

# HARMONIZATION OF ETHICS IN HEALTH TECHNOLOGY ASSESSMENT: A REVISION OF THE SOCRATIC APPROACH

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**Background:** Ethics has been part of health technology assessment (HTA) from its beginning in the 1970s, and is currently part of HTA definitions. Several methods in ethics have been used in HTA. Some approaches have been developed especially for HTA, such as the Socratic approach, which has been used for a wide range of health technologies. The Socratic approach is used in several ways, and there is a need for harmonization to promote its usability and the transferability of its results. Accordingly, the objective of this study was to stimulate experts in ethics and HTA to revise the Socratic approach.

**Methods:** Based on the current literature and experiences in applying methods in ethics, a panel of ethics experts involved in HTA critically analyzed the limitations of the Socratic approach during a face-to-face workshop. On the basis of this analysis a revision of the Socratic approach was agreed on after deliberation in several rounds through e-mail correspondence.

**Results:** Several limitations with the Socratic approach are identified and addressed in the revised version which consists of a procedure of six steps, 7 main questions and thirty-three explanatory and guiding questions. The revised approach has a broader scope and provides more guidance than its predecessor. Methods for information retrieval have been elaborated.

**Conclusion:** The presented revision of the Socratic approach is the result of a joint effort of experts in the field of ethics and HTA. Consensus is reached in the expert panel on an approach that is considered to be more clear, comprehensive, and applicable for addressing ethical issues in HTA.

**Keywords:** Ethics, Moral, Values, Norms, Health technology assessment

Ethics has been part of health technology assessment (HTA) from its beginning in the 1970s (1), and is currently part of HTA definitions adopted by all prominent networks of HTA, such as the International Network of Agencies for Health Technology Assessment (INAHTA), the Health Technology Assessment international (HTAi), and the European network for Health Technology Assessment (EUnetHTA). A wide variety of methods for addressing ethical issues are available, and some are specially adapted to be used in HTA (2–6). Nevertheless, ethics is rarely addressed explicitly in HTA reports (6–11).

One of the methods that have been most frequently applied in practice, is the Socratic approach (3). It was introduced in 2005 (4;12) and poses a set of morally relevant questions to

highlight overt and covert value issues with regard to a health technology. The issues include general moral issues and moral issues related to stakeholders, methodology, characteristics of technology, and to the HTA process itself. The objective is to inform decision makers (on various levels) about values, viewpoints, and arguments which appear to be important for actual decisions in context. The Socratic approach incorporates several methods in ethics, such as deontology, utilitarianism, principlism, casuistry, and virtue ethics, and it has been used for assessing a wide range of health technologies, such as human papillomavirus vaccination, neonatal screening for inborn metabolic disorders, stem cell transplantation, routine ultrasound in pregnancy, bariatric surgery (for adults, persons with diabetes, and adolescents and children), intracytoplasmic sperm injection (ICSI), opioid dependence, amalgam fillings, peripheral arterial disease, palliative surgery, and welfare technology. See the Supplementary Table, which can be viewed online at <http://dx.doi.org/10.1017/S0266462313000688>, with references.

However, the Socratic approach has been subject to various interpretations and it has been implemented differently by

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several HTA agencies (13;14). Moreover, it has also been used for different purposes in HTA processes, including:

- to write an expert statement.
- to review the literature narratively.
- to review the literature systematically. This includes using the question list for:
  - o identifying the ethical issues / values relevant to a health technology of interest (presearch to process a systematic information retrieval)(14),
  - o framing the assembled and assigned information (arguments) from the literature,
  - o structuring the synthesis of arguments.
- To identify and balance the benefit and harm of health technologies systematically (using the question list together with some other instruments such as the criteria list of the UK National Screening Committee addressing technologies related to screening) (15).

A revision is needed to harmonize how the Socratic approach is used in HTA to increase transferability, and to ensure that the Socratic approach can meet the purposes for which it is used.

## METHODS

To reach a consensus on the form and content of the revised Socratic approach, a panel of ethics experts ( $n = 11$  from nine countries) involved in HTA with several years of experiences met during a workshop on methodology in ethics for HTA in Cologne on January 19–20, 2012, hosted by The Institute for Quality and Efficiency in Healthcare (IQWiG) and organized by the INAHTA/HTAi Ethics Interest Sub-Group on Ethical Issues in HTA (EISG). The group of experts critically analyzed the existing Socratic approach for consistency, coherence, exhaustiveness, overlap, clarity, and ease of use in HTA.

The results of the critical analysis were used to guide the revision of the Socratic approach. An implementation of the analysis and suggested revision was sent by the lead author (B.H.) by means of e-mail to the experts who had provided substantial contributions and who signed up. Critical comments and suggestions were fed back, analyzed and integrated in a revised version of the draft. The revised draft was then sent back to the members for continued critical analysis. The process of analysis, comments, suggestions, and revision of the Socratic approach was performed in three rounds among the experts until consensus was reached.

## RESULTS

### Limitations of the Socratic Approach

The main limitations of the Socratic approach identified by the expert group are:

1. The list of questions included in the Socratic approach is not exhaustive. Accordingly, there is a danger to neglect ethical issues which are not addressed by the questions. Therefore, the list may need to be supplemented and altered according to the health technology in question and the assess-

ment context. Such additional questions may be identified by literature search. The need to add questions was already stated at the emergence of the Socratic approach in 2005 (4).

2. Some issues specific to screening are lacking or underrepresented in the current list of questions, for example, whether appropriate treatment exists or whether early treatment is recommended on the basis of evidence, whether specialized centers are necessary for adequate screening, whether technologies for diagnosis are available, as well as whether ethical implications of the consequences of each possible test result and further diagnostic investigations are challenging. Moreover, a question about the patient group benefiting from the health technology is needed: are the people who benefit most from the studied technology the same as those who are benefiting most from other technologies? Are they vulnerable? Do they belong to a group of patients who have low(er) prestige or priority?
3. How to balance benefits and harms in a systematic way is not indicated in the Socratic approach. Although this has to be done in the relevant context (of the decision-making process), some indications could be given by the approach.
4. The Socratic approach addresses the issue of distribution of health care (original Q14), but the questions of justice are complex and may be difficult to address. More specific guidance would be useful, for example, addressing issues of resource allocation, access to care, and distribution.
5. Conflicting legal norms are not addressed.
6. Most of the assessed technologies are not so much afflicted by problems of human dignity and human integrity, or basic human rights. Therefore, it might be justifiable to summarize these issues into one question, in the same way as already done in the Norwegian version of the Socratic approach (16).
7. Some other questions of the approach are related and these could be integrated. For example: Q12: “Are there any related technologies that have turned out to be morally challenging?” and Q32: “Are there related technologies that have or have not been assessed?” These two questions could easily be summarized as follows: “Are there any related technologies that have turned out to be morally challenging or related technologies that have not been assessed yet?” However, the questions differ in character. Q12 is a casuistic question, and Q32 is a question highlighting values of selection.
8. In practice the answers of some questions are closely related to the answers of other questions, which can make it difficult to assign arguments. Sometimes it is helpful to assign them to more than one question as there appear some facets or varieties, but often it would be more feasible to reduce the number of questions which are closely related. This point is more important in systematic literature reviews than in reflectively answering the questions. Moreover, all questions do not have to be addressed for all technologies. Additionally, complex ethical issues may not subsume under the listed questions.
9. Not all questions are self-explanatory. The explanations provided (4) are helpful, but some of them should be supplemented/elaborated to make the questions easier to answer.
10. Q33 (What are the moral consequences of the HTA?) depends on the context of HTA, such as the healthcare system, the status of science in society, the decision-making system, etc. The actual wording in the explanation of this question is focused on rationing, but implementing the recommendations from the HTA may also provide evidence for a more effective technology. This question should not be biased neither toward investment nor disinvestment.
11. Some would like to use different schemes for data extraction in systematic literature reviews and argument assignment in an ethical analysis. However, based on our experience it is not recommended to change the framework during the review process. The list of questions has shown to be useful as it results in a detailed list of challenges and arguments.

12. The relationship between physicians and patients is addressed, but the relationship to other health professionals may also change and should, therefore, be addressed.
13. Social, cultural, and religious issues are often related, and should be addressed in one question.
14. The question “Does the widespread use of the technology change our conception of certain persons?” (Q8) is not clear and should, therefore, be clarified.

Hence, there are several limitations and suggestions for revising the Socratic approach. As a result, the following revised Socratic approach was elaborated.

### The Revised Socratic Approach

The revised Socratic approach consists of six steps:

1. Identify the intended purpose of the health technology and reveal the background for the assessment;
2. Identify involved persons, groups, and stakeholders (e.g., patients, relatives, professionals, industry, health policy makers);
3. Identify relevant moral questions (from a list of questions, Table 1) and justify the selection;
4. Perform literature search in accordance with the identified moral questions;
5. Analyze and discuss the moral questions identified (in step 3) on the basis of: (a) Existing literature and (b) Hearings / statements of involved parties (or their representatives) or qualitative studies (relevant qualitative studies should be included in the literature search);
6. Wrap up and summarize the process.

The revised question list is presented in Table 1 and consists of seven basic questions and thirty-three explanatory and guiding questions. The calling of the Socratic approach is “to ask questions, not to give answers,” to paraphrase the poet Henrik Ibsen. In addition, practical guidance on information retrieval and selection has been developed.

### Information Retrieval and Selection

The steps 1–6 should be documented and reported comprehensively and reproducibly according to accepted standards (17), including the information retrieval process, inclusion and exclusion criteria, and the result of the sifting (flowchart). The expert group assessed the following methods to do this.

1. A four-step process for a systematic review for arguments, as suggested by McCullough (18):

1. Identify the focused question;
2. Conduct a literature search;
3. Assess the adequacy of the argument-based methods of the papers identified;
4. Identify conclusions drawn in each paper and assess whether they apply to the focused question.

Based on the expert panel’s experience, steps 1 and 2 work well. Steps 3 and 4 are not applicable to a review of ethical implications of health technologies as ethics experts have to retrieve

relevant issues and challenges not only complete publications and conclusions.

2. A systematic review of reasons: Sofaer and Strech (19) argue that the research question should be different from classic systematic reviews, that there is a need to extract detailed information on reasons/arguments, and that there is no need to assess the degree to which we should believe each conclusion. Their four-step model consists of: (i) formulating the review question and eligibility criteria, (ii) identify all of the literature that meets the eligibility criteria, (iii) extract and synthesize data, and (iv) derive and present results (20).

Again based on the panel’s experience, applying these four steps will work well, but the practical implementation of step iii and iv will only fit to few health technologies: most technologies are subject to many and often complex ethical issues, and often, HTAs are in need of descriptive assessments rather than normative conclusions.

3. Finally, what works well from the panel’s experience:

1. Identify the actual ethical issues (including values) of a given health technology, for example by reflexive answering of the question list (4) and when necessary the criteria list of the UK National Screening Committee (15).
2. Conduct a systematic literature search, according to the results of step 1. The literature search—more or less comprehensive—can be performed by following the common retrieval workflow of effectiveness assessments (3). However, the search should be specifically adapted to ethical issues and should be undertaken separately to achieve an appropriate result with an adequate sensitivity and precision, Due to the reduced functionalities in several literature databases some prescreening has to be done during information retrieval.
3. Sift the documents identified by the literature search according to predefined inclusion and exclusion criteria.
4. Extract the data (ethical issues and arguments) from the selected literature and check them by the methods of content analysis for logic and coherence (separated by categories), reliability, validity, and actuality (20). If the information identified consists of qualitative data, the available appraisal methods could be applied (21).
5. Assign the issues to the chosen framework of ethical issues and arguments, and synthesize them. Synthesizing the results includes addressing identified gaps in the literature concerning relevant ethical issues and values. In many cases a presentation of a descriptive synthesis is sufficient and will be integrated into the HTA report. In some cases an additional ethical analysis is necessary. This can be done by appropriate use of the results generated by literature analysis.

### Applying the Socratic Approach in Context

The Socratic approach can be applied in a reflexive dialogue with stakeholders or as a checklist. While the former may qualify for the name “Socratic method,” the latter is more like a HTA tool (11). Although the panel has strong preferences for the first, it accepts that the question list may be used as a checklist as it is important that value issues are addressed.

Some panelists have good experience with using the question list of the Socratic approach for reflections at the beginning

**Table 1.** Morally Relevant Questions with Respect to Assessing Health Technology

1. What are the morally relevant issues related to the disease and the patient group?	<p>Q1 What is the severity of the disease? May this change?</p> <p>Q2 What patient group is the beneficiary of the technology? (Are they particularly vulnerable, have low socioeconomic status or priority, or are they subject to prejudice? Are issues of underdiagnosis and undertreatment relevant?) Will any of these conditions change?</p> <p>Q3 Does the widespread use of this technology change the patient role? (Does it change the prestige or status of the disease, the conceptions, prejudice or status of persons with certain diseases?)</p> <p>Q4 Does the technology involve healthy persons (screening, asymptomatic cases, disease prediction), and how are potential challenges addressed (false test results, overdiagnosis, futile or harmful treatment)?</p>
2. What are the ethical, social, cultural, legal, and religious challenges related to the health technology?	<p>Q5 Does the implementation, use, or withdrawal of the technology challenge patient autonomy, integrity, privacy, dignity or interfere with basic human rights?</p> <p>Q6 Does the technology challenge social or cultural values, institutions, or arrangements or does it affect religious convictions?</p> <p>Q7 How does the implementation, use, or withdrawal of the technology affect the distribution of health care? (Justice in allocation, access, and distribution).</p> <p>Q8 What are the morally relevant <i>consequences</i> (benefits and harms) of the implementation, use or withdrawal of the technology? (In particular from a patient perspective). How should the harms be balanced against the benefits? Are there alternatives?</p> <p>Q9 Can the implementation, use, or withdrawal of the technology in any way conflict with existing law or regulations or pose a need for altered legislation?</p> <p>Q10 Will there be a moral obligation related to the implementation, use, or withdrawal use of a technology? (E.g., are there special difficulties with informing patients, with privacy, or confidentiality?)</p>
3. What are the moral challenges with structural changes related to the health technology?	<p>Q11 How does the assessed technology relate to more general challenges of modern medicine? (Underdiagnosis, undertreatment, medicalization, overdiagnosis, overtreatment, reduced trust)</p> <p>Q12 Does the technology in any way challenge or change the relationship between patients and health care professionals or between health professionals?</p> <p>Q13 Are there morally relevant aspects with respect to the level of generalisation?</p>
4. What are the moral issues related to the characteristics of the health technology?	<p>Q14 What is the characteristic of the technology to be assessed? (E.g., function, purpose, intention)</p> <p>Q15 Is the symbolic value of the technology of any moral relevance? (Prestige, status?) May this change as a result of the health technology?</p> <p>Q16 Are there moral challenges related to components of a technology that are relevant to the technology as such?</p> <p>Q17 Are there any related technologies that have turned out to be morally challenging? (Are the same challenges relevant for this technology?)</p>
5. What are the moral issues related to stakeholders?	<p>Q18 Are there third party agents involved? (E.g. donors, relatives)</p> <p>Q19 What are the interests of the users of the technology?</p> <p>Q20 How does the technology contribute to or challenge or alter health professional's autonomy?</p> <p>Q21 What are the interests of the producers of technology (industry, universities)?</p> <p>Q22 Are the users of the technology in the studies representative of the users that will apply it in clinical practice?</p>
6. What are the moral issues related to the assessment of the health technology?	<p>Q23 Are there morally relevant issues related to the choice of end points, cut of values, and outcome measures in the assessment?</p> <p>Q24 Are there morally relevant issues related to the selection (criteria) of studies to be included in the HTA?</p> <p>Q25 What are the reasons that this technology is selected to be assessed?</p> <p>Q26 Are there morally relevant issues in the planning of the HTA (e.g., scoping process, expert group selection), in the structuring of the HTA work, and in selecting, synthesizing, and presenting the results?</p> <p>Q27 What are the morally relevant presumptions made in the economic analysis (e.g., on justice, equity (the quasi-egalitarian presumption that "a QALY is a QALY"), definition of a target population, as well as in the choices of analysis perspective, outcome measures, discount rates, and (p)reference value)</p> <p>Q28 What are the interests of the persons participating in the technology assessment?</p> <p>Q29 At what time in the development of the technology is it assessed (and what are the morally relevant consequences)? What morally relevant challenges follow from knowledge gaps?</p> <p>Q30 Are there related or analogous technologies that have not been assessed? (Why not?)</p> <p>Q31 What are the moral consequences of the HTA? (What are the results of implementing/not implementing the health technology? Will other non-effective technologies be abandoned? Will certain sub-groups benefit more than others? Are calling for further studies justified?)</p>
7. Are there additional moral issues?	<p>Q32 Are there moral issues in research ethics that are important to the HTA?</p> <p>Q33 Are there morally relevant questions that have not been covered by this list, but that have been identified by the scoping process or literature search? (Which values and challenges do they pose?)</p>

of the HTA process and at the start of the writing of the HTA report. In time- and resource-restricted conditions, and without an option to apply an integrative method or to do an extensive literature review, the approach is useful to make the HTA doers think about ethical issues and values for decision making.

The perspectives of those who are involved in framing the problem, in the HTA process and in the decision-making process must be made explicit and transparent. The aim of HTA is to inform rational decision making, suggesting that those who produce and/or use HTA should explain their underlying objectives. However, this is often not the case. For example, in setting priorities it is important to have good understanding of which actors are involved and their objectives for selecting technologies in need of assessment. Their views are reflected in the objectives of the process which will determine the criteria to be used as well as the nature of the process (e.g., involvement of external experts). Involvement of different stakeholders will inevitably reflect different views and will suggest different judgments (subjectivity). It is, therefore, of utmost importance that such procedures are transparent and explicit (22). Also, the use of arguments in decision making using HTA is not always consistent or clear. For example, inclusion of sildanefil (i.e., Viagra—a cost-effective treatment of erectile dysfunction) in the benefit package of the Netherlands was highly debated. According to the Minister of Health (23) Viagra could not be regarded as necessary care. However, different interpretations of “necessary care” were given, for example, that the individual medical condition is not severe enough and does not prevent normal social functioning. According to Stolk et al. (24) these arguments are directly or indirectly related to implicit norms and values of decision makers. If these norms and values are not made explicit, we may question the value of these arguments as useful criteria for health care decisions.

Hence, the core of the Socratic approach, revealing underlying values, does not stop with the formal assessment of the technology, but should address the whole process from scoping to decision making.

## DISCUSSION

Although the revised Socratic approach resembles the original approach, several changes are made in accordance with the critical analysis. The revised approach has a broader scope and provides more guidance than its predecessor. Several questions have been added, and many of the questions have been altered.

### The Need of Having a Standard When the Standard Is (Supposed) to Be Implemented in Context

The aim of the revision of the Socratic approach is to harmonize the assessment, rather than the outcomes of the assessment. The answer to the same question can differ depending on the context within systems as well as between systems. Within systems, a changing economic climate, for instance, may influence how the different questions in the Socratic approach are assessed as

well as the relative importance of different ethical considerations in the decision-making process. Also, if the assessment is purely based on literature reviews by experts the result will be different than if participatory techniques are applied. An health professional expert assessment of various treatments for Chronic Fatigue Syndrome may be different from a broad stakeholder based assessment.

Correspondingly, differences in context (e.g., wealth in terms of GDP) may lead to different outcomes of ethical assessments. Additionally, societal preferences may differ between and within countries (e.g., regions), suggesting differences in choices, even if the same approach for ethical analysis is used.

Hence, the structure for the ethical analysis is transferable, but the outcome of the analyses will differ. This is analogous to economic evaluations, where outcomes may vary due to differences in prices, clinical practice patterns, organization of care, but also due to different choices regarding the perspective to be used, the cost items to include and the outcome measure to apply.

### Impact on Policy Making

The Socratic approach allows researchers to present different policy options with their respective pros and cons from an ethical point of view. The Socratic approach presents the value issues without taking a stance or presenting recommendations. However, the approach provides the experts responsible for the appraisal with a broad basis for making open and transparent value judgments. The various arguments, reasons, and options can be weighed in the appraisal process, leading to the final recommendation or decision. This allows the appraisal procedure to become more transparent and policy makers to be more aware of the variety of moral values at stake in deliberations and decisions and to be more transparent (25).

### Methodological Limitations

With this document, we have reached consensus on a Socratic approach that fits what experts in ethics and HTA consider to be important when addressing ethical issues in HTA. However, there are other experts who would have identified different limitations and demands, and who would have made a different revision of the Socratic approach. That is true, but all EISG members were invited, and all experts who recently have used the Socratic approach were present. An all-encompassing consensus is hardly obtainable.

Is the revised Socratic approach better than the original one? This question has not been addressed in this study. It has not been the aim of the study either, as there is no agreement on what a good approach or method in ethics (in HTA) is. Hence, the assessment of the robustness of the Socratic approach is beyond the scope of this article. Here the aim has been to revise the approach in accordance with the assessment and demands of the expert group. As the experts themselves have demanded and performed such a revision, it indicates that the revised version

will be used, and that it will harmonize the approach (but not the result in context). This may increase the transferability.

Although we have taken all the identified limitations and challenges with the original Socratic approach into account in our revision of the Socratic approach, we may have ignored some, and new limitations may arise in the course of the development of HTA. Hence, this may not be the last revision. It only shows that we are reflexive and strive for improvement in the field of ethics methodology, as in other parts of HTA.

## CONCLUSIONS

Health technologies raise ethical issues, and assessments of health technologies need to address these issues. Moreover, the HTA process involves a series of value judgments, for example, when selecting the health technologies to assess, when deciding on comparators and outcome measures, when selecting studies to include, and when deciding on how to frame, present, summarize or synthesize information in systematic reviews. The same goes for economy analysis. Addressing such value issues is relevant for open and transparent health technology assessments. The Socratic approach aims at making value issues explicit. However, it has been interpreted and implemented in a variety of ways. A joint effort by an expert panel has revised the Socratic approach to make it clear, comprehensive, and applicable for addressing ethical issues in HTA. We hope that this will be an important contribution to improvement and harmonization of ethics in HTA.

## SUPPLEMENTARY MATERIAL

Supplementary Table 1:

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## CONFLICTS OF INTEREST

The authors report they have no potential conflicts of interest.

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