INAHTA/HTAi Interest Group Ethical Issues and HTA

Co-chairs: Ken Bond and Dario Sacchini

ETHICS IG Methodology Meeting

Dec 6 – 7, 2018, The Generator Hostel, Amsterdam

Meeting Participants

Ilona Autti-Ramo, Social Insurance Institution of Finland, Finland

Francoise Barten, Radboud University, The Netherlands

Bart Bloemen, Radboud University, The Netherlands

Ken Bond, Institute of Health Economics, Canada

Charlotte Michels, Radboud University, The Netherlands

Claudia Mischke, IQWiG, Germany

Jani Mueller, CMeRC, Charlotte Maxeke Research Cluster, Johannesburg, South Africa

Sylvia Nabukenya, Infectious Diseases Institute, Uganda

Wija Oortwijn, Radboud University, The Netherlands

Pietro Refolo, Università Cattolica del Sacro Cuore, Italy

Dario Sacchini, Università Cattolica del Sacro Cuore, Italy

Gert Jan van der Wilt, Radboud University, The Netherlands

Kas Woudstra, Radboud University, The Netherlands

SUMMARY OF THE SCIENTIFIC MEETING

Topic 1: Summary and commentary on Federica Lucivero's *Ethical Assessments of emerging technologies*

Gert Jan van der Wilt and Bart Bloemen presented Federica Lucivero's approach on emerging technologies. See Powerpoint presentation.

Discussion points:

- Questions of Plausibility and Desirability of technologies: in terms of? In reference of?
- Perceptions and concerns that may arise through involvement of the healthy citizens as the end users
- Collection of relevant facts to build public trust and the use of elaborations to describe different scenarios for the development and implementation of technologies that are either already existing or new technologies.
- Assessment of the technologies' relevance in respect to societal values and engagement of different stakeholders.
- Further discussion needed on the applicability of Federica's work to HTA

  For example; based on interviews with engineers and healthcare professionals responsible for the implementation of screening programs in the Netherlands, Lucivero showed that this technology could be developed among the lines of two different scenarios. In one scenario, the technology may be used in a self-monitoring setting that promotes privacy and autonomy. In another scenario, it may be used as part of a national screening programme, potentially promoting the efficiency of the healthcare system but threatening privacy (because the results are directly sent to the healthcare system). In addition, it raises questions about the moral appropriateness and affordability of self-monitoring without a medical follow up

- A collaborative work discussing the application of this approach to HTA– open to all ISGoE members – will be drafted aimed at a publication, possibly in a good impact journal.

Room for improvement/ open questions

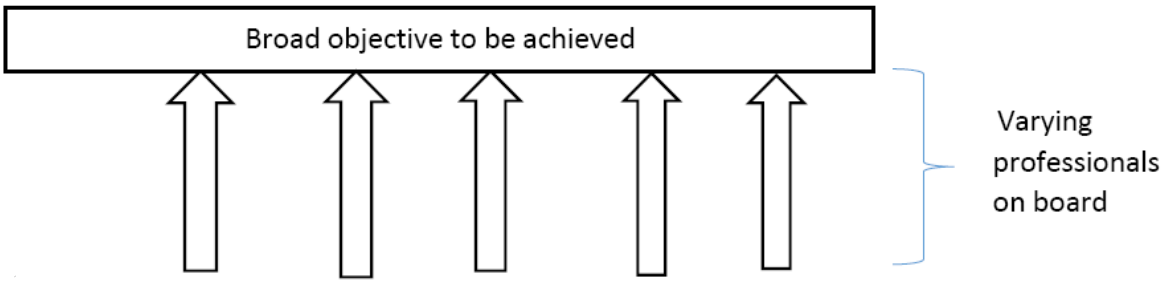
- What is the meaning of "democratic deliberation" for assessments of emerging technologies and what concerns relate to desirability?
- Cultures of plausibility? How do actors with different knowledge and values harmonize the plausibility of the same vision?
- How do we ensure that the different alternatives contribute to a vision of a desirable society that is not only technology driven and focused?
- What should "ethics of promising technology" look like?
- What does "ontology" and "normative" mean in Lucivero's approach?

Topic 2: Core competences for ethics in HTA

A proposal of Core Competencies for HTA Ethics expert was described by Dario Sacchini and Pietro Refolo. See PowerPoint presentations. The proposed framework of competencies has three main dimensions: *knowledge* (basic and advanced, either scientific/philosophical knowledge or HTA); *skills* (ethical assessment, HTA process, and interpersonal skills); *attitudes* (multidimensional culture - eclectic culture), open mind, integrity, courage, prudence).

Discussion points

1. The need for collaboration with other HTA interest groups (e.g. Patient and citizen involvement, Hospital Based HTA) for a better discussion on how various ethical domains influence each other and also demonstrate the relevance of ethics to HTA.
2. Ethicists to develop a glossary which will provide standard definitions of the main concepts used in the core domains.
3. The use of the T-Professional model that brings together other professions with specific skills and knowledge for a quality ethical analysis.



4. Bioethicists should always be involved in complex situations especially involving conflicting moral values and also in HTA processes. In situations of “what can I do when I can’t do anything”, moral reasoning is highly needed for appropriate decision making.
5. Defining the role of an ethicist right from the start of any HTA process is recommended as one of the solutions that will clearly describe how ethicists work can be done and also help other professionals appreciate the role of an ethicist.
6. Expand on the definition of competences in ethics; ethicists should be able to articulate and clarify the moral commitments underlying the different views of others.
7. It is important to point out the limitations of ethical analyses in HTA and how they can be avoided or solved.
8. To develop standard frameworks that can be used appropriately for ethical analyses. Ethicists should make a clear distinction between descriptive and normative approaches when drawing conclusions.
9. The need to clarify the role of ethics in HTA, appreciate the different ideas underlying specific problems and analyze ethics at each stage of the technology life cycle.
10. A collaborative work – open to all ISGoE members – will be drafted aimed both at a publication, and as a possible “position paper” to be submitted to HTAi Board of Directors.

Topic 3: Ethical issues in Disinvestment

Wija Oortwijn and Ken Bond presented the state of the art on disinvestment in general and a specific example from Canada. See PowerPoint presentations.

Discussion points

1. Opportunity cost to provide treatment for both patients who are termed as “worse off” and those who may not be worse off.

- How can we be fair to both categories?
- What health technology should be excluded and at what stage?
- Dilemmas of offering treatments that have no cost value to the whole population and how to ascertain that an intervention may be of low value.
- From a moral point of view, if a patient has been offered treatment, should we stop it on grounds of opportunity cost?
- “To Go” or “NOT to go”- this may be a very crucial decision especially for emerging technologies

2. Can insurance companies offer to cover a bigger percentage of expensive treatments?

- For some countries, the payment models are not very clear and the disadvantaged always fall victim of inability to access health care especially treatments with high technology input.
- Insurance services are usually earmarked and do not cover all conditions.
- How can we balance the relationship between the “clinician and insurance company”, clinician’s professional values and patient?

3. Ethics around rationing of resources.

- How best can we define the appropriate rationing method to be used? For example, selection, dilution, deterrence, deflection, delay, denial and interruption.
- Involvement of stakeholders with major impact in decision making on the above methods.
- How can we adopt HTA methodologies in both explicit and implicit rationing of resources?

4. There is a need to have a thorough assessment of frameworks adopted for disinvestment and involvement of stakeholders.
5. Establish clear policies to define the proposed health technologies, their role, where and how they will be accessed, the payment model and the consideration of equity among all populations. However, sometimes, we may not be very certain about the possible harm relating to the intervention.
6. Few concrete examples of disinvestment decisions driven by the kind of formal analysis that is being proposed by those writing on this topic. An example of the process for and challenges encountered in disinvesting in the fetal fibronectin test for preterm labor in Canada was described.
7. We could think about working with Euroscan to develop a project under this topic.
8. A collaborative work – open to all ISGoE members – will be drafted and aim for a publication.

TOPIC 4: Methodological issues in HTA ethics

Ken, Claudia, and Gert chaired this session, showing different methodologies adopted for addressing ethical issues in HTA processes.

Discussion points

1. There are a number of key stakeholders when developing HTA topics and these include; the public and patients, clinicians, economists, ethicists, biomedical engineers and other professionals. We need to define clear modes of communication with the audience (stakeholders), policy makers and end users.
2. Who is the decision maker on the topics listed by the stakeholders and what criteria is used to choose the most appropriate option at a given time with respect to the available resources?

3. How can we estimate the resources required for handling ethical issues in HTA? The use of evidence-based results may be a starting point. However, other strategies may be important to think about.
4. The need to define the various approaches for structured handling of ethical aspects in HTA and relevance of ethics in HTA.
5. The challenge of defining the structure of presenting ethical domains in HTA.
6. We need to reach out to academic groups or institutions to build capacity in most countries involved in HTA. Also, linking up with different ethicists from all parts of Europe and the rest of the world.
7. There is continuing interest in some HTA environments to develop an ethics checklist to identify ethical issues at topic identification or prioritization and to help determine the effort that should be devoted to ethics analysis.
8. A collaborative work – open to all ISGoE members – will be drafted aimed both at a publication, possibly in a good impact journal.

TOPIC 5: VALIDATE PROJECT

VALIDATE Project (Values in doing assessments of healthcare technologies) is a three-year (2018-2021) Research Project funded by European Commission “Erasmus + Programme” (Key Action 2: Cooperation for Innovation and the Exchange of Good Practices. Strategic Partnerships in the field of Higher Education), with nine partners (The Netherlands (3); Spain (2), Sweden, Norway, Turkey, Italy), and chaired by Radboud University Medical Center, Nijmegen, The Netherlands. Kick-off meeting will be held next Dec 20, 2018 in Amsterdam.

Within VALIDATE, a consensus statement will be developed that delineates areas of expertise and skills that are considered critical for HTA professionals (in addition to generally recognised areas of expertise). The transdisciplinary approach in VALIDATE, involving higher education institutes (HEIs), public health agencies, professional organisations (such as patient organisations) and other stakeholders, will infuse HTA with insights and perspectives from other

disciplines, such as policy sciences and moral and political philosophy. Main outcomes of VALIDATE include a handbook and e-learning module (open-access) that will encourage students with an interest in HTA to develop their knowledge and skills for understanding a specific problem from multiple perspectives (e.g. patient, healthcare provider, third-party payers) and in fostering mutual understanding and respect among stakeholders. This will enhance the relevance and quality of students' knowledge and skills in supporting critically important societal issues (e.g. coverage decisions).

Discussion points

1. Develop clear definition of HTA to avoid confusions. A revised definition is currently under development by an international task group with members from INAHTA, HTAi, GIN, and others.
2. Development of a lifecycle that can clearly define the stages of the health technology and it should aim at informing decision makers.
3. Building on existing materials for a good proposal.
4. Keeping track of the timelines.

Conclusion of the scientific meeting

1. We need to continue examining how ethical analyses makes a difference to HTA and their integration in the practice of HTA. we need to also study and define what the meaning of quality is in the context of ethical analyses in HTA.
2. Need to continue the promotion of development of quality methodologies for ethics assessment that can be used to make informed decisions in health technologies.
3. There is a need to help decision makers recognize and balance technological biases and emotional reasoning when drawing conclusions on health technology disinvestment.
4. Identifying ethical issues at all stages of the technology life cycle and stakeholder involvement in order to have a common understanding between patients and professionals.

MINUTES OF THE ETHICS INTEREST GROUP BUSINESS MEETING

Agenda

- *Welcome and approval of the agenda*. Attendees approved.

- *Approval of June minutes.* Attendees approved.

- *Funding for 2019*. Attendants agreed that the IG should conclude pending funded tasks before asking for new funding. Intent to submit a proposal for the June/July call for funding.

- *Euroscan collaboration update:* Hans-Peter Dauben provided a report on the current status of Euroscan. He noted that our previous contact, Andrea Kirfel, left the organization; her successor will be recruited by February 2019. Suggestions made to the future collaboration between the Ethics Interest group and Euroscan include:
  - Strategies on how we may collect evidence based results for assessment at an academic, clinical or agency level.
  - How can we set up a plan on rising new technology investments to support their implementation while incorporating ethical analyses and protecting the values and morals across continents?
  - We may need to clarify on a topic by March 2019 and call upon the IG members who have expressed their interest of participation to this collaboration. They were eight (8).
  - We also need to have a memorandum of understanding between HTAi and Euroscan
  - Next Euroscan meeting will be held in Rome in spring 2019. Hans-Peter proposes that Dario, one of the ISGoE members involved in Euroscan, can help in the organization of the meeting. It was agreed that Dario will represent ISGoE at Rome meeting.
- *ECN Handbook contribution*. The Chair will contact the people who expressed their interest to contribute towards the development of this handbook. The Ethics IG may plan to have a teleconference with the ECN Chair in 2019.

- *HTA 2019 update:*
  - A number of individuals submitted to the panels and we may need to collaborate with the patients and citizens' interest group
  - Ken provided an updates from the PIG meeting held in Stockholm in October where members discussed how to explore new areas and methods.
  - Creation of 'meet and greet' small groups where members with the similar topics of interest come together and expand on significant ideas and also create a platform for people from different cultures to meet.

Other business.

- Need to update the ethical analyses in the HTA database
- We may consider deliberations for HTA appraisal
- The chair will request the HTAi secretariat to schedule the Ethics IG Business meeting on a day that is free of other related interest groups meetings, e.g., PCIG, so that members from other interest groups can attend our business meeting and vice versa.
- Develop a learning tool to involve people who may not be able to physically attend the 2019 Annual HTAi meeting.
- Formulate potential topics and collaborations with HTA people from China whom we already know (Yingyao Chen, Maoling Wei) in preparation for HTAi 2020 submissions.
- Ken to investigate what happens to the unspent meeting funds and whether it's possible to request an extension.