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ORIGINAL PAPER

Toward a Method for Exposing and Elucidating Ethical Issues with Human Cognitive Enhancement Technologies

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Abstract To develop a method for exposing and elucidating ethical issues with human cognitive enhancement (HCE). The intended use of the method is to support and facilitate open and transparent deliberation and decision making with respect to this emerging technology with great potential formative implications for individuals and society. Literature search to identify relevant approaches. Conventional content analysis of the identified papers and methods in order to assess their suitability for assessing HCE according to four selection criteria. Method development. Amendment after pilot testing on smart-glasses. Based on three existing approaches in health technology assessment a method for exposing and elucidating ethical issues in the assessment of HCE technologies was developed. Based on a pilot test for smart-glasses, the method was amended. The method consists of six steps and a guiding list of 43 questions. A method for exposing and elucidating ethical issues in the assessment of HCE was developed. The method provides the ground work for context specific ethical assessment and analysis. Widespread use, amendments, and further developments of the method are encouraged.

Keywords Cognitive · Enhancement · Method · Assessment · Axiology

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Introduction

Human cognitive enhancement (HCE) technology is a group of emergent technologies that aim at altering (improving) cognitive capacities, such as attention, concentration, memory, and reasoning. A wide range of emerging technologies for HCE is making its way from mice to men (Bostrom and Sandberg 2009; Farah 2015). HCE technologies can be categorized in many ways (van Est et al. 2012; Baldwin et al. 2013). One suggestion is to differentiate between *internal hardware*, such as biological modifications (genetic modifications, surgery, tissue engineering, pharmaceutical or nutritional interventions and neural implants), *internal software*, such as mental training, and *external hardware and software*, such as external tools and methods to enhance memory (Sandberg and Bostrom 2006).

HCE technologies are special as they may not only change a person's ability to reason and reflect, but also the person's self-conception and identity, and the way that person socialises. As such, the technology has significant potential implications for individuals and society, which raise a series of ethical challenges which are discussed in the abundant literature (Butcher 2003; Cakic 2009; Chatterjee 2013; Forlini et al. 2013; Gaucher et al. 2013; Goodman 2014; Gyngell and Easteal 2015; Harris 2011; Lanni et al. 2008; Mordacci 2014; Sahakian and Morein-Zamir 2011; Santoni de Sio et al. 2014). Several technologies have now come so far in their development that they merit more systematic assessments, e.g., various drugs, smart-glasses, and external magnetic stimulators that are commercially available.

Public attitudes towards HCE have been studied (Fitz et al. 2014), and a range of policy implications were identified and discussed (Sarewitz and Karas 2012; Schermer et al. 2009). HCE is also thoroughly analyzed in light of innovation theory (Baldwin et al. 2013), and a shared European "normative framework [that] should be based on fundamental and uncontroversial values such as autonomy, fairness, and the right to physical integrity" has been suggested (Coenen et al. 2011). A wide range of perspectives and frameworks to analyze and address social, legal, and ethical aspects of HCE are available, e.g., within a responsible research and innovation (RRI) framework (Stilgoe et al. 2013) or in technology assessment, such as real-time technology assessment (Guston and Sarewitz 2002), participatory technology assessment (Klüver et al. 2000), constructive technology assessment (CTA) (Kiran et al. 2015; Rip and Te Kulve 2008), ethical technology assessment (eTA) (Palm and Hansson 2006), anticipatory ethics for emerging technologies (Brey 2012), and others (Ely et al. 2014; Klüver et al. 2015; Fisher et al. 2006).

Despite the many available frameworks, there is little agreement on how to handle ethical issues in HCE. One reason for this is that the available frameworks come from different theoretical perspectives. Another reason is that the technologies are quite different. So are the contexts. There may be different demands at a policy level compared to a consumer level. Hence, it may be difficult to find one all-purpose framework that captures it all. Nonetheless, what unites most of the perspectives or frameworks is the need to expose and elucidate the relevant ethical issues related to HCE. Every open and transparent assessment, policy- or decision-making process needs to reveal the ethical issues related to an HCE

technology. Any framework that does not include a comprehensive review of the ethical issues may become biased and hamper an open and transparent appraisal.

Accordingly, the objective of this article is to develop a method for exposing and elucidating ethical issues with HCE in a systematic and comprehensive manner. The purpose of the method development is to support and facilitate open and transparent deliberation and decision making with respect to a crucial kind of emerging technology.

Exposing ethical issues here means to reveal and identify ethical issues with an HCE technology. Ethical issues may be overt and covert. They may be hidden in the presentation of facts, in concepts (such as enhancement or intelligence), and in framings. An open and transparent deliberation (of any kind) will need to take all these issues into account (in various ways).

Elucidating ethical issues goes beyond just mentioning an ethical issue, and explains why the issue is ethically relevant. For example, pointing out that transcranial brain stimulation may challenge authenticity is not enough. We need to know why it is an ethical challenge. In order not to frame or bypass certain steps in the consecutive deliberation process, detailed discussions of the issues or evaluation of the soundness of arguments are not included. Elucidating the ethical issues only includes what is necessary for the preparation of an open and transparent process.

Hence, the goal of this article is to present an issue-oriented method for the preparation of deliberation on HCE, both within the development of science, technology and innovation (STI) policies and for the deliberation on developing, regulating, and implementing specific HCE technologies.

Methods

A literature search on the assessment of emergent technologies was performed in order to identify relevant approaches. The search term [("technology assessment") AND ("method" OR "approach" OR "framework") AND ("review" OR "overview" OR "display" OR "elucidate" OR "expose" OR "highlight" OR "reveal") AND ("ethics" OR "moral" OR "ethical" OR "normative" OR "evaluative" OR "evaluation")] was applied in PubMed (until December 31 2015).

Conventional qualitative content analysis (Hsieh and Shannon 2005) of the identified papers and methods was performed by the author to assess the suitability for assessing ethical issues in HCE technologies. The criteria for assessing approaches suitability are based on (Rhodes 2015; Beekman et al. 2006) and result from a group deliberation as part of a research project (see acknowledgement). The criteria were selected with respect to whether they could promote exposing and elucidating ethical issues, as defined above. The various approaches were assessed with regards to whether it could: (a) contribute to an open and transparent policy- and decision making processes in a deliberative democracy setting, (b) was easy to apply, and (c) was able to address the many health related aspects of HCE and (d) as well as HCE's ability to change basic human capabilities.

Based on these criteria a value based approach was selected as a starting point and was modified in a group deliberation process in order particularly to target HCE technologies. The developed method was then tested for a specific type of HCE, i.e.,

smart-glasses (Hofmann et al. 2016). Based on the experience from this pilot test, the method was revised and amended. A flowchart of the process is presented in Fig. 1.

Results

A wide range of approaches to address ethical issues in the assessment of existing and emerging technologies was identified in 417 references. Many of the approaches were identified within the field of health technology assessment (HTA) and most of them are summarized in a recent systematic review by Assasi and colleagues (Assasi et al. 2014), which was identified by the search.

Based on the selection criteria three approaches appeared to be particularly suitable: EUnetHTA Core model (Lampe et al. 2009), The approach by The Swedish Council on health technology assessment (SBU) (Heintz et al. 2015), and the "Socratic approach" (Hofmann 2005; Hofmann et al. 2014), see Table 1.

The EUnetHTA Core model consists of nine domains, where "ethical analysis" is one domain which is divided into six topics (beneficence/non-maleficence; autonomy; justice and equity, respect for persons, legislation, and ethical consequences of the assessment). Each topic consists of two to four questions, adding up to nineteen issues of assessment. The SBU approach consists of twelve items, which are organized into four different themes: the effects of the intervention on health, its compatibility with ethical norms, structural factors with ethical implications, and long term ethical consequences of using the intervention. Each item is provided with sub-questions, short explanations, and a concluding overall summary. The Socratic approach consists of six steps and 7 main questions and 33 detailed questions to guide the assessment (Hofmann et al. 2014).

As can be seen from Table 1, all three approaches appear applicable according to the criteria. Due to familiarity the Socratic approach was selected, and was adjusted

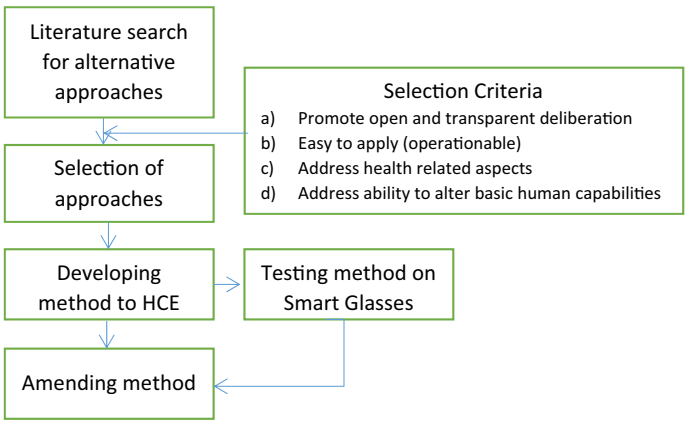

Fig. 1 Flow chart of the process for developing the method to expose and elucidate the ethical issues of human cognitive enhancement technologies

Table 1 Assessment of the approaches for exposing and elucidating ethical issues with human cognitive enhancement technologies

Criterion	EUnetHTA Core model	SBU's approach	The Socratic approach
Contribution to an open and transparent policy-and decision making processes in a deliberative democracy setting	Addresses six topics (beneficence/non-maleficence; autonomy; justice and equity, respect for persons, legislation, and ethical consequences of the assessment) where each topic consists of two to four questions, adding up to nineteen issues of assessment. The approach is fairly well described and can be applied in an open and transparent way	The SBU approach consists of twelve items, which are organized into four different themes (the effects of the intervention on health, its compatibility with ethical norms, structural factors with ethical implications, and long term ethical consequences of using the intervention). Each item is provided with sub-questions, short explanations, and a concluding overall summary. This provides a well-defined approach facilitating openness and transparency	The Socratic approach consists of six steps and 7 main questions and 33 detailed questions to guide the assessment The approach is well described and can be used in an open and transparent manner
Is easy to apply	This is developed to be applied by HTA experts (with assistance by ethicists). The core model has been used for some health technologies	This is developed to be applied by HTA experts (with assistance by ethicists). This approach is quite new and has not been applied for many assessments yet	This is developed to be applied by HTA experts (with assistance by ethicists). The Socratic approach has been applied for several health technologies
Is able to address the many health related aspects of HCE	This is developed to assess health related aspects, but not specifically to HCE	This is developed to assess health related aspects, but not specifically to HCE	This is developed to assess health related aspects, but not specifically to HCE
Is able to address HCE's ability to change basic human capabilities	Has not been applied for HCE yet, but appears to be applicable (if extended to HCE-specific issues)	Has not been applied for HCE yet, but appears to be applicable (if extended to HCE-specific issues)	Has not been applied for HCE yet, but appears to be applicable (if extended to HCE-specific issues)

and amended during the group process with participants from the research project (see acknowledgement) and from the experiences with applying the developed method on smart-glasses (reference to JSEE-D-16-00020). Some steps were added, and some questions of the model were modified.

The final steps of the approach is presented in Table 2 and the questions in step 3 are listed in Table 3.

Table 2 Six steps for exposing and elucidating ethical issues in the assessment of (HCE) technologies

Step	What to do?	Key questions to guide action
1	Identifying scope: identify the intended purpose of the technology and reveal the background for the assessment	What are the functions and purposes of the technology?
		Why is this technology subject to attention and assessment?
		What are the directions for the assessment?
		What is the context and capacity of the assessing organization?
2	Identify potential stakeholders (e.g., target persons, groups, affected persons, professionals, industry)	Who is affected by the use of the technology?
		Who affects the introduction of the technology and how?
		What are the interests of the various stakeholders?
3	Identify relevant moral questions (from a list of questions, see Table 3) and justify the selection	What are the questions selected?
		Why are these questions selected and others omitted?
		Are there other questions which are relevant for this technology?
4	Gather information and evidence on the introduction and application of the technology	Perform literature search in accordance with the identified moral questions in step 3. (Method is described in Hofmann et al. 2014 and Droste et al. 2011)
		Where feasible, do primary research and engage stakeholders
5	Elaborate on the moral questions identified (in step 3). (clarifying analysis)	What are the arguments for the various ethical issues?
		From which ethical perspective are they presented?
		Are they morally relevant, consistent, and coherent?
6	Wrap up and summarize the process. Given the results of the scoping (step 1) synthesize the information (4) and the results (5) in an open and transparent way	What is the knowledge status for the technology?
		What are the main ethical issues?
		What are the main arguments with respect to these issues?
		Are the arguments sound?

Depending on the result of the scoping in step 1, the presented method may be used by a single person and by a team. In principle it could be performed as an armchair exercise (with good access to the literature) or preferably as an interactive process (Hofmann et al. 2015b) with full stakeholder involvement, depending on the context. It is important that these choices are openly and explicitly argued for.

Although the questions 1–36 in Table 2 are directed toward highlighting ethical issues while the questions 37–43 point to governance issues, there are overlaps between the questions.

Table 3 Questions to expose and elucidate ethical issues of human cognitive enhancement technologies using smart-glasses as an example (cross-reference to article on smart-glasses)

Question	Specification	Question relevant?	Answer/explanation/ justification/argument with smart-glasses as an example
1. What is the characteristic of the technology?	Function/purpose/intension	Yes	"Smart-glasses" are wearable devices that display images to the visual field of a user designed to add visual elements to the vision of a person without significantly distorting or disturbing the person's ordinary vision
			The purpose is to expand the access to information and tools (such as navigation)
			The intension is to compensate for loss or extend human capabilities
2. What cognitive capacity/ ability/characteristic is enhanced or modified?	What is the capacity or the ability that is enhanced, and how is it valued?	Yes	Primarily vision, but ultimately a broad range of capacities, such as memory, navigation, calculation etc.
			Vision and related cognitive abilities are highly valued in western cultures
3. What kind of enhancement does this represent?	Augmentation/improvement of existing performance/ ability	Yes	Vision
	New sense/ability/capacity	Yes	Compensating or enhancing existing sense and abilities
	Qualitative/quantitative	Yes	Expanding extension (quantitative) and content (qualitative) of available information
4. What is the target group (users) of the technology?	Group or subgroup	Yes	Specific professionals (in logistics or health care), affluent or technology savvy persons
5. Is the main target group (users) of the technology	Vulnerable	Yes	No, not primarily/not yet
	High socioeconomic status or priority	Yes	Yes
	Low socioeconomic status or priority	Yes	No
	Subject to prejudice or discrimination	Yes	Examples of prejudice against smart-glasses exist. Potential discrimination towards those who do not have access when widely used

Table 3 continued

Question	Specification	Question relevant?	Answer/explanation/ justification/argument with smart-glasses as an example
6. Is the technology targeted towards healthy persons?	Whether it is targeted towards healthy or diseased persons may have implications for priority setting	Yes	Yes, primarily
7. Does the (widespread) use of this technology change the human condition?	Does it alter basic conceptions, behaviours, life-styles, etc.?	Yes	Yes, it may alter behaviours in many fields of life, e.g., ways to communicate and socialize
8. Does the use of this technology potentially change any conceptions of If yes, how?	Self(hood)	Yes	Extended abilities
	Agency	Yes	Extended responsibility (violating privacy)
	Integrity	Yes	Unknown
	Authenticity	Yes	May be increased if the background information for deliberation is increased and reduced if decisions are made by "the system"
	Equality	Yes	May challenge fair play
	Dignity	Yes	Unknown
9. Can the implementation and use of the technology alter human morality or responsibility?	Does accountability change in any way?	Yes	Privacy may be violated by audio-visual information transfer, and hence the accountability
10. Does the technology change human perception, experience, and/or conception of reality (virtualness)?		Yes	Yes, visual perception (see above) May also cause nausea (see below)
11. Does the implementation, use, or withdrawal of the technology challenge persons'	Autonomy?	Yes	Yes
	Privacy?	Yes	Yes, as mentioned in Q9
	Confidentiality?	Yes	Yes, as indicated in Q9
	Human rights?	Yes	Unknown
12. Can the technology change human socialization or interaction?		Yes	Yes, as visual contact and "telepresence" is feasible with smart-glasses
13. Does this technology contribute to solving important societal problems, tasks, or challenges?	Do the functions, purposes, and intensions solve societal challenges?	Yes	Smartglasses are envisioned to solve a wide range of problems, but so far only a few applications have demonstrated usefulness
14. Is there evidence that the technology challenges social, cultural, or religious norms, values, institutions, arrangements or convictions?	Are there barriers or facilitators?	Yes	Altered behaviour and socialization may both be a barrier, but also facilitating

Table 3 continued

Question	Specification	Question relevant?	Answer/explanation/ justification/argument with smart-glasses as an example
15. How can the implementation, use, or withdrawal of the technology affect the distribution of resources? (Justice in allocation, access, and distribution)	Just/fair/equal distribution of resources and attention	Yes	Access may be unequally distributed May give unfair advantage for those with access.
16. Will the implementation and use of the technology create inequalities? (E.g., due to difference in effect, uptake, application etc.)	Will only certain persons or groups be able to apply (and benefit) from the technology?	Yes	Yes, only persons who can see, can use smart-glasses, but some types of smart-glasses may also be useful for persons with reduced vision
17. What are the main ethically relevant benefits and risks/harms/costs of the implementation, use or withdrawal of the technology? (positive and negative consequences)	Benefits Safety Risk	Yes	Extension of body and mind, enhance interaction with environment, improve learning, safety, health behaviour, situational awareness, recognition (of objects and persons), empowerment, communication (across language barriers), compensate for impaired functions, and provide evidence May make people uncomfortable, dependent, Radiation related risk, harms on vision, threatened security, breaching privacy, potential steering, are identified in the literature
18. Is it clear how risks arising from the implementation, use or withdrawal of the technology should be handled?	Are there well developed risk analysis?	Yes	Context dependent. Some risks are well-known, e.g., in gaming, while others are uncertain (radiation hazards), while others are unknown (privacy breaches)
19. Is there consensus on how the benefits balance the harms?	Do risk benefit-analyses exist?	Yes	No
20. Are there good existing alternatives to this application?	Do related technologies exist? Does it replace or extend an existing technology?	Yes	Smart-glasses extend many functions that smart-phones have

Table 3 continued

Question	Specification	Question relevant?	Answer/explanation/ justification/argument with smart-glasses as an example
21. Are there any related technologies that have turned out to be ethically challenging? (Are the same challenges relevant for this technology?)	Are there relevant analogues that give important information on ethical issues?	Yes	Many of the same benefits and harms/challenges which are found with smart-phones and wearables may appear with smart-glasses
22. Does the technology have potential alternative or dual use?	Could the technology be used for other purposes with unintended consequences?	Yes	Yes, military use exists already, and raises ethical issues, such as authenticity and responsibility. However, dual use is not extensively discussed in the literature
23. Are there ethically relevant interests at stake for the following stakeholders	Users/consumers	Yes	Competitive advantages
	Producers	Yes	Revenues. Framing of information (advertisement). Recording of activity (privacy)
	The environment	Yes	Directly: As with consumer electronics
			Indirectly: through altered behaviour
	The society at large	Yes	Altered social interaction
	Other stakeholders (please specify)	Yes	Surveillance, sousveillance
24. Might third parties benefit from the enhancement?	Do authorities, enterprises, employers, schools, family members benefit? Does the enhancement imply a pressure on the individual user?	Yes	Primary envisioned benefit to the user, but others may benefit (e.g., by surveillance)
			Pressure to use may come to exist
25. Are there special difficulties with informing persons about the potential implications of using the application?	Is the scope and consequences of using the technology easy to understand?	Yes	Depends on application context
			Unexpected (emergent) use is likely
26. Can the technology be used to mislead persons?	Can the technology be used for deception?	Yes	Yes
27. Are there ethically relevant third party agents involved in the production, implementation, or use of the HCE	Donors	Yes	No
	Relatives	Yes	Yes, if used at home (raising privacy issues when recording)
	Research subjects	Yes	Yes
	Research animals	Yes	No
	Others, e.g., workers with in industries/countries with low labour condition standards	Yes	When recording smart-glasses raise privacy issues

Table 3 continued

Question	Specification	Question relevant?	Answer/explanation/ justification/argument with smart-glasses as an example
28. Does the technology inherently contribute to or challenge the agency/ autonomy/personhood of other persons (who do not use the HCE)?	With widespread use of the HCE how is the agency/ autonomy/personhood of non-users affected?	Yes	Non-users may be and feel disadvantaged
29. Are the users of the technology in the (case) studies presenting the application representative of the users that will apply it in general practice?	Are the users in assessment typical users?	Yes	In the early stage users are mainly persons with special interests. The discrepancy with "ordinary users" may result in ethical challenges
30. Does the enhancement exist in a functional and testable version?	At what stage of the development/ implementation is the technology assessed?	Yes	Commercially available Limited practical applications Several feasibility studies,but few outcome studies
31. Are there (obvious) biases in the presentation and documentation of the technology (e.g., status quo bias, precautionary principle, high hope, automatic escalator, etc.)	Can specific framings be identified in the presentation of the HCE technology?	Yes	Hype and lack of critical awareness is identified in the literature, but also scepticism
32. Are there specific reasons that this technology has (not) obtained attention or is assessed?	What are the reasons for attention or omissions of attention?	Yes	Novelty and limited applications
33. If the technology is implemented, will other non-effective technologies be abandoned?	Will the implementation affect the use of other technologies?	Yes	Potentially: smartphones, TV-sets, computers (for visual purposes), travel
34. Can the enhancement lead to (measureable) non-reversible changes in the human body or the human mind or lead to dependency?	How may the technology change human being (mind, body, behaviour)?	Yes	May change behaviour and interaction. May become vulnerable without smart-glasses
35. Judging from media discussions or technology assessments; is there evidence that the application is socially controversial?		Yes	

Table 3 continued

Governance issues Questions	Specification	Question relevant?	Justification/explanation/answer
36. Does the application fall under the following legislation	Medical device legislation	Yes	Depending on use
	Research ethics legislation	Yes	Depending on field of research
	Pharmaceutical legislation	Yes	No
	Chemical legislation	Yes	No
	Food and nutrition legislation	Yes	No
	Consumer legislation	Yes	Yes
	Privacy legislation and data protection	Yes	YES
	Environmental legislation	Yes	Unlikely
	Biotechnology legislation	Yes	Potentially
	Radiation legislation	Yes	Potentially
37. Can the implementation, use, or withdrawal of the technology in any way conflict with existing law or regulations or pose a need for altered or new legislation?		Yes	Privacy legislation
38. Does the technology change or create (the need for) social institutions or specific policies?		Yes	Social interaction, public spaces
39. Have users or members of the public been involved in the development and/or the assessment of the technology?		Yes	Partly. Mainly enthusiasts
40. For this application, is there a need for standardisation of	Terminology	Yes	Some, on typology of smart-glasses
	Impact/efficiency measurements	Yes	Yes, no standards exist
	Side effect measurements	Yes	Vision
	Technical specifications	Yes	No specification standards yet
41. Are there sufficient risk assessment frameworks for this application?		Yes	Not specifically for this technology Frameworks from other fields can be relevant.

Table 3 continued

Governance issues Questions	Specification	Question relevant?	Justification/explanation/answer
42. Are there sufficient risk management frameworks for this application?		Yes	Not specifically for this technology Frameworks from other fields can be relevant
43. Are there other relevant ethical issues?		Yes	Technological and cultural obstacles for the uptake of smart-glasses

Discussion

There are several challenges with this study. First, searching in PubMed obviously covers HTA approaches much better than parliamentary technology assessment (PTA) and science and technology studies (STS) approaches. Moreover, it does not cover approaches presented and discussed in books or methods developed and used in other areas, such as the Ethical Matrix for the assessment of food (Cotton 2014). However, an initial search in Google Scholar with the search term [("technology assessment") AND ("method" OR "approach" OR "framework") AND (("review ethical issues" OR "overview ethical issues" OR "display ethical issues" OR "elucidate ethical issues" OR "expose ethical issues" OR "highlight ethical issues" OR "reveal ethical issues") OR ("review moral issues" OR "overview moral issues" OR "display moral issues" OR "elucidate moral issues" OR "expose moral issues" OR "highlight moral issues" OR "reveal moral issues")) AND ("ethics" OR "moral" OR "ethical" OR "normative" OR "evaluative" OR "evaluation")] only gave 6 references of little relevance. A search in PubMed with the same search term gave 70 references of higher relevance. This, together with the acknowledgement that methods for exposing and elucidating ethical issues have been much more appreciated in health technology assessment than in PTA or STS, warrants a search in PubMed.

Correspondingly, the selection criteria may be criticized, as the selection of other criteria may obviously have identified other approaches. However, the first selection criterion is based on overall goals in modern democracies. The second criterion is straight forward and pragmatic. If the method is not fairly easy to use, it will not be applied. The third and fourth criteria are based on core characteristics of HCE found in the literature, i.e., that it can affect people's health, and that it can alter basic human abilities and human self-conception.

Moreover, other selection criteria may have identified other approaches or frameworks as a starting point for the development of this method, and many of them are mentioned in the introduction. However, the aim of this method development was not to provide yet another STS framework, but rather to provide practical input to such frameworks. Moreover, many of the available frameworks and methods for assessing technologies have limited practical applications (Hofmann et al. 2015a). The selected approaches, however, have been applied for

practical assessment of a wide range of health technologies, and the developed method was demonstrated to be useful for smart-glasses. One obvious objection is that the author has been involved in the development of the selected method, and may have been biased. Here the reader is encouraged to repeat or critically assess the study and investigate whether this is the case.

The developed method embraces a wide range of ethical approaches, such as consequentialism, deontology, casuistry, virtue ethics, and other mixed approaches, such as principlism. This avoids the critique of being too narrow, but opens it up for the criticism for being eclectic. However, this is reasonable when aiming at a comprehensive and systematic approach for exposing and elucidating ethical issues.

Moreover, the steps and questions are not carved in stone. Contextual adjustments may be necessary. All the questions may not be relevant for all types of HCEs and other questions, not mentioned, may be relevant (see step 3 and Q43). The point is that the method is a guidance for reflective application and not a checklist for blind use.

Accordingly, the approach may not be perfectly suited to address the full diversity of future HCE technologies. Further amendments and adjustments may be necessary. However, the method is designed to be flexible, and future applications will show whether it is flexible enough to address ethical issues in the emerging range of HCE technologies. General amendments and local adjustments would be most welcome.

Another relevant critique is that there are so many other methods and frameworks available and that HCE does not merit a specific approach, and if it does, no approach is needed specifically to expose and elucidate the ethical issues. The ethical issues can be addressed directly without exposure and elucidation. However, as stated in the introduction, HCE is a special kind of technology as it alters basic human capabilities. Moreover, the various specific frameworks tend to address specific ethical issues and may not be transferable from one context to the other. Here, a broad range of ethical issues will be exposed and elucidated and can be used (as input) by a wide range of frameworks. Moreover, other and less explorative frameworks may ignore or bracket important ethical issues.

Yet another source of criticism is that the terms “exposing” and “elucidate” can be subject to a wide variety of interpretations. This is certainly true, but as defined in the introduction, these terms refer to what contributes to an open and transparent process of assessment, decision- or policy making. That is, if a type of HCE raises issues of privacy this will be important for the subsequent analysis. The same goes for in what way privacy is relevant, and how the arguments are framed, challenged or supported. However, how the arguments about the various aspects of privacy are to be taken into account in the specific assessment, policy-making or decision-making process is beyond the scope of this method. The method only provides the basis for such processes.

Both step 1 and Q1 contain a description of (the purpose of) the technology. This may appear confusing. However, in step 1 the goal is to identify the scope of the assessment and in Q1 the goal is a more detailed description of the technology with respect to function, purpose, and intention. In Q1 characteristics and applications that were not thought of in the initial step may be identified.

Another relevant objection to the development of this method is that the assessments of HCE technologies may be performed with the Socratic approach for HTA, as this is a flexible approach where existing questions can be ignored (if justified) and new issues and questions can be added. That is, no new approach is needed. This is correct. However, the purpose of HCE is so special (e.g. in potentially altering agency) that it warrants a special version of the approach. Having a specific approach may also increase the user-friendliness and the uptake. Moreover, there are significant differences between the Socratic approach for health technologies and HCE, as illustrated in Table 3. Q2, Q3, Q7, Q9, Q18, Q26, Q28, Q31, Q34–42 are new, while other questions have been modified to be better attuned to HCE, such as Q5, Q12, Q2, and Q27. Hence, the method development for HCE can be seen as an input for a revision or expansion of the Socratic approach in HTA.

It may also be argued that there are other and more fruitful ways to group and order the questions in Table 3. Moreover, several questions are closely related and some questions overlap. Here it is important to acknowledge that the question list in Table 3 is not the end product of the approach, but only a step to provide information and content for the analysis. As illustrated by the example with smart-glasses (Hofmann et al. 2016), the context and the analysis of the literature will determine how the ethical issues will be grouped and presented. Hence, instead of grouping by generic questions, themes should be grouped by technology-specific ethical issues. That said, the questions do follow a certain logic, where Q1–3 are related to the *technology*, Q4–6 is concerning the *target group/users*, Q7–12 relate to human *personhood*, Q13–16 address *social aspects*, Q17–19 are related to (potential) *consequences*, Q20–22 address *alternative and dual use*, Q23–24 are related to *stakeholders*, 25–35 relate to *use* and *implementation*, and Q36–43 target *governance* issues. This could of course have been highlighted in Table 3. However, in order not to direct or complicate the analysis unnecessary, this has not been done.

Lastly: who can use the approach? Preferably persons skilled in ethics. However, in the HTA-setting the Socratic approach is used by HTA-experts without special training in ethics.

Conclusion

A method for exposing and elucidating ethical issues with HCE was developed. The method highlights ethical issues that are relevant for open and transparent deliberation processes when assessing HCE technologies. The identified issues can be used directly in deliberation processes or as input to other assessment frameworks. It has been tested on smart-glasses and hopefully the approach can be helpful for the practical assessments of emerging HCEs and colleagues are encouraged to use, amend, and develop the method.

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