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Adopting European Network for Health Technology Assessments (EunetHTA) core model for diagnostic technologies for improving the accuracy and appropriateness of blood gas analyzers' assessment

Abstract

Background: Point-of-care testing (POCT) is a successful methodology for meeting clinical expectations of rapid and accurate results. Scientific literature has moreover highlighted and confirmed the necessity of individuating the best technological solution, in accordance with clinical requirements and contextualized to the whole health organization, where it will be implemented. Health Technology Assessment (HTA) can assist in reaching an appropriate and contextualized decision on a health technology. The aim of this study is to adapt a HTA core model for improving the evaluation of a POCT technology: blood gas analyzers.

Methods: The European Network for Health Technology Assessment (EUnetHTA) core model for diagnostic technologies was applied for evaluating globally marketed blood gas analyzers. Evaluation elements were defined according to available literature and validated using the Delphi method.

Results: A HTA model of 71 issues, subdivided into 26 topics and 10 domains, was obtained by interviewing 11 healthcare experts over two rounds of Delphi questionnaires. Ten context parameters were identified in order to define the initial scenario from which the technology assessment was to begin.

Conclusions: The model presented offers a systematic and objective structure for the evaluation of blood gas analyzers, which may play a guidance role for healthcare operators approaching the evaluation of such technologies thus improving, in a contextualized fashion, the appropriateness of purchasing.

Keywords: appropriateness; assessment; blood gas analyzers; efficacy; health technology; point-of-care testing.

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Introduction

Point-of-care testing (POCT) is becoming far more popular because of the technological possibilities it holds for meeting clinical expectations of rapid and accurate results. A number of papers and textbooks describes technologies and clinical applications of POCTs in hospital and outpatient settings [1], in particular, highlighting the appropriateness and benefits related to the reduction of turnaround time and clinical decision-making time in critical care [2, 3], even if strictly correlated to methodological and quality controls set by the core laboratory [1].

The possibility of having a blood gas analyzer at the same location as a critically ill patient and being able to perform analysis at the bedside significantly affects the accuracy of the diagnostic results and the appropriateness of treatment and patient management [4], while maintaining a simplicity that allows the use of POCT technologies by non-laboratory healthcare professionals [5].

The continuous improvement of diagnostic quality, as confirmed by numerous positive results that compare the analytical performance of POCTs and core laboratory [6, 7], has extended the sectors where POCT can be applied and has identified new requirements in terms of both diagnostic accuracy and interface/usability improvement.

Not-operator dependent approaches to POCT quality control and improvement were implemented [8, 9] for identifying problems, developing corrective actions, and evaluating their effectiveness, showing that addressing the high dependence of POCT results on operator technique is the main way to solve targeted problems and provide reliable results at the bedside. Moreover, there have been many reports describing individual POCT technologies and their benefits, despite there are few recent studies relating to the organizational target and impact of a POCT program in large medical centers [10]. The structure and organization of a successful POCT management program continues to evolve and remains problematic [1]. The successful management of POCT technologies requires an interdepartmental team (clinical laboratories, nursing, and hospital administration) for the correct identification of: sites performing POCT technologies; menu of the tests on each POCT unit; and possible alternative technologies according to the actual clinical justification for POCT. Furthermore, in large institutions, a quality assurance manager is also required [1] for carrying out inspections necessary to establish a baseline performance of the quality assurance program, also aimed at streamlining workflow and enhancing the quality of POCT. This sort of organization is not always easy feasible, particularly in those nations where a specific legislation regulating the POCT management is lacking.

These results highlight and confirm the necessity of individuating the best technological solution to the real clinical needs identified by clinicians; and contextualized to the whole health organization [9, 11] where it will be implemented. Health Technology Assessment (HTA) can answer this need. Its aim is to inform the formulation of safe and effective health policies and/or decisions, patient-focused and which seek to achieve best value [12]. Its methodology consists of the systematic evaluation of properties, effects or other impacts of health technology. For this reason, it may address the direct and intended consequences of technologies as well as their indirect and unintended consequences [12]. Interdisciplinary groups using explicit analytical frameworks usually conduct HTA projects, because proprieties and impacts of a technology are related to different evaluation fields.

Due to the possibility of performing a variety of methods as opposed to the need of harmonization (in order to avoid duplications, spread knowledge and share results), HTA activities were soon approached as a matter of cooperation and networking [13]. European Network of HTA (EUnetHTA) was established in 2005, to answer the European Commission's call for the "urgent need for establishing a sustainable European network on HTA" (http://www.eunethta.eu/). EUnetHTA is a network of government-appointed organizations and a large number of relevant regional agencies and non-for-profit organizations that produce or contribute to HTA in Europe. In its vision, EUnetHTA would be a preferred facilitator of high-quality HTA collaboration in Europe and its first mission is to support efficient production and use of HTA in European countries. During 2006–2008, EUnetHTA produced a methodological framework (EUnetHTA core model) for collaborative production and sharing of HTA information about medical and surgical technologies and diagnostic technologies [14].

In this study, we therefore described our experience in adopting the EUnetHTA core model for diagnostic technologies [14] in order to implement a model aimed at improving the individuation of peculiar characteristics of an important POCT within the whole process of the management of critical care: blood gas analyzers. For this study, we considered models of analyzers that perform blood gas, pH, chemistry, and electrolyte testing at the patient's bedside (or any other patient vicinity). Some of these devices are handheld; others require bench-top space (from the ECRI definition of "Point-of-Care Analyzers, Blood Gas/pH; Chemistry; Electrolyte", see www.ecri.org). Starting from this definition of POCT blood gas analyzers, we characterized the EUnetHTA core model for diagnostic technologies to obtain a model useful for evaluating these POCT devices and adoptable in every sort of clinical and laboratory context. To identify the evaluation criteria of POCT blood gas analyzers, we employed the Delphi questionnaires, because of their peculiarity of employing multiple iterations to establish consensus on a specific topic [15].

Materials and methods

EUnetHTA model for blood analyzer assessment and systematic bibliographic searching

The HTA core model for diagnostic technologies was published at the end of 2008 in EUnetHTA Work Package 4 [14] to support a clear structure, and transparent and rigorous handling of information in any assessment of diagnostic technologies. One of its main aims is to equalize significant differences in the international practical

application of HTA [16]. It is in accordance with the well-accepted hierarchical model for the evaluation of diagnostic technologies proposed by Fryback and Thornbury [17].

The proposed model consists of *elements*, single pieces of information that describe the technology or the consequences or implications of its use, or the patients and the diseases to which it is applied [14]. Elements taken into consideration for the assessment are consistent with the following requirements: they deal with context-independent information; and they are particularly significant from the viewpoint of HTA. A single assessment element is a combination of a domain, a topic and an issue. The domain is a wide framework within which the technology is considered; the topic is a more specific area of consideration within any of the domains; and the issue is an even more specific area of consideration within any of the topics.

The EUnetHTA core model for diagnostic technologies was adapted to better fulfill the goal of commercial blood gas analyzers assessment. The aim of this adaptation is a simplified model, tailored on specific laboratory technologies, which can exploit the knowledge and contribution of laboratory experts in the process of evaluation and selection of technologies. There were 10 assessment domains, the same as proposed by the European network. Topics were those considered in the EUnetHTA core model, even though some of them were modified and others added while developing the project. Issues were identified by the authors, consulting documents from 15 international bibliographical resources and assessment agencies (AHRQ, CADTH, COCHRANE, CRD, ECRI, EUNETHTA, EUROSCAN, FDA, HTAI, INAHTA, ISI, MEDLINE, NCCHTA, NHS, and NICE) and other technical and/or legislative sources. Definition of indicators related to various topics and issues must comply with some specific criteria: 1) indicators must be "a priori" assessable (mandatory); 2) indicators should be preferably measurable (or objectively observable); and 3) repetition or redundancy is not allowed (i.e., some EUnetHTA issues claim the comparison of some characteristics among different technologies, but this is the main aim of the project itself, thus such kind of topic/issue is discarded in our model; mandatory).

We based the selection criteria of the bibliographical documents on the following keywords and their logical combinations: "Point of care AND HTA"; "Blood gas analyzer AND HTA"; "Blood gas analyzer AND errors"; "Blood gas analyzer AND organization"; "Blood gas analyzer AND clinical laboratory"; "Point of care AND clinical laboratory"; "Blood gas analyzer AND emergency"; "Blood gas analyzer AND management"; "Blood gas analyzer AND safety". The search was limited in finding those keywords and logical combinations in "abstract/title" OR "keywords" fields. From these documents, we retrieved information for describing and quantifying each assessment issue: we chose papers and other essays according to how they reply to our search of information.

Delphi method

The Delphi method is a proven objective technique [18] for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem [19]. A series of questionnaires, interspersed with controlled opinion feedback [20], was submitted to a panel of anonymous experts composed of professionals, researchers and providers in the field of primary health care and diagnosis (who were also members of national and international health technology assessment networks) and professionals from the diagnostic technology industries. Using questionnaires to build a technological evaluation framework (that is the core of any HTA process) makes the cooperation of experts of different fields (including laboratory experts) easier, comprehensible and practicable for those not so experienced in conducting a technology assessment. Each professional contributes for his/her own expertise in the assessment process; therefore, both the assessment model and the technology evaluation itself include the knowledge and opinions of involved specialists.

Stemming from the definitions of EUnetHTA Core Model Domains, we identified six areas of expertise to be comprised in the study: Healthcare (clinical and laboratory) Professionals, Clinical Engineers, Healthcare Managers, Policy Makers, Manufacturers and HTA Professionals (whose role is merely to coordinate activities and to supervise the methodology). Our aim was initially to include at least three experts (with different years of experience) for each area (also allowing a single expert to contribute for more than one area of expertise) to guarantee a plurality of opinions. We consulted 11 experts, who are representative of parts of the healthcare sector: industry (27%), academic (64%) and health services (45%), with different professional roles (Table 1). In some cases, the expertise fulfills more than one professional role and/or belongs to different sectors (e.g., academic and health services). The mean age of experience of the professionals is 16 years and all of them come from Europe. We contacted the experts by e-mail and invited them to contribute to the study, either by e-mail or through interviews with the authors.

Questionnaires and interviews

Figure 1 shows the workflow adopted to implement the adaptation of EUnetHTA core model for assessing blood gas analyzers. Firstly, we developed a preliminary questionnaire (Supplementary Data, Table 1, which accompanies the article at http://www.degruyter.com/view/j/cclm.2014.52.issue-11/issue-files/cclm.2014.52.issue-11.xml) using criteria [21] that summarized properties of the diagnostic applications of blood gas analyzers, and their impacts on different aspects of life [12]. The questionnaire was structured as a series of questions depicting each specific assessment issue and related to the 10 levels of technology assessment: the laboratory context;

Table 1 Panel of the 11 interviewees who participated to the Delphi rounds.

Field		Profession		Mean age of experience		Region of practice
Academic	7	Clinical Engineers	5	17	9	Europe
		Health Technology Assessment	5		13	
		Healthcare Professional	2		30	
Health Service	5	Clinical Engineers	2	22	15	
		Healthcare Professional	3		30	
		Health Technology Assessment	3		20	
		Management	5		24	
Industry	3	Marketing	1	12	20	
		Research	1		5	
		Teaching	1		10	

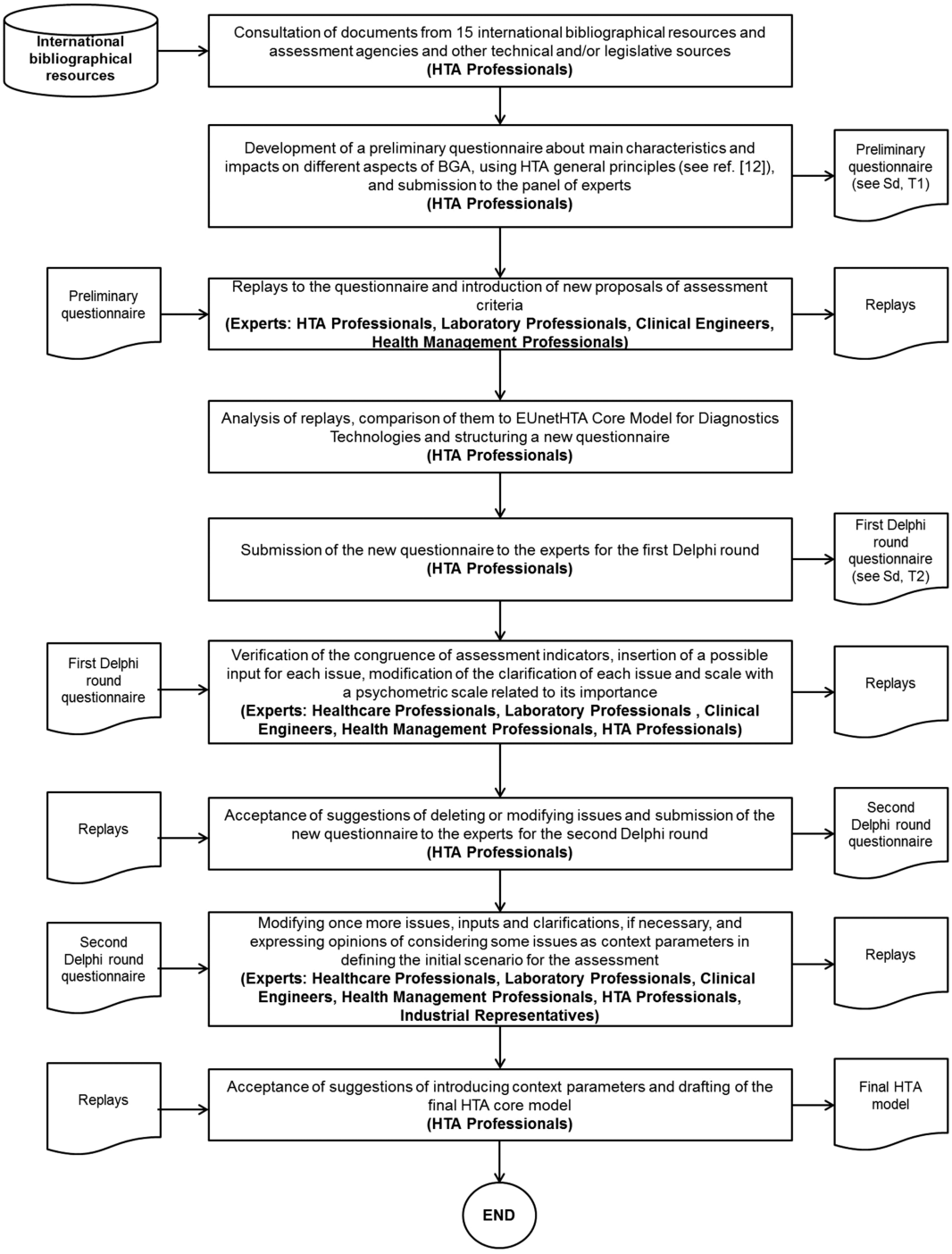

Figure 1 Flowchart of the workflow adopted to implement the adaptation of EUnetHTA core model for assessing blood gas analyzers. BGA, blood gas analyzer; Sd, T1: Supplementary data, Table 1; Sd, T2: Supplementary data, Table 2.

health problems and current use of technology; technical characteristics; safety; clinical effectiveness; cost and economic evaluation; ethical aspects; organizational aspects; social aspects; and legal aspects.

However, for the first Delphi round, we structured the preliminary questionnaire in the same way as the EUnetHTA diagnostic core model form (Supplementary Data, Table 2), divided into the following: domains; topics; issues; input (qualitative/quantitative measure); clarification (explanation of the issue topic). We submitted this first model to the panel of respondents, asking them to: 1) verify the congruence of each proposed assessment element with the specific health technology under assessment; 2) insert a possible input for each issue; 3) modify the clarification; and 4) scale each issue with a psychometric scale (strongly disagree; disagree; neither agree nor disagree; agree; strongly agree) related to its importance in the technology evaluation [22].

We approved suggestions on deleting an issue only if two-thirds of the panel strongly disagreed on the importance of an issue. In this step, none of the industrial field representatives was called to participate: the reason was to dedicate a preliminary stage to the need for a high-level identification of indicators mainly drawn from the scientific literature.

A second questionnaire, still in the form of the EUnetHTA core model, was then developed according to the suggestions and opinions received. Each interviewee was informed of the reason for changes proposed by others, and was asked to: 1) modify once more issues, inputs and clarifications, if necessary; and 2) express their opinions related to the possibility that some of the issues may be considered as context parameters in defining the initial scenario for the assessment. This particular requirement arose from comments gathered in the first interview stage.

A smaller group of experts reviewed questionnaire responses during a focus panel of frontal interviews conducted by HTA professionals. The authors declare that no ethical approval was required for this study.

Results

Assessment model for blood gas analyzers

Seventy-one issues (included 10 issues about the evaluation's context) were obtained based on two rounds of Delphi questionnaires, and subdivided into 26 topics and 10 domains (Table 2). Supplementary Data, Table 2 shows inputs, clarifications and information sources (documents obtained by the systematic bibliographic searching) consulted for defining all the issues shown in Table 2. A total of 1823 relevant articles and documents were identified through the search strategy described. We excluded 1732 documents because of duplications or irrelevant details for our research. Only 91 publications were included in the literature analysis and considered useful for defining the set of indicators, their input and clarification. Supplementary Data, Table 3 shows the number of topics and issues for each domain of the EUnetHTA core model and how it was modified during the first and second Delphi rounds.

The Delphi questionnaires (rounds)

A number of topics and issues were discarded in the first and second round of Delphi questionnaires (details are shown in Supplementary Data, Table 4). Except for the "*Description and technical characteristics of technology*" domain, the remaining domains underwent a mean decrease of topics by 64.22% and 51.03% during the first and the second round, respectively. The first round of questionnaires led to a decrease of issues by 38.40%; the second one led to a further decrease of issues by 25.59%. Moreover, it led to the definition of a supplementary list of context parameters (level 0 in Table 2). In addition, for better evaluating some organizational and technological aspects, the experts introduced new topics and issues (Supplementary Data, Table 2).

Two new topic and 19 new issues were introduced into the "*Description and technical characteristics of technology*" domain for underlining the importance of the management of medical equipments, considering the peculiar features of these devices in the health care.

In the "*Safety*" domain, risks related to the pre-analytical, analytical and post-analytical phases were separately considered for streamlining the assessment. Issues related to the "*Patient dependent safety risks*" topic were excluded because no patient factor modifies the safety of the diagnostic technology.

The increase of the number of accuracy measures issues was motivated by the importance of this feature. Issues related to the variance of the test accuracy in different settings in the "*Accuracy*" domain and to the incremental cost-effectiveness ratio in the "*Costs and economic evaluation*" domain were excluded during the second questionnaires' round because no sufficient scientific literature was available.

In the evaluation of the "*Costs and economic evaluation*" domain, during the first Delphi round the need to contemplate the amount of resources allocated has been identified, thus it has been defined a new issue named "*Budget allocation*". This issue has been moved, during the second Delphi round, from the "*Cost and economic evaluation*" domain to the "*Context parameter*" one.

During the questionnaire rounds, a specific EUnetHTA ethical issue ("*What are the benefits and harms for patients, and what is the balance between the benefits and harms when implementing and when not implementing the technology? Who will balance the risks and benefits in practice and how*?") was modified and subdivided into two sections to highlight the value of different treatments and, at the same time, their potential benefits and possible harmful effects.

In the "*Organizational aspects*", "*Social aspects*" and "*Legal aspects*" domains, several issues were excluded by the evaluation model for better emphasizing the peculiarities of these technologies.

Discussion

In this study, we have developed a model for evaluating globally marketed blood gas analyzers. Using a Delphi consensus method and with the involvement of 11 experts,

Table 2 HTA model for evaluating blood gas analyzers.

0. Context parameters
  0.1.1. Budget allocation (relates to Cost and economic evaluation)
  0.1.2. Pathologies (Diseases and health conditions of the patient) (relates to Health problem and Current Use of the Technology)
  0.1.3. Turnaround time (TAT) (relates to Health problem and Current Use of the Technology)
  0.1.4. Test requests (relates to Health problem and Current Use of the Technology)
  0.1.5. Current methods for diagnosing the pathology/health condition (relates to Health problem and Current Use of the Technology)
  0.1.6. Device panel (relates to Health problem and Current Use of the Technology)
  0.1.7. Main users (relates to Organizational aspects)
  0.1.8. Technology manufacturer or supplier (relates to Health problem and Current Use of the Technology)
  0.1.9. Negative consequences of further testing and delayed treatment in patients with false negative test result (relates to Clinical Effectiveness)
  0.1.10. Negative consequences of further testing and delayed treatment in patients with false positive test result (relates to Clinical Effectiveness)
1. Health problem and current use of the technology
  1.1. Current management of the condition
    1.1.1. Continuous monitoring of the patient
2. Description and technical characteristics of technology
  2.1. Features of the technology
    2.1.1. General technical features
    2.1.2. Analytical panel
    2.1.3. Technology diffusion
    2.1.4. Reference values of measurable analytical parameters, according to scientific literature
    2.1.5. Automatic resolution of failures
    2.1.6. Technology productivity
    2.1.7. Maximum operative time
    2.1.8. System connectivity and interfaces (hardware)
    2.1.9. System connectivity and interfaces (software)
  2.2. Investments and tools required to use the technology
    2.2.1. Reagents and consumables
  2.3. Training and information needed for utilizing the technology
    2.3.1. Training courses for health operators about the use and the ordinary maintenance of the technology
  2.4. Management of the technology
    2.4.1. Preventive maintenance of first level
    2.4.2. Preventive maintenance of second level
    2.4.3. Corrective maintenance (on demand)
    2.4.4. Remote monitoring system of technology functioning
    2.4.5. Traceability of performed operations and tests
    2.4.6. Instrumental mean down-time
    2.4.7. Instrumental up-time
    2.4.8. Easy-usage
    2.4.9. Easy-usage of management software
    2.4.10. Easy-transport
3. Safety
  3.1. Technology dependent safety risks
    3.1.1. Patient safety (pre-analytical phase)
    3.1.2. Patient safety (analytical phase)
    3.1.3. Patient safety (post-analytical phase)
    3.1.4. Safety systems
  3.2. Accuracy problems and incidental findings
    3.2.1. Non-existent diagnostic parameters
  3.3. Use or user dependent safety risks
    3.3.1. Operator-dependent errors and learning curve
    3.3.2. Type of necessary training
  3.4. Occupational safety
    3.4.1. Usage of Personal Protection Equipment (PPE)
    3.4.2. Contact with waste
  3.5. Environmental safety
    3.5.1. Consumable toxicity
    3.5.2. Waste

(**Table 2** Continued)

4. Accuracy
4.1. Accuracy measures
4.1.1. Test accuracy related to gold standard
4.1.2. Sensibility
4.1.3. Specificity
4.1.4. Analytical repeatability
4.1.5. Calibration and Quality Control (QC)
4.1.6. External Quality Assessment (EQA)
5. Clinical effectiveness
5.1. Comparative accuracy of a replacement technology
5.1.1. Comparative accuracy
5.2. Change-in management
5.2.1. Improvement of pathological survey
5.2.2. Therapeutic decisions
5.3. Health outcomes
5.3.1. How the technology modifies the efficacy of following treatments
6. Costs and economic evaluation
6.1. Resource utilization
6.1.1. Type of employed human resource
6.1.2. Amount of employed resources
6.2. Unit costs
6.2.1. Test cost
6.3. Indirect costs
6.3.1. Other Costs
7. Ethical analysis
7.1. Beneficence/nomaleficence
7.1.1. Treatment differences (benefits)
7.1.2. Treatment differences (damages)
8. Organizational aspects
8.1. Process
8.1.1. Improvement of diagnostic process
8.1.2. Clinical decision based on results
8.2. Structure
8.2.1. Test performance in core lab
8.3. Management
8.3.1. POCT users' guidelines
8.4. Culture
8.4.1. Level of acceptability of a new technology
9. Social aspects
9.1. Major life areas
9.1.1. Technology employment in areas without hospitals
9.1.2. Resource and support for using it outside an hospital
10. Legal aspects
10.1. End-user
10.1.1. POCT commission
10.1.2. POCT unit coordinator
10.2. Privacy of the patient
10.2.1. Diagnostic information for the treatment
10.2.2. Data safety
10.3. Ownership & liability
10.3.1. Users' manual

we agreed 71 indicators, classified according to the evaluation elements' scheme proposed by the EUnetHTA Work Package 4 [14]. To our knowledge, this is the first study to adapt the EUnetHTA core model in order to realize an HTA-based tool for the assessment of blood gas analyzer and using the Delphi method.

We considered two rounds of Delphi questionnaires for identifying evaluation criteria to be sufficient. According to the method proposed by Keeney et al. [23], the first one was not used to generate ideas, as it is traditionally, but was considered as a revision approach in which pre-existing information is provided for either ranking or response, and thereby reduces the number of rounds required to reach consensus.

We defined the presented model following EUnetHTA indications for identifying a common core that can be used in multiple countries or regions. For this reason, the inclusion of an issue in the core model was definitely based on its importance and transferability, as well as its compliance with our selection criteria. Importance was considered to be related to the capacity of an issue to facilitate the decision-making process about choice of a technology. Transferability is defined as the possibility of identifying issues that contain information that are very significant from the viewpoint of HTA in a wide range of contexts [14]. The introduction of evaluation issues related to the management of blood gas analyzers was motivated by the importance of this evaluation aspect to these technologies. Using a blood gas analyzer whose technological characteristics may possibly reduce the maintenance needs is a basic requirement for clinicians, for whom the equipment needs to be available at all times. The interviewees found this aspect to be particularly important for the decision-making process.

We discarded more than 30% of topics and issues during the first round of the questionnaire, by following both EUnetHTA criteria (importance and transferability) and selection criteria defined in the Methods section. This is consistent with the stakeholders need to work with a simple evaluation tool. Here is an example of this simplification. The application of the first selection criterion (i.e., possibility of an "a priori" assessment) led to the exclusion of the issue "How does training and quality assurance affect the management or effectiveness". This exclusion is justified because it is not possible to have an objective understanding of the quoted indicator for the evaluator's specific context (at least one could find some literature evidence not very adaptable to his/her own context). Only the "*Safety*" and "*Description and technical characteristics of technology*" domains remained constant: this confirms the particular interest in these two fields of assessment due to the technological peculiarities of blood gas analyzers that mainly affect patient [24, 25] and worker safety.

The definition of context parameters, with strong agreement among the same interviewees, confirms the need for stakeholders to take into account their specific settings for gaining a well-defined and contextualized evaluation of blood gas analyzers [26].

The panel of issues also guarantees a framework for the selection and associated in-depth assessment of new diagnostic technologies. The possibility of weighting the issues and topics differently, depending on stakeholder priorities, may lead to an automatic implementation of this form of evaluation by means of mathematical algorithms for data processing.

Our study has one main weakness. We encountered difficulties in enrolling policy makers in the interviews, so we may have missed some important feedback. In particular, whereas some of the experts enrolled have also responsibilities in managing healthcare services, the principal consequence of that weakness is due to the absence of "Policy Maker" representatives. Such limitation has determined the impossibility to approach the problem with a broadened perspective, in particular, also including aspects pertaining to regional or national level (i.e., where regulations and policies of healthcare programs are defined), thus limiting the possibility of adopting the derived model only at hospital level.

However, the interviewees whose participation we were able to secure represented several different sectors and areas of expertise, and provided a wide range of perspectives on the healthcare context comprising both hospital and outpatient settings.

The ability to generalize the findings of the Delphi consensus approach may be limited by the relatively small number of participants: the model presented is therefore dependent on the views of professionals from one healthcare area or that work in a particular healthcare system or country. Further studies to verify and refine our results in different or extended groups of participants should be considered.

The HTA model presented in this study provides an objective structure for the evaluation of blood gas analyzers. This methodology could expedite the purchasing of health technologies, in particular regarding the formulation of detailed requests for proposal to be submitted to providers within the procurement process.

We encourage HTA units to adopt the models proposed by EUnetHTA for implementing HTA processes within their facilities.

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