

HOW TO AVOID GIVING THE RIGHT ANSWERS TO THE WRONG QUESTIONS: THE NEED FOR INTEGRATED ASSESSMENTS OF COMPLEX HEALTH TECHNOLOGIES

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Health technologies are becoming increasingly complex and contemporary health technology assessment (HTA) is only partly equipped to address this complexity. The project “Integrated assessments of complex health technologies” (INTEGRATE-HTA), funded by the European Commission, was initiated with the overall objective to develop concepts and methods to enable patient-centered, integrated assessments of the effectiveness, and the economic, social, cultural, and ethical issues of complex technologies that take context and implementation issues into account. The project resulted in a series of guidances that should support the work of HTA scientists and decision makers alike.

This issue of the journal presents the main findings of the project. These are among others: integration needs to start from the beginning, stakeholder need to be involved throughout the process, and traditional methodologies in HTA need to be adapted to allow for integrated assessments. In addition, in this issue members of a Canadian HTA-agency describe the application of some of the guidances in real practice and members of a national HTA-agency, the HTAi Interest Group on Developing Countries, and the European network for Health Technology Assessment (EUnetHTA) offer reflections on the usefulness of INTEGRATE-HTA in providing meaningful and relevant HTA.

The psychologist and Nobel laureate Daniel Kahneman has spent a great part of his career on analyzing how humans (be it “ordinary citizens” or academics) behave when confronted with difficult questions for which they do not have an immediate answer. Rather than trying to answer the difficult (and relevant) question we tend to simply substitute it for an easier question and answer the latter. For example, the question “How far will a certain candidate go in politics?” will often be substituted by the question “Does this candidate look like a

political winner?” (1). As a result, we often end up answering the questions that we *can* answer, however, these are not necessarily the questions that we *should* answer. Do we also see this in health technology assessment (HTA)? The answer is yes, and in this theme issue of the journal we provide some steps toward solutions for this.

Delivery of health care that is effective, efficient, and of good quality depends, among others, on the added value of the health technology. To inform decision makers regarding what is considered a valuable health technology, is the purpose of HTA. However, this is more difficult than it sounds. Among the questions HTA-researchers are typically confronted with are: Does this health technology work better for some people than for others? What qualifications or skills are needed to use the health technology? To what extent does a specific context enable or limit its potential? And what do we actually mean by a valuable health technology?

The more complex a health technology and/or the conditions it is addressing, the more complex is its assessment. A pertinent case is palliative care: patients differ with regard to their underlying diseases and their family situation, and their needs may be quite different. Palliative care comprises multidisciplinary delivery modes and is provided in different settings, ranging from family-based homecare to high-tech oncology units or specialized hospices. The delivery of palliative care is very personal and the quality highly depends on the empathy and the personal and professional skills of those delivering it.

Furthermore, some technologies have opposing effects on different outcomes: for example, relieving pain through opioids can worsen symptoms such as fatigue or nausea, or can negatively influence the spiritual wellbeing of a patient. This results in making “trade-offs” between different outcomes, which

can vary enormously between different patients, and which makes a “personalized approach” to care challenging. Finally, palliative care affects not only the patient but also his or her family and friends.

Palliative care is thus a perfect example of a so-called complex intervention. In the definition of the U.K. Medical Research Council (MRC) complex interventions are characterized by several interacting components, the number and difficulty of behaviors required by those delivering or receiving the intervention, multiple groups or organizational levels targeted, many and variable outcomes, and explicitly permitted flexibility or tailoring of the intervention (2).

Assessing complex technologies always involves implicit and/or explicit strategies for simplifying the complexity, each of which is potentially deceiving: (i) The first strategy simply *ignores* certain components or at least ignores their variability. In the case of palliative care, the modifying effects of different contexts might be ignored or for example only considering spouses in the assessment that focusses on lay-caregivers. Also, considering the “average patient” is a common strategy to ignore the varying characteristics and preferences of the patients. (ii) *Reducing* the complexity by ignoring the interactions and interdependencies between the different components is a second strategy. In the case of palliative care this would suggest, for example, assessing the effect of different caregivers independently from different patient types or the contexts in which they operate. Another example would be if the effectiveness and ethical implications of a technology are assessed completely independent from each other (i.e., side-by-side analysis of evaluation aspects); (iii) The third strategy consists of *shifting* away from questions that are relevant, but difficult to assess, to topics that are less relevant but easier to assess. For example, spiritual wellbeing is considered to be quite important for palliative care patients but it is rarely assessed because it is difficult to measure. Instead, assessments often include physical pain, an outcome for which various well-established instruments exist. To be sure, physical pain is an important outcome in palliative care but if spiritual wellbeing is ignored, the benefit for the patient will only partly be assessed.

How far can strategies for simplification go? Following Kahneman, when simplification becomes substitution the strategies have gone too far. Therefore, we need to recognize when we start to give answers that are meaningful but are addressing the wrong (i.e., not relevant) questions.

The EU-funded research project INTEGRATE-HTA, that ran from January 2013 until December 2015, aimed at developing a process that supports asking questions that are relevant and finding answers that fit to the questions. It also aimed at developing concepts and methods that enable an integrated assessment of the effectiveness, and the economic, social, and ethical issues of complex technologies that takes different patient characteristics, contexts and implementation issues into account.

HTA experts from seven European countries collaborated in the project, using palliative care as a case study. The main products are seven guidances that are publicly available at www.integrate-hta.eu.

This issue of the journal presents the results of the project, as well as the application of some of the guidances by the Canadian Agency for Drugs and Technologies in Health (CADTH) in real practice. Furthermore, the issue offers reflections on the usefulness of INTEGRATE-HTA in providing meaningful and relevant HTA from the perspectives of a national HTA-agency, the HTAi Interest Group on Developing Countries, and the European network for Health Technology Assessment (EUnetHTA).

In the first contribution from INTEGRATE-HTA, Wahlster et al. (3), provide an operationalization of integrated assessments through the INTEGRATE-HTA Model. This model consists of five steps that involve, among others, the development of a logic model to structure the different outcomes and to take the variability of participants, context, implementation issues, and their interactions into account. Each of the steps involves relevant stakeholders. How this can be done is illustrated in the contribution from Brereton et al. (4) who describe how stakeholders in seven countries have been involved to define the scope of the HTA on palliative care, thus helping to ask the relevant questions.

Patients’ heterogeneity and their varying preferences should not be ignored as it modifies treatment outcomes or at least the value which is placed on them. Kievit et al. (5), therefore, provide guidance on retrieving and critically appraising available evidence on patient-related moderators and predictors that have an impact on treatment effects and on patient preferences for treatment outcomes. Bakke Lysdal et al. (6) extend the methodology to assess various outcomes for the application on complex technologies so that lack of methods will be presented less often as an argument for not assessing the relevant questions. Polus et al. (7) developed a tool that enables the assessment of factors that might facilitate or hinder the adaptation of a technology in a given context. Finally, van der Wilt et al. (8) lay out the significance of evaluative frameworks as a basis for collecting evidence that is considered relevant and plausible to stakeholders.

Bond and Weeks (9) describe their experience in applying some of the concepts and methods developed in INTEGRATE-HTA in an assessment on dialysis for the treatment of end-stage kidney disease in Canada. They found it helpful in many aspects, although they realize the challenges in aligning the guidances from INTEGRATE-HTA with their current HTA-processes.

In an interview, staff members from the Belgian Health Care Knowledge Centre (KCE) expect a shift from current HTA, that is, with its narrow focus on assessment of health technology toward a broader perspective of the effects of the technology on health systems and the health of a population

(10). They welcome especially those elements of INTEGRATE-HTA that strengthen the input from stakeholders, scoping of the HTA question, and logic models. However, they also highlight that INTEGRATE-HTA cannot help them to meet one of the current key challenges: to do more work in less time, with the same amount of resources.

Bijlmakers et al. (11) address the question whether the approach suggested by INTEGRATE-HTA could be useful, appropriate, and feasible in the context of low and middle-income countries (LMICs). They mention that HTA has not yet been fully established in many LMICs, but see its potential for example in making priority setting more explicit, transparent and legitimate.

Finally, Lampe and Schnell-Inderst (12) examine the similarities and differences between the INTEGRATE-HTA Model and the HTA Core Model® that has been developed by EUnetHTA. Identifying synergies and opportunities for future collaboration they present three options how both models could be aligned in future.

Taken together, the articles in this issue introduce a new approach for an integrated assessment of (complex) technologies: the INTEGRATE-HTA Model. They also present first applications, and offer viewpoints from different perspectives. Hopefully, they will serve as a first step in the direction of providing the right answers to meaningful and relevant questions in HTA.

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