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RESEARCH ARTICLE

Early realistic assessment of the development of innovative medical technologies in hospitals (EARTH): a conceptual model

[Évaluation réaliste précoce du développement de technologies médicales innovantes dans les hôpitaux (EARTH): un modèle conceptuel]

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Abstract: Hospital innovation centres increasingly make decisions concerning early development of and investment in innovative medical technologies (IMTs). At present, decisions are often made without applying a formal early assessment process to ensure selection of the most promising candidates for further development. This paper conceptualises and presents a novel model for early realistic assessment of the development of innovative medical technologies in hospitals (EARTH). The development of EARTH was based on results from a qualitative interview study exploring early assessment models in 11 organisations and a literature review of 24 models. The findings, combined with an appraisal of the models holding the most promise for hospital decision makers, led to EARTH. Eleven early assessment principles for EARTH were identified and used to create a guideline for performing and organising early assessment. The guideline consists of an analysis track and a decision track supported by three templates and five methods. In the analysis track, an impact case, a risk analysis and a "critical questioning" procedure are key elements, while in the decision track, an "evidence threshold" for "go" to usual clinical testing is essential. A model for early assessment in hospitals is proposed. EARTH (theoretically) demonstrates how a hospital can add rigour to decision making on which IMTs to pursue for further development and usual clinical testing. EARTH exhibits several desirable features relevant for early assessment, compared to traditional assessment models actually applied in hospitals. We thus believe that early assessment carries the promise of improving hospitals' investment decisions and resource allocation during development.

Keywords: early assessment, hospitals, health technology assessment, model.

Résumé : Les centres d'innovation hospitaliers prennent de plus en plus de décisions en matière de développement précoce et d'investissement dans les technologies médicales innovantes (TMI). À l'heure actuelle, les décisions sont souvent prises sans recourir à un processus d'évaluation précoce formel afin de garantir la sélection des candidats les plus prometteurs pour un développement ultérieur. Cet article conceptualise et présente un nouveau modèle d'évaluation réaliste précoce du développement de technologies médicales innovantes en milieu hospitalier (EARTH). Le développement d'EARTH est basé sur les résultats d'une étude qualitative par interviews explorant les modèles d'évaluation précoce de 11 organisations et d'une revue de la littérature de 24 modèles. Les résultats, combinés à une évaluation des modèles les plus prometteurs pour les décideurs des hôpitaux, ont conduit à EARTH. Onze principes d'évaluation précoce pour EARTH ont été identifiés et utilisés pour créer une ligne directrice permettant d'effectuer et d'organiser une évaluation précoce. La ligne directrice comprend une piste d'analyse et une piste de décision reposant sur trois modèles et cinq méthodes. Dans la piste d'analyse, un cas d'impact, une analyse de risque et une procédure de «questionnement critique» sont des éléments clés, tandis que dans la piste de décision, un «seuil de preuve» pour «passer» aux tests cliniques habituels est essentiel. EARTH montre (théoriquement) comment un hôpital peut ajouter de la rigueur à la prise de décision concernant les TMI à choisir pour poursuivre un développement approfondi et procéder aux tests cliniques habituels. EARTH présente plusieurs caractéristiques souhaitables pour une évaluation précoce, par rapport aux modèles d'évaluation traditionnels actuellement appliqués dans les hôpitaux. Nous pensons donc que l'évaluation précoce permet d'améliorer les décisions d'investissement des hôpitaux et l'allocation des ressources au cours du développement.

Mots clés : évaluation précoce, hôpitaux, évaluation des technologies, modèle.

Introduction

Why is early assessment in hospitals needed?

Traditionally, the implicit agreement between industry and hospital when developing innovative medical technologies (IMTs) has been: "hospitals are buying" and "industry is developing and delivering" [1]. However, as part of the increasing technology development and digitalisation of the healthcare systems, hospitals establish centres for innovation [2, 3] and dedicate substantial local funding and resources in developing IMTs. Hospital-based strategic venture funds exist for innovations [4], grant funding programs to promote innovation at academic research hospitals [5, 6], public-private partnership programs [7], etc. In this setting, hospital innovation centres are increasingly involved in designing, developing, testing and optimising IMTs, either internally or in close collaboration with industrial partners. However, as argued later, current assessment models in hospitals aim to support the adoption decision which is not appropriate for supporting hospitals in making choices about pursuing or discontinuing the development of IMTs. Early decision support and a formal early assessment process are needed and may provide hospitals with the following benefits:

1) The ability to discriminate potentially promising IMTs from less advantageous ones early in the process, and thus avoiding misallocating public resources [8]

2) Early influence on an IMT's value proposition [9] by setting goals for the IMT and getting confirmation of need by clinicians and patients early on

3) A system that safeguards against "pro-innovation bias" [10], i.e. the perception that any innovation will lead to increased performance, often due to unrealistic assumptions and optimism bias [11].

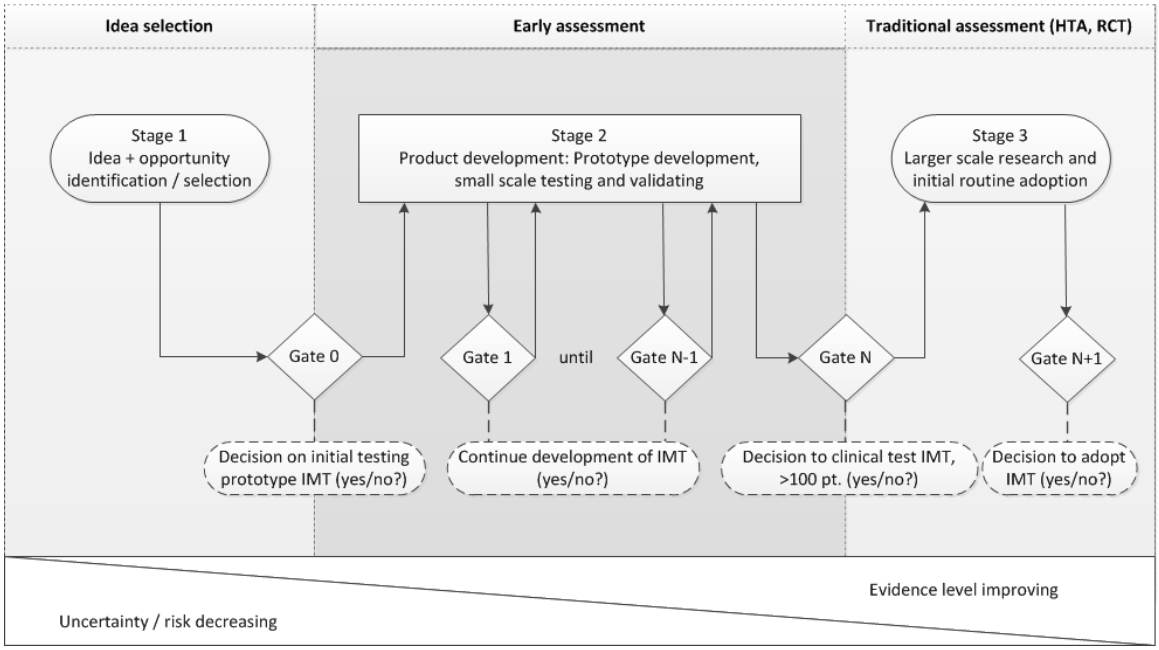
Describing IMTs

Figure 1 provides an overview of key concepts and decision points relating to the development of IMTs in hospitals. This figure was developed with inspiration from the stage-gate model [12] which is widely used for controlling R&D processes in large companies. In Figure 1 there is a distinction between idea selection, early assessment (the topic at hand) and traditional assessment.

IMTs are characterised by significant modification in features, design, or properties before introduction into clinical practice and the challenge in the early assessment stage (stage 2) is that limited data are available with a high level of uncertainty concerning the expected effects, as illustrated in the bottom part of Figure 1 [13]. Examples of hospital developed IMTs are medical devices, medical/surgical procedures, processes of care, and clinical health information systems, e.g. telemedicine, eHealth, health apps, robotics, etc. Recent examples include an app for early discharge postnatally [14], an automatized medical ultrasound examination and interpretation robot [15], telemedicine training after hospitalisation with severe chronic obstructive pulmonary disease [16], and 3D camera for ulcer treatment and care [17].

Defining early assessment in hospitals

Early assessment or early HTA (health technology assessment) to inform the industry has received much attention over the past 25 years [18-20] but still lacks clear terminology [19] and the methods applied vary substantially [8, 19, 21]. Due to the novelty in a hospital setting, it is unclear what constitutes early assessment (stage 2 in Figure 1) in a hospital context. Hence, in order to develop a hospital definition the most frequently used industry definition is used as a starting point [22]: *early HTA is referred to as the use of economic evaluation in early stages of product development mainly to inform industry at the time that investment decisions are made*. In this context, decision support is provided for the early mitigation of risks associated with market access and reimbursement [19].



HTA Health Technology Assessment; RCT Randomised Controlled Trial. Figure 1 is reproduced with permission from [13].

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

However, hospitals have limited need of decision support regarding risks associated with market access and reimbursement, and, if relevant, market access activities will happen elsewhere and at a later stage in the technology development. Moreover, only 30% of IMTs are devices [5] and hence hospital developed IMTs often require none or very limited regulation. Furthermore, the narrow focus on economic evaluation in the definition above is inadequate in a hospital context. IMTs developed by hospitals are adapted and developed in the setting where they may be introduced into clinical practice later. It is thus relevant to include effects for the patients and the organisation [23] and the necessary behavioural changes for staff and patients as they may be a prerequisite in achieving clinical and economic effects of an IMT [24]. Lastly, when assessing an IMT early in the process, an iterative approach, rather than conventional single-point-in-time evaluations, is advocated [25, 26]. In view of the above considerations we propose the following definition of early assessment for hospitals:

Early assessment supports hospitals in making choices about pursuing or discontinuing development of IMTs by iteratively assessing the potential of IMTs in the absence of evidence from usual clinical studies and a high degree of uncertainty

The concept *early* refers to when an initial selection of ideas or rough prototyping has taken place, but prior to traditional clinical trials, i.e. stage 2 in Figure 1. *Assessment* is the task of valuating or evaluating the consequences or effects of an IMT. Thus, *early assessment* is iteratively evaluating the expected effects based on feasibility, pilot or initial effect data from small scale testing of the IMT up until Gate N in Figure 1. The term *potential* is applied to describe the likelihood of realising the expected effects once in clinical practice. As argued above, the expected effects must cover a broader range of domains compared to the industry definition.

Where to gain inspiration for early assessment in hospitals

The traditional HTA model [27] was developed for health technologies ready for

adoption or use in clinical practice, and not focused on technology in the early (development) stages [28]. Hospital-Based HTA [23, 29] and MAST (Model for ASsessment of Telemedicine) [30] essentially originate from traditional HTA. These frameworks are not relevant for an early assessment since adoption and not development decisions are supported. Lastly, Horizon Scanning Systems (HSS) and Early Warning Systems (EWS) [31-33] are not suitable as they are developed to alert the national level to changes on the horizon and not to support development.

Table 1 below presents an overview of all the above-mentioned assessment models and the suggested new model for early assessment in hospitals (model 2) and compares them in four dimensions.

Table 1: Similarities and differences between commonly used assessment models and the suggested new model

Model / Dimension	1: Early HTA for industry	2: Early HTA for hospitals	3: Horizon scanning, i.e. HSS and EWS	4: Traditional HTA, (MAST and HB-HTA)
1) Domains assessed	Clinical, economics	*Broader than model 1	Clinical, economics, organisational	Clinical, economics (+strategic, patients and organisational)
2) Decision support (for whom, on what)	Manufacturers and investors Design and management of a technology + regulatory and reimbursement strategy	Hospitals (and public investors) Design and management of a technology + behavioural change strategy	National or regional public agencies Pointing awareness to changes on the horizon that could impact adoption and diffusion	Management on various levels (local hospitals, national etc.) Adoption decision
3) Available evidence/data	Feasibility, pilot, or initial effect data from early clinical experience and previous generations of the technology			Usually evidence from clinical studies
4) Influence on technology	High		Medium (development decisions elsewhere)	Limited

This table is inspired by data published in Pietzsch and Paté-Cornell [20]. Information on assessment models presented in columns three and four: Horizon Scanning Systems (HSS) and Early Warning Systems (EWS) [31, 32], traditional HTA [27], MAST (Model for ASsessment of Telemedicine) [30], and HB-HTA (HospitalBased-HTA) [23, 29].
* The decision on which domains to include is made later in this study.

Table 1 is based in part on data published by Pietzsch and Paté-Cornell [20] but augmented and adapted to include horizon scanning and the suggested new model for early assessment in hospitals. Table 1 shows how available evidence and influence on technology (dimensions three and four) are similar in early HTA for industry and hospitals. Decision support is also partially similar. Hence, private sector early assessment models may provide relevant inspiration for the development of a

hospital model. However, the differences in decision support and domains assessed between early HTA for industry and hospitals suggest some important transferability issues which need to be considered when developing an early assessment model for hospitals.

Objective

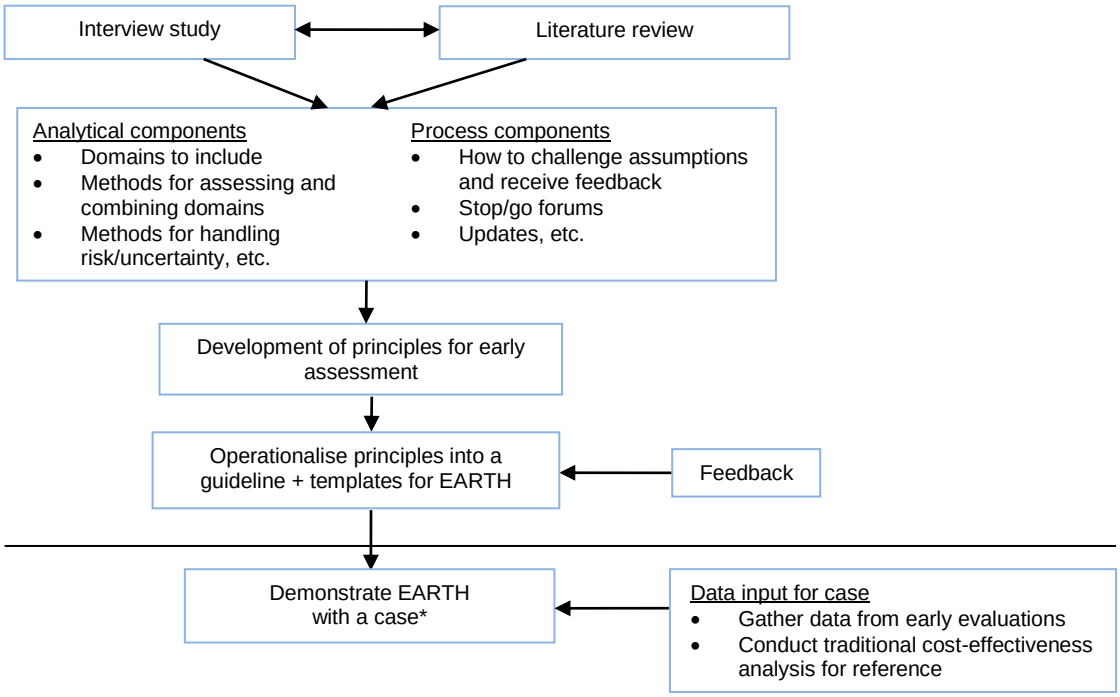
On this background, this conceptual paper aims to develop and present a model for early assessment of the potential of IMTs from the hospital management's point of view. The model is developed in two steps:

1. To develop analytical and process principles for early assessment in hospitals based on findings from a literature review and interviews in different health organisations
2. To present the EARTH model, i.e. the guideline for the analysis and processes of early assessment and the supporting templates needed for carrying out early assessment in hospitals

In the following, *principle* refers to a fundamental value, rule or basic notion extracted and generalised from a series of data/cases which ought to be followed [34]. A *guideline* is used for setting a course of action and streamline particular processes according to a set of routines or sound practices [35] which should make activities more transparent and predictable by outlining the division of labour; who does what, when and how in early assessment. *Templates* constitute a set reporting format for the early assessment analysis.

Methods

The following presents the reasoning on how EARTH was developed. This is rarely seen as most assessment approaches, e.g. HTA and economic evaluation (cost-effectiveness analysis, cost-utility analysis), evolved over time through trial and error along with analytical work. To a considerable extent, even the fairly new MAST model was an extension of HTA. The construction of EARTH followed the process outlined in Figure 2.



* The practical application of EARTH (the first step below the black line in the figure) is presented in Appendix 3 while the complete data input for the case is presented elsewhere [13].

Figure 2. Process to construct EARTH.

In summary, EARTH is based on the findings from two studies. First, a qualitative interview study explored how early assessment is performed and perceived in 11 Danish organisations, eight in the private pharmaceutical and medical device industries and three in public hospitals [36]. A mix of convenience and the purposive sampling procedure of maximum variation was used to select interviewees. The study population consisted of experts and professionals from large device and pharmaceutical companies and university hospitals, working in an R&D or innovation unit. Eleven interviews were conducted: ten face to face and one as a telephone interview. Content analyses of interview notes were performed. Secondly, a scoping review of published studies between 1996 and 2015 was performed using nine databases [37]. Each of the included full-text articles was appraised independently by two reviewers. This literature review provided an overview of 24 models for early assessment of innovative medical technologies used in the medical device industry and public healthcare organisations. The two studies are interlinked, indicated by an arrow between the two top boxes in Figure 2. The literature from the preliminary review guided the themes in the interview, while data retrieved in the review was in part guided by topics identified in the interview study. As indicated in Figure 2, the findings from the two studies were reported as possible components for early assessment and then converted into principles for EARTH. Based on these principles, a guideline was developed for an early assessment in a hospital context, and the templates needed are described in general terms. Together, the guideline and templates constitute the EARTH model.

All findings from the interviews and the literature review were initially grouped into similar topics and into analytical or process components. The analytical components are the domains to be included, methods used to assess domains and risk, how to combine domains, etc. The process components are the organisational processes, e.g. who decides what and when are updates used in the process of early assessment, etc. These components were converted into a set of principles that steered the development of a guideline supported by templates and methods for carrying out early assessment. The principle(s) on which each step in the guideline is based is documented in Appendix 1. When formulating the principles, any disagreement between the findings from the two data sources was resolved by using the literature on the subject in order to reach a decision. However, the contents of a few principles were formulated in very general terms, e.g. methods for assessing and combining domains, and they needed further operationalising to be useful in the development of the early assessment model. In these cases, a principle was unfolded and concrete methods were suggested or justified through a discussion and appraisal in relation to the specific decision problem and context of hospitals.

To simplify, Figure 2 depicts a linear process, although the development of EARTH was an iterative process, much like the processes of developing the Danish HTA model [27], the mini-HTA model [29] or the MAST model [30]. As indicated in Figure 2, there was a feedback session after the guideline and template development to improve the quality and relevance of EARTH. We obtained external feedback from an academic seminar with three health economists and four PhD students in the field of health economics and a two-hour presentation of the guideline in an HTA module on IMT for six engineers and an HTA senior researcher in IMTs. An external review of the proposed model was performed by a total of four experienced individuals thoroughly versed in the area of evaluating IMTs.

Standard project management terminology and tools are used in the result section. They are assumed known to readers and can be found in any project management literature, e.g. Olsson and Ahrengot [24].

Results (the EARTH model)

EARTH principles

Table 2 contains two groups of principles for EARTH: six analytical principles (A0-A5) and five process principles (P0-P4). The development of these principles was based on the findings from the review and interviews reported in Appendix 1.

Table 2: Analytical and process principles for EARTH

Analytical principles for EARTH	Process principles for EARTH
A0) Use EARTH as an internal hospital decision aid to provide a transparent and easy to communicate analysis and process of early assessment	P0) Use neutral and experienced employees in the early assessment process, including a routine procedure for declaring competing interests. The use of standard project management tools should be integrated in the evaluation model.
A1) Include several domains in the model, e.g. strategic fit and clinical and technological aspects, and do not aggregate by weighing and construction of an overall value	P1) Establish dedicated prioritising committees for IMTs
A2) Address risk/uncertainty using simple techniques	P2) Perform critical review or challenge of assumptions and falsification whenever possible, invite dissent and broad involvement, and include an external challenge on the analysis
A3) Use a limited number of Key Performance Indicators (KPIs), track progress over time, and invest considerable effort into estimating the relevant target group or patient population for a given IMT as often this is a vital KPI	P3) Use fixed categories when reporting the potential of an EARTH assessment
A4) Use a mandatory evaluation plan to gradually increase evidence on KPIs, indicate strength of the evidence and data sources	P4) Use a phase model or iterative model with updates every 1 to 12 months
A5) Use fixed evaluation templates and include a "What has changed since last update" field	

A=Analytical; P=Process; Key Performance Indicators (KPIs); Innovative Medical Technologies (IMTs)

Analytical principles

The A0 (A is short for analytical in the following section) principle points to EARTH as an internal decision aid providing a transparent and easy to communicate analysis and process, e.g. how the stop/go decision is reached. It may be difficult to promote honest and realistic assessments if these are made broadly available outside the hospital.

The A1 is the principle of including many domains and not scoring them. The five main domains stressed in the interviews are: 1) strategic fit, 2) clinical or technological aspects, 3) patients' aspects, 4) organisational aspects, and 5) economic aspects. However, the five domains do not correspond with findings from the literature review study, where the majority of models includes only domain two and five from the above list. The five domains are supported by another literature study on European

hospital managers' need for information on health technology investments [38]. Furthermore, for simplicity, a tradition for non-scoring in hospitals, and ease of communication of the EARTH model, a non-scoring approach is preferred. Scoring implies that domains included are assigned a weight and a score, and by multiplying these a rating is obtained which can be used for ranking projects [39]. Although scoring approaches were found to be popular in our review study, we believe it may complicate the model unnecessarily. In addition there is no tradition for applying scoring in hospitals [23] or in the organisations investigated in the interview study. Some examples of non-scoring models in healthcare include the Canadian decision determinant framework [40], the (Danish) HTA model [27] and HB-HTA models in Europe [23, 29].

The A2 principle is using simple methods for handling and illustrating risk and uncertainty, which is supported by both inspiration sources for the model. For both qualitative and quantitative domains, traditional project management tools, like probability of an event multiplied by impact, are popular for this purpose. A simple method called the "risk burn down" approach [41] combines the much used method of probability of an event multiplied by impact with the development in expected and actual risk. Over time, the risk needs to be reduced, i.e. burned down.

The A3 principle is picking and tracking a limited number of key performance indicators (KPIs), including the patient/target group – a vital KPI for most IMTs. A maximum of 5-10 KPIs is considered manageable [42]. Goal-setting for KPIs are done after the SMART principle, i.e. goals must be Specific, Measurable, Achievable, Relevant and Time-bound [24]. In recent project management literature a concrete method, a so-called impact case, is recommended [24]. An impact case describes the impact resulting from the project (IMT), for instance increased wound healing, and how to measure this impact during and after the project. The overall impact (potential) is decomposed into three groups of KPIs: the overall impact, business impacts and behaviour impact. In a hospital context, business and behaviour impact roughly translates into economic and organisational/patient aspects while the overall impact equals the clinical aspects. The strategic fit can be assessed by the SWOT method (Strengths, Weaknesses, Opportunities, and Threats) [39], whereas an impact case can cover relevant KPIs from the remaining four domains [24]. The "waterfall method" can be used to improve the estimation of the relevant patient group by breaking down the total patient population into greater detail [36].

The A4 principle points to the mandatory use of an evaluation plan. It is important to plan for gradually better data gathered to act as "reality checks" on KPIs. Early estimates, like expert opinions, should meet reality in the form of hard(er) data as soon as possible to steadily build a stronger evidence base for the IMT. An evaluation plan can do exactly this and is a tool similar to the concept of a pre-analysis plan in clinical research. Like a pre-analysis plan, the evaluation plan should be decided at the onset of the IMT development, and when agreed to, it must be followed. Making the evaluation plan mandatory and not to be deviated from is essentially imposing a Ulysses contract, a freely decided strategy designed and intended to bind oneself in the future to one desired course of action [43].

The A5 principle recommends the use of templates and tracking of changes. Fixed templates are recommended in the literature [44] and help reduce the cognitive load or stress for busy executives (and so does the use of a phase-model advocated later on in P4).

Process principles

The P0 principle (P is short for process in the following section) is neutrality, experience, and integrating standard project management tools in the evaluation model. Experienced employees can draw on knowledge from previously assessed IMTs

when performing the early analysis and also provide a more effective challenge (elaborated in P2). Conflict of interest disclosures must be signed as recommended for HTA reports to avoid bias [45].

The P1 principle points to the need for a dedicated prioritising committee for IMTs. It is important to separate the IMT development processes and involved staff from the stop/go decision.

The P2 principle stresses the importance of challenging assumptions along with an external review. In the interview study it appeared that a devil's advocate process was common in many of the organisations. A person takes on the role of the devil's advocate trying to point out weaknesses of the assumptions/logic underlying expected effects, internal contradictions, and problems, which may lead to failure [46]. The premortem ("early death") tool [47] can further help identify risks early on by picturing that the IMT has failed and identify why. In a premortem process, each person independently writes down every reason for the failure they can think of and this information is subsequently used for strengthening the risk analysis [47].

The P3 principle is the principle of using fixed categories when reporting the potential of an EARTH assessment. An A-E-rating is used with the following categories: A—recommended for development, B—may go forward, but need to collect more data, C—recommended to go forward, benefits likely modest, D—doubtful, further development not recommended, E—strongly recommend to stop further development. When the committee rates the potential of an IMT, it should be kept in mind that only 8-15% of IMTs (across a portfolio) will become successful and end up in routine clinical practice [36].

P4 stresses the use of an iterative model with updates every 1 to 12 months on KPIs depending on the calendar length of the early assessment stage. A dynamic assessment of the potential is important for the tracking of the development in the potential over time. Consequently, a follow-up on the uncertainty/risk and expected effects (KPIs) is necessary as indicated in principles A2 and A4 as they constitute the two cornerstones of potential.

The guideline and needed templates

In order for the 11 principles in Table 2 to become relevant in practice, the principles were converted into a guideline structured along two tracks, an analysis track and a decision track. Figure 3 provides an overview of the EARTH guideline with the two tracks separated by a timeline in the centre. An early assessment process involves a total of six steps with step 3 to 5 repeated for each update.

It is useful to distinguish between four groups of individuals, A-D, involved in early assessment (proposed members of all groups can be seen in Appendix 2):

A. The evaluation team headed by a neutral analyst (an experienced person from an independent analysis unit without personal contact with the entrepreneur)

B. The prioritising committee (senior management, clinicians, external members, patients)

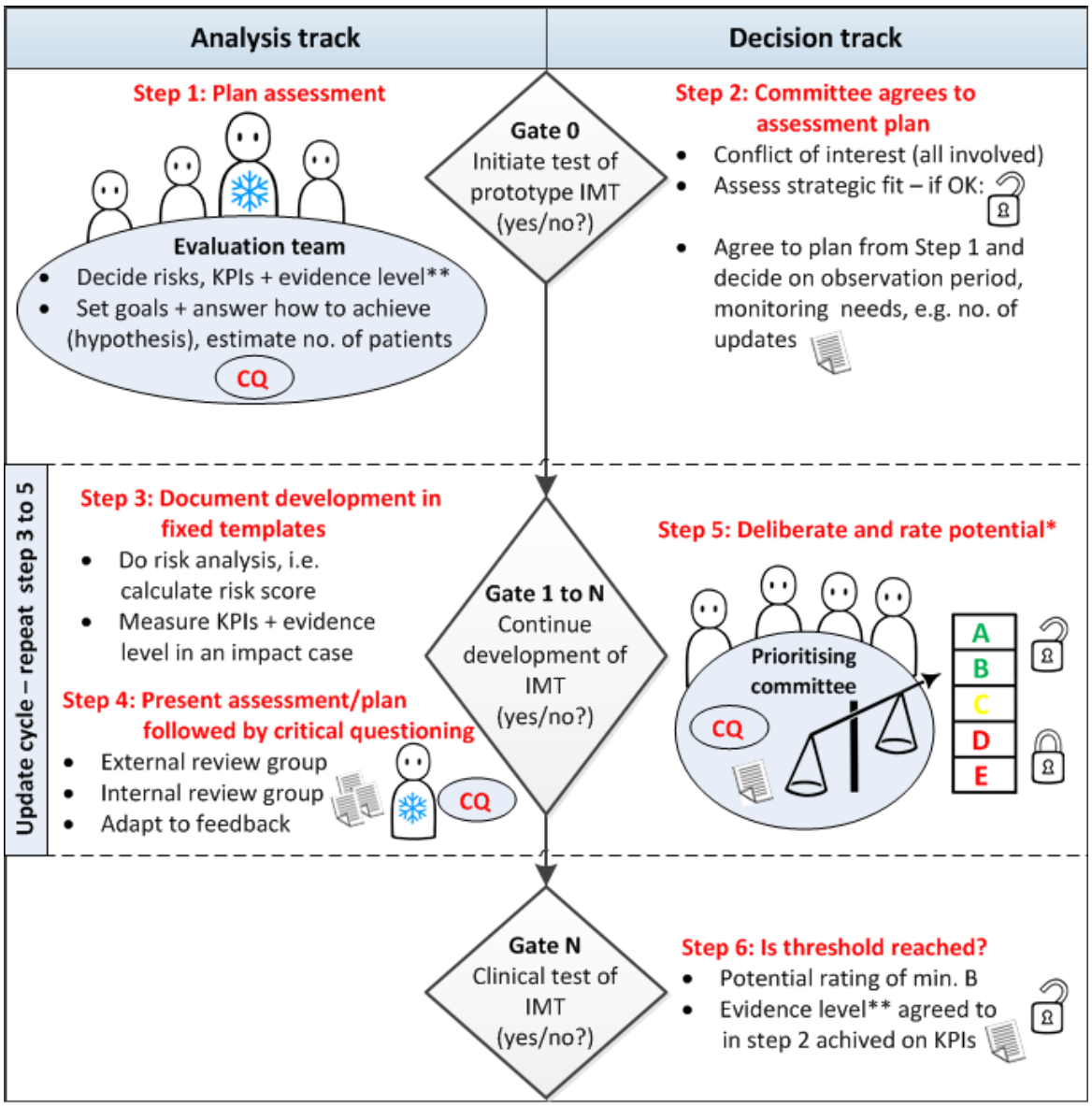
C. An internal review group

D. An external review group

Group A constitutes the evaluation team with the analyst acting as "project manager" for the early assessment responsible for securing neutrality and critical questioning of the analysis. In the decision track, the prioritising committee (group B) carries out the tasks outlined in the right-side part of Figure 3 and makes the decisions in the diamonds, the decision nodes. Here, the analyst has an assisting role supporting the committee in their work, e.g. presenting the EARTH analysis, answering questions that the prioritising committee may have and documenting their decisions. The prioritising committee, which could be the senior management level at the hospital, uses the early assessment to discriminate potentially promising IMTs from less advantageous ones and thus ensures the selection of the most promising candidates for further development. Groups C and D are part of

the critical questioning, i.e. feedback activities.

To support the processes described in the two tracks of the guideline, local templates should be developed adhering to the EARTH principles.



* When rating the potential the following A-E-rating is used: A—recommended for development, B—may go forward, but need to collect more data, C—recommended to go forward, benefits likely modest, D—doubtful, further development not recommended, E—strongly recommend to stop further development

** When deciding and assessing the evidence level, an evidence hierarchy developed for innovations is used with a 1 to 5 scale, where a higher number indicates stronger evidence [48]. A plan for evidence development on all KPIs is part of the evaluation plan accepted in Step 2 at Gate 0.

Figure 3. Visualised guideline with two tracks on how to perform an EARTH assessment

The templates can serve as a summary device of EARTH and in compact form constitute the EARTH model and reporting format. However, this article only describes the objective and contents of the required templates in general terms as a practical application and the use of some of the suggested templates is reported in Appendix 3. The three templates needed are: 1) an overview of the current EARTH assessment, 2) the impact case, and 3) the risk analysis. The overview template consists of three main parts. Firstly, it documents decisions by the prioritising committee, e.g. regarding strategic fit, observation period, and monitoring needs. Secondly, it summarises the analysis reported in the impact case and the risk analysis template and any important changes occurring over time. Lastly, it documents the prioritising committee's ratings of the potential of the IMT at each update. The impact case template keeps track of KPIs, including the clinical effects or technological aspects, the patients' perspectives, organisational aspects, and economics. A current and planned evidence level is tracked on all KPIs in the impact case template. The risk analysis template contains the most important risk elements and keeps track of whether risk is reduced over time.

Elaborating the six steps in the guideline

The most important elements in the six steps in Figure 3 are elaborated and when and how to use templates are described.

Step 1: To support the hospital on whether to start testing the IMT, i.e. Gate 0, the analyst, in cooperation with the evaluation team, sets up a draft evaluation plan. Based on the formulation of an objective hierarchy for the project, KPIs are developed and documented in the impact case template. Risks are identified and entered into the risk analysis template. Goals or expectations for KPIs and the initial risk score and expected risk level at each update are stated in the templates. An evaluation plan is drafted containing three parts: 1) all KPIs and the logic, arguments, or hypothesis behind how to achieve each KPI, 2) when and how each KPI should be measured and achieved, and 3) how the evidence level is planned to evolve over time. The critical questioning process then begins. First, the size of the patient group is estimated using the waterfall method. Subsequently, the evaluation plan, the impact case template (all KPIs), and the risk analysis template are challenged by the evaluation team using the devil's advocate and premortem methods (explained in the previous section).

Step 2: The prioritising committee convene and the first task is to assess with a SWOT analysis whether the IMT fits the strategy of the hospital. Given a strategic fit, the prioritising committee deliberates and challenges the initial evaluation plan from step 1, especially investigating if the hypothesis or logic is clear on how to achieve the KPIs and whether the goals are realistic. Deliberation refers to a type of discussion in which there is a careful weighing of reasons for and against some proposition [49, 50]. When the proposed evaluation plan from step 1 is agreed upon by the prioritising committee, the planned development in evidence level on KPIs is made binding. Also, the prioritising committee decides on the observation period and monitoring needs, i.e. how long they wish to follow a particular IMT and the number of updates.

Step 3 to step 5 (the update cycle): Any new information or available data, from the planned evaluations or other sources, is used to update the impact case and risk analysis templates at the current update. The templates thus constitute the reported early assessment and each template must be filled in at every gate with new data. However, data representing earlier updates must be preserved and any deviations from the original evaluation plan clearly documented. In step 4 the neutral analyst presents the current early assessment and the underlying analysis and receives critical questioning and feedback from the internal/external review group. In step 5 the current analysis is presented to the

prioritising committee, including which direction the current KPIs and risks are taken, feedback from above is discussed, etc. The prioritising committee then deliberates and challenges the current early analysis. The early assessment is updated by the neutral analyst incorporating relevant output from the described feedback loops. Lastly, the prioritising committee rates the potential of the IMT choosing between the five fixed categories (from A to E) mentioned previously.

Step 6: At the last planned update of the early assessment an evidence and potential threshold is imposed. This threshold entails that a final "go" at Gate N is not allowed if the evidence level is less than agreed to in step 2 or if the prioritising committee issues a potential rating below B. Whether the current evidence has reached the planned level from step 2 is established by the neutral analyst.

Discussion

This study developed 11 principles for an early assessment of IMTs in hospitals giving rise to a research-based guideline on how to perform and organise early assessment. The guideline is divided into an analysis and a decision track and the tasks outlined in the guideline are supported by five methods (SWOT, an evaluation plan, and three methods for the "critical questioning" procedures: devil's advocate, premortem and the waterfall method) and three templates. The guideline, templates, and methods constitute EARTH. EARTH offers a novel approach to gauging the potential of an IMT early in the process by simultaneously assessing whether the development in KPIs is positive, whether the overall risk level is decreasing, and whether the strength of the evidence on KPIs is getting stronger.

Contribution to the literature

Insights from behavioural economics in relation to reducing the cognitive load and cognitive biases were used in the development of EARTH. Applying EARTH is a novel approach deviating from the most commonly used evaluation models in healthcare, which assume rationality in decisions and analysis. EARTH is designed to reduce the cognitive load for the members of the prioritising committee by using fixed templates and focusing only on the 5-10 most important KPIs. Also, EARTH actively counteracts the most important human biases when doing early assessments, e.g. optimism, hindsight bias, and group think. This is done by: 1) using methods for critical questioning, 2) a neutral analyst and committee, 3) a binding evidence threshold regarding whether to initiate usual clinical testing, and 4) confronting the decision makers with the past by displaying the complete history on the development in KPIs, risks, assumptions and beliefs throughout the entire early assessment period. Maintaining history helps minimise both hindsight and optimism bias for the involved persons [42, 51]. The combined potential and evidence threshold is an example of an explicit criterion for stop/go to further testing, which is desirable according to the literature [52]. The binding evidence threshold decided a priori also helps mitigate optimism bias.

A comparison of EARTH to other commonly used evaluation models in hospitals with regard to nine features important in early assessment is presented in Table 3. Overall, when compared to the hospital models, it is a novelty that EARTH uses updates and incorporates ideas from project management into the evaluation model, e.g. the risk analysis and impact template. Although evidence already plays an important role in hospitals, a fixed plan for building an appropriate evidence base over time and a minimum evidence threshold to issue a "go" is new.

In Denmark the use of so-called "business cases" is popular. However, clinical effects often have a low priority or are neglected altogether in business cases. At other times, time-consuming traditional evaluation models like HTA, CEA, or RCT are applied in early stages – often inappropriately in the sense that the special features of IMTs are not clearly integrated,

e.g. high uncertainty, in particular regarding evidence, and limited data. The most relevant comparator for EARTH in Table 3 is probably hospital-based-HTA (HB-HTA), which exhibits several desirable features important in early assessment. However, there is no risk assessment; updates are not supported, and thus KPIs cannot be selected and tracked; there is no threshold for go/no-go including a plan for evidence development; and lastly data available from a literature review is required. Hence, the applicability of EARTH in hospitals seems promising, at least theoretically, because EARTH appears to support all of the nine features in Table 3. However, especially how well EARTH complies with features 1 and 3 in a real setting will have to be investigated in the future.

Table 3: Nine features of commonly used evaluation models for (early) assessment in hospitals and EARTH (% indicates absent)

Model / Feature	EARTH	Hospital Based-HTA (HB-HTA)	HTA, MAST (RCT and CEA)	Business Cases
1) Fast and low time-consumption in performance + easy to communicate, i.e. high transparency	(+)	+	%	%
2) Evidence level indicated on used data	+	+	+	%
3) Low data requirements and limited number of assumptions and KPIs	(+)	%	%	(%)
4) Broad value proposition, i.e. more than two domains	+	+	+	(%)
5) Updates, i.e. evaluations are not one-off events	+	%	%	+
6) Clear history and tracked development in KPI, risk, and evidence (+ document changes)	+	%	%	%
7) Threshold for go/no-go + plan for evidence development	+	%	%	(%)
8) Fixed evaluation templates	+	+	%	(+)
9) Risk analysis	+	%	%	+

Note: + signals that the model exhibits this feature, a % that it is absent, () indicate unclear. The nine features are based on the identified principles in this study. Literature on the mentioned models: HB-HTA [23], HTA [27], MAST (Model for ASsessment of Telemedicine) [30], business case [53], and CEA (cost-effectiveness analysis) [54].

Our choice of a non-scoring approach and an iterative approach (updates) in EARTH is supported by a discussion in a paper from a Health Technology Assessment International (HTAi) Policy Forum on HTA and innovation [25]. Furthermore, an evolving evidence base (updates) rather than conventional single-point-in-time evaluations is advocated by Husereau, Henshall and Jivraj [26]. Also, the Canadian Know4Go HB-HTA framework is currently exploring ways to move beyond the paradigm of one-off single technology assessments, to progress to dynamic assessment [55].

Strengths, weaknesses, and future directions

The research group behind the interview, review, and EARTH studies was

multidisciplinary and had representatives from both the clinical and the health economic fields and has been involved in various types of evaluations and in evaluating IMTs in the early stages in hospital settings. Triangulation was used, investigating early assessment from two angles, an interview and a review study approach. Also, feedback predominately from academia was obtained developing the guideline.

Since early assessment of IMTs in hospitals is a new research area, the author group sometimes had to make choices based on their own experience when developing EARTH. For instance, what exactly is a fast evaluation in a hospital context and how is low data requirements defined? Clinicians cannot realistically contribute much more time than when making a HB-HTA. Between 1-10 hours are probably realistic [56]. Performing an EARTH assessment must also take considerable less time than a traditional HTA. Fast is taken to mean that a new early assessment analysis (step 1 and 2 in the guideline) can be done in about one business week or less by an experienced analyst, provided that data is present (and 1 day per update planned). A low-level data requirement is achieved with a maximum of 5-10 KPIs, a simple risk-analysis, and a non-scoring approach of domains. Others might have defined these two concepts differently.

New methods are needed in HB-HTA [57] and this article has presented a novel model for early assessment of development of IMTs in hospitals. The next logical step is that EARTH needs to be piloted on real world IMTs, preferably in several hospitals to test the applicability and how well the above choices work. Currently EARTH is applied to a case study on health drones. It is important to get feedback from both members of the evaluation team and the prioritising committee (decision makers) in order to improve EARTH. Furthermore, it must be investigated if simplification of the model is needed, e.g. to make sure that EARTH is fast.

Conclusion

Based predominately on input from private sector early assessment models, and with insights from behavioural economics, this paper presents EARTH, a model for early assessment of development of IMTs in hospitals. EARTH consists of a guideline on how to perform and organise early assessment in hospitals supported by five methods (SWOT, an evaluation plan, and the "critical questioning" procedures: devil's advocate, premortem and the waterfall method) and three templates. EARTH assessments should be fast, iterative, require few data, and provide critical and realistic assessments. To see how well EARTH performs on these parameters, EARTH must be piloted in hospital innovation centres supporting actual decisions concerning stop/go to usual clinical testing of IMTs.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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