were made to discern the *impacts* of the novel technology—while domains focus on *aspects* of the technologies. The differences between the domain “organizational aspects” and the dimension “organizational impacts” (Table 1) can be illustrative. The domain includes issues that originate from organizational aspects, but might exert

**Table 1.** Comparison between EUnetHTA Domains and VTS Dimensions (with One Illustrative Example of Operationalization)

EUnetHTA domains	VTS dimensions
1. Health problem and current use of technology 2. Technical characteristics of technology 3. Safety 4. Clinical effectiveness 5. Cost and economic evaluation 6. Ethical analysis 7. Social aspects 8. Legal analysis 9. Organizational aspects	1. General Relevance 2. Safety 3. Efficacy 4. Effectiveness 5. Economic and financial impacts 6. Impact on Equity 7. Social/Ethical Impacts 8. Organizational impacts
<b>Operationalization of Domain with EUnetHTA Issues:</b> G0001 - What kind of work flow and patient flow processes are needed? G0002 - What kind of patient involvement in treatment or care has to be mobilized? G0003 - What kind of staff, training and other human resources is required? G0004 - What kind of cooperation and communication of activities have to be mobilized?	<b>Operationalization of Dimension with EUnetHTA Issues:</b> G0001 - What kind of work flow and patient flow processes are needed? G0002 - What kind of patient involvement in treatment or care has to be mobilized? G0003 - What kind of staff, training and other human resources is required? G0004 - What kind of cooperation and communication of activities have to be mobilized?
G0005 – What consequences the new technology will have in respect of centralization? G0006 – What kinds of investments are needed (material or premises)? G0007 – What is the budget impact of the implementation of the technology for the payers?	<i>These issues are included in the dimension “Economics and Financial Impacts”</i>
G0008 - What management problems and opportunities are attached to the new technology? G0009 - Who decides which patients are to undergo a treatment and on what basis?	G0008 - What management problems and opportunities are attached to the new technology? G0009 - Who decides which patients are to undergo a treatment and on what basis?
G0010 - How is the new technology accepted? G0011 - How will other interest groups be taken into account in planning/implementation?	<i>These issues are included in the dimension “Social Impacts”</i>
<i>These issues are included in the domain “Safety”</i>	C0020 - What kind of occupational harms may exist using the technology? C0040 - What kind of environmental risks may use of technology cause? C0060 - How does the safety profile vary between different generations, versions, products? C0061 - Is there evidence that harms increase/decrease in different organizational settings? C0062 - How can one reduce safety risks for patients? C0063 - How can one reduce safety risks for professionals? C0064 - How can one reduce safety risks for environment?

impacts elsewhere. The issue G0006—that is, economic investments to guarantee viable organizational premises—is moved in the dimension “economic impacts” because it exerts an impact on the costs spent for the technology.

Second, EVIDEM criteria are incorporated to support the appraisal stage. The Core Model does not define a structured approach to appraise the results of its assessment; EVIDEM does so by implementing the MCDA approach. The appraisal is structured in a set of criteria (cf. Table 2) which “reflect ex-

plicitly the thinking process underlying appraisal/prioritization of healthcare interventions” (13). The MCDA approach replicates decision-making process by: (i) considering together all relevant criteria that intervene in the decision, (ii) assigning a weight to each criteria that reflect how relevant that criterion is for decisions, (iii) recognizing how strongly a new technology makes improvement in each criterion. To our knowledge, EVIDEM provides the most advanced and used definition of criteria for appraisal (14;15), and was thus adopted as reference

**Table 2.** Correspondence between EVIDEM and VTS Criteria

VTS	EVIDEM
<b>General Relevance</b> Disease severity (D1) Size of population (D2) General Healthcare Goals (T1) Description of technology and benefits areas (T2) Completeness and consistency of documentation (Q2) Relevance and validity of documentation (Q3+Q1)	<b>Disease impact</b> D1. Disease severity D2. Size of population <b>Type of benefit</b> T1. Public health interest T2. Type of medical service <b>Quality of evidence</b> Q1. Adherence to decision-making body Q2. Completeness of reporting evidence Q3. Relevance and validity of evidence
<b>Safety</b> Improvement of Safety and Tolerability (I2) <b>Effectiveness and Efficacy</b> Improvement of Effectiveness and Efficacy (I1) Improvement of patient related outcomes (I3) Guidelines & good practice recommendations (C1) Limitations of alternative technologies in use (C2)	<b>Intervention outcomes</b> I1. Improvement of efficacy/ effectiveness I2. Improvement of safety & tolerability I3. Improvement of patient reported outcomes <b>Context of intervention</b> C1. Clinical guidelines C2. Comparative interventions limitations
<b>Economic and Financial Impact</b> Financial Impact on Health system (E1) Cost-effectiveness (E2) Impact on other spending (E3) Impact on efficiency (cost-opportunity) (ET2)*	<b>Economics</b> E1. Budget impact on health plan E2. Cost-effectiveness of intervention E3. Impact on other spending
<b>Equity</b> Impact on equity and accessibility (ET3)* <b>Social and Ethical Impact D7</b> Coherence with national regional planning (ET1)* Impact on healthcare needs (ET1)* Pressure of interest groups (O2)* Historical and political context (O3)* <b>Organizational Impact D8</b> System capacity, appropriate technology use (O1)*	<b>Et. Ethical framework</b> ET1. Goals of healthcare – <b>utility</b> ET2. Opportunity costs – <b>efficiency</b> ET3. Population priority & access – <b>fairness</b> <b>O. Other criteria</b> O1. System capacity, appropriate use of intervention O2. Stakeholder pressures O3. Political/historical context

*Note.* Asterisks indicate implicit criteria.

model. The VTS framework provides minor changes to EVIDEM criteria to maintain consistency with EUnetHTA issues (cf. Table 2).

The changes respect the four properties required to apply MCDA, that is, mutual independence, completeness, nonredundancy, and operationalizability of criteria. In particular, criteria are operationalized through EUnetHTA issues (cf. Table 3), and independence and nonredundancy between criteria are guaranteed by imposing that an issues could be included in only one criteria.

## PROCESS OF VTS FRAMEWORK

The VTS framework is applied in a three-step process comprising (i) a prioritization of requests, grounded on a “quick and dirty” assessment limited to VTS dimensions; (ii) a full assessment of the prioritized technologies, provided by answering EUnetHTA-based issues; (iii) an appraisal of the assessed technologies, grounded on the analysis of multiple criteria. Each step is performed by a specific agent that is formally assigned by RL after getting clearance over conflict of interest. Figure 1 provides an overview of VTS elements, process, and actors.

**Table 3.** Illustrative Criteria in the VTS Framework

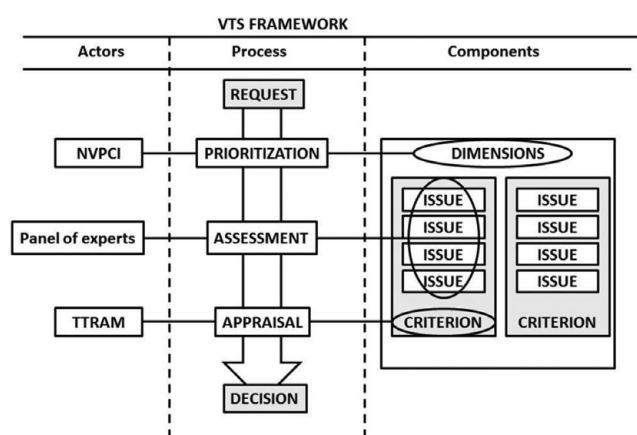
## Criterion C7: Improvement of Safety and Tolerability

## Topic: Mortality/Morbidity

1. What is the mortality and morbidity related to the diagnostic technology?
2. What is the mortality related to the technology studied?

## Topic: Patient Safety

3. What are the consequences of false positive, false negative and incidental findings brought about using the technology to the patients from the viewpoint of patient safety?
4. What kind of harms can use of the technology cause to the patient and what is the incidence, severity and duration of harms?
5. What are the special features in using (applying/interpreting/maintaining) the technology that may increase the risk of patient safety?
6. What is the dose relatedness of the harms to patients?
7. What is the timing of onset of harms to patients: immediate, early or late?
8. Is the incidence of the harms to patients likely to change over time?
9. Are there susceptible patient groups more likely to be harmed through use of the technology?
10. What is the safety in comparison to alternative technologies used for the same purpose?

**Figure 1.** Actors, processes, and components of the VTS (*Valutazione delle Tecnologie Sanitarie*) framework.**STEP 1: PRIORITIZATION**

RL receives every year a large amount of requests from different stakeholders about different types of new health technologies (drugs, devices, equipment supplies, procedures, and organizational systems). The Regional Act 7856/2008 formalized who can ask for the assessment, and how. Requests can originate only from “accredited actors,” ranging from no profit (i.e., care-giving organizations included in the Regional Health Database, scientific and professional societies, patients associations, and universities) to for-profit organizations (i.e. pharmaceutical, biotech, diagnostic firms). Proponents must fill a form with information about: (i) their details, (ii) the current technologies that will be considered as comparators and candidates for disinvestment, (iii) evidence on the impacts of the new technology on the eight *dimensions* of the VTS framework. Incomplete documentation will meet a desk-rejection. Appro-

appropriate requests are prioritized to identify which technologies deserve full assessment and which should be assessed first.

**Process of Prioritization.** Requests are sent to the Regional Unit of Prioritization and Conflict of Interests (NVPCI from the Italian wording) which includes twenty-four members—three members from Regional Health Directorates; eight from Hospital Directorates; eight from Health Authority Directorates; five from Care Scientific Centers. The members are formally appointed in regional deliberations and serve for 3 years. Each prioritization involves eight members—two members from each typology of directorate.

The NVPCI gathers twice—at the beginning to define the object of investigation and consolidate the comparators that would be used as candidates for disinvestment and at the end to deliver the prioritization decision. The stage lasts normally 45 days. Most of their work can be done online, through a dedicated Web-platform. The NVPCI provides a first rapid assessment, according to the eight dimensions (cf. Table 1).

The prioritization follows two steps. First, the NVPCI checks the attached documentation and removes all requests for new technologies which (i) cause a significant deterioration in efficacy/effectiveness, (ii) endanger patient safety, (iii) are irrelevant for healthcare purposes. Later, The NVPCI applies a Multi-Dimension Decision Analysis (MDDA) which takes the following form: Rank (technology  $j$ ) =  $\sum_{i=1}^8$  [weight (dimension  $i$ ) \* point (dimension  $i$ , technology  $j$ )]. Moving from right to left in the equation, each health technology receives a 1–5 point for each of the eight dimension of the VTS framework. The score defines to which extent the novel technology improves the status quo in that particular dimension (i.e.,



1 = high aggravation; 3 = no differential impact; 5 = high improvement).

Each dimension has a weight that tells how relevant it is compared with the other seven dimensions. The weight is elaborated by the NVPCI and is valid for any technology used within a specific care pathway. Each member defines to which extent the dimension was relevant for decision making, on a 1–8 scale (1 = irrelevant; 8 = essential). Individual ranks are then gathered and elaborated to define for each dimension a relative measure of importance (a weight).

The health technology under prioritization has specific points for each dimensions (i.e., how enriching the technology is for a specific dimension) and each dimension has a specific weight (i.e., how relevant the dimension is for prioritization). The product of these factors gives an overall rank that asserts how relevant the technology is for prioritization. Technologies can be then put in a ranking and divided into high, moderate, and low priorities, and move forward to full assessment. Technologies that have a rank <2 (i.e., low improvement) are rejected.

The decision is then communicated to all interested stakeholders—who are given: (i) an executive summary of the prioritization, which explains the decision; (ii) an explanation of the process followed to produce the prioritization decision; and (iii) the weight, points, and comments of the NVPCI—with contributors properly anonymized. Proponents of the technology are given an opportunity to appeal against a rejection decision.

## STEP 2: FULL ASSESSMENT

Health technologies that pass prioritization proceed to the “full assessment” stage. Evidence about the multidimensional impacts of the technology is systematically collected and processed by a panel of experts identified by NVPCI. Specifically, the NVPCI assigns experts to one of the eight dimensions of the framework and have no conflicts of interest.

The panel gathers on average four times for each assessment—at the beginning to gather initial information about the goal of the assessment, typically two more times to discuss critical issues in the assessment and at the end of a process to consolidate the assessment. The process lasts on average 3/4 months.

Within the panel, one actor is appointed as the conductor and given the responsibility to assign specific criteria to each expert and synthesize their contributions. The panel of experts is responsible for elaborating knowledge on each of the twenty-one criteria of the framework, by collecting evidence and answering to the relevant *issues* in each criterion.

### Review and Grading of Evidence

The starting point in full assessment is the systematic review of scientific evidence. The experts are required to search for contributions in databases of primary studies (e.g., MEDLINE, Embase, Cochrane Controlled Trials Registry, Clinicaltrials.gov)

and of secondary studies (e.g., Cochrane Reviews Database, Web sites of HTA Agencies (e.g., ANSM, CADTH, DHMA, DIMDI, HAS, IQWIG, NICE, Osteba, etc.), specifying the research strategy—that is, keywords and database queries—and the criteria for inclusion and exclusion of contributions.

The resulting publications are registered according to the typology of study design—meta-analyses, randomized controlled clinical trials, observational studies, etc. The classification is the first step in the grading of evidence. Relevant included contributions are graded on a 1–4 scale according to the degree of scientific validity and applicability to Lombardy of their findings. In practice, the panel of experts assesses the validity and applicability of evidence using distinct assessment models for: (i) epidemiological documentation; (ii) clinical outcomes; (iii) economic/organizational documentation; (iv) budget impact analysis.

### Assessment of Impacts

The collected evidence is used to address the issues in each criterion. As we observed, issues represent in fact the basic questions that experts must address to inform the assessment. The inclusion of issues in criteria and dimensions allows breaking down the technology assessment into smaller units that can be assigned separately to field experts. All the answers to the issues provided by the experts are included in a shared document, called Multidimensional Impacts Form (MIF). The contents of the MIF document are processed and later synthesized into a comprehensive assessment of technology impacts. The MIF represents the primary input of the next stage of appraisal.

## STEP 3: APPRAISAL

The appraisal is performed by the Regional Technical Roundtable for Medical Appropriateness (TTRAM from the Italian wording). The TTRAM includes forty members selected from curricula by the Regional Health Directorate; from Hospital Directorates; Health Authority Directorates; Care Scientific Centers, Professional Associations and Universities. The members are formally appointed in a regional deliberation and serve for three years. Each appraisal “uses” twenty members.

The TTRAM gathers twice—at the beginning and at the end of a process that normally lasts 45 days. Most of their work can be done online, through a Web-platform. The TTRAM appraises the results from the assessment by using EVIDEM-based *criteria* in the MCDA approach.

The appraisal follows two steps: (i) the definition of a quantitative score for fifteen explicit criteria, (ii) the definition of qualitative comments for six implicit criteria. Consistently with EVIDEM, in fact, the VTS framework distinguishes between fifteen explicit and six implicit criteria (cf. Table 3).

Criteria are deemed explicit if they can be measured using approach and indicators that are independent from the specific technology, context of application or the time of decision. The fifteen explicit criteria can thus be treated in a linear additive

equation, that is:  $\text{Score}(\text{technology } j) = \sum_{k=1}^8 [\text{weight}(\text{explicit criterion } k) * \text{point}(\text{criterion } k, \text{technology } j)]$ .

Each explicit criterion is first weighted on a 1–15 scale (1 = criterion *k* does not contribute to value; 15 = criterion is the most important one for value). Then, based on the assessment included in the MIF, each member of the TTRAM assigns as EVIDEM a 0–3 point to each criterion that reflects how significant s/he considers the improvement made by the new technology. The individual points are then aggregated, and the regional board finally applies the Multiple Criteria Decision Analysis (MCDA) to quantify the multidimensional impact of the novel technology.

The linear additive model cannot include the six implicit criteria. These criteria are deemed implicit because no “universal” score can be assigned to them. Their evaluation is entangled with an evaluation of the setting of application and moment of adoption. The criterion “Historical and Political Context” is illustrative, in this regard, as the consistency of the new technology with the context depends on where, when and by whom the appraisal is performed.

Each implicit criterion can add important clues to the overall appraisal, but their inclusion in the linear additive equation would make the MCDA spurious. The appraisal of implicit criteria is, in fact, “subjective” and contextual while the MCDA manifests “objective,” evidence-based impacts of the technology. Implicit criteria are then elaborated with a *qualitative* assessment of whether the technology would produce a positive, negative, or nonsignificant impact.

The appraisal thus results in a quantitative result—that is, the score for fifteen criteria—and six qualitative evaluations that the regional policy maker will use to substantiate and legitimize the final decision and to communicate it to the public, the industry, the providers and any relevant stakeholder.

At the end, all information produced in the assessment and appraisal stages are made public, that is, (i) the contents of the MIF, (ii) the scores and comments made by the TTRAM (properly anonymized), (iii) an executive summary of the final appraisal decision. Proponents of the new technology are given the opportunity to appeal against a negative decision.

## STATE OF PRACTICE

The application of the VTS framework started at the end of 2011. As we write, almost 2 years passed from its inception and twenty-six technologies have been signaled: seven diagnostic devices, eight interventional devices, two vascular procedures, six categories of drugs, one imaging technology, and two special food formulations.

Thus far, fourteen proposals were rejected at step 1 (prioritization) because their effectiveness could not be sufficiently documented or was judged inferior to available alternatives, while two proposals are currently awaiting prioritization. Nine of the remaining ten proposals have been admitted to step 2

(full assessment): three assessments proceeded to step 3 (appraisal, one finished and two ongoing) while six assessments are ongoing. Another proposal was judged clearly superior to alternatives at priority phase and proceeded directly to quick appraisal, which ended positively.

At present stage, no relevant issue has emerged in neither the prioritization stage, for instance, priority rejections have been accepted as legitimate, nor the assessment stage, for instance, the groups of experts are working steadily in data collection, issue assessment, and criteria weighting.

## DISCUSSION

Regione Lombardia (RL) sought to institutionalize HTA methods and pragmatics through: (i) high standardization of activities, actors, criteria involved in the process; (ii) reliance on normative regulation to compel actors into performing VTS standards; (iii) central role assigned to scientific evidence.

RL had to deliver a framework that was both an effective decision-support system and a powerful agent of change in stakeholders’ behaviors. Facing stakeholders that were reluctant, unaccustomed, or unaware of HTA (16), RL designed interventions—for example, the mobilization of regulatory support, conferring status to NVPCI and TTRAM—to legitimize HTA as a new routine.

In this regard, a crucial intervention was the application of the EUnetHTA Core Model in a normative process that includes prioritization, assessment, and appraisal of requests. The operationalization of the Core Model occurred through (i) a full adoption of its issues and topics for data collection and impact assessment and (ii) the inclusion of EVIDEM criteria and MCDA for the appraisal of requests. The integration between EUnetHTA and EVIDEM models is unproblematic, as the former provides elements for collecting data and assessing impacts while the latter instruments for supporting decisions. Moreover, the integration ensured the implementation of the Core Model in RL, at the expense of a few changes such as the redefinition of EUnetHTA domains in dimensions and the repositioning of topics and issues in a different, goal-oriented, structure of criteria, and dimensions.

This approach has both strengths and drawbacks. On the positive side, the standardization and explicit regulation of the HTA process instill uniformity and transparency in a process that may be highly elusive. While subjectivity cannot be completely removed, the framework seeks to minimize discretion in decision making and to produce decisions perceived as legitimate by the stakeholders. The adoption of EUnetHTA and EVIDEM models, the commitment to systematic reviews and the reliance on field experts all manifest an intention to legitimize a rigorous decision making. On the negative side, the VTS framework unfolds a complex process whose standards and requirements might limit flexibility, adaptability, and timeliness. Time is, at present, the key issue under consideration. The

process now lasts 6/8 months from prioritization to the final appraisal and significant time containments have been achieved by a recent introduction of a Web-platform that allows members to collaborate on remote without frequently meeting face-to-face; and by focusing on technologies which already have advanced evidence bases. RL is presently seeking to move a step further and couple situations in which RL needs to perform the whole process of prioritization, assessment and appraisal (acting as “HTA-Doer”) with others in which it can use pre-existing assessments and focus only on the appraisal of results (thus acting as “HTA User”). The use of external assessments (properly validated and adapted) thus represents the second stage in the institutional change of HTA for RL—with the expectation of ramping-up the production of evidence-based decisions to a steady high level.

## CONCLUSIONS

The VTS framework was designed in RL as an application of the EUnetHTA Core Model to inform investment/disinvestment decisions. The Core Model is adopted unabridged in the topics and issues that are meant for data collection and technology assessment. The VTS framework provides however changes in those components – dimensions and criteria—that are meant for prioritization and appraisal. These changes move in addition to, not in substitution of, the Core Model. They serve the purpose, in fact, to address those areas that are not explicitly covered by EUnetHTA and allow the direct use of the Core Model also for decision making. Changes leave unaltered the core aspects of the model, such as breaking down the assessment into small, standardized and replicable units, the nature of collected data and the process of full assessment.

The adoption of EUnetHTA issues into a structure of criteria can suggest that the Core Model can be used not just for assessment purposes, but also to support directly the appraisal. The VTS framework hints to a promising implementation of the EUnetHTA assessment tools with the EVIDEM multiple criteria appraisal methods, without compromising their respective objectives and approaches.

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## CONFLICTS OF INTEREST

Michele Tringali serves in the Board of Directors of the EVIDEM Collaboration, a NGO non-profit organization, without receiving funding for the work. The other authors report they have no potential conflicts of interest.

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