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Expert Review of Medical Devices

ISSN: 1743-4440 (Print) 1745-2422 (Online) Journal homepage: https://www.tandfonline.com/loi/ierd20

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To cite this article: Melody Ni, Simone Borsci, Simon Walne, Anna P. Mclister, Peter Buckle, James G. Barlow & George B. Hanna (2020): The Lean and Agile Multi-dimensional Process (LAMP) – a new framework for rapid and iterative evidence generation to support health-care technology design and development, Expert Review of Medical Devices, DOI: 10.1080/17434440.2020.1743174

To link to this article: https://doi.org/10.1080/17434440.2020.1743174

View supplementary material

Accepted author version posted online: 13 Mar 2020.
Published online: 20 Mar 2020.

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EXPERT REVIEW OF MEDICAL DEVICES
https://doi.org/10.1080/17434440.2020.1743174

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PERSPECTIVE

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The Lean and Agile Multi-dimensional Process (LAMP) – a new framework for rapid and iterative evidence generation to support health-care technology design and development

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ABSTRACT

Introduction: Health technology assessments (HTA) are tools for policymaking and resource allocation. Early HTAs are increasingly used in design and development of new technologies. Conducting early HTAs is challenging, due to a lack of evidence and significant uncertainties in the technology and the market. A multi-disciplinary approach is considered essential. However, an operational framework that can enable the integration of multi-dimensional evidence into commercialization remains lacking.

Areas covered: We developed the Lean and Agile Multi-dimensional Process (LAMP), an early HTA framework, for embedding commercial decision-making in structured evidence generation activities, divided into phases. Diverse evidence in unmet needs, user acceptance, cost-effectiveness, and market competitiveness are being generated in increasing depth. This supports the emergence of design and value propositions that align technology capabilities and clinical and user needs.

Expert opinion: We have been applying LAMP to working with medical device and diagnostic industry in the UK. The framework can be adapted to suit different technologies, decision needs, time scales, and resources. LAMP offers a practical solution to the multi-disciplinary approach. Methodologists drive the process by performing evidence generation and synthesis as and by enabling interactions between manufacturers, designers, clinicians, and other key stakeholders.

ARTICLE HISTORY
Received 13 January 2020
Accepted 12 March 2020

KEYWORDS
Evidence generation; early stage; health technology assessment; human factors; systems approach; health economics; innovations

1. Introduction

Health technology assessments (HTAs) are traditionally used to inform health policy, resource allocation, and decision-making [1]. Of the three fundamental questions of test evaluation, namely *can it work* (efficacy), *does it work* (effectiveness), and *is it worth it* (value), the focus of HTAs has been on generating and synthesizing clinical and health economic evidence in order to establish the effectiveness and value of a technology [2]. Used with Multi-Criteria Decision Analysis (MCDA), HTAs also play a key role in hospital-based implementation studies [3–5]. This enables the selection of technologies (medicine, devices, or procedures) that are most compatible with the perspectives and values of the local decision-makers [3], and with the local contexts [6]. However, and especially as digital platforms and interventions gain wider penetration, it has increasingly been recognized that far-reaching consequences on patients, clinicians, and health-care providers are ideally captured early on so that risks can be mitigated and value can be co-created [7,8]. This requires the development of new approaches to HTAs.

Over the past decade, the idea of early HTAs has gained traction [9–12]. Instead of only assessing a product after it has been developed, clinical efficacy and wider socioeconomic benefits can be considered alongside technical validity during its development [13,14]. Incorporating clinical needs, acceptance [15] and end-user preferences at an early stage [16,17] has the potential to transform product design and development [18], that is, by providing insights into the question of '*how to make it* work', so that the technology becomes a better fit of the clinical and payer environments. Integrating HTAs into technology design and development also improves the fidelity of assessments, when technology, in particular devices and digital platforms, must be adapted for local settings, such as by conducting implementation studies [4].

The transition of HTAs from tools of resource allocation to tools of commercialization has many challenges. Notably, evidence is scarce at an early stage of development whereas uncertainties are abundant. Lack of evidence in terms of both quantity and quality adds structural uncertainties to decision models [19] and undermines the reliability and generalizability of an assessment [20]. Secondly, multiple stakeholders have diverse objectives and preferences [21] – these must be reconciled. Thirdly, a lack of awareness and resource constraints [15] mean that early HTAs are not universally adopted. This is especially true for diagnostic and device companies, which are predominantly small-to-medium sized

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enterprises (SMEs). Paradoxically, foregoing early assessments renders SMEs more prone to product failure, of which they are more vulnerable compared to their larger counterparts [17]. To meet these challenges, a multi-disciplinary approach to evidence generation has been proposed, with a greater emphasis on qualitative tools (e.g. stakeholder analysis) and expert knowledge [6] in relation to quantitative modeling approaches. Specialized early HTA tools have also been developed [9,22], which incorporates perspectives from payers, to support commercialization activities. However, manufacturers continue to find it challenging to utilize the diverse evidence emerged. For early HTAs to gain wider penetration, they need to be able to cope with substantial uncertainties, easy to use as well as resource efficient.

We developed the **Lean and Agile Multi-dimensional Process** (**LAMP)** to enable rapid cycles of evidence generation and staged evidence synthesis for supporting manufacturers in achieving incremental changes in product design, whilst developing robust commercialization strategies. LAMP arose from our experiences as a specialized research unit in England working with medical device industry since 2013 [16,21,23]. It is underpinned by successful practices in decision analysis [24], manufacturing and digital technology, notably the *lean* and *agile* approaches. A concept or prototype is screened based on its technical feasibility, filtered through unmet clinical needs, and then explored through multi-faceted assessments in terms of user needs, user preferences, health economics, and market competitiveness. Final recommendations emerge from a facilitated focus group meeting to lend clarity to the next steps of commercialization. Although LAMP was developed for medical devices, due to resource constraints and the need for such a lean and agile tool, we have also applied LAMP to digital platforms used for medical training and education.

In what follows, we first discuss unique challenges facing early stage health technology assessments, which led to the development of LAMP. We introduce its underpinning frameworks and describe its stages in detail. We illustrate how LAMP works by presenting three case studies drawn from our collaborations with the UK diagnostic industries. We conclude by exploring implications for health-care innovations, key considerations when using the framework, its limitations, and proposing plans for future development.

2. Challenges in early stage health technology assessment

The International Network of Agencies for Health Technology assessment (INAHTA) defines Health Technology Assessment as 'the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies'.[1] As the innovation they support, HTA activities progress in stages: from *basic research* at a very early stage aimed at verifying the working mechanism of a technology, to *translational research* at an early stage for defining unmet needs and market potential, to the *later mainstream HTA* where evidence of clinical validity, utility, and socio-economic benefits are generated and synthesized [9,25]. A variety of tools, both quantitative and qualitative, have been developed to support these activities (Table 1).

Decision-making at the early, translational stage is especially complex – uncertainties are abundant whereas evidence is scarce. Manufacturers simultaneously engage in strategic planning, deciding on which R&D activities to invest in and by how much, and in commercialization, optimizing technical performance, design, pricing, and value propositions for validation, adoption, and implementation. Translational research, which happens as early as the concept stage of an innovation, has been used to understand clinical needs and user requirements to shape product design, forecast market potential and justify funding acquisitions. Decision needs continue to evolve as evidence of technical validity and clinical relevance accumulates.

Supporting commercial decision-making at an early stage thus requires tools that are far more dynamic and multi-faceted than those typical of mainstream HTAs for ascertaining effectiveness and cost-effectiveness of a product *after* it has been developed. An example of early HTA tools is the headroom approach [22]. The headroom of a technology is the sum total of potential cost savings to the health-care provider plus gains in monetary terms from improvement in patient's health-related quality of life (HRQoL) or another acceptable

Table 1. Core stages of evidence generation and HTA methods to inform decision-making, based on Ijerman and Steuton [9].

		Methods	
Core stages	Key goal	Qualitative	Quantitative
Basic research (very early)	Inform decision about the value of the concept to justify the investment	• Literature review/ analysis • Peer review • User profiles building • Focus groups • Interviews • Informal discussions • Qualitative weighing of relevant factors • Use cases writing • Key informant interviews	• Headroom analysis • Cost-effectiveness analysis • Probabilistic sensitivity analysis • Best worst scaling • Conjoint analysis
Translational research (early)	Inform decision about the prototype and product development	• Strategic planning methods, e.g. Political, Economic, Socio-cultural and Technological (PEST), Strength, Weakness, Opportunity, Threat (SWOT) • Expert panels/elicitation • Technology profiling (uncertainty profile and evidence profile) • Workshops • Surveys	• Potential years of life lost • Cost-benefit analysis • Cost-utility analysis • Opportunity costs
Mainstream HTA (advanced)	Inform the device usage in the clinical setting	• Decision conferencing • Facilitated focus group meetings • Multi-criteria decision analysis (MCDA)	• Health economic modeling • Multi-criteria decision analysis (MCDA)

outcome measure. This sets the upper limit of further investment based on an estimation of the market size (as the number of units sold), the cost of production as well as the investment that has already been made (sunk costs). Manufacturers can reach go/no-go decisions by building various scenarios with different headrooms (e.g. by assuming minimum and maximum units sold). Compared to mainstream methods, early stage tools might appear 'simplistic'. However, they provide key insights by merging perspectives from the supply-side (company) and the demand-side (payer) in a way that is both transparent and actionable to the manufacturer.

Early stage evidence generation is also characterized by being multi-dimensional, multi-perspective, and cross-disciplinary. This reflects the complexity of the health-care system and the innovation process, with far-reaching consequences on a wide range of stakeholders. These stakeholders play different roles and reside in different organizations. Their objectives are diverse; so are their evidence needs for decision-making. We developed the Point of Care Key Evidence Tool (POCKET) by interviewing patients, laboratory experts, clinicians, commissioners (payers), regulators, industry, and methodologists. What emerges was a consensus checklist comprising 65 different evidence requirements encompassing technology, clinical pathway, stakeholder, health economics, and test performance [21]. This spectrum of evidence requires the use of both *quantitative* tools, e.g. clinical studies and modeling studies to quantify test performance in realistic settings and estimate health economic benefits, and *qualitative* tools, e.g. through interviews, simulation studies, and focus groups to understand the contexts, risks, attitudes, needs, pathways, usability, and potential adoption and implementation barriers.

However, unlike the summative assessments embodied in classic HTAs, early HTAs strive to inform 'how to make it work' by drawing insights from assessments of 'does it (potentially) work' and 'will it be worth it (for the company and for the payer)'. Develop robust value propositions requires balancing considerations of the technology (technical validity, clinical validity, and utility) and design (usability, user experiences) with socio-economic benefits (health economics, pathways) and stakeholder attitudes (acceptance, perceived risks). Classic HTAs have primarily relied on systematic literature reviews to reconcile differences in study design, settings, patient populations, and findings. This is not suitable at an early stage not only because there is a lack of evidence but also because the multi-dimensional evidence can give rise to different adoption scenarios. To incorporate insights into product design and development requires 'translation' by specialists who understand both evidence and its implications for commercialization. Decision analysis [26,27] and facilitated focus group meetings [24] have been used successfully to achieve design solutions. We have also developed a process to integrate health economics and human factors so that costs (value) are considered alongside design [16]. Further, more systematic integration of evidence is needed to maximize the utility of the limited amount of evidence so intrinsically linked at an early stage of innovation.

3. Design rationale of the Lean and Agile Multi-dimensional Process (LAMP)

Using a grounded-theory approach [28,29], we developed the Lean and Agile Multi-dimensional Process (LAMP, Figure 1), an early stage HTA tool, for evidence generation and synthesis to meet the challenges facing early stage assessments. LAMP has a number of distinct characteristics. Firstly, it is multi-dimensional, incorporating modules of generating both qualitative and quantitative evidence. Secondly, it emphasizes the 'width' of evidence, rather than the 'depth', and can be implemented over a relatively short period of time, by a multi-disciplinary team working closely together. Thirdly, it is manufacturer-facing, embedding the assessments in a phased structure to support commercial decision-making.

LAMP is underpinned by successful practices in manufacturing and digital technology, namely the *lean* and *agile* approaches, to meet the unique challenges facing medical device industries. Lean focuses on eliminating, at an organizational level, redundancies in product development and managerial processes [30,31]. An *agile* approach toward product development entails using iterative, incremental changes to achieve significant improvement in end-products [32]. Through a series of *sprints*, an existing idea is continuously refined through multiple evaluations, leading to its eventual implementation.. The joint execution of lean and agile, or *le-agility* [33], produces a process that is highly dynamic and outcome-driven with demonstrable results. Applied to evidence generation, le-agility gives rise to a diffused and iterative approach embodied in LAMP in contrast to a more focused and sequential approach adopted by mainstream HTAs.

LAMP incorporates four phases (stages) to support manufacturer utilize the multi-dimensional evidence that is being generated [34]. We start by reviewing available evidence, identifying gaps, and setting up basic parameters for the assessments (*preparing*). We then ascertain the unmet needs (*filtering*) [35–37] and carrying out multi-modality assessments of clinical, health economic, human factors, and market feasibility to *explore* implications for design and commercialization. Final recommendation was achieved through a focus group meeting attended by key stakeholders (*evaluation*).

We aim to generate a minimum set of evidence (*lean*) relevant to manufacturer needs (*agile*), especially in terms of design requirements and value propositions. Our basic premise is that a successful technology combines favorable market conditions with well-aligned technology capability, design, and clinical utility. Therefore, we focus on three broad categories of evidence based on their distinct roles in technology translation:

- ***human factors*** related (e.g. usability and user experiences), which underpins the interaction between the human operator and the technology as well as the wider system of which the technology is a part, e.g. [38], through a consideration of intended users, e.g. ISO 62366 [39].
- ***clinical outcome*** related (e.g. sensitivity and specificity in the context of diagnostic products) which drive performance characteristics of a product and determine its clinical validity and clinical utility [40].
- ***market intelligence*** (e.g. competitors, strengths, and weaknesses) which highlights competitive advantages

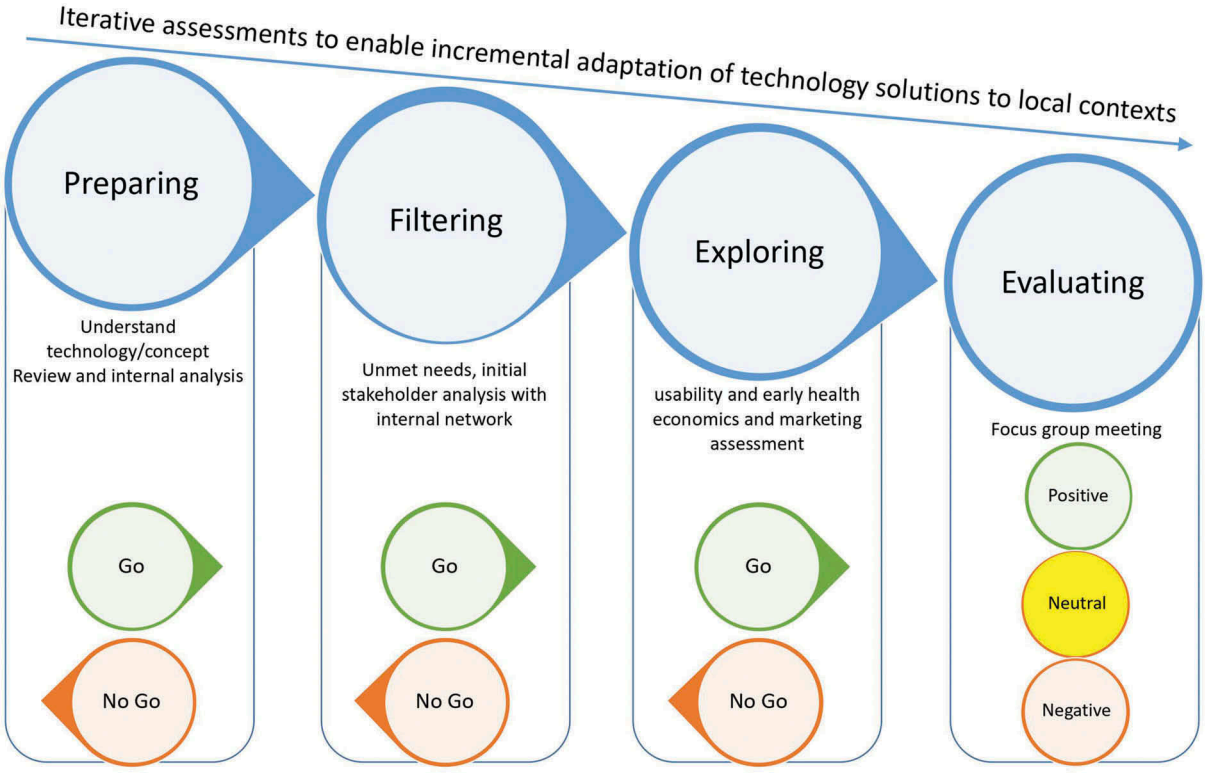

Figure 1. The Lean and Agile Multi-dimensional Process (LAMP) – an overview.

and disadvantages of a technology, its innovative level, and readiness for adoption and implementation. From this perspective, early health economic evidence captures the trade-off between potential improvement in clinical outcomes (and therefore benefits for patients, clinicians, and health-care systems) and market competitiveness (and therefore prospect for adoption).

Within each of the four phases of LAMP, we (methodologists) simultaneously consider these three categories of evidence in terms of human factors, clinical outcomes, and market intelligence. Following each phase, based on discussions with the manufacturer, we reach three possible outcomes:

- *positive*, when the benefits substantially outweigh the risks – the new product is expected to face minimal barriers to adoption and a great uptake in the market;
- *neutral*, when the benefits counterbalance the risks – certain aspects of the alignment are positive whereas others are negative. The assessments generate insights about key features and functions to fulfill clinical and user needs, and a more calibrated set of expectations given economic impact;
- *negative*, when the risks substantially outweigh the benefits – the product is expected to face severe barriers to adoption due to a lack of clinical relevance or utility; the product is unlikely to be cost-effective for the health-care system.

Following each phase, manufacturers may decide to continue as planned (*proceed*), halt the evaluation until they have revised design or market strategies (*review*) or stall the product development altogether *(exit)* [5]. Over the course of LAMP, the alignment between technology, user (contexts), and market is repeatedly assessed, with increasing depth. The process can be repeated, continuing to support manufacturers as they progress through various stages of product development and commercialization.

We developed LAMP by collaborating with the Academic Health Science Networks (AHSNs) which are organizations in England responsible for bringing innovations into the NHS. The initial group of experts involved in the co-design of LAMP comprised a team of seven experts in health economics, human factors, decision-making and marketing, and technology development. We then revised the framework through a series of co-design sessions with a group of 15 professionals including methodologists, designers, engineers, clinicians, and experts of hospital procurement. We continued to apply LAMP and refine the framework based on our experiences and the feedbacks we gathered. In what follows, we present the LAMP framework in detail.

4. The Lean and Agile Multi-dimensional Process (LAMP)

The main users of the LAMP framework are a team of methodologists (referred to as 'we' throughout this discussion) with expertise in health economics, human factors, and marketing/market access. The team carry out the assessments, generating and synthesizing evidence to supporting decision-making by manufacturers and designers. We use the term 'evidence' loosely, which encompasses everything from technical reports,

design features, physical models, published or unpublished studies, or other supporting documents the company is willing to share under a non-disclosure agreement. We use both standard tools (SUS, UMUX, UEQ, NPS, Section 4.3) and have developed tailor-made instruments for assessments (POCKET, MedKET, Appendix). The LAMP framework is summarized in Table 2.

4.1. Preparing: review technology readiness level and identifying evidence needs

Aims To 1) establish with the company the objectives of the assessment, 2) build common ground of understanding in terms of what to expect from the process, and 3) ascertain that sufficient information is available for the assessments.

Screening The assessment team meets with the developer to examine all available evidence (including physical models, technical reports, marketing intelligence, published or unpublished studies, etc.). We perform a preliminary assessment of the technology, appraising its risk-benefit and ascertaining our capacity and expertise in supporting the evaluation (see **Appendix** for the risk-benefit tool). Ideally, the developer has a good understanding of the design and process of use of the technology, as well as of the target clinical settings and patient cohorts. Views from the public health experts, when relevant are captured through representatives from the Academic Health Science Networks, which are our collaborators.

Stakeholder Identification Once the decision to proceed has been jointly agreed, we start by interviewing the manufacturer for initial identification of stakeholders for interviews, using the WHO stakeholder tool.[2] As assessments progress, we widen our reach by using the later-stage stakeholder identification tool adapted from the WHO tool.

Evidence Review Evidence checklists, such as the Medical device Key Evidence Tool (MedKET) [23] and the Point of Care Key Evidence Tool (POCKET) [21] are used to assess technology readiness level, by understanding what evidence has been generated, the quality of such evidence and evidence needs and gaps that need to be addressed next. POCKET tool encompasses evidence on stakeholders, clinical outcomes, health economics, technologies among others.

Based on the technology, the intended use, the evidence needs and gaps, we reach out to our internal network of clinical experts. We develop an evaluation protocol, including the roles of key stakeholders, interview protocols, and the instruments for the multi-dimensional assessments. Working with the developer, we build a slide deck and/or a mock-up for showcasing the technology during the interviews. The marketing expert starts to review competing technologies and the health economist starts to review literature and map out preliminary clinical pathways by working with expert clinicians. Design, value propositions, and pathways are refined throughout the assessment process.

Decision-making Assessment may be negative if 1) we are unable to identify a clear value proposition of the technology, 2) the technology is not ready for translation, e.g. no evidence to suggest that the technology could work or 3) we fail to reach an agreement with the developer in terms of what to expect from the assessments.

4.2. Filtering through unmet needs and identifying feasible care pathways

Aims To 1) verify how well the technology capability and design align with unmet needs, 2) ascertain that the technology is acceptable in the clinical settings, and 3) identify suitable clinical pathways to implement the technology.

Clinician interviews and preliminary stakeholder analysis We carry out semi-structured interviews with clinical experts. These interviews last 30–60 min, ideally face-to-face, during which we present the technology, the available evidence, preliminary value propositions, and preliminary pathway maps (see Section 4.1). Clinicians are invited to comment on the technology, its value propositions and to help identify other key stakeholders. We

Table 2. Four phases of the LAMP framework for supporting health technology design and development.

		CAN it work? I. Preparing	*WILL it work?* II. Filtering	*HOW to make it work?* III. Exploring	*Nest steps?* IV. Evaluating
Evidence Generation	*Qualitative Methods*	• Stakeholder Identification • Evidence Checklists (MedKET, POCKET)	• Preliminary stakeholder analysis • Clinicians and user interviews	• Market analysis • Stakeholder analysis • Usability studies • User experience studies	-
	Quantitative Methods	-	-	• Early health economic studies • Database analysis	-
Evidence Synthesis		• Methodologist-led review	• Literature review • Clinical expert-led review	• Methodologists and clinical expert-led review	• Facilitated focus group meetings
Key Outputs		• Technology credibility • Clinical feasibility • Evidence need	• Clinical pathway linking technology to benefits for patients, clinicians, and the NHS	• Unmet needs • Clinical pathways • Stakeholder perceptions • Adoption barrier • Design recommendations • Cost-effectiveness • Value propositions	• Consensus recommendations
Manufactures Decision Making		*Technology ready for translation?*	*Unmet needs that can realistically fulfilled by the technology?*	*Clarity on* • *User needs, user context* • *Product design* • *Marketing strategies*	• *Updated commercialization strategies* • *Further evidence requirements*

work with clinicians to refine the care pathways, understanding the impact of the technology, potential settings where the technology might be implemented (e.g. primary care, pharmacy, secondary care) and variations in health-care settings (London versus elsewhere).

We assess technology acceptability, perceived usefulness and likelihood of adoption by using scales adapted from the standardized instruments, including the technology acceptance model [41], perceived usefulness questionnaire [42] and the net promoter score [43], which predicts its market potential. At this stage, experts are mainly recruited from local clinical settings. When such expertise is not available or when the views emerged diverge, we engage with our wider network of health-care professionals.

Decision-making The assessment team holds a meeting with clinicians and manufacturers to refine the evaluation protocol for the exploration phase, taking into account the preliminary findings. Multiple user scenarios may emerge, which can be considered during the exploration phase, alongside the identification of additional key stakeholders. Assessment may be negative if 1) we are unable to identify clinical utility of the technology or 2) the care settings cannot accommodate the new technology without substantial re-configurations, implying substantial risks which overshadow the foreseeable benefits of the technology.

4.3. Exploring by multi-dimensional evidence generation

Aims To 1) carry out feasibility assessments by simultaneously generating evidence in user preferences, stakeholder acceptance, and health economics, 2) inform product design, and 3) refine value propositions.

Human factors We carry out hour-long, face-to-face semi-structured interviews with experts recruited from our wider research networks. Simulation studies – often with clinical users in realistic scenarios – are used to understand risks, decision-making and enhance external validity of available clinical evidence, e.g. [38]. The experts are asked to comment on the design and safety in use, as well as barriers to adoption. As potential users, they also assess usability and user experiences by using standardized usability tools, e.g. SUS [44], UMUX [45], UEQ [46] and the net promoter score [43]. We also confirm the clinical pathways to incorporate the technology.

Health economics From the interviews we extract variables describing clinical and socio-economic impact of the technology, which we complement by a narrative review of the literature. We carry out early economic assessments to quantify the trade-offs between costs and benefits using the technology. Multiple sensitivity analyses are carried out, taking into account human factors evidence, to understand drivers of the costs and benefits, the trade-offs between sensitivity and specificity and other key performance characteristics, such as time to results and location of the tests. Clinical evidence is incorporated if and when it is available. In its absence, we build various scenarios and carry out sensitivity analyses to consider boundary conditions of device performance and inform future study designs.

Marketing strategies We survey the literature, including the NIHR innovation observatory, to identify existing/emerging technologies targeting the same/similar applications and assess their respective advantages and disadvantages. We summarized the market size (patient cohort, current and projected burdens of disease), manufacturing costs, price to purchaser, and market growth. This is sometimes complemented by an analysis using established clinical and/or administrative databases.

Decision-making We hold a half-day meeting with the manufacturer to review the dynamics between the *market* (e.g. is the product attractive and competitive), *performance* (e.g. accuracy, time to results), *human factors* (e.g. how likely errors are made, how easily device can be cleaned, how likely the device will be used to inform clinical decisions) and *health economics* (what are the minimum requirements for the device to be cost-effective). We help manufacturers to consider implications for *design* (e.g. the process of use, weight, size, how results are presented) and marketization (e.g. which technologies to displace or to complement). Sensitivity analyses using the early health economic model are carried out to develop adoption scenarios. Facing neutral or negative evidence, manufacturers may decide to exit the process in order to reconsider marketing strategies and/or engage in design reviews.

4.4. Evaluating through a facilitated focus group meeting

Aim To achieve consensus in recommending next stages of product development and commercialization strategies.

Focus group meeting We compile an evidence package containing findings and recommendations in terms of design, usability, safety in use, clinical utility, cost-effectiveness, potential pathways for adoption and marketing plans. We share the package with the company and with an independent board of experts, drawn from across the health-care system. The board of experts frequently include representatives from the AHSNs, expert clinicians, and patient representatives. Industry is also present to provide insights into the technology. We facilitate the meeting to drive consensus in recommending next steps for the product.

Decision-making Given positive assessment outcomes, the manufacturer may continue existing strategies but with greater clarity in terms of value propositions, further evidence requirements, and marketization (e.g. **Case 1**). If the assessments are neutral, with a mixture of perceived benefits, risks, and doubts, the manufacturers may consider changes in clinical settings and design for embedding the technology, resulting in market pivot (e.g. **Case 2**). Finally, an overwhelmingly negative verdict may lead to high-stake decisions such as stalling the product and pursuing new opportunities (e.g. **Case 3**).

5. Case studies

Through our collaborations with academic health science networks in the UK, we have applied LAMP to work with companies developing diagnostic, screening, and monitoring tools in cancers, gastroenterology, mental health, chronic conditions, emergency medicine, etc. In what follows, we present three case studies to illustrate how commercialization was

supported by the multi-dimensional assessments. A summary can also be found in Table 3.

5.1. Case 1

A new generation of pH strips for locating blindly inserted nasogastric tubes in adult patients was developed which met previously identified unmet clinical needs. We generated multi-dimensional evidence in human factors, health economic and stakeholder perceptions, over multiple iterations, to support the manufacturer in developing product design and value propositions. The prototype was tested in 10 NHS hospitals, with highly positive outcomes. We hosted an adoption workshop attended by the manufacturer, representatives from the AHSNs, clinicians, and the methodology team. The meeting was facilitated by an independent expert in innovation management. The panel reviewed the evidence and discussed how the new pH strips might have routine use inside the NHS hospitals. The company gained clarity in business models and ideas of developing a second-generation product, which could bring even greater patient benefits, was discussed. The company has applied and received funding to test the (first-generation) strips in a new patient cohort (neonates) which the panel identified as having high unmet needs.

5.2. Case 2

The concept of a portable anticoagulation device was proposed by the manufacturer for use inside the operating theater where such tests are routinely done using laboratory-based devices. During assessments of unmet needs, the idea of using the new portable device in emergency settings was raised by

Table 3. Summary of case studies.

	Product	Product Stage	Company
Case Study 1	Novel pH strips	Prototype stage	SME with a strong track record in health care
Preparing	• Well-evidenced unmet needs; • A small proof of concept clinical study with promising results		
Filtering	• Strong clinical interests and support; • Technology solutions match unmet needs; • No change to existing product design means minimum disruptions to clinical service • Lack of information about the process of use and the unmet needs		
Exploring	• Usability and user experiences studies found a strong preference for the novel test with an updated design – idea for 2nd-generation product emerging; • Straightforward health economic argument; • A company considering collaboration with market leaders		
Evaluating	• Strongly positive assessment outcomes; • Commissioners welcomed the new product; • Unmet needs identified internationally and in other age groups		
Outcome	• Proceed with existing commercialization plans • 1st generation product developed • New funding acquired to test the product in a new clinical area		Time: **16 Weeks**
Case Study 2	Point of care anticoagulation device	Concept stage	Micro-company with successful track record outside health care
Preparing	• The new test is a point of care, faster, more precise and more resilient compared to the existing bench-top model; • Only laboratory evidence available		
Filtering	• Emerging unmet needs identified in the emergency settings that could best match technology capability; • Strong clinical interests and clinical support.		
Exploring	• Favorable usability and user experience assessments; • Potential savings in patient lives; • Substantial unfulfilled needs; • Lack of emerging alternative solutions.		
Evaluating	• Stakeholders strongly favored the new test in managing trauma patients and in other emergency settings		
Outcome	• Market pivot from the operating theater to trauma emergency; • Significant interests from private investors; • Substantial funding award for product development		Time: **12 Weeks**
Case Study 3	Cancer drug toxicity test	Concept-prototype stage	Medium-sized company with a strong R&D profile
Preparing	• Predominantly laboratory evidence available; a very small group of patients; very scarce clinical evidence		
Filtering	• Unmet needs not identified; existing pathway unlikely to change; • A small group of patients, difficult to access without clinical traction		
Exploring	• Lacking clinical utility and therefore not cost-effective; • Usability and user experiences also failed due to lack of clinical relevance and interests; • Marketing assessment suggested the USA as a possible alternative but uncertain		
Evaluating	• Not implemented		
Outcome	• Product development stalled		Time: **9 Weeks**

an expert clinician. This suggestion was unexpected but welcomed by the manufacturer. Subsequent interviews with stakeholders, early health economic studies, and marketing research confirmed the viability of the idea. The company, having considered the implications for design (e.g. ambient environment, rough handling, transportation, interface, etc.), decided to pursue the development of a point-of-care anticoagulation device for treatment planning in emergency settings. The new application was considered a superior alignment between technology capability and unmet needs, as well as fulfilling a market niche. Consequently, there was a multi-fold increase in the company's valuation by investors following the market 'pivot'. The company has been successful in acquiring further funding, which enabled us to continue to work with the company to refine product design and interface through a series of human factors studies. More in-depth health economic studies are being planned alongside phased clinical studies to validate and assess the technology in realistic settings.

5.3. Case 3

A dosage planning tool for chemotherapy treatment of a rare type of cancer was being developed as a laboratory-based test. However, our initial assessments failed to identify viable clinical pathways that could change clinical decision-making. The tool, though valid in indicating the level of toxicity in patients receiving the chemotherapy, was not compatible with the current care. The clinicians had few alternatives other than the existing regimes and did not consider the chemotherapy overly toxic. During the exploring phase, we carried out extensive stakeholder analyses and market studies in order to rule out selection bias as a possible explanation of the negative assessment outcomes. However, the results continued to support the lack of clinical utility. Cost-effectiveness and user experiences were not assessed since both would require the identification of feasible clinical pathways. Overseas markets (e.g. the US) were proposed. However, in the presence of the cumulative negative assessment outcomes, the company decided that the risks were too high and the product development was subsequently stalled.

6. Conclusion

We developed the Lean and Agile Multi-dimensional Process (LAMP) to help developers to navigate innovation process from an early stage of product development, where uncertainties are abundant and fundamentally irreducible [47]. LAMP achieves this by generating insights into a number of key questions gathered from a wider perspective. Firstly, how would a technology influence key stakeholders, and how can such influences be prioritized and incorporated into the design to optimize performance and streamline adoption in chosen clinical contexts? Secondly, how do performance and design of a device jointly influence its perceived risks and benefits and its market potential against competitors (or comparators), thus shaping value propositions? Thirdly, how can developers maximize market value while meeting payers' expectations, e.g. by considering the cost-effectiveness threshold [48,49]? Evidence underpinning these issues is diverse. It would be extremely challenging for manufacturers to act upon these evidence unaided, as they become available. Using LAMP, decision-making is embedded in a phased structure, whilst these issues are explored in increasing depth by methodologists working closely with manufacturers and key stakeholders. The utility of the multi-dimensional evidence is maximized, allowing satisfactory design solutions and value propositions to emerge.

As a decision-making tool, LAMP is characterized by its flexibility. The activities are routinely re-configured to reflect the evolving evidence base and priorities and the framework is adapted to accommodate different needs, time scales, and available resources. For instance, in Case 3 the focus was on ascertaining unmet needs (i.e. Phase 2). In Case 1 and Case 2, manufacturers have both ascertained technical validity and generated preliminary insights in the clinical applications of a device but have different business models and resources. Because the evidence differed in quality and quantity, our subsequent assessments focused either on exploration (Case 1) or on ascertaining clinical utility (Case 2), leading to different outcomes and commercial decision-making (Table 3). One iteration of LAMP can be completed in as little as 3 months, especially when the evidence is affirmative (positive) and therefore no substantial revision of the evaluation protocol is required. In an ideal scenario, the framework is applied iteratively, thus providing continued insights into alignment between the product, the user, the clinical contexts, and the market, as the technology progresses through innovation stages.

As an early HTA tool, LAMP embodies an evolutionary approach to evidence generation, which emphasizes the *breadth* of assessments rather than their *depth* [50,51]. Manufacturers are supported to implement *incremental* revisions, using assessments that are formative rather than summative, exploratory rather than definitive, constructive rather than prescriptive. Therefore, recommendations are conditional on the evidence gathered, experts interviewed, and subject to biases in human cognition [52,53]. Its strength lies in a structured approach and a robust process driven by impartial methodologists who gather, generate, interpret, and synthesize evidence. However, to implement LAMP would require concerted effort from methodologists, manufacturers and clinicians and key inputs from other stakeholders including patients, laboratory technicians, commissioners, etc.

7. Expert opinion

For technology translation, large clinical studies and in-depth health economic evaluation are neither necessary nor feasible, especially for small companies that dominate the medical device and diagnostic industries. Since its inception over a decade ago, early HTAs have been used to gain insights into market uptake and technology design. Its popularity continues to rise, evidenced by a growing number of published studies [54]. Specialized research units applying its methodologies are also being established [55].

Nevertheless, as we move away from the classic paradigm of full-scale, targeted, and largely linear approach embodied in

mainstream HTAs, we are confronted with new challenges. For early stage assessments, a multi-disciplinary approach has been recognized as essential, and international collaborations have been forged toward this end [11]. Many methods, including a host of qualitative ones, are now used alongside quantitative tools to cope with the lack of clinical evidence. Despite many favorable developments, early HTAs are frequently not implemented, due to a combination of factors including a lack of knowledge [17], a lack of access to expertise and a lack of motivation from the manufacturers [10,56]. The diverse range of tools and expertise required for early assessments can be overwhelming even for methodologists (e.g. Table 1). From this perspective, LAMP offers a solution to realizing the multi-disciplinary approach that supports commercial decision-making by synthesizing key evidence, harmonizing perspectives from key stakeholders, and taking into account local contexts [6,57], in a way that is 'lean' in its activities whilst 'agile' in its operation.

The ultimate goal of early HTAs is the wide dissemination of the practice to transform product design and development, thereby optimizing resource allocation, reducing waste, and adding value to the health-care systems. This implies a high degree of integration of HTA practices into the design, manufacturing, and marketing activities, and can be achieved in a number of ways. Firstly, tools can be developed for use by manufacturers. An example is the aforementioned headroom approach (Section 2). We are also developing an on-line version of the POCKET evidence checklist, which will be freely available to SMEs. These tools are widely accessible, easy to use, and useful for raising awareness, improving knowledge and helping the initial stages of problem identification and problem structuring. These would not help issues surrounding designing and commercializing a specific product, however, which would require fine-tuning of the evidence specific to the technology.

A second option is to train an in-house team carrying out assessments within a company. This solution has the advantage of being highly tailored toward the company, its culture, organization, products, and aims. Once established, the team could serve to horizontally integrate decisions across various departments, e.g. basic R&D, marketing, design, etc. However, to build such a team would require a product pipeline (economy of scale), thereby limiting how widely this could apply. Further questions remain as to how such teams might gain routine access to a wide range of clinical expertise fundamental to the quality of early assessments.

A third option is an expert-led solution intermediating between commercial decision-making, clinical needs and payers, as adopted in LAMP. As a methodologist team, we are funded externally, embedded in a large teaching hospital, forming part of a large national network of research infrastructure. A main challenge of this model is perhaps the integration with manufacturers. However, we are working toward the same goal developing safe, useful, value-for-money and commercially viable products. By reconciling differences in working habits, culture, organization, logistics, etc., we are also developing capabilities, expertise, and insights – LAMP itself results from our attempt to meet industry needs from an academic perspective. As long as manufacturers, clinicians, and methodologists continue to operate in different environments, the 'cultural shocks' could stimulate debate, critical thinking, and hopefully the emergence of best practices within various organizations.

However, LAMP has a number of limitations. Firstly, scaling up remains challenging. As a multi-dimensional tool, its implementation requires expertise in quantitative and qualitative methods. Such diverse expertise takes time to develop so does training individuals with different expertise to work seamlessly together. This cannot happen without a friendly policy environment and funding support. One option we have successfully applied was to train a researcher to execute all the assessments, supported by a methodologist team. To improve access, we are also in the process of developing an on-line version of LAMP, freely available to SMEs and researchers. Secondly, still more work needs to be done to improve interactions with external experts and stakeholders, as well as to continue engagement beyond the assessment process. Thirdly, there is a need to formalize learning as we continue to apply the framework, which we currently do informally by group discussions.

Finally, the transition from evidence appraisals to decision-making remains challenging. Within LAMP, this is currently done by facilitated discussion. Going forward, we envisage a more transparent and accountable process which may be achieved by incorporating decision analytic frameworks, such as Multi-criterial Decision Analysis (MCDA). This would enable a discussion of the underpinning values and the assessments of how a prototype might perform on various decision criteria [3,24,58]. We could also incorporate methods such as the Expected Value of (Perfect) Information analysis (EV(P)I) [59] which would inform whether or not further evidence generation is worthwhile. From a company's point of view, this would lend to a more systematic examination of how design iterations evolve based on the multiple criteria and the decision-making (go/no go) at each stage can be better articulated.

7.1. Five-year perspective

As digital economy gains maturity and major breakthroughs are being made in artificial intelligence, algorithms are increasingly incorporated into device software. This, alongside the advent of new technologies, e.g. miniaturized sensors, phone apps, internet of things, health-care activities are increasingly diffused, enables unprecedented solutions to health-care challenges [60], shifting care increasingly away from the hospitals and into communities and patient homes [61]. These new developments present tremendous opportunities for innovators as well as challenges in regulatory, technology development, assessments, and adoption.

Firstly, the amount of available data is growing exponentially [62,63]. These data, combined with artificial intelligence and data mining techniques, already provide insights into disease profiles, care pathways, unmet needs, patient risks, market size, and growth. Importantly, to convert data into outputs relevant for decision-making require expertise that is not yet, or perhaps never will be, digitalized [64]. Such expertise resides in human decision-makers. HTA experts can play a vital role in ensuring such knowledge underpins the validity of decision algorithms and thereby the technologies.

Secondly, patients increasingly have to navigate different environments, between their own homes, primary care, hospitals, pharmacies, etc. Ideally, they are supported by the same technologies recognizing the changing environments, e.g. monitoring in a hospital environment with outputs being read by clinical staff and monitoring post discharge at patient home, with outputs being read by patients and carers. To achieve this requires development of a basic prototype that can be adapted to different contexts.

Closely related to this is integration of new technology in terms of both functionalities and interfaces during its implementation. Technologies developed and introduced sequentially, by different manufacturers, at different times seldom work well together. Worse still, by competing for limited attention of busy clinicians, the benefits they are designed to deliver are being canceling out. For instance, alarm fatigue has become a well-known issue in a busy clinical environment. The issue is becoming acute as health-apps are being developed at an unprecedented speed and are routinely used in combination with other apps. This threatens the fidelity of clinical guidelines which underpins standard clinical practice. To achieve smooth integration requires forward thinking in regulation, clinical guideline development, and technology assessments. Assessments of 'compatibility' of a new concept with the existing clinical environment should become an integral part of early assessments, above and beyond the comparison against current practice for establishing value. Such considerations must also inform design of clinical studies so that relevant risks can be measured and mitigated before introducing the technology into the clinical practice.

Early HTAs are powerful tools that can inform design and development of new technologies so that these challenges can be systematically considered. For instance, a series of parallel assessments of a new digital tool can be carried out in various environments, highlighting their commonalities (for basic prototype) and discrepancies (for adaptation and integration). Feasibility studies will also include endpoints that focus on transition between various environments after use within each context has been tested. Such endpoints are continued to be monitored beyond adoption and implementation to allow local adaptations. Early HTAs have also been used in hospital-industry collaborations to improve procurement and local adaptation [14,65,66]. Going forward, we envisage that these multi-dimensional assessment frameworks, such as LAMP, are adapted and streamlined across innovation pathways, to enable needs idenfications and design iterations in face of fundamental uncertainties [67].

Notes

1. http://htaglossary.net/health+technology+assessment+%28HTA%29. Accessed: 29 August 2019.
2. https://iris.wpro.who.int/bitstream/handle/10,665.1/5508/9290611863_mod2_eng.pdf.

Key Issues

- Mainstream health technology assessments (HTAs) are in-depth and largely sequential;
- To inform product design and development at an early stage of innovation requires evidence generation approaches that are dynamic and iterative, in order to cope with substantial uncertainties;
- A multi-disciplinary approach and the use of qualitative methods, alongside quantitative modelling tools, are being recognized as essential for early stage assessments;
- The integration of evidence into commercialization is extremely challenging for innovators;
- Companies, especially small-to-medium sized, lack resources and expertise to carry out health technology assessments on their own;
- We developed the Lean and Agile Multi-dimensional Process (LAMP), an early HTA framework, to operationalize the multi-disciplinary approach. Key evidence in clinical needs, human factors, health economics, and marketing are generated in increasing depth to support design iterations and commercial decision-making.

Acknowledgments

We wish to thank Mamta Bajre and Julie Hart (Oxford Academic Health Science Network) and Shirlene Oh (Imperial Oxford Academic Health Science Network) for their contributions in applying the LAMP framework. We also thank the anonymous reviewers for their constructive comments.

Funding

The research was supported by the funding from the English National institute for Health Research Medtech and In vitro diagnostics Co-operative (MICs) program. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Declaration of Interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Reviewer Disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

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References

Papers of special note have been highlighted as either of interest (•) or of considerable interest (••) to readers.

1. Dakin H, Devlin N, Feng Y, et al. The influence of cost-effectiveness and other factors on nice decisions. Health Econ. 2015;24(10):1256–1271.
2. Luce BR, Drummond M, Jonsson B, et al. EBM, HTA, and CER: clearing the confusion. Milbank Q. 2010;88(2):256–276.
3. Goetghebeur MM, Wagner M, Khoury H, et al. Bridging health technology assessment (HTA) and efficient health care decision making with multicriteria decision analysis (MCDA): applying the EVIDEM framework to medicines appraisal. Med Decis Making. 2012;32(2):376–388.
4. Poder TG. Challenges to make cost-effectiveness studies usable by decision makers. J Thorac Cardiovasc Surg. 2018;156(5):1931–1932.
5. Martin J, Lal A, Moodie J, et al. Hospital-Based HTA and Know4Go at MEDICI in London, Ontario, Canada. In: Sampietro-Colom L, Martin J, editors. Hospital-based health technology assessment. Cham: Adis; 2016: 127–152.
6. Poder TG, Bellemare CA. Importance of contextual data in producing health technology assessment recommendations: a case study. Int J Technol Assess Health Care. 2018;34(1):63–67.
7. Martelli N. Health technology assessment, eHealth and organizational impact: challenges ahead! Int J Hosp Based Health Technol Assess. 2020;1(1): 1–1.
8. Abrishami P, Boer A, Horstman K. Value in co-creation: subjecting innovative in-hospital technologies to multi-stakeholder appraisal. Int J Hosp Based Health Technol Assess. 2017;1:12–30.
9. Ijzerman MJ, Steuten LM. Early assessment of medical technologies to inform product development and market access: a review of methods and applications. Appl Health Econ Health Policy. 2011;9(5):331–347.
   •• **A framework of health technology assessments by dividing HTA activities into stages, namely mainstream (classic), early and very early and discussed relevant tools and activities associated with each stage.**
10. Pietzsch JB, Pate-Cornell ME. Early technology assessment of new medical devices. Int J Technol Assess Health Care. 2008;24(1):36–44.
    •• **One of the earliest publications to propose the concept of early health technology assessments as opposed to mainstream (classic) HTAs.**
11. Polisena J, Castaldo R, Ciani O, et al. Health technology assessment methods guidelines for medical devices: how can we address the gaps? The International federation of medical and biological engineering perspective. Int J Technol Assess Health Care. 2018;34(3):276–289.
    • **International consensus advocating a multi-disciplinary approach towards early health technology assessments.**
12. Bartelmes M, Neumann U, Luhmann D, et al. Methods for assessment of innovative medical technologies during early stages of development. GMS Health Technol Assess. 2009;5:Doc15.
13. Fryback DG, Thornbury JR. The efficacy of diagnostic imaging. Med Decis Making. 1991;11(2):88–94.
    •• **A classic framework of evidence hierarchy for diagnostic testing.**
14. Fasterholdt I, Kidholm K, Yderstræde KB, et al. Early realistic assessment of the development of innovative medical technologies in hospitals (EARTH): a conceptual model. Int J Hosp Based Health Technol Assess. 2019;1(4):19.
15. Poder TG, Bellemare CA, Bedard SK, et al. Social acceptance and population confidence in telehealth in Quebec. BMC Health Serv Res. 2015;15:72.
16. Borsci S, Uchegbu I, Buckle P, et al. Designing medical technology for resilience: integrating health economics and human factors approaches. Expert Rev Med Devices. 2018;15(1):15–26.
    • **A novel framework that integrates health economics and human factors for design of medical devices.**
17. Manetti S Incorporating health technology assessment (HTA) into Medical Device R&D: the costs and benefits of being an early bird [Doctoral Thesis]. Institute of Management, Sant'Anna School of Advanced Studies. Pisa, Italy; 2018.
18. Butler D. Translational research: crossing the valley of death. Nature. 2008;453(7197):840–842.
19. Shinkins B, Yang Y, Abel L, et al. Evidence synthesis to inform model-based cost-effectiveness evaluations of diagnostic tests: a methodological review of health technology assessments. BMC Med Res Methodol. 2017;17(1):56.
20. Bossuyt PM, Reitsma JB, Bruns DE, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. BMJ. 2003;326(7379):41–44.
21. Huddy JR, Ni MMisra S, et al. Development of the point-of-care key evidence tool (pocket): a checklist for multi-dimensional evidence generation in point-of-care tests. Clinical Chemistry and Laboratory Medicine. 2019;57(6):845–855.
    • **checklist of evidence requirements from the perspectives of patients, laboratory experts, clinicians, commissioners (payers), regulators, industry and methodologists, not limited to point of care tests.**
22. Girling A, Lilford R, Cole A, et al. Headroom approach to device development: current and future directions. Int J Technol Assess Health Care. 2015;31(5):331–338.
23. Manetti S, Turchetti G, Ni M. Development of Medical Device Key Evidence Tool ('MEDKET'): an evidence-based framework to explain device future success in selected European and US companies. In: MEMTAB (Ed.^(Eds); Utrecht, the Netherlands; 2018.
24. Phillips LD Decision Conferencing. In: Edwards W, Miles RF, Winterfeldt DV, editors. *Advances in decision analysis: from foundations to applications*. Cambridge: CUP; 2007.
    •• **seminal paper proposing the concept of decision conferencing which is a facilitated focus group whereby key stakeholders are supported by decision models and guided by facilitators to reach consensus despite conflicting objectives.**
25. Markiewicz K, van Til JA, IJ MJ. Medical devices early assessment methods: systematic literature review. Int J Technol Assess Health Care. 2014;30(2):137–146.
26. Keeney RL. Decision analysis: an overview. Oper Res. 1982;30 (5):803–838.
27. Keeney RL. Stimulating creative design alternatives using customer values. IEEE Trans Syst Man Cybern Part C Appl Rev. 2004;34(4):450–459.
28. Martin PY, Turner BA. Grounded theory and organizational research. J Appl Behav Sci. 1986;22(2):141–157.
29. Strauss A, Corbin J. Grounded theory methodology an overview. In: Denzin NK, Lincoln YS, editors. Handbook of qualitative research. London: Sage Publications. 1994. p. 273–285.
30. Aronsson H, Abrahamsson M, Spens K. Developing lean and agile health care supply chains. Supply Chain Manage Int J. 2011;16 (3):176–183.
31. Ries E. The lean startup: how constant innovation creates radically successful businesses. New York: Crown Business; 2011.
32. Tolf S, Nystrom ME, Tishelman C, et al. Agile, a guiding principle for health care improvement? Int J Health Care Qual Assur. 2015;28 (5):468–493.
33. Naylora JB, Naima MM, Berry D. Leagility: integrating the lean and agile manufacturing paradigms in the total supply chain. Int J Prod Econ. 1999;62(1–2). [published Online First: Epub Date]. DOI:10.1016/S0925-5273(98)00223-0.
34. Pietzsch JB, Shluzas LA, Paté-Cornell ME, et al. Stage-gate process for the development of medical devices. J Med Devices. 2009;3(2). DOI:10.1115/1.3148836.
35. Jordan J, Wright J. Making sense of health needs assessment. Br J Gen Pract. 1997;47(424):695–696.
36. Robinson J, Elkan R. Health needs assessment: theory and practice. London: Churchill Livingstone; 1996.
37. Stevens A, Gabbay J. Needs assessment needs assessment. Health Trends. 1991;23(1):20–23.
38. Borsci S, Buckle P, Huddy J, et al. Usability study of pH strips for nasogastric tube placement. PloS One. 2017;12(11):e0189013.
39. International Organization for Standardization. IEC 62366-1:2015 Medical devices Part 1: application of usability engineering to medical devices. Eds B, CE: CEN; 2015.
40. Bossuyt PM, Reitsma JB, Linnet K, et al. Beyond diagnostic accuracy: the clinical utility of diagnostic tests. Clin Chem. 2012;58 (12):1636–1643.

••• **Guideline for reporting diagnostic accuracy studies.**

•• **Proposed the concept of clinical utility of a diagnostic test, key to its value and dependent on the relevance of the diagnostic test in decision making.**

41. Venkatesh V, Morris MG, Davis GB, et al. User acceptance of information technology: toward a unified view. MIS Quarterly. 2003;27(3):425–478.
42. Davis FD, Usefulness P. Perceived ease of use, and user acceptance of information technology. MIS Quarterly. 1989;13(3):319–340.
43. Reichheld FF. The one number you need to grow. Harv Bus Rev. 2003;82,133–133.
44. Brooke J. SUS-A quick and dirty usability scale. In: Jordan PW, Thomas B, Weerdmeester BA, et al., editors. Usability evaluation in industry. London: Taylor and Francis; 1996. p. 189–194.
45. Finstad K. The usability metric for user experience. Interact Comput. 2010;22(5):323–327.
46. Laugwitz B, Held T, Schrepp M. Construction and evaluation of a user experience questionnaire. In: HCI and Usability for Education and Work, 4th Symposium of the Workgroup Human-Computer Interaction and Usability Engineering. (Ed.^(Eds); Graz, Austria: the Austrian Computer Society; 2008.
47. Hogarth RM, Lejarraga T, Soyer E. The two settings of kind and wicked learning environments. Curr Directions Psychol Sci. 2015;24(5):379–385.
48. Devlin N, Parkin D. Does NICE have a cost-effectiveness threshold and what other factors influence its decisions? A binary choice analysis. Health Econ. 2004;13(5):437–452.
49. National Institute for Health and Care Excellence. Methods for the development of NICE public health guidance. 3rd ed. 2012. Available from: https://www.nice.org.uk/process/pmg4/chapter/incorporating-health-economics#economic-evidence-and-guidance-recommendations
50. Barder O Development, complexity and evolution (Ed.^(Eds); 2010 [cited 2019 Nov 29]. http://www.owen.org/wp-content/uploads/Evolution-and-Development.pdf
51. Barlow J. Managing innovation in healthcare. London: World Scientific Europe Ltd; 2017.
52. Kahneman D, Klein G. Conditions for intuitive expertise: a failure to disagree. Am Psychol. 2009;64(6):515–526.
53. Tversky A, Kahneman D. Judgment under uncertainty: heuristics and biases. Science. 1974;185(4157):1124–1131.
54. Ijerman MJ, Koffijberg H, Fenwick E, et al. Emerging use of early health technology assessment in medical product development: a scoping review of the literature. Pharmacoeconomics. 2017;35(7):727–740.
55. Abel L, Shinkins B, Smith A, et al. Early economic evaluation of diagnostic technologies: experiences of the NIHR diagnostic evidence co-operatives. Med Decis Making. 2019;39(7):857–866.
56. Hartz S, John J. Contribution of economic evaluation to decision making in early phases of product development: a methodological and empirical review. Int J Technol Assess Health Care. 2008;24(4):465–472.
57. Poder TG, Carrier N, Bedard SK. Health technology assessment unit processes for the validation of an information tool to involve patients in the safety of their care. Int J Technol Assess Health Care. 2018;34(4):378–387.
58. LD. Evaluation, prioritisation and resoure allocation: application of decision analysis in pharmaceutical research and development. In: PA, BMaB, editor. Pharmaceutical Manufacturing International. London: Sterling Publications International; 1991.
59. Claxton K, Ginnelly L, Sculpher M, et al. A pilot study on the use of decision theory and value of information analysis as part of the NHS health technology assessment programme. Health Technol Assess. 2004;8(31):1–103, iii.
60. Sim I. Mobile devices and health. N Engl J Med. 2019;381(10):956–968.
61. Mackey TK, Kuo TT, Gummadi B, et al. 'Fit-for-purpose?' - challenges and opportunities for applications of blockchain technology in the future of healthcare. BMC Med. 2019;17(1):68.
62. Katkade VB, Sanders KN, Zou KH. Real world data: an opportunity to supplement existing evidence for the use of long-established medicines in health care decision making. J Multidiscip Healthc. 2018;11:295–304.
63. Makady A, van Veelen A, Jonsson P, et al. Using real-world data in health technology assessment (HTA) practice: a comparative study of five HTA agencies. Pharmacoeconomics. 2018;36(3):359–368.
64. Pearl J, Mackenzie D. The book of why: the new science of cause and effect. London : Allen Lane; 2018.
65. Poder TG. Using the health technology assessment toolbox to facilitate procurement: the case of smart pumps in a canadian hospital. Int J Technol Assess Health Care. 2017;33(1):54–62.
66. Fasterholdt I, Krahn M, Kidholm K, et al. Review of early assessment models of innovative medical technologies. Health Policy. 2017;121(8):870–879.
67. Poder TG, Godbout ST, Bellemare C. Dual vs. single computer monitor in a Canadian hospital archiving department: a study of efficiency and satisfaction. Health Inf Manag. 2011;40(3):20–25.