



Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol



Review/Comparative article

Review of early assessment models of innovative medical technologies

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ARTICLE INFO

Article history:

Received 21 December 2016

Received in revised form 11 June 2017

Accepted 19 June 2017

Keywords:

Early assessment

Scoping review

Health technology assessment

Innovation

ABSTRACT

Introduction: Hospitals increasingly make decisions regarding the early development of and investment in technologies, but a formal evaluation model for assisting hospitals early on in assessing the potential of innovative medical technologies is lacking. This article provides an overview of models for early assessment in different health organisations and discusses which models hold most promise for hospital decision makers.

Methods: A scoping review of published studies between 1996 and 2015 was performed using nine databases. The following information was collected: decision context, decision problem, and a description of the early assessment model.

Results: 2362 articles were identified and 12 studies fulfilled the inclusion criteria. An additional 12 studies were identified and included in the review by searching reference lists. The majority of the 24 early assessment studies were variants of traditional cost-effectiveness analysis. Around one fourth of the studies presented an evaluation model with a broader focus than cost-effectiveness. Uncertainty was mostly handled by simple sensitivity or scenario analysis.

Discussion and conclusions: This review shows that evaluation models using known methods assessing cost-effectiveness are most prevalent in early assessment, but seems ill-suited for early assessment in hospitals. Four models provided some usable elements for the development of a hospital-based model.

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1. Introduction

A major focus for hospitals and health systems are the establishment of centers for innovation [1,2]. In this setting hospitals engage in designing, developing, and testing innovative medical technologies (IMTs), e.g. an app for being discharged early post-natally [3], telemedicine training after hospitalisation with severe chronic obstructive pulmonary disease [4], 3D camera for ulcer treatment and care [5]. However, early assessment is needed in order to discriminate potentially promising IMTs from less advantageous ones since the drive for the collection of further evidence on expected effect diminish once the IMT enters clinical practice [6].

IMT include medical devices, medical/surgical procedures excluding drugs, processes of care, and clinical health information systems, e.g. telemedicine, eHealth, health apps, etc. IMTs often require interdepartmental cooperation and significant modification in features, design, or properties before widespread clinical use or adoption, i.e. the IMT is not yet fully developed. At the time of assessment and early decision on continuation in developing IMTs data are limited and a high level of uncertainty concerning clinical, patient, and organisational effects exists. In addition, considerable costs and large investments may often be involved.

Fig. 1 is inspired by the stage-gate model which is widely used for controlling R&D processes in large companies. As Fig. 1 indicates, early assessment is different from traditional assessment, by being performed when the initial selection of ideas or rough prototyping has taken place, but prior to large-scale testing or traditional clinical research. Hence, early assessment is based on data from early phases, i.e. feasibility, pilot, or initial effect data generated for the IMT up until Gate N.

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<http://dx.doi.org/10.1016/j.healthpol.2017.06.006>

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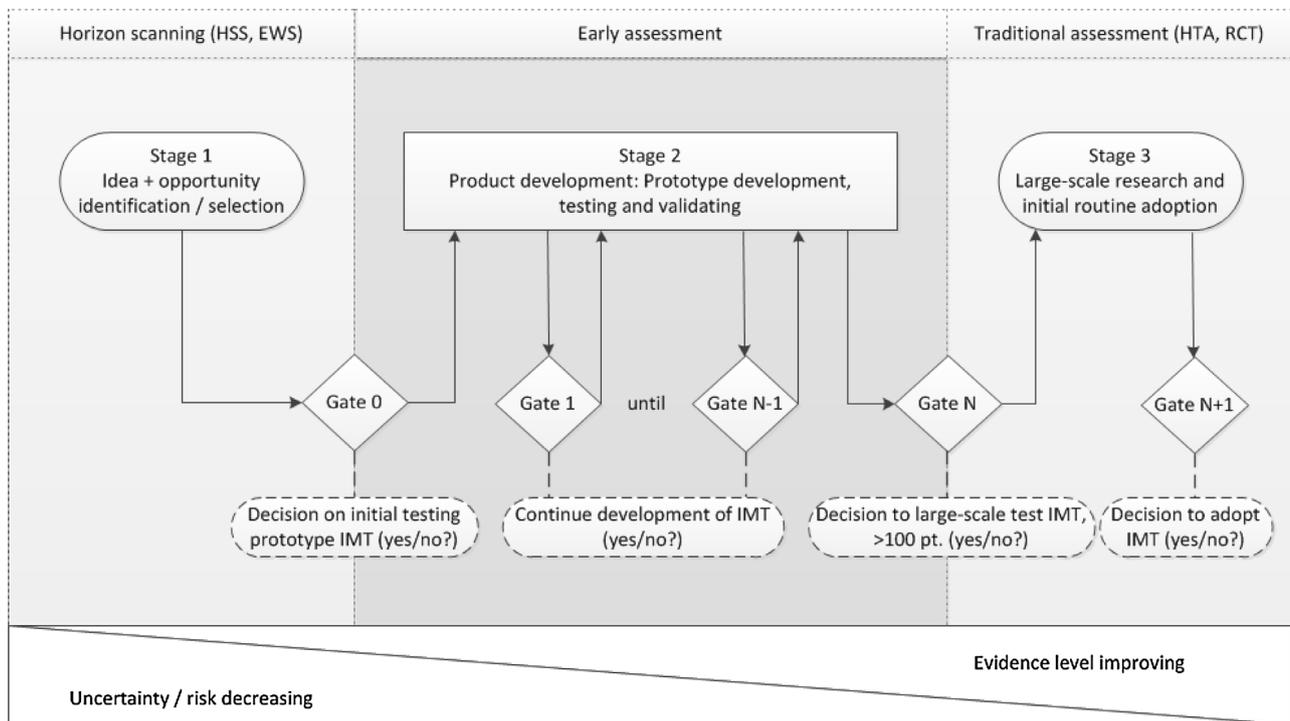


Fig. 1. Simple stage-gate model for a hospital illustrating key concepts and decision points for innovative medical technologies.

Note: HSS Horizon Scanning Systems; EWS Early Warning Systems; HTA Health Technology Assessment; RCT Randomised Controlled Trial. Fig. 1 first appeared in [7].

Traditionally, the process of product development and the related decisions depicted in “the early assessment” bar in Fig. 1 has taken place in an industry setting. After industry development and testing hospitals made a purchasing decision, i.e. decided to start large-scale clinical tests or adopt the IMT as indicated in the “the traditional assessment” bar in Fig. 1. The agreement between the two stakeholders, industry and hospital, was: “hospitals buying” and “industry developing and delivering” [8]. However, we argue that this agreement is gradually changing in many areas. Among other aspects because of an international focus on promoting public-private partnerships [9], and the aforementioned creation of dedicated innovation units in large hospitals. Consequently, hospitals are increasingly involved in developing IMTs, either internally or by working in close collaboration with the industry. However, assessing whether to invest in IMTs early on in the development process is completely different from the task of assessing mature technologies later on to see if adoption is warranted, i.e. the “hospitals buying” decision.

Today, many IMTs are developed and introduced into the health-care system before any early formal and systematic assessment is performed [10]. The lack of early evaluation is unfortunate, because it can introduce “pro-innovation bias” [11], also known as over-optimism bias in the literature [12]. It refers to the perception that any innovation will lead to increased performance or better effects, often due to unrealistic and optimistic assumptions. Also, lacking early critical assessments carries the risk that resources spend on IMT development could be used more efficiently elsewhere. Consequently, early assessment of IMTs is needed to ensure continued development of only the IMTs that have the highest potential. We use the term *potential* to describe the likelihood of realising expected effects once in routine use. Thus, potential is basically a function of the size of the expected effects and the probability of the realisation of these effects (uncertainty).

If formal evaluation is performed, it is often conducted late in the developmental process [13,14], i.e. in stage 3 in Fig. 1

using approaches like Health Technology Assessments (HTA), hospital-based HTAs, cost-effectiveness analyses, and clinical trials. However, the most commonly used assessment models in hospitals today were originally developed to assess drugs and support clinical trials, i.e. not specifically focused on the early stages [15], but rather to support stage 3 in Fig. 1. IMTs are different from these more mature technologies, e.g. in lacking late-stage trial data, involving a learning curve, and frequent price changes and product modifications occur over time [16–18].

Currently, formal early evaluation models adapted for the above challenges are used in the private health industry but often lack in hospitals [19]. Since the best approach for early assessment of IMTs in hospitals is unknown the overall aim here is to identify elements to establish a model for early assessment of the potential of IMTs in hospitals. This review provides the first stepping-stone giving a comprehensive overview of early assessment models for IMTs in health organisations described in the literature. Secondly, the review provides the basis for an initial discussion of which early assessment models or elements hold the most promise for hospital decision makers.

2. Methods

A scoping review was performed in August and September 2015 covering early assessment models in different health organisations described in the literature. Compared to a systematic review, a scoping review tends to address broader topics, where a diversity of study methodologies and designs exist. It is a fairly novel review approach, where synthesis of the included articles will often be more narrative in nature compared to a systematic review [20]. This scoping review used the methodological steps outlined in the Arksey and O'Malley framework [21] and further substantiated by Levac *et al.* [22].

The review was structured according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [23].

The following data were collected from the identified early assessment models:

- a The decision context or setting: public/private sector, technology stage/phase when evaluated, technology type
- b The decision problem (aim of the evaluation)
- c The dimensions included in the early assessment model
- d The methods used to measure, assess, or value the above dimensions focusing on:
 - a. Description of methods used
 - b. Data sources used
 - c. Handling of uncertainty in included studies, e.g. scenario analysis, probabilistic sensitivity analysis, value of information analysis, etc.
- a If iterations/updates/stages are used and how these were incorporated into the model
- b Whether cognitive biases are accounted for

In the present review an evaluation model consists of a structure of dimensions, methods and how included dimensions are synthesised (combined). Dimensions are the aspects evaluated. Further, in this review an evaluation model is multidimensional, i.e. at least two dimensions must be included for a study to constitute an evaluation model and be included in the review. Methods refer to the way the dimensions are assessed or valued (in the literature sometimes methods are referred to as an approach or procedure). Dimensions can be synthesised in a quantitative or qualitative way, or both. A well-known example of an evaluation model is the cost-effectiveness model, which apply quantitative synthesis to combine the cost and effect dimension. In contrast, the HTA model does not combine the included dimensions but typically use deliberation to discuss the included dimensions.

A scoping review usually consists of five stages, i.e. stage 1: Identifying the research issues; stages 2 and 3: Identifying relevant studies and study selection; and stages 4 and 5: Charting and collating of data, and summarising and reporting the results. This is also the organising principle below.

2.1. Stage 1: Identifying the research issues

The choice of which abstracted data to include in the review was based on the above definition of an evaluation model and partly inspired by the elements included in a systematic review in the area of early economic evaluation of emerging health technologies [24].

Further, existing practices for early assessment of IMTs have been explored in a separate interview study of early assessment models used in Denmark in pharmaceuticals, medical device industries, and public hospitals [19]. This study identified five characteristics promising for early assessment in hospitals and these findings were used to guide data abstraction of identified articles. Thus, when reviewing the included evaluation models in this review, a special focus was on 1) How early assessment studies handle uncertainty when evaluating IMTs and 2) To what extent the included evaluation models are broad, iterative, transparent, and handle cognitive biases. Cognitive bias implies a systematic pattern of deviation from norm or rationality in judgment, whereby inferences about other people and situations may be drawn in an illogical manner [12]. The term iteration is the act of repeating a process, e.g. measuring or assessing an expected effect of interest several times or update existing beliefs.

2.2. Stages 2 and 3: Identifying relevant studies and study selection

The search strategies were developed in collaboration with research librarians. Nine databases were searched: Medline (Ovid), Embase (Ovid), Cochrane, EconLit, ScienceDirect (Elsevier) as well as the following grey literature and working paper resources: ProQuest Dissertations & Theses Global, OpenGrey, Summon (Danish academic university database), and Google Scholar. A reference list search on key articles was performed. The final search strategy consisting of two clusters and the complete search strategy, including keywords and the selection criteria and how they were developed; can be found online (appendix).

Table 1 shows the final in- and exclusion criteria agreed by the review team. References from each database search were imported into database-specific folders in EndNote version X5 and duplicates were eliminated. Abstracts were first assessed by IF using the selection criteria listed in Table 1 and next each of the full-text articles was appraised independently by two reviewers (IF and KMP). Disagreements were resolved by discussion or referred to a third author. Reliability between the two reviewers' appraisals were judged by calculating the unweighted Kappa coefficient using Stata version 13 and interpreted using a described standard for strength of agreement for the Kappa coefficient [25].

2.3. Stages 4 and 5: Charting the data and collating, summarising, and reporting the results

The data described at the beginning of the methods section were extracted. Regarding data on type of IMT evaluated and sector, it was based on the actual case presented in each study. Stage of development when evaluation was carried out was based on the actual terminology applied in each study. Methods were not pre-specified but categorised on the basis of the data obtained and with inspiration from an existing table with categories (supplementary Table S2 in [26]). Data were initially extracted by IF and questions were resolved by consulting KMP. Bibliographic data and study content was collected and analysed using templates developed iteratively with feedback from the other co-authors. As recommended, the author team piloted the charting form on ten studies to determine whether the approach to data extraction was consistent with the research issues and purpose. Thus, the list of abstracted data was developed in an iterative manner with input from this piloting.

3. Results

3.1. Literature retrieval

Fig. 2 represents a flow chart of the literature selection process. In total, the literature search yielded 2362 papers. Going through the 102 full text studies, agreement to include studies was high, i.e. the calculated unweighted Kappa coefficient is 0.87, falling into the category of "almost perfect" agreement. 12 articles met the inclusion criteria, while a further 12 articles were included based on screening of reference lists in these included articles.

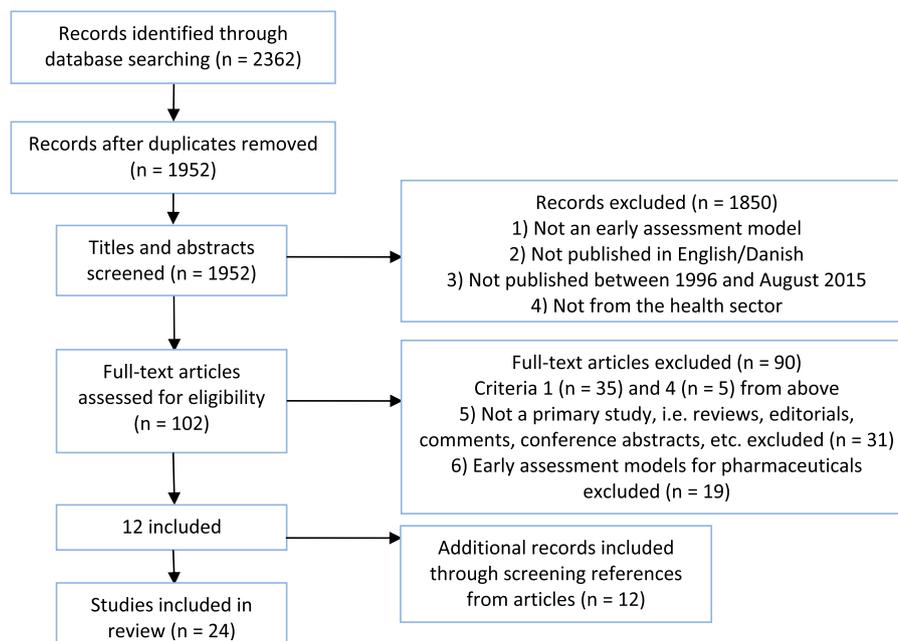
3.2. Overview of included studies

Table 2 presents the decision context and the decision problem of the 24 included studies (two studies were pooled, because they represent a similar evaluation model from the same author and thus results are reported for 23 unique entities). Eight studies present an early assessment model with a private sector perspective, seven studies have a joint perspective, seven studies indicate having a public perspective, and one study is unclear regarding perspective. Most studies evaluate medical devices (10/23), while five evalu-

Table 1
Selection criteria.

Inclusion criteria	<p>1) Studies must report the use of an early assessment model defined as:</p> <ul style="list-style-type: none"> • Study assess or evaluate the expected: success, value, (commercial) potential, routine use, impact, performance, or a similar measure, of an IMT. • At least two dimensions are included, i.e. the early assessment model deals with several aspects of an IMT. • The stage of technology development must be early (stage 2 in Fig. 1), i.e. prior to large-scale testing and after the initial selection of ideas/concepts. Hence, studies must evaluate an actual product (IMT), such as a particularly early ^apharmaceutical, technology, or early device, and a prototype must be at hand. <p>2–4) Study must be published in English or Danish, between 1996 and August 2015, from the health setting, e.g. medical device and pharmaceutical companies, hospitals and universities.</p>
Exclusion criteria	<p>5) Not a primary study, i.e. reviews, editorials, comments, thesis projects, conference abstracts, and posters.</p> <p>6) ^a Studies focusing primarily on pharmaceuticals.</p>

^a As mentioned in the online appendix, developing the selection criteria was an iterative process, which is the reason why pharmaceuticals are found in both categories.

**Fig. 2.** Flow chart: selection of the literature.

ate a subset of devices used for diagnostic purposes (tests), and three studies assess medical or surgical procedures. The remaining five studies fall into various categories. The category “Technology (broad)” is used to indicate evaluation models used for choosing between IMTs, e.g. technology transfer offices or a portfolio of IMTs and thus type of technology evaluated may vary. The stage at which evaluation is performed is usually stated in the articles, but as can be seen in Table 2, the terminology used is broad and general with most studies using some kind of variation on the terms of “early stage” or “development”. Given that most evaluation models have an industry perspective, it is not surprising that 9/23 of studies state that the reason for the early assessment is to help decide whether to continue investment in the evaluated IMT. In the public sector, it is often to support the adoption decision or to guide research efforts.

Further, Table 2 indicates that two academic research groups have been particularly active in the early assessment field and are responsible for almost half of the included studies. With one exception, all studies have an industry or joint perspective. Five studies [14,15,30,31,35] were conducted by authors affiliated with the MATCH (Multidisciplinary Assessment of Technology Centre for Healthcare) research project, which is an academic-industry-healthcare professional collaboration created in 2003 by four UK universities, see [31]. Six studies [13,34,39–41,44] were conducted by a group of researchers from the Netherlands affiliated with the

University of Twente and HTSR (Health Technology and Services Research). A further two studies [29,38] are from the Netherlands and affiliated with the University of Groningen. The remaining 11 studies [6,27,28,32,33,36,37,42,43,45,46] come from other academic institutions, e.g. universities in north America and Italy.

3.3. Analysis of early assessment models identified

Table 3 presents the included early assessment models in more detail. An explanation of all the methods mentioned below and in Table 3 can be found online (appendix). As seen from the table, the majority of studies use a quantitative evaluation model, including the two dimensions cost and clinical effectiveness ($n = 17$). The 17 cost-effectiveness studies can be subdivided into the following main methods in order of actual use in the studies: decision-analytic modelling ($n = 12$), headroom method ($n = 6$), Bayesian modelling ($n = 5$), and analytic hierarchy process ($n = 3$).

The remaining six studies (author field coloured light grey in Table 3) include more than a cost-effectiveness analysis. Retel *et al.* (2008) [39] use scenario drafting or road mapping, including patient and organisational aspects in addition to cost and clinical dimensions. Guemes-Castorena *et al.* (2014) [33] also use roadmapping, while Cosh *et al.* (2007) [30] judge the strategic fit as step one in an early assessment. Strategic considerations can be assessed by the SWOT method (Strengths, Weaknesses, Opportunities, and

Table 2
Characteristics of included early assessment models: Decision context and decision problem.

Author (year) [citation]	Decision context (sector, stage, type)			Decision problem identified?
	Sector	Stage of evaluation	Type of technology	
Ahn et al. (2010) [27]	Other industry	Research and Development	Technology (broad)	Invest/not invest, i.e. portfolio selection
Ballini et al. (2010) [6]	Public healthcare	Development	Device	Invest in research or not
Berry (2005) [28]	Joint – PPP/Both	Development	Device	Proceed to next stage of development
Cao et al. (2013) [29]	Device industry	Early, novel	Device	Invest/not invest in further development
Cosh et al. (2007) [30]***	Other industry	Early stages of technology development	Medical/surgical procedure	Invest/not invest
Craven et al. (2009) [31]***	Joint – PPP/Both	Early stage	Device	Unclear
Fenwick et al. (2006) [32]	Public healthcare	NA	Process of care	Adoption decision + future research
Guemes-Castorena et al. (2014) [33]	Public healthcare	Early stage of innovation	Technology (broad)	Invest/not invest, i.e. portfolio selection
Hummel et al. (2012) [34]****	Other industry	Development stage	Medical/surgical procedure	Invest/not invest
McAteer et al. (2007) [35]***	Other industry	Yet to be developed/development phase	Medical/surgical procedure	Invest/not invest
Pecchia et al. (2013) [15]***	Joint – PPP/Both	Development/early stage HTA	Device	Unclear
Pertile (2009) [36]	Public healthcare	Unclear	Device	Adoption/investment decision
Pietzsch et al. (2008) [37]	Device industry	Design and development	Device	Invest/not invest and support design decisions
Postmus et al. (2012) [38]	Other industry	Early stages of development	Diagnostic/biomarker	Invest/not invest
Retel et al. (2008) [39]****	Public healthcare	Early phase/early implementation	Diagnostic/biomarker	Implementation in clinical practice
Retel et al. (2012 + 2013) [40,41]****	Joint – PPP/Both	Early stages of development	Diagnostic/biomarker	Adoption, development, and research decisions
Schwander (2014) [42]	Public healthcare	Pre-clinical settings	Device	Unclear
Steuken et al. (2014) [13]****	Joint – PPP/Both	Early stage of technology development	Diagnostic/biomarker	Steer evidence development along the innovation process
Tarricone et al. (2011) [43]	Joint – PPP/Both	Early stages of use of the product	Device	Unclear
Vallejo-Torres et al. (2008) [14]***	Device industry	Early, mid, and late development stages	Device	Invest/not invest
Van de Wetering et al. (2012) [44]****	Joint – PPP/Both	Early development stage	Diagnostic/biomarker	Whether or not to continue developing the innovation
Yao et al. (2012) [45]	Public healthcare	Design stage/pre-implementation	Process of care	“Go/no go” to continue development
Ástebro et al. (2006) [46]	Unclear/unknown	Early stage R&D	Technology (broad)	Invest/not invest, i.e. venture/project selection

PPP = Private public partnership; NA = Data not available.

MATCH studies by UK Universities, **HTSR (Health Technology and Services Research) at the University of Twente and the work of Professor Ijzerman's group.

Table 3
Early assessment models: Dimensions, data sources, and methods used.

Authors	Dimensions ^a assessed?	Data sources	Quantitative synthesis (yes, no, both)? ^b	Risk analysis/uncertainty ^b
Ahn et al. (2010) [27]	a Target product profile b Market size and growth rate c Development costs d Development time e Technological complexity, novelty, etc.	Primary (internal reports) and secondary data (workshops, survey, focus groups). Multifunctional experts (e.g., scientists, business development, intellectual property)	No. Use of simple recommendation categories, Portfolio/project management approach	Unclear
Ballini et al. (2010) [6]	a Technical performance b Feasibility c Safety d Clinical effectiveness e Cost-effectiveness	Systematic literature review, expert panel	No. Adapted GRADE	Adapted GRADE
Berry (2005) [28]	a Clinical effectiveness b Costs c Cost-effectiveness	Data from related trials, historical databases, and other related diseases	Yes. Bayesian	
Cao et al. (2013) [29]	a Health outcomes b Costs	Literature, interview with clinical experts	Yes. CEA	PSA, sensitivity or scenario analysis
Cosh et al. (2007) [30] ^c	a Strategic fit b Clinical effectiveness c Costs d Cost-effectiveness		Both. Strategic planning methods, Headroom analysis, CEA, ROI	NA
Craven et al. (2009) [31] ^c	a Clinical effectiveness b Utilities c Costs d Cost-effectiveness	Literature	Yes. CUA in an Excel spread sheet	Sensitivity or scenario analysis
Fenwick et al. (2006) [32]	a Health outcomes b Costs	Literature search	Yes. CEA, Bayesian	PSA, VOI
Guemes-Castorena et al. (2014) [33]	a Technology b Investment perspective c Intellectual property d Market e Roadmap (skills, materials, equipment, milestones)	Experts	Yes. Roadmapping, AHP	NA
Hummel et al. (2012) [34] ^d	a Quality of life b Medical and technical complications c Costs	Questionnaire, expert panel of engineers and surgeons	Yes. AHP, decision tree analysis	Sensitivity or scenario analysis
McAteer et al. (2007) [35] ^c	a Health benefit b Market size c Costs	Literature, article bibliographies and references, expert opinion	Yes. Headroom analysis	Sensitivity or scenario analysis
Pecchia et al. (2013) [15] ^c	a Clinical needs b Economic needs c Technical needs	Domain experts (e.g. specialised clinicians) and potential users of the device	Yes. AHP, CEA	PSA
Pertile (2009) [36]	a Costs b Effects		Yes. Real options analysis	Unclear

Table 3 (Continued)

Authors	Dimensions ^a assessed?	Data sources	Quantitative synthesis (yes, no, both) ^b	Risk analysis/uncertainty ^b
Pietzsch <i>et al.</i> (2008) [37]	a Safety b Effectiveness c Cost	Clinical/actuarial data, expert opinion, published data, surrogate data (results from other applications)	Yes. CEA, Bayesian, system analysis	PRA, PSA, sensitivity or scenario analysis
Postmus <i>et al.</i> (2012) [38]	a Costs b Effects		Yes. Headroom analysis	PSA, sensitivity or scenario analysis
Retel <i>et al.</i> (2008) [39] ^d	a Clinical b Economic c Patient-related d Organisational		Scenarios building/drafting, roadmapping	Sensitivity or scenario analysis
Retel <i>et al.</i> (2012 + 2013) [40,41] ^d	a Effects b Costs c Cost-effectiveness	Ten scenario-related options presented as “What if . . .” statements to experts	Yes. Scenarios building/drafting, CEA	PSA
Schwander (2014) [42]	a Costs b Effects c (indirectly) high unmet medical need		Yes. CEA	PSA, sensitivity or scenario analysis
Steuten <i>et al.</i> (2014) [13] ^d	a Costs b Effects	Expert elicitation	Yes. CEA, headroom analysis	VOI
Tarricone <i>et al.</i> (2011) [43]	a Costs b Effects	Registries, observational studies, controlled trials	Yes. CEA	VOI
Vallejo-Torres <i>et al.</i> (2008) [14] ^c	a Costs b Effectiveness	Early phase: elicited beliefs and plausible assumptions	Yes. Bayesian	VOI, sensitivity or scenario analysis
Van de Wetering <i>et al.</i> (2012) [44] ^d	a Costs b Effects	Literature sources, interviews, preliminary data available, expert opinions	Yes. Headroom analysis and later CEA + Bayesian	PSA, sensitivity or scenario analysis, VOI
Yao <i>et al.</i> (2012) [45]	a Adverse events b Costs c Cost-effectiveness	Expert opinion, literature	Yes. Headroom analysis, CEA	Sensitivity or scenario analysis
Astebro <i>et al.</i> (2006) [46]	See all 37 inputs in study. Examples: a Need b Learning c Potential market d Development risk e Payback time	Questionnaire from entre-preneur: background info. of entrepreneur, brief description of the idea, patent applications, sketches, and test reports. Data from similar projects in library of previous reviews.	Yes. Simple decision heuristics	

NA = Data not available.

^a In some studies different levels are used for each dimension, e.g. sub-dimensions. However, sub-dimensions are not included in the table. Further, some of the included studies put expected, likely, or potential before the included dimensions to underline forecasting/assessing the situation at some point in the future, but almost none describe exactly when they refer to, i.e. the decision context is unclear.

^b The two last columns show the methods used to assess included dimensions, i.e. valuation, and methods used to assess risk/uncertainty. A detailed description corresponding to the roman numbers mentioned below in parenthesis can be seen in the table online (appendix). **Valuation methods:** strategic planning methods (10), portfolio/project management approach (16), headroom analysis (I), CEA (cost effectiveness analysis, II), CUA (cost-utility analysis, VI), roadmapping (VIII), scenarios building/drafting (IX), ROI (Return on investment, X), AHP (analytic hierarchy process, XIII), Bayesian (Bayesian modelling/statistics, XV), real options analysis (XVII), decision tree analysis (XIX), system analysis (XX), simple decision heuristics (XXI). **Risk methods:** PSA (Probabilistic sensitivity analysis, III), sensitivity or scenario analysis (XXII), VOI (Value of information analysis, XIV), PRA (Probabilistic Risk Analysis, XVI, adapted GRADE (XXIII).

^c MATCH studies by UK Universities.

^d HTSR (Health Technology and Services Research) at the University of Twente and the work of Professor Ijzerman's group.

Threats [47]. The remaining three studies, Åstebro et al. (2006) [46], Ahn et al. (2010) [27], and Ballini et al. (2010) [6] use five or more dimensions. In Åstebro et al. (2006) [46], a simple decision heuristics is developed to weight the different dimensions. Ahn et al. (2010) [27] use a portfolio/project management approach and simple recommendation categories regarding further development, while Ballini et al. (2010) [6] have their own methods with an “evidence mapping” exercise at the core.

As indicated in Table 3, a total of 17 studies (74%) handle risk/uncertainty. Popular methods include sensitivity/scenario analysis (mentioned 11 times) and probabilistic sensitivity analysis (mentioned eight times). Not so commonly used methods are value of information (mentioned five times), engineering risk analysis, and adapted GRADE (once each). Further, information about the use of iterations or stop/go rules in the early assessment model was collected. A total of 13 studies (54%) mention that iterations or updates should be used or are advisable in their early assessments, but only five studies (21% of all included studies) seem to have actually incorporated iterations or stop/go rules into their early assessment model [6,13,14,30,44].

Lastly, some studies mention cognitive biases in relation to early assessments, e.g. the issue of optimism bias is found in five studies (21%) and two studies (8%) comment on being aware of involving people with commercial interests in the IMT. Yao et al. (2012) [45] note: “. . . estimates of effectiveness should be elicited from domain experts who do not have a psychological or material personal stake in the outcome”. Most of the studies do not account for these biases actively in the early assessment model, neither analytically nor process wise.

4. Discussion

4.1. Findings

The presented scoping review regarding early assessment models of the potential of innovative medical technologies in the private and public sector yielded 24 papers matching the inclusion criteria. These studies were almost evenly divided into three groups based on their perspective: 1) Manufacturers of IMTs, 2) A public health care perspective, or 3) Joint perspective evaluation models. Terminology was generally unclear regarding stage of evaluation and it was often difficult to identify the decision context or problem, which was neither specific nor concrete. The majority of studies presented some kind of quantitative cost-effectiveness analysis for doing early assessment and uncertainty was most often handled by simple or unspecified sensitivity or scenario analysis. Around one fourth of the studies presented an evaluation model with more than clinical end economic effects, i.e. a focus broader than cost-effectiveness. Iterations or stop-go rules were advised by most studies and actually implemented into about one fifth of the described evaluation models. A few studies mentioned cognitive biases in relation to early assessments.

4.2. Comparing findings with the literature

The current review found that the majority of included evaluation models had a narrow focus on cost-effectiveness, and that fairly similar methods were used to measure the cost and effect dimensions with a high weight on quantitative synthesis. In contrast, a recent systematic review of theory and practice in early assessments of medical devices showed that more dimensions than costs and clinical effects are relevant in early assessments, and in the studies included in this review, the methods to measure dimensions varied a lot [26]. This difference in findings between the two reviews may reflect that the present review is limited to evaluation

models defined as more than one dimension, whereas the other review includes early assessments of only one dimension, i.e. user aspects or strategic aspects, etc.

This review highlights the often weak characterisation of the decision problem and context, e.g. the very general terminology used in the area of early assessment models. Only rarely the included studies devote efforts towards defining the exact meaning of “early phase” and often what is meant by early assessment of “value/potential”, is unclear. This challenge is also raised in a report from the EuroScan International Network regarding methods used in early awareness and alert systems [10]. Further, a study reviewing decision making in the early phases of product development in the health industry found that only 13 out of 83 included early assessment studies disclose any concrete decision context [48]. Part of the reason for the underdeveloped terminology in the area is probably that the area of early assessment is still rather new and immature. For instance, this review identified only two large research groups working in the area. Another explanation could be that many studies aim at an early assessment model that can be used in both private and public contexts, which may hinder a precise terminology since the sectors differ, e.g. the decision problem is not identical.

4.3. Promising elements for an early assessment model for hospitals

A separate aim of the current work was to discuss promising elements for an early assessment model for hospitals. Results from an interview study [19] suggest that a hospital early assessment model will most likely benefit from having the following characteristics: 1) Including a broad set of dimensions, 2) High transparency, 3) Incorporating iterations, and 4) Describing uncertainty and risks regarding the IMT. Next, the relevance of the 24 evaluation models for hospitals will be discussed in the light of these findings, i.e. the four characteristics.

About three quarters of the evaluation models in this review only assess two dimensions (cost-effectiveness). Further, the most common methods used to assess cost-effectiveness are undoubtedly time-consuming to perform, like the Bayesian modelling, decision-analytic modelling, and analytic hierarchy process (descriptions of all the mentioned methods are found online in appendix). However, six studies present an evaluation model with a broader focus than cost-effectiveness. Three of the evaluation models are developed for venture or portfolio selection: In Åstebro et al. (2006) [46], a simple decision heuristics is developed to weight the different dimensions, Ahn et al. (2010) [27] use a portfolio/project management approach, while Guemes-Castorena et al. (2014) [33] use roadmapping. Roadmapping is also used by Retel et al. (2008) [39] as well as scenario drafting. Cosh et al. (2007) [30] judge the strategic fit as step one in an early assessment, while Ballini et al. (2010) [6] have an “evidence mapping” exercise at the core of their evaluation model. Examining the six studies in detail, it became apparent that the two roadmapping studies [33,39] are very difficult to understand, i.e. they have low transparency, and further seem to be time-consuming. Promising and seemingly transparent elements in the remaining four studies are: 1) the idea of a “strategic fit” gate, 2) the evidence mapping exercise, 3) integrating project management tools directly in the early assessment model, and 4) the use of simple recommendation categories (from A-E) going from “recommended for development” down to “strongly recommend to stop further development”.

Regarding iterations or stop-go rules the evaluation model by Cosh et al. (2007) [30] is of particular interest. They present a simple stop/go algorithm for investment decisions for IMTs with the following stages: strategic considerations, clinical problem, headroom analysis, return on investment analysis, and further economic

analysis. This approach can be augmented with a broader selection of dimensions or considerations more relevant for hospitals. In the 24 evaluation models, uncertainty was most often handled by univariate or unspecified sensitivity analysis or scenario analysis, which should be adequate for hospitals as well.

4.4. Strengths and limitations

To the best of our knowledge, this work is the first attempt to review early assessment models in a wide area of health organisations and technologies. A comprehensive search including nine databases was performed. Due to the immaturity of the early assessment area, the systematic review approach was abandoned and the scoping review methodology was applied. Scoping reviews are an increasingly popular methodology for synthesising evidence [49], especially regarding health topics, where a scoping review of scoping reviews shows that nearly three quarters of reviews addressed a health topic [20]. Scoping reviews have the potential to be less critical in their approach. In this case, a research librarian participated in the development and execution of the search strategy, and choices in our review are very explicitly stated to improve reproducibility as recommended in a guide to obtain validity and reproducibility in reviews [50]. For example, how the search strategy was developed and the criteria for inclusion (see online appendix for details about the choices made) are transparent with much effort going into refining both components and documenting the iterative nature of this process. Further, supporting the high reproducibility and reliability of this review is the high kappa value between the two reviewers who judged studies for final inclusion.

While performing preliminary searches for this review, a systematic review of early assessment of medical devices was found [26]. Their aim was to review methods for early assessments of devices, whereas this review investigates evaluation models for early assessments of devices, medical/surgical procedures, and processes of care. On the one hand, the present review is wider and not limited to studies on devices. But still, far fewer studies were included than in the device review [26], because inclusion in our review was limited to studies having at least two dimensions to qualify as an evaluation model. The few included studies in this review made it feasible to report systematically and in detail on all the included studies, i.e. giving a novel and thorough overview decomposing each evaluation model into included dimensions, sources of data, methods, and other assumptions regarding the early assessment models. This level of detail is required when looking for promising elements for an evaluation model based on needs from the hospital perspective.

Looking at a similar topic, but from different angles and with different aims, there was great inspiration in the published search strategy in [26] while constructing the final search strategy. Still, it is a challenge to construct a solid search strategy in this immature area and important studies might have been overlooked by a simpler search strategy or the stricter inclusion criteria compared to [26]. For example, using the criteria for inclusion of studies that an actual product must be developed could have been too narrow and have overlooked important evaluation models. Also, excluding Horizon Scanning System studies in the review might have excluded interesting evaluation models. The innovation literature regarding evaluation might also have yielded interesting evaluation models. An update of the literature search may have added extra studies. However, the authors have been keeping a close eye on any new literature arriving and no substantial new early evaluation models have been detected since the review was performed in late 2015. Lastly, that 100% new eligible references came from reference list searching in the originally identified studies support that this is an immature area which is difficult to cover.

4.5. Future directions

Markiewicz, van Til and Ijzerman [26] concluded that for early assessment to become an integral part of activities in the development of medical devices, methods need to be clarified and standardised. We agree with the need for clarifying methods, but argue that this need for clarity should be preceded by or extended to include more precision when describing the decision problem, context, and terminology like “early” and “value”. The key point in building an early assessment model must be to know exactly to which end the early assessment model serves, i.e. the decision problem and context must be clearly described, which, as this review shows, is often not the case. Further, deciding upon how fast the early assessment should be to conduct, which dimensions to include in an early assessment, how to synthesise the evidence, etc. is important. Having settled all that, focus can move on to which means (methods used to measure the included dimensions) to apply to achieve that part.

5. Conclusion

Early assessment exists in healthcare and this review has identified 24 early assessment models. The majority of these evaluation models are considered immature, i.e. the terminology describing the decision problem, context, and key terms is very unclear. Known methods focusing on assessing cost-effectiveness constitute the core of the majority of evaluation models and they lack clarity about the meaning of “early” in this context, and how this translates into an evaluation model, e.g. cost-effectiveness analysis. Thus, most evaluation models are characterised by: 1) few dimensions, 2) recommendations on an iterative approach – but not actually doing it, and 3) handling uncertainty in simple ways. A few studies acknowledge the importance of human cognitive biases, but few handle this issue analytically.

Lacking a large number of included dimensions most of the identified evaluation models are not suitable candidates as inspiration for the development of an early assessment model aimed at assessing the potential of an innovative technology for hospitals. Four of the “broad evaluation models” included in this review did contain some relevant knowledge for hospitals and could be applied as inspiration for further development. In view of the huge investments in IMTs we advocate for a general basic tool for early assessment of innovative technologies in particular within the health service sector. As shown by this scoping review no such instrument is generally agreed upon.

Conflicts of interest

None.

Acknowledgements and funding

We would like to thank librarian Joanna Bielecki from Toronto Health Economics and Technology Assessment Collaborative (THETA) for very professional and competent guidance in helping to focus the search strategy and with performing searches. Tove Faber and colleagues from the hospital library service “Videncentret” at Odense University Hospital (OUH) provided valuable comments regarding a very early search strategy. From the HTA unit at OUH, Janne Buck Christensen and Mette Bøgg Horup provided valuable comments on an early draft of the article while Anne Mette Ølholm provided literature about the Kappa statistics.

This work has been supported by: 1) The faculty of Health Sciences at University of Southern Denmark through a PhD stipend, 2) the European Union (EU) project SmartCare. The funders had no

part in the study design, data collection, analysis, interpretation of data, or the writing of the article. Also, they had no influence on the decision to submit for publication. Writing assistance was used and paid by the University of Southern Denmark.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.healthpol.2017.06.006>.

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