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HEOR in the Broader Context of HTA/CER

# Early Assessment of Proof-of-Problem to Guide Health Innovation

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## ABSTRACT

*Background:* Although the relevance of both push and pull factors is acknowledged in models of innovation, needs, broadly defined, are rarely considered, whereas supply-driven innovation in publicly funded health systems carries the risk that it may not match the underlying problems experienced by patients and consumers.

*Objectives:* To explore a mixed-methods, multistakeholder approach that focuses on pertinent problems when assessing the potential value of an innovation as applied to a case of surgical innovation in meniscus surgery.

*Methods:* Through interviews of stakeholders (n = 11) we sought to identify current problems of meniscus surgery in the Netherlands. On the basis of the subsequent problem definitions, we used stakeholder and literature input to quantify the room for improvement and stakeholder engagement to uncover possible barriers and facilitators to the implementation of the proposed innovation.

*Results:* Despite being enthusiastic about the ingenuity of the proposed innovation and seeing some potential for cost saving, most stakeholders (n = 10) agreed that there are no major problems in current meniscus surgery meriting the innovation. They even discerned pragmatic barriers that would challenge the potential cost savings.

*Conclusions:* By adopting a problem-oriented multistakeholder approach to early health technology assessment, we were able to estimate the potential value of an innovation in its social context, finding that, beyond the initial enthusiasm, the proposed innovation was unlikely to resolve the problems distinguished by the stakeholders. We concluded that our multistakeholder, mixed-methods approach to early health technology assessment is feasible and helps foster more demand-driven innovations.

*Keywords:* early HTA, innovation, needs assessment, problem-oriented approach

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## Introduction

In principle, innovation in health technology has much to offer to society. Because of innovative technologies, both the expected duration and the quality of our lives have improved.[1] Simultaneously, however, healthcare costs have increased to a point where the sustainability of publicly funded healthcare systems may be in jeopardy.[2] Although innovation is not the only factor driving up costs, it does play a part.[3,4] Increasingly, scientists and policy advisors are questioning whether all these innovative technologies really do deliver what they promise.[5–9]

Health technology assessment (HTA) attempts to determine the actual benefits of innovations, but because of its reliance on data it is traditionally performed when a new technology has already withstood clinical trials or has been applied in practice for some time. By then, vested interests have arisen, public demand for the novel technology has grown, and any assessment that concludes the technology may not provide societal value for money is often "too little, too late." In response to this challenge, the past decade has seen the emergence of early HTA applications.[10,11] Unlike traditional HTA, early HTA is performed throughout the development cycle of a novel technology. The key philosophy here is that in the early stages there still is ample room to anticipate problems and make adjustments. Put more critically, Greenhalgh et al[12] recently noted that health technology development is full of avoidable waste and that early HTA is a powerful tool in realigning technological progress.

In practice, early HTA often has a strong technology-focused or supply-driven character. Nevertheless, technology-driven innovations often neglect the question of the underlying needs or problems that major stakeholders experience in the current care situation. Innovation offers solutions, but to what, for whom, and

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of what magnitude? Is there even a problem to begin with? We argue that the potential value of an innovation depends crucially on the answers to these questions—where it is important to consider the different perspectives of those involved—and that early assessments should therefore adopt a problem-oriented focus before considering a specific technology (or solution) in more detail. Ideally, proof-of-problem precedes proof-of-principle or proof-of-concept. Such an approach could then foster the development of innovations that truly address the needs and demands that are currently underserved.[13,14]

In our view, a proof-of-problem analysis requires a methodology that combines the strengths of early health economic modeling with the timely involvement of relevant stakeholders. The latter is vital to ensure the legitimacy of the HTA process and its outcomes.[5,15,16] In addition, involving stakeholders at an early stage provides the opportunity to identify contextual barriers to and facilitators of the proposed innovation, providing relevant cues as to its potential value or necessary adaptations before major investments have been made. To our knowledge, such an early approach to HTA has not been described before.

In this article we test the feasibility and relevance of a problem-oriented, multistakeholder approach to the early HTA of a surgical innovation in meniscus surgery.

## Methods

Combining various qualitative and quantitative methods, we assessed the potential value of an innovative, laparoscopic surgical instrument currently under development in the context of meniscus surgery. Although the innovation may be applied in several surgical contexts, we chose to focus on meniscus surgery because the instrument was originally targeted at this procedure. The claims for this specific instrument were that it replaces a range of existing instruments, optimizing operation conditions for the surgeon and reducing the risk of infection, improving patient comfort and health outcomes.

### *Qualitative Assessment of the Problem*

First, we identified a broad range of relevant stakeholders in meniscus surgery, defining stakeholders as actors directly involved in the decision-making process and actors who are, or may be, affected by any action taken by an organization or group.[17–19] Adhering to this definition during a brainstorm session, we selected the following stakeholders to be considered for our problem and needs assessment of current meniscus surgery practice: orthopedic surgeons, patients, medical sterilization specialists, infection-prevention specialists, researchers focusing on arthroscopic interventions, innovation consultants, physical therapists, innovation developers, and hospital purchasing managers.

On the basis of affiliations and expertise, we contacted stakeholders by email in which we briefly introduced ourselves, explaining the aim of our assessment, and inviting them to participate in a face-to-face interview. At the end of each interview, we asked the stakeholder if there was anyone else—either type of stakeholder or additional stakeholder from the same category—we should approach. We also asked the surgeons we interviewed to bring us into contact with patients.

We held semistructured, face-to-face interviews with all stakeholders separately to obtain their perspectives on current meniscus surgery and the proposed innovation. After mutual introductions and various procedural questions (eg, about the interviewee's available time and permission to make audio-recordings of the interview), the interviewer gave a brief recap of the reason for the interview (summarizing the information detailed in the contact email). The stakeholders were then asked about current practice and any problems they experienced with this, as well as the perceived room for improvement and any potential solutions or alternatives to current practice.

Next, we explained the concept of the innovation, asking the stakeholders about their ideas of the value of such an innovation and potential barriers to or facilitators of its implementation. We subsequently specified our questions on the basis of the stakeholder category, matching our queries to his or her expertise. Thus, we focused on the surgical procedure itself if the interviewee was a surgeon, on infections when talking to an expert in infection prevention, and on the entire care pathway if the stakeholder was a physical therapist. Our interviews were interactive in that comments of previously interviewed stakeholders were quoted anonymously to help build a shared perspective on current practice and the added value of the proposed innovation. When the stakeholders' perspectives diverged, we posed follow-up questions. Afterwards, the audio-recordings of the interviews were transcribed and summarized by the interviewers.

### *Quantitative Assessment of the Problem*

We combined the stakeholder interviews with decision-analytic modeling,[20–22] with the points the stakeholders raised serving as the direction and input for the further quantification of the perceived problems in meniscus surgery. We used headroom and threshold analyses to delineate the room for improvement in current procedures on the basis of the stakeholders' input.

In our headroom analysis we quantified the room for improvement by comparing current aspects of meniscus surgery as raised during the interview to a hypothetical perfect scenario.[11,23–25] Thus, if complications occur in association with current procedures, the headroom analysis compares their consequences to those of a care strategy in which no such complications occur. The difference in quality-adjusted life-years (QALYs), for example, quantifies the effectiveness gap in current care practice. We understand headroom as the monetary expression of the effectiveness gap—that is, the product of the difference in QALYs and the willingness to pay for a QALY—minus the additional costs of the perfect-care strategy. The headroom analysis accordingly provides an estimate of the maximum potential value that any innovation could add given the shortcomings of current care, and, together with the stakeholder input, can be used to identify problems in a given care situation.

Assuming that the innovation itself will not be perfect, we followed up our headroom analysis with threshold analysis to determine which requirements should a minimally viable product meet to be considered cost-effective compared with current instruments.[26] For these latter analyses we needed a cost approximation for the new instrument, which we estimated at €2000. We performed univariate sensitivity analyses for a price range between €1500 and €2500.

## Results

### *Qualitative Assessment of the Problem*

Eleven stakeholders agreed to participate in our evaluation: 3 orthopedic surgeons from an academic, community, and private hospital, respectively; 1 patient having had arthroscopy of the knee; 2 medical sterilization specialists, 1 infection-prevention specialist, 1 researcher specialized in arthroscopic interventions, 1 innovation consultant, 1 physical therapist, and 1 of the innovation's developers.

**Table 1.** All quantitative inputs used in the analyses of procedure time and risk of infection.

| Parameter | Value | Source |
|---|---|---|
| *General* | | |
| Assumed price of novel instrument, per piece | €2000 | Assumption |
| *Procedure time for meniscus removal* | | |
| Number of orthopedic surgeons per procedure | 1 | Stakeholder input |
| Average number of minutes per procedure | 20 | Stakeholder input |
| Estimated number of minutes lost trying to reach the meniscus | 5 | Stakeholder input |
| Cost of orthopedic surgeon, per minute | €1.93 | Radboud University Medical Center[29] |
| Cost of an OR with 2 assistants and 1 half-time anesthesiologist, per minute | €8.66 | Radboud University Medical Center[29] |
| Total cost of meniscus surgery, per minute | €10.59 | Radboud University Medical Center[29] |
| *Risk of infection after meniscus surgery* | | |
| Probability of infection after meniscus surgery | 0.001 | Thorlund et al[30] |
| Probability that infection is mild | 0.500 | Assumption |
| Cost of reoperation (severe infection) | €4204 | Rongen et al[31] |
| Cost of 1-d IV stay (mild infection) | €575 | Tan et al[28] |
| QALY lost due to severe infection | 0.010 | Rongen et al[31] |
| QALY lost due to mild infection | 0 | Assumption |

IV indicates intravenous; OR, operating room; QALY, quality-adjusted life-year.

After these 11 interviews, saturation was achieved where no significant new insights or information were forthcoming about the potential added value of the novel surgical instrument or the room to improve patient/health outcomes. Because the observations we derived from the interviews were cumulative, with stakeholders commenting on or adding to the views and suggestions of other stakeholders, we will discuss the results by topic instead of by stakeholder.

Although the innovation developer contended that surgeons often struggle to reach parts of the menisci, causing avoidable stress on both the surgeons' and patients' physiques, none of the other stakeholders noted any substantial problems or shortcomings in current meniscus surgery practice. They all felt that the procedure had undergone various critical improvements in the past and that no major health benefits are foregone by current practice. All 3 surgeons we spoke to shared the perception that the procedure is always successful and that patient outcomes are already optimal.

When asked about potential room for improvement, the surgeons, researcher, and physical therapist mentioned improving patient selection for meniscus surgery, providing surgical training in meniscus repair, and setting up a collaborative network to enable orthopedic surgeons and physical therapists to improve postsurgical care.

When asked about the instruments used in meniscus surgery, the surgeons indicated an occasional struggle in reaching posteromedial parts of the menisci (partly confirming the developer's observation). They estimated that of the average procedure time of 20 minutes, they spent about 5 minutes reaching these parts, which could, in theory, be saved by having more flexible instruments. Although the developer claimed health benefits of the novel instrument through infection reduction due to fewer instrument insertions into the knee, all the other stakeholders regarded infections in meniscus surgery as a nonissue. The infection-prevention specialist specifically mentioned the 0% infection rate after knee replacement surgery for the past 2 years—arguably a more invasive procedure than meniscus surgery.

When the proposed innovation was described to them, the stakeholders were enthusiastic about its technological novelty. Nevertheless, all but the innovation developer remained skeptical about its benefits for the patient, an aspect the surgeons perceived as a decisive factor in their estimation of the innovation's potential value.

In brief, our stakeholder interviews revealed that the new instrument might resolve 2 assumed problems in current meniscus surgery in that it could (1) reduce procedure time by an estimated 5 minutes by offering easier access to the menisci, as was suggested by the developer and confirmed by the surgeons, and (2) achieve a reduction in postsurgical infection, which was mentioned exclusively by the developers and not shared by the other stakeholders. To further inform the potential value of the innovation, we synthesized the available evidence to quantify the 2 topics and to estimate the costs saved and QALYs gained.

## Quantitative Assessment of the Problem

To quantify the problems, we developed 2 models, thereby deriving the room for improvement in terms of reductions in procedure time and risk of infection. Where available, we used data from the literature. Otherwise, we used expert opinion or assumptions that were corroborated by experts. All quantitative inputs are presented in Table 1. All costs were determined from a healthcare perspective and were converted into 2018 prices using price indices for the Netherlands.[27]

### Procedure time

We used the prevailing standard costs and costing data as derived from the financial records of our university medical center to calculate the per-minute cost of meniscus surgery. Assuming that the operation involves 1 orthopedic surgeon (€1.93/min) and an operating room with 2 assistants and 1 half-time anesthesiologist (together €8.66/min),[28,29] the costs of meniscus surgery approximated €10.59/min. Given the maximum of 5 minutes that could be saved because of improved flexibility of the surgical instruments, the headroom in procedure time would then amount to €53 per procedure. With the costs of the new instrument estimated at €2000, it would take at least 38 procedures during its lifetime to break even. If the instrument were to save half of the 5 minutes used in the headroom scenario, this threshold doubles to 76 procedures. If the instrument would cost €1500, these

thresholds would decrease to 29 and 57 procedures, respectively, and at a cost of €2500 to 48 and 95 procedures, respectively.

### Risk of infection

We consulted the literature to determine the risks, costs, and health consequences of infection after meniscus surgery. In their systematic review, Thorlund et al[30] found infection to occur in about 1 in 1000 patients. We assume that half of these infections are mild in nature, in which case, treatment would consist of intravenous antibiotics. With the other half of the infections assumed to be severe, a reoperation would be required.

Intravenous treatment costs about €575, including the costs associated with a 1-day stay in an academic hospital.[28] We furthermore assumed that a mild postoperative infection would not affect quality of life. With a severe infection necessitating reoperation of the knee, additional expenses would consist of the costs of reoperation (ie, €4204, similar to the costs of meniscus surgery in our hospital), whereas quality of life was estimated to be reduced by 0.01 QALY.[31] In current meniscus surgery, per patient approximately €2.39 is then lost to infections ($0.0005 \times €575 + 0.0005 \times €4204$) and approximately 0.000005 QALY in terms of health benefit lost ($0.0005 \times 0.01$).

For the new tool to be cost-effective, at the assumed €2000 per device, each instrument purchased should be used in at least 804 patients, with all infections being prevented. If the instrument were to cost €1500, this number reduces to 603 patients, whereas at a cost of €2500 the figure would increase to 1005 patients.

Note that with 27 000 meniscus surgeries performed annually in the Netherlands,[32] about 27 patients are expected to incur an infection each year.

### Stakeholder Perspectives on the Potential Value of the Innovation

Asked to reflect on the potential reductions in procedure time and infection the new tool is claimed to generate, the surgeons mentioned that a reduction in procedure time would not guarantee efficient reuse of the time saved. Some stakeholders conjectured that the 5-minute reduction in procedure time was likely to be lost because of patient logistics and care surrounding the procedure itself, thus not yielding any net cost savings. Regarding infection reduction, the surgeons, researcher, and infection-prevention specialist remained skeptical that changes in surgical instruments would reduce the already low rate of infection in meniscus surgery.

### Views on Implementation

All stakeholders welcomed technological advances and were enthusiastic about the novelty of the proposed innovation. According to its developers, the instrument would improve working conditions for surgeons and enhance surgical efficiency. When asked about its implementation, the stakeholders noted the following challenges.

First, there was concern that the innovation would result in extra costs instead of cost savings. On the basis of their experiences with previous surgical innovations, the surgeons doubted that the innovation would replace all existing instruments, and far rather expected it would be used in addition to existing instruments because of individual preferences.

Second, the surgeons and researcher mentioned that the future of meniscectomy is unsure because of criticism of its long-term consequences. Recent studies cast doubt on its effectiveness and revealed that meniscectomy is associated with knee replacement surgery later in life.[33–35] According to the stakeholders, the field is moving toward the preservation and repair of meniscus tissue. The proposed innovation does not fit into this trend.

Third, the lack of transparency of the purchasing process of novel surgical instruments was identified as a potential barrier. Many factors weigh in on the decision to acquire new technology, one of which is the depreciation period of surgical instruments. The surgeons indicated they could request new instruments only if they provided hospital purchasing managers with a solid business case. Because purchase managers declined to participate in our evaluation, we were not able to explore this issue further.

Finally, the medical sterilization specialists we spoke to expect that the proposed instrument is harder to sterilize than existing instruments, commenting that it may even be impossible to guarantee safe reuse.

## Discussion

In this pilot study we explored a mixed-methods, problem-oriented, multistakeholder approach to early HTA to gain an evidence-informed, deliberate understanding of the room for improvement in current care and the expected challenges pertaining to a specific innovation. Any potential value of the new technology would be through cost savings rather than an improvement in patient/health outcomes. Even though the stakeholders we interviewed were enthusiastic about the innovation, considering the current procedure and postoperative care, they collectively concluded that there was no underlying problem or need for the new instrument, whereas they perceived both social and practical barriers to its implementation and that its suggested benefits seemed too limited. Although there might be other arguments or indications to pursue the innovation, no relevant patient benefits were expected in the case of meniscus surgery.

A key advantage of the approach we adopted is the combination of qualitative and quantitative methods. The insights we gathered from our preliminary study are quite different from those we obtained using a standard stand-alone early cost-effectiveness analysis (CEA), which yielded a headroom of €55.49 per patient (on the basis of reduced procedure time and infections) or €1.5 million annually, justifying the conclusion that in the Netherlands there was ample room for improvement in this context. In a standard CEA, trends in the field, barriers preventing the innovation to reach its full potential, and other potential innovations put forward by the stakeholders were not considered. The combination of stakeholder interviews and an early CEA allows stakeholders to be better informed about all the data, possibly prompting them to adjust their previous conceptions. Given the results obtained, we conclude that the approach we adopted adds to the legitimacy of our assessment method and its conclusions.

Nevertheless, six limitations to our evaluation should be acknowledged. First, although we endeavored to obtain an unbiased selection of stakeholders, participation was voluntary. Because several physical therapists and hospital purchasing managers declined to participate without motivation, we cannot be sure how our assessment would have turned out had they agreed to participate. Second, and related to the first point, we reached saturation with regard to the potential added value of the innovation and the implications for patients' health outcomes but not with respect to the problems associated with meniscus surgery that were mentioned. For example, unlike the surgeons we spoke, the physical therapist did offer several suggestions with regard to potential room for improvement in meniscus surgery and the care pathway. We believe saturation could have been achieved here as well had we included more stakeholders, but

practical limitations prevented us from doing so. Third, to ensure the feasibility of our assessment we had to select a specific context. It is well possible that the innovation at hand may offer considerable benefits in surgical contexts other than the one we investigated, which may be worth pursuing. Fourth, although the assessment was iterative in the sense that the stakeholder interviews provided input to conduct quantitative assessments and vice versa, our evaluation is still a one-off exercise conducted at a point in the development of the innovation. Ideally, health technology innovations should be assessed continuously to foster an optimal product and a health-promoting and cost-effective implementation.[36] Fifth, a more comprehensive interpretation of the magnitude of the headroom figures depends on macro-level factors such as the lifetime of the instrument and the number needed per hospital. Such a detailed analysis was, however, beyond the scope of this study. Finally, our evaluation was still supply-driven, with novel technology triggering the innovation. As alluded to in the introduction, we feel that innovations should be problem- or demand-driven to truly result in patient and societal benefit.

Despite these limitations, our approach to early HTA has several advantages. Our pilot study showed that, most importantly, the problem-oriented focus enabled us to look beyond the initial enthusiasm about the innovation itself and gain a thorough impression of the room for improvement in meniscus surgery and the perceived value of the proposed innovation from the stakeholders interviewed. The timing of our assessment was opportune in that there was still room to steer the development of the innovation and reflect on the added value of the device in other surgical contexts. Related to that, our assessment is formative rather than summative. Instead of concluding that the innovation is value*less*, our assessment should be used to reconsider the target population/field. In addition, by evaluating its implementation early on, we identified crucial concerns, arguably preventing unwelcome surprises later on. Anticipation of stakeholder concerns throughout the research and development process will improve the odds of successful implementation.

## Conclusions

The innovation we investigated in this exploratory study was rather straightforward and there was relatively little disagreement or conflicts of interest among the stakeholders we interviewed. Of course, our methodology could be extended to more complex innovations[37] and to gauge and manage conflicting beliefs and interests.[38] Although assessments like ours require resources, the expectation is that by committing this relatively small investment at this early stage, greater expenses—such as those associated with large-scale, multicenter randomized trials—may be avoided. These resources may then be used for the development of innovations that better match unmet needs in the particular healthcare setting. Whether it is the funding agency that seeks to commit public resources to effective innovations or the small innovation company that wants to manage its portfolio better, or a hospital that craves reliable information on which to base its decision to purchase an innovative instrument, in each of these cases a problem-oriented approach could help direct the development of innovations such that they match real-world problems, needs, or demands.

At times, ingenious innovations may, in hindsight, not have been as beneficial or cost-effective as anticipated. Health innovation development should be aimed at resolving existing problems and improving relevant health outcomes, not at technological advancement alone. Acknowledging the importance of integrating innovation assessment with innovation development, we believe the approach described here is a step in that direction. We hope to see further case studies that investigate the feasibility and added value of evidence-informed, deliberative early HTAs to promote high-value innovation.

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