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## Commentary

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# On the integration of early health technology assessment in the innovation process: reflections from five stakeholders

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**Abstract**

Early health technology assessment (HTA), which includes all methods used to inform industry and other stakeholders about the potential value of new medical products in development, including methods to quantify and manage uncertainty, has seen many applications in recent years. However, it is still unclear how such early value assessments can be integrated into the technology innovation process. This commentary contributes to the discussion on the purposes early HTA can serve. Similarities and differences in the perspectives of five stakeholders (i.e., the hospital, the patient, the assessor, the medical device industry, and the policy maker) on the purpose, value, and potential challenges of early HTA are described. All five stakeholders agreed that integrating early HTA in the innovation process has the possibility to shape and refine an innovation, and inform research and development decisions. The early assessment, using a variety of methodologies, can provide insights that are relevant for all stakeholders but several challenges, for example, feasibility and responsibility, need to be addressed before early HTA can become standard practice. For early evaluations to be successful, all relevant stakeholders including patients need to be involved. Also, nimble, flexible assessment methods are needed that fit the dynamics of medical technology. Best practices should be shared to optimize both the innovation process and the methods to perform an early value assessment.

## Introduction

Innovative healthcare technologies are constantly being developed and marketed with the claim that they promote value in healthcare. Whether a technology, which encompasses everything from new medical devices to organizational services, indeed has potential value for the patient and society can be evaluated with a health technology assessment (HTA). According to the new definition of HTA recently released by an international joint task group co-led by the International Network of Agencies for Health Technology Assessment (INAHTA) and Health Technology Assessment International (HTAi), HTA is a multidisciplinary process that uses explicit methods to *determine the value of a health technology at different points in its lifecycle* (1). Extending the traditional HTA that informs coverage/reimbursement decisions, early HTA informs early research, development, and investment decisions. This allows the potential value of a new health technology to be determined at an early stage of its development (2).

As the process of determining the (added) value of a technology during its development and pilot phases may optimize its market pathway (3), HTA is increasingly being applied in earlier stages of its development process (4). IJzerman et al. define this "early HTA" as "all methods used to inform industry and other stakeholders about the potential value of new medical products in development, including methods to quantify and manage uncertainty" (4). While there is no strict distinction between "traditional" and "early" HTA, the authors emphasize that in early HTA the innovation is still under development, noting that "the definition includes early HTA of medical products just before and also at the early stages of clinical use, while accepting that product development can continue after regulatory approval" (4).

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In early HTA, traditional HTA methodology is commonly applied, but with a different timing and purpose (4–6). It is now used to explore the potential value of the technology in its intended context when there still is insufficient evidence on the technology. Early HTA asks the following questions: Does the innovation meet an unmet need? How may the technology impact the designated context? What are potential barriers for and facilitators of its use? What needs to be researched when and how? How can the value of the technology be optimized after implementation? Early assessment allows researchers and developers to proactively address uncertainty, anticipate the extent of acceptance, and potentially improve the efficiency of evaluation research and the development of new technologies—shifting the goal of HTA from summative to formative, and from retrospective to prospective, to guide further research and development (7;8).

Recent years have seen many applications and methodological studies of early HTA (4;5;7;9–13). However, it remains unclear how early HTA can be made to fit in with day-to-day healthcare decision making and how it can be integrated into the innovation process. What does early HTA add to current practices and what are its advantages and challenges? The aim of this commentary is to contribute to the discussion on the purposes an early HTA can serve by providing personal reflections from different perspectives: the hospital, the patient, the assessor, the medical device industry, and the policy maker.

## Views on early HTA from different perspectives

### *The hospital—Laura Sampietro-Colom*

Hospitals are one of the main entry doors of health technologies, but they are also the place where innovation usually flourishes in pursuit of solutions to health and healthcare needs not solved in every-day clinical practice. While sometimes the ideas brought by healthcare professionals seem at first very interesting; only very few of them reach the market. This is due to several reasons, but one of the most important is the lack of a systematic analysis about the potential value of the technology in the early stages of development. Clinicians are usually not familiar with the type of information that is required for making adoption decisions, neither do they know how to analyze whether the product has a chance of properly solving the identified problem (considering all stakeholder perspectives). HTA brings the scientific knowledge and the accumulated life experience on how technologies should be valued, and how they actually are valued by those who will decide on their incorporation and coverage in health systems. By applying early HTA in hospitals, developers can demonstrate the value of their prototypes. Moreover, hospitals can become a perfect lab for start-ups/spin-offs to co-develop technologies and to test their value. An example of this is the evaluation of software (integrated in magnetic resonance technology) developed within a hospital to visualize existing conductivity channels in the heart tissue after a massive myocardial infarction (14).

Nevertheless, there are challenges to carry out early HTA that need to be overcome at the hospital level. Still many healthcare professionals are not aware of what HTA is, and those who know it see HTA far from their clinical practice, like something that happens on a macro level and cannot help them in advancing the development of their technologies. One solution is to apply existing expertise on hospital-based HTA in hospitals. Unfortunately, although there is an increasing interest to adopt hospital-based HTA (15), as exemplified by countries like China and Poland and some European countries, still most university hospitals lack this expertise.

### *The patient—Dominique Hamerlijnck*

Involving patient experts and patient organizations early in the development process of new innovations increases the possibility that innovations will capture the values that are important to patients. To achieve this, technology developers and researchers need to work closely together with patient experts and patient organizations, co-creating from the very beginning. This is also emphasized by Patients Active in Research and Dialogues for and Improved Generation of Medicines (PARADIGM), a European initiative and public-private partnership co-led by the European Patients' Forum (EPF) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). PARADIGM develops tools to achieve the co-creation process, especially with patients. All stakeholders, including patients, should be invited to join in an early dialogue. Based on the good evidence input from all stakeholders, joint inquiry can help formulate the right questions and perspective. Where do the needs and requirements of all participants (e.g., patients, scientists, companies, physicians, researchers) meet and which new technologies will benefit all? What are viable options for improvement? How can the technologies, whether medicines or devices, create a positive result for all? What are the relevant questions to ask? And, most importantly from the patient perspective: What outcomes merit improvement? How can these be measured in a fit-for-purpose way? How can we attain content and construct validity and reliability, and measures sufficiently sensitive to detect meaningful within-group and within-patient change (16)? By listening to patients and translating their views, wishes, and needs into questions that are germane for all stakeholders, we can ensure that the health outcomes will be relevant for the patients targeted.

Early HTA can be useful to monitor whether stakeholders agree on the chosen approach, whether advice and scientific evidence is obtained from all, to record progress, and verify whether each step reflects the various ideas and desired outcomes and how this can be improved if needed. Finally, it is recommended to obtain the regulator's perspective on the plans and next steps. This will help save money and effort in both the research and health budgets.

### *The assessor—Øyvind Melien*

While in the inception of health technologies there is a tendency to focus on the launch phase, it is crucial to extend the scope to the innovation's life cycle for the benefit of the patients. Research and development, introduction, follow-up, improvement, or disinvestment of health technologies all rely on continuous information and evaluation with reference to relevance, needs, efficiency, safety, and economic viability. In this chain of events, early HTA may fill a gap by facilitating the interaction among and information dissemination to relevant stakeholders such as patient representatives, health professionals, research and development, industry, authorities, and procurement organizations. A major driving force and consideration in modern medicine is to promote targeted interventions in accordance with the concepts of personalized medicine to address the needs of both the individual patient and the healthcare system in general. Early HTA may then support the development of such targeted health interventions by

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capturing, evaluating, and sharing valuable data at an early stage to steer the research and development processes into the desired direction. That way it may help improve the life-cycle perspective of novel health technologies from their inception and inform stakeholder dialogues early in the process.

### *The medical device industry—Markus Siebert*

In medical device industry, early HTA is first and foremost an internal process that needs to be established within the company. Because it is so different from traditional HTA, we would prefer to call the approach an "early value assessment." It involves a multidisciplinary venture initiated at the inception phase of a technology or during the due diligence process of a potential acquisition. Input from Pricing Health Economics & Reimbursement, Sales & Marketing, Regulatory Affairs, and Clinical Affairs is gathered, incorporating the voices of the relevant geographies. By factoring in its values for payers and/or society early on, the value proposition and price of a technology can be determined in such a way as to improve its acceptability and adoption rate. If this approach is not followed, this may result in an innovation that is not needed or brought to market at costs (and hence prices) that are unrealistic in the eyes of both payers and customers—ultimately impeding market access.

Accordingly, an early value assessment should be a standard component of any pre-market strategy for medical device innovations that are "disruptive" from a technological or financial perspective, at the stage of technology scanning and product conception. For this approach to be successful, robust internal processes need to be established, starting with a decision-making tool that helps determine when an early HTA is needed. Outreach initiatives, comprising early dialogues, need to be launched targeting the most important external stakeholders—payers, hospitals, and where appropriate, patients—to assess their needs and willingness and ability to pay. The technology in question needs to be positioned against the current and possible future realities of coverage, reimbursement, and cost-effectiveness in major geographies of the world.

The results from the early HTA need to inform product design, clinical and economic evidence strategies, and price setting. Although we can draw from existing academic expertise in HTA and hospital-based HTA, it is fair to say that early value assessment also requires new tools and skills. It needs to move much faster than traditional HTA, simulate scenarios, elicit multistakeholder input through early dialogues, and ultimately combine the rigor of science with pragmatic advice to industry.

### *The policy maker—Payam Abrishami*

New medical and data-driven technologies are often developed and introduced in the healthcare system in a highly dynamic process. From the policy maker perspective, two characteristics of this process signify the importance of early HTA: the diversity of stakeholders involved and a traditional separation of development and evaluation in the innovation process.

Decisions on the development and introduction of novel technologies are typically made by diverse stakeholders in decentralized arrangements (i.e., at the discretion of local stakeholders in advance or absence of explicit national assessments). Second, new technology is often introduced in a sequential fashion: from ideation to prototype design, to proof of principle, market entry, financing, acquisition, spread, and implementation. Since these tasks are distinctive in terms of execution and immediate information needs, a division of labor in the introduction of innovations seems inevitable. While the responsibilities are dispersed, the purpose is fairly shared: providing value for the patient and value for society (16). Early HTA can be seen as an (as yet missing) "link" between the different loci and foci of technological innovations and the desirable value for patient and society. Early HTA is also congruent with the current policies of regulatory agencies and health authorities to favor promising innovations without imposing strict actuarial controls or top-down restrictions, and is well-attuned to the decentralized, market-oriented processes in introducing medical innovations.

Accordingly, early HTA should have an iterative nature, particularly for expensive technologies or innovations with a broad application field and a potential for large-scale, drastic changes such as telecare, artificial intelligence, gene editing. It helps stakeholders to:

- clarify the innovation's value proposition, with stakeholders collaboratively identifying claims of benefit of a new medical technology and clarifying its place in the entire care pathway, and
- establish and sustain "innovating-in-research"/managed entry schemes, where early HTA enhances mutual understanding and alignment between regulatory and HTA agencies, and among innovators, medical professionals, and health insurers/payers on what kind of evidence is relevant to demonstrate the claimed (added) benefits. This involves agreeing on the design of clinical and cost-effectiveness studies early on, including the target population, comparator, relevant outcome measure(s), follow-up period, and, notably, consideration of all relevant patient perspectives. In so doing, early HTA can promote a shift from a first-innovate-then-evaluate approach toward an iterative innovate-and-evaluate approach.

## Implications and recommendations

From the perspectives presented above, we can derive that early HTA can help to shape and develop health technology, inform early research and development decisions, and guide evidence generation. Using diverse, systematic methodologies, early assessments can provide insights that are relevant for developers and decision makers. Implementation of an innovation may fail when key players have different perspectives as to whether there is a problem in the first place. If implementation fails, costs are incurred without appreciable benefits. Here, an in-depth analysis of the extent and consequences of the perceived problem may be at least as informative as evidence on the effectiveness of the proposed solution.

Before early HTA can become standard practice, several challenges need to be addressed. First, at present, it is unclear who is responsible for evaluating the potential value of a technology in the early stages of its development and who should fund it. In the view of the medical device industry, early value assessments preferably are an integral part of research and development or marketing process. However, HTA bodies, hospitals, and regulators may all have different stakes in the systematic investigation of a technology's potential value, as well as different criteria for decision making (e.g., profitability, quality of life, value for money). This emphasizes the importance of early HTA being a joint effort of the key stakeholders, with a clear and specific aim (17).

A second related and key challenge is the inclusion of patients in the development and research of new technologies. Here,

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stakeholders can learn from initiatives like co-creation that are gradually gaining ground in healthcare decision-making (18).

Third, the implementation of early HTA must be feasible and fit in with the innovation process. It should not delay or stop the development of technologies but rather create an environment in which all parties can make informed decisions. This may then result in the early discontinuation of technologies that do not align with existing needs, while it will expedite the adoption of valuable technologies. Ideally, this is an iterative process where the design of research is informed and the assessment is updated as more information becomes available, either about the technology itself or the environment in which it would be used (6;7;19;20).

Fourth, technology developers (in industry and hospitals) often lack knowledge of early HTA, its use and usefulness, hampering the implementation and advancement of the evaluation method during the inception and early development of innovations. Initiatives to update institutions to advance and guide implementations of early HTA are recommended.

Fifth, most of the early HTA applications focus on the early assessment of a new medical device, while it is also possible and relevant to use early evaluations to determine the potential of organizational or service innovations.

Sixth, by definition, early HTA is oriented toward the early phases of technology development and, as such, needs to be more nimble and flexible than traditional HTA. Arguably, introducing a different term for the approach may be helpful. One can think of early value assessment or developmental value assessment as these terms underscore that the goal of the evaluation is not to assess the evidence on the technology but to explore its potential value and guide evidence generation, which is why there also is greater emphasis on qualitative methods than is customary in conventional HTA (5). In early HTA it is not necessarily the new technology but rather current care pathways that are being assessed, where the leading questions should be: What technologies are currently available/applied? What benefits do they offer? Where do they fall short? And what is the potential marginal value of the proposed technology?

The integration of early HTA in the innovation process may be influenced by legislative developments. For example, the recent legislative proposal to strengthen European Union cooperation on HTA aims to make effective, innovative health tools available to patients faster (21). However, this carries the risk that also expensive yet low-value health technologies reach clinical practice faster, thereby jeopardizing the sustainability of national healthcare systems. It is hence crucial that HTA is employed to prioritize the most valuable innovations at the earliest stage possible, preferably before or during its development.

Finally, under the new European Union Medical Device Regulation, evidence generation will also need to be stepped up (22;23), with the new legislature requiring early assessment methods that adequately address uncertainty and improve the efficiency of research and development of innovations. By sharing best practices and (experiences with) newly developed methodologies, all actors can profit.

In this commentary, five personal perspectives are presented, highlighting similarities, all endorsed the importance of early HTA to shape and refine an innovation, and inform research and development decisions, but also differences. To advance the field, we considered it valuable to share these perspectives, and to search for the challenges that arise from these views. With this we revealed important questions, such as who is responsible, how can we develop nimble assessments, how can we make sure all stakeholders are included? The next step would be to reach consensus on these questions. To achieve this is, it is necessary to create conditions in which learning among stakeholders is possible. Stakeholders have different views of what challenges we are facing, what strategies are likely to work, and what is needed to take the issue further. However, the underlying assumptions remain implicit, and as such, are unavailable for critical scrutiny. By making them explicit, stakeholders gain a better understanding of their own position, but may also gain a better understanding in how and where they differ from other stakeholders. Deliberative methods, such as interactive interviews and focus groups, can support this learning. Continuous action and reflection will be necessary to evaluate the process of reaching consensus, in order to really integrate early value assessment in the innovation process.

## Conclusion

In this commentary, the value and challenges of integrating early HTA or early value assessments in the medical innovation process are discussed from different perspectives. Representatives of five key stakeholders largely agreed that it is more effective to steer innovations in an early phase of their development rather than having to modify or retract them in the final stages, or after they have been introduced in clinical care, due to their having insufficient or no added value. For early evaluations to be successful, all relevant stakeholders, including patients, need to be involved as early as possible. To become standard practice in health innovation, methods need to allow for nimble and flexible assessments that fit the dynamics of medical technology, while experiences with their development and use need to be shared to foster best practices and contribute to the optimization of early value assessments.

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## References

1. **O'Rourke B, Oortwijn W, Schuller T, International Joint Task G**. The new definition of health technology assessment: A milestone in international collaboration. *Int J Technol Assess Health Care*. 2020;**36**:187–190.
2. **Lehoux P, Miller FA, Daudelin G, Denis JL**. Providing value to new health technology: The early contribution of entrepreneurs, investors, and regulatory agencies. *Int J Health Policy Manag*. 2017;**6**:509–18.
3. **Campbell B, Campbell M, Dobson L, Higgins J, Dillon B, Marlow M, et al.** Assessing the value of innovative medical devices and diagnostics: The importance of clear and relevant claims of benefit. *Int J Technol Assess Health Care*. 2018;**34**:419–24.

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4. **IJzerman MJ, Koffijberg H, Fenwick E, Krahn M**. Emerging use of early health technology assessment in medical product development: A scoping review of the literature. *Pharmacoeconomics*. 2017;**35**: 727–40.
5. **Stome LN, Moger T, Kidholm K, Kvaerner KJ**. Early assessment of innovation in a healthcare setting. *Int J Technol Assess Health Care*. 2019;**35**:17–26.
6. **Sculpher M, Drummond M, Buxton M**. The iterative use of economic evaluation as part of the process of health technology assessment. *J Health Serv Res Policy*. 1997;**2**:26–30.
7. **Grutters JPC, Govers T, Nijboer J, Tummers M, van der Wilt GJ, Rovers MM**. Problems and promises of health technologies: The role of early health economic modeling. *Int J Health Policy*. 2019;**8**:575–82.
8. **Kluytmans A, Tummers M, Van der Wilt GJ, Grutters JPC**. Early assessment of proof-of-problem to guide health innovation. *Value Health*. 2019;**22**:601–6.
9. **Girling A, Lilford R, Cole A, Young T**. Headroom approach to device development: Current and future directions. *Int J Technol Assess Health Care*. 2015;**31**:331–8.
10. **Frempong SN, Sutton AJ, Davenport C, Barton P**. Economic evaluation of medical tests at the early phases of development: A systematic review of empirical studies. *Expert Rev Pharm Out*. 2018;**18**:13–23.
11. **Abel L, Shinkins B, Smith A, Sutton AJ, Sagoo GS, Uchegbu I, et al.** Early economic evaluation of diagnostic technologies: Experiences of the NIHR diagnostic evidence co-operatives. *Med Decis Making*. 2019;**39**: 857–66.
12. **Markiewicz K, van Til JA, Steuten LMG, IJzerman MJ**. Commercial viability of medical devices using Headroom and return on investment calculation. *Technol Forecast Soc*. 2016;**112**:338–46.
13. **Fasterholdt I, Krahn M, Kidholm K, Yderstraede KB, Pedersen KM**. Review of early assessment models of innovative medical technologies. *Health Policy*. 2017;**121**:870–9.
14. **Crespo C, Linhart M, Acosta J, Soto-Iglesias D, Martinez M, Jauregui B, et al.** Optimisation of cardiac resynchronisation therapy device selection guided by cardiac magnetic resonance imaging: Cost-effectiveness analysis. *Eur J Prev Cardiol*. 2020;**27**:622–632.
15. **Sampietro-Colom L, Martin J**, editors. *Hospital-based health technology assessment: The next frontier for health technology assessment*. Switzerland: ADIS; 2016.
16. **FDA**. FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making. [cited 2019 October 25]; Available from: https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical.
17. **Fasterholdt I, Lee A, Kidholm K, Yderstraede KB, Pedersen KM**. A qualitative exploration of early assessment of innovative medical technologies. *BMC Health Serv Res*. 2018;**18**:837.
18. **Abrishami Shirazi 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**(1):12–30.
19. **Drummond MF**. Modeling in early stages of technology development: Is an iterative approach needed?; comment on "problems and promises of health technologies: The role of early health economic modeling". *Int J Health Policy*. 2020;**9**:260–262.
20. **Partington A, Karnon J**. It's not the model, it's the way you use it: Exploratory early health economics amid complexity; comment on "problems and promises of health technologies: The role of early health economic modelling". *Int J Health Policy*. 2020. doi: 10.15171/ijhpm.2020.04. Online ahead of print.
21. **European Commission**. Assessing health technology in the EU: Commission proposes to reinforce cooperation amongst Member States. https://ec.europa.eu/commission/presscorner/detail/en/IP_18_4862018.
22. **Official Journal of the European Union**. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. [cited 2019 March 5]; Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG&toc=OJ:L:2017:117:TOC.
23. **Rothery C, Claxton K, Palmer S, Epstein D, Tarricone R, Sculpher M**. Characterising uncertainty in the assessment of medical devices and determining future research needs. *Health Econ*. 2017;**26**(Suppl 1):109–23.


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