Workshop on Methodology in Ethics for Health Technology Assessment:

Assessing the Need For and Quality of Ethics Analyses in HTA

Institute of Health Economics, Edmonton, Canada

October 18-19, 2013

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Cologne, German

October 25-26, 2013

Report prepared by

Anna Stoklosa, The University of Sydney, Australia

Ken Bond, Institute of Health Economics, Canada

On behalf of the Edmonton and Cologne Workshop Participants

The workshop organizers gratefully acknowledge the support of the following sponsors:

Alberta Health, Edmonton, Canada

Alberta Innovates-Health Solutions, Edmonton, Canada

Canadian Agency for Drugs and Technologies in Healthcare, Ottawa, Canada

Charles Perkins Centre, University of Sydney, Australia

Health Technology Assessment International

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Cologne, Germany

Institute of Health Economics, Edmonton, Canada

International Network of Agencies for Health Technology Assessment

NHMRC Clinical Trials Centre, University of Sydney, Australia

Executive Summary

Two workshops focusing on methodology for ethics in health technology assessment (HTA) were held, one in Edmonton, Canada (October 18-19, 2013) and one in Cologne, Germany (October 25-26, 2013). In total, the workshops included 32 participants from 10 countries (Australia, Canada, Germany, Norway, Spain, Sweden, United Kingdom, Italy, France and The Netherlands). Workshop participants represented a variety of professional backgrounds, including academics, HTA producers, clinical ethicists, members of government bodies/decision-makers, and members from research funding agencies.

Workshops were structured to be as similar as possible in content and process. The workshop reports were combined into a single document to allow workshop participants to become easily acquainted with the discussions and issues raised by participants at the other workshop.

The goal of Day 1 of both workshops was to assess the extant methodological tools for identifying the *need* for an analysis of ethical issues around a particular health technology. The aim of Day 2 of was to generate tools for *quality assessment* of analyses of ethical issues around a particular health technology (because few such tools currently exist).

Some of the European jurisdictions already have the capacity for performing methodological work in ethics for HTA and are integrating such work into their HTA processes. In both Australia and Canada, on the other hand, there is capacity for this type of ethics work, although, at present, ethical issues are poorly integrated in HTA processes. The Edmonton workshop presented an opportunity for both ethicists and HTA personnel in Canada to come together, and it is hoped that, through engagement and collaboration with the European workshop participants, the integration of ethical issues in HTA in Canada may be advanced.

Workshop participants discussed the approaches to considering ethical issues in HTA currently in use or being trialled at the following HTA agencies: OSTEBA in Spain, IQWiG in Germany, HAS in France, and SBU in Sweden. Goals, benefits, and limitations of these tools have already been identified. However, some of the outstanding issues remain, such as: appropriateness to purpose, enablers of use, barriers to use, necessary and unnecessary elements, conceptual clarity around included items, appropriate methodology for addressing the included items, and convergence between the included items and the HTA and/or jurisdictional context.

The workshop yielded rich discussion among participants on the main topics and proposals for a variety of subsequent work, including manuscripts for publication, presentation of the workshop findings at upcoming HTA conferences, adopting and adapting of some of the workshop materials into an educational module for ethics in HTA, and inclusion of the workshop material in the "Ethics in HTA 101" workshop to be held at the HTAi 2014 Annual Scientific meeting in Washington, D.C.

Institute of Health Economics (IHE), Edmonton, Canada: October 18-19, 2013

IHE Workshop Day 1: October 18, 2013

Aim of Workshop Day 1

The goal of this session is to compare the existing approaches that have been developed to help HTA producers and decision makers determine if an ethics analysis might assist with decision making regarding a candidate technology. Checklists are currently being used by several HTA agencies, and researchers from these agencies will present the checklists and discuss their experiences with them.

Objectives for Workshop Day 1

Part 1: Describe the debates regarding the appropriateness of these checklists, describe the checklists currently in use by HTA agencies, and discusses their potential benefits and drawbacks.

Part 2: Develop a checklist, with a strong ethical foundation, that might be used by HTA agencies either as-is or as the basis for the development of their own checklist, and provides guidance with respect to how agencies ought to develop or modify such checklists.

Schedule for Workshop Day 1

Friday, October 18, 2013: Workshop Day 1: Assessing the need for an ethics analysis in HTA		
Time	Topic	Method / Speakers
8:30-9:00	Welcome & Introductions. Objectives for the workshop.	**Ken Bond, Anna Stoklosa**
9:00-10:00	What goals does the use of an ethics checklist aim at?	Introduction: **Ken Bond** Group discussion and consensus building
10:00-11:00	Under what conditions might the use of an ethics checklist in HTA be appropriate or inappropriate?	Introduction: **Shawn Winsor** Group discussion and consensus building
11:00-11:30	Tea/Coffee Break	
11:30-12:30	Ethics checklists currently in use in HTA: how were they developed, what are the components of these checklists, and what has been the experience of those who use them?	Presentation: **Iñaki Gutiérrez-Ibarluzea (recorded presentation)** Presentation: **Sigrid Droste (via Skype)**
12:30-1:30	What components ought to be included in a standard or basic checklist?	Introduction: **Anna Stoklosa** Group discussion and consensus building
1:30-2:30	Lunch	
2:30-3:30	What ought to be considered when modifying the standard or basic checklist?	Introduction: **Bernard Keating** Group discussion and consensus building
3:30-4:00	Tea/Coffee Break	
4:00-5:00	Should different checklist be used for different health technologies (screening vs. intervention vs. diagnostic technologies, pharmaceuticals vs. non-pharmaceuticals, etc.)?	Introduction: **Daryl Pullman** Group discussion and consensus building
6:00-8:00	Workshop dinner at Sabor Divino Restaurant	

Organizers
Ken Bond, Institute of Health Economics, Edmonton, AB
Anna Stoklosa, University of Sydney/NHMRC Trials Centre, Australia

Recorder
Katherine Duthie, Fraser Health Ethics Services, Surrey, BC

Participants
Yvonne Bombard, University of Toronto, Toronto, ON
Lori d'Agincourt-Canning, Children's and Women's Health Centre of BC, Vancouver, BC
Sigrid Droste, Institute for Quality and Efficiency in Health Care (IQWiG), Germany (via Skype)
Katherine Duthie, Fraser Health Ethics Services, Surrey, BC
Iñaki Gutiérrez-Ibarluzea, Basque Office for HTA (OSTEBA), Spain (Recorded presentation)
Glenn Griener, University of Alberta, Edmonton, AB
Christa Harstall, Institute of Health Economics, Edmonton, AB
Bashir Jiwani, Fraser Health Ethics Services, Surrey, BC
Don Juzwishin, Health Technology Assessment and Innovation, Alberta Health Services, Edmonton, AB
Bernard Keating, University of Laval, Québec City, QC
Jason Lau, Health Technology Services and Policy Unit, Alberta Health, Edmonton, AB
Karine Morin, National GE3LS Program, Genome Canada, Ottawa, ON
Kristen Moulton, Canadian Agency for Drugs and Technologies in Health, Ottawa, ON
Daryl Pullman, Memorial University, St. John's, NL
Lisa Schwartz, McMaster University, Hamilton, ON
Shawn Winsor, University of Toronto, Toronto, ON

Discussions on Day 1:

Day 1, Item 1: Welcome and Introductions

The workshop began with participants introducing themselves, describing their connection with ethics and HTA, and providing an indication of to what extent ethics is incorporated in HTA in their jurisdiction. Participants were predominantly academic researchers (with many having doctoral training in philosophy). Four participants represented the perspective of provincial ministries of health—either as decision makers (DJ, JL) or as health ethicists (KD, BJ), four the perspective of HTA producers (KB, CH, KM, AS), and one (KM) participant represented a major federal funder of medical research (Genome Canada).

Day 1, Item 2: What goals does the use of an ethics checklist aim at? Introduced by Ken Bond (Institute of Health Economics)

Presentation Summary
Ken Bond began the workshop by asking the question of how ethics is infused in/with HTA. There is an emerging sense that HTA itself is a project of ethics; hence, ethics is not a single piece within the process. Ken described the HTA process (consisting of 7 main steps---see Appendix 1) and suggested that ethics checklists are most likely to be used at the prioritization stage of HTA (step 2), the assessment itself (step 3) and appraisal and recommendation (step 4). The main aims of a checklist are to make sure that the process and results of ethics work are useful; to help identify further types of information needed (clinical, economics), identify other people who need to be considered in the process; and ensure values of the decision process are upheld.

Issues Raised in Discussion[1]
- In clarifying the information provided in the presentation, it was noted that the question of goals is determined, in part, by the answers to two questions:
  (1) Are we going to incorporate ethics in to existing framework?
  (2) Are we going to advocate for a change in the process, which, it was argued, does not align well with ethics work?
- Concern that, though the "checklist" vocabulary fits well with other HTA work, it may not fit well with the work of ethics. For example, the checklist leaves unaddressed how the relational conversational dimension of ethics should proceed and who should be at the table when the checklist is used.
- A checklist may give ethicists a place to start discussion with HTA colleagues and stakeholders involved in assessment, help to reduce the perception that ethics is "fuzzy," and a structured process would help to give the ethics process legitimacy. However, the issue of at what point in the process ethics is addressed remains unaddressed. A checklist may also serve as a "capacity building tool" by enabling policy makers to see ethics issues as points for further consideration.
- One important goal of using a checklist should be to reframe the narrow ethics work of the checklist and situate it against the broader ethics enterprise of HTA overall. However, it was pointed out that government (specifically policy makers) like short answers, so may have little appetite for the extended and nuanced conversations promoted by ethics work.

---

[1] Points have been amalgamated from the discussions that took place in both the small groups and the larger group as a whole.

Day 1, Item 3: Under what conditions might the use of an ethics checklist in HTA be appropriate or inappropriate? Shawn Winsor (University of Toronto)

Presentation Summary
Shawn noted the importance of clarifying the concepts of HTA and checklists as the definitions we employ will have consequences for how we think about the when and how ethical issues might be addressed. It is also important to distinguish between frameworks and checklists. A framework was defined as an instrument designed to aid in the performance of certain actions appropriate to resolving a focal problem or phenomenon, both as a metatheoretical guide and a pragmatic device and to achieve this aim irrespective of the problem being addressed. Shawn shared the three-step approach to ethics in HTA currently being developed by a working group at OHTAC: (1) identify the social values that should be used to inform questions relevant to all stages of the assessment process, and to weigh and balance the implications of the use/ non-use of the technology; (2) pose evaluative questions that can be used to identify ethical issues in all stages of the assessment process, or in the use/non-use of the technology; and (3) develop processes that identify opportunities to integrate other perspectives and new information/ evidence into the HTA process. Shawn posed the question of whether a checklist is a set of principle-based questions (which may leave values implicit and not be amenable to change) or a methodology that guides questioning (and which is mutable and tied explicitly to the social values at play in a particular assessment).

Issues Raised in Discussion
- Point of departure for the discussion was the distinction made between frameworks and checklists.
- Current approach at OHTAC is to view frameworks as tailored to particular processes and to gather information on relevant social values from research. The framework is meant to be mutable, so there is a concern that a checklist may not have the flexibility of a framework.
- HTA producers and users (including those from OHTAC) have made clear their desire to have a tool to determine whether ethics is required or of added value for a particular assessment.
- Concern about leaving the decision about the appropriateness of an ethics analysis up to the HTA producer. Since philosophy by its very nature is a critical enterprise, analysts need to be sensitive to the perception on the part of non-ethicists that ethics is "dragging down" the process. Though ethics in HTA ought to avoid the bureaucratic element that has pervaded research ethics; research ethics might provide exactly what decision makers and ethicists are looking for, namely, an assessment that concludes "yeah, this is good enough" or "this is ethically acceptable."
- Participants observed that checklists have been useful in other areas of HTA, so why do we think we are different? Checklists in other areas have had their limitations and benefits.
- Noted that while science can give us some certainty, moral philosophers and ethicists see decision making in a context of uncertainty. The philosopher/ethicist is in a special position to remind us that there is a level of uncertainty in the decisions being made.

Day 1, Item 4: Ethics checklists currently in use in HTA: how were they developed, what are the components of these checklists, and what has been the experience of those who use them?

Presentation Summary
Sigrid Droste from IQWiG gave a presentation on the development of the "Ethics Check" process that she has helped to institute at the agency. The Ethics Check process is conducted in 2 stages. The first part of the process uses a set of criteria to assess the elevated potential for ethical issues to arise with respect to a particular technology. There are 6 main steps in the process: (1) research the question of interest (previously published in a plan), (2) apply ethics criteria, (3) identify ethical issues (if one or more criteria met), (4) literature search, (5) report on ethical issues, and (6) share report with Project group (it is up to the project group to decide what to do with the report.)

The ability for the process to identify relevant ethical issues and to determine whether detailed ethics assessment is required is being evaluated. Resource use for the process has also been tracked for the 3 reports: time to complete the ethics process has ranged from 27 to 65 hours.

There had been a plan to hear and discuss Iñaki Gutiérrez-Ibarluzea's presentation on the ethics process developed by and used at OSTEBA. At this point, the group elected not to view the presentation to ensure that the subsequent topics could be covered in sufficient detail within the day's schedule.

Issues Raised in Discussion
- Sigrid acknowledged that the selection of the 10 questions from Hofmann's list was a subjective choice and vulnerable to influence from stakeholders, political interests, etc.
- At this point there are currently no resources to commission empirical or conceptual research in ethics to fill in gaps within the ethics literature. A lack of literature addressing a particular question may be an opportunity to commission a particular piece of work from an ethicist to write on a particular point.
- The question was raised about whether any technology that made it through a prioritization process for HTA would always qualify for an ethics analysis.
- Some participants wondered whether the Ethics Check is a needs assessment or if the Ethics Check is being used as the ethics analysis, not just the assessment of need for the ethics analysis.

Day 1, Item 5: What components ought to be included in a standard or basic checklist? Introduced by Anna Stoklosa (University of Sydney)

Presentation Summary
Anna Stoklosa introduced the topic of what components ought to be included in a standard or basic checklist by noting that social/ethical issues do not arise equally across all technologies. Hence, there is a question about how to differentiate when they are required or not. The best approach appears to be a middle ground between claiming that all HTAs require ethics analysis and none require it. The middle approach might look for aspects of the technology that ought to "trigger" an ethics analysis. However, if the middle approach is adopted, there is a question whether it is the step prior to check list or the checklist itself that drives the issues to the forefront and triggers the need for an ethics analysis. Potential triggers might be:
- particular features of the technology (such as its invasiveness)
- extraordinariness or degree of innovation presented by the technology
- co-dependent health technology (e.g. diagnostic + therapy)
- stage of development, e.g. experimental
- newly established
- anticipated consequences of the technology
Is the HTA context also relevant, and by extension, the context of where the HTA is functioning, for example, public system vs. public/private?

<u>Issues Raised in Discussion</u>

- Participants raised the question whether the case study is a good method of looking at decisions in HTA (moving from questions at the case level and applying them at the policy level). With any technology there are always ethical issues, but for policy analysts/makers, it is important to keep the policy decision clearly in mind when asking ethics questions.
- Not every ethical issue related to a technology is relevant to the policy question being considered. The ethical issues should be linked to the original policy question so that the relevance of the issues is clear.
- Question of relevance to policy is based on the assumption that individual-level issues are not relevant at the population-level at which decisions are made. Though this assumption is highly contentious, the advent of personalized medicine means that the population approach may become less relevant—we are moving to looking at sub-population-based decisions.
- In one jurisdiction (BC), three broad questions relevant to policy might be asked, each of which requires different responses:
  (1) What is our allocation of resources?
  (2) What is our recommendation about this particular technology?
  (3) What should our approach be to various communities/sub-populations, e.g. deaf community?
- Importance of the process was highlighted. We need to know who we're consulting, what the purpose of that consultation is, and why information is being gathered, for example, to understand values, to identify options. Need to be clear about what we do with this information and how it informs a final recommendation.
- Issue of language figured prominently. It was observed that if we try to adopt a new term/framework like "values" we could start bridging what is otherwise in silos. Cost effectiveness is about "value-added," but we are also talking about "values at play." The language of values might create a common ground.
- Concern about using the language of a "trigger" for ethics analysis. It might be more accurate to describe this as a "screen." This choice of terminology might facilitate hosting the conversation around the screening questions and allows for someone who knows more about the technology to start thinking in a certain way, and start to raise the questions that may be morally relevant (this is a conversation, not a solo checklist).
- Should a particular perspective be adopted for the checklist? To be useful to a particular group, the checklist ought to reflect their needs.
- Different checklists may also be needed for different parts of the HTA process. C
- Capacity of the checklist user with respect to ethics is a relevant consideration.
- Ethicist should not be seen as the moral conscience of the HTA panel. Criteria that people have to account for in their HTA proposal would make the responsibility more diffuse. If they cannot answer those questions there is more ethics work for them to do.
- Assessment committee may find that the assessment does not sufficiently respond to predetermined criteria and so triggers a more in depth ethics analysis.
- It is unlikely for a technology that doesn't somehow affect people in a way that would motivate an ethics analysis to come before an HTA group. Nevertheless, we may be able to identify technologies that would only have a minor or insignificant ethical impact.
- Overall agreement that a checklist is insufficient: A checklist is only of value only if it is accompanied by rich justification.
- The potential for law to offer a useful perspective on methodology was mentioned as a way to counter the pressure to make ethics work "sound" more like the work of medical science and to counter the skepticism often expressed by non-ethicists. It may be more productive to see ethics in terms of process and burden of proof (as is the view with respect to legal analysis) rather than in terms of medical science.

Day 1, Item 6: What ought to be considered when modifying the standard or basic checklist? Introduced by Bernard Keating (University of Laval)

<u>Presentation Summary</u>
Bernard Keating introduced the topic of modifying the checklist (or set of questions) with a reflection on the need to have a clear goal of the tool being used. We need to be very reflexive about our motivation for altering a tool. In ethics work we work back and forth with our moral intuition and the tool. A good tool must honour our moral intuition. Does the tool reflect the moral theory that we use in the theoretical debate? Main considerations in the checklist are autonomy, risk, justice, dignity, and rigour. When we alter the checklist we ought to ask ourselves whether the change will have a practical impact on our decision. We need the tool to be context sensitive.

<u>Issues Raised in Discussion</u>
- Is it a normative comment that our value-commitments in the checklist reflect our social understandings of what is important? Bernard emphasized that he is careful to distance his personal views from his perspective as an ethicist in thinking through these issues.
- Participants continued to struggle with the purpose of a checklist. While a checklist may give us some direction about what needs to be attended to, it does not tell us the principles that ought to be considered and how these ethical issues ought to be addressed.
- In jurisdictions where an expert advisory group has most of the influence about setting the research agenda for an HTA, there may be a concern about downplaying the importance of ethical issues. A checklist might assist in getting these issues onto the agenda without putting the onus for raising the issues on the ethicist or other research involved in the ethics analysis.

Day 1, Item 7: Should different checklist be used for different health technologies (screening vs. intervention vs. diagnostic technologies, pharmaceuticals vs. non-pharmaceuticals, etc.)? Introduced by Daryl Pullman (Memorial University)

<u>Presentation Summary</u>
Daryl Pullman began his introduction to the issue of the assessment of different technologies with a brief description of the potential for positions in philosophy of technology to enlighten our work in ethics. The work of Albert Borgmann and Jacques Ellul were particularly relevant. Two key concepts from these thinkers, the device paradigm and autonomous technology, respectively, can help make us sensitive to the assumptions behind and the influence of HTA. When we're developing the checklist we're trying to take messy amorphous stuff and firm it up in a checklist for HTA.

<u>Issues Raised in Discussion</u>
- Drawing a parallel with categorizations of mental illness and how revisions of classifications (e.g. DSM) affect people's sense of themselves, the conversation of HTA might profit from explicitly considering what is lost in conducting an HTA.
- It is very important to understand who is at the table when the checklist is being used.
- Need to consider the significance of the question about why are we assessing this technology, and why now. This question; however, may be seen as irrelevant from the policy perspective as this question takes place at the pre-HTA level.
- Need to understand better the reason for a reluctance to provide this information as the reason for assessing the technology is key to understanding some of the dominant values at play within the HTA.
- Observation that perhaps the group is looking for specificity in the checklist that is unnecessary for the work that we want the checklist to do.

Summary of Day 1 discussions and issues raised

Key Issues and recurrent Themes from Day 1:

1. There are many conceptual issues that need to be discussed in order to move forward with a checklist (or list of questions) that might help to determine if an ethics analysis is likely to be helpful, the scope and detail of an ethics analysis, not only about when and where, but issues about processes, vocabulary, and about the focus on process instead of principle.
2. An ethics "checklist" may provide a way for ethicists to begin discussions with HTA colleagues about ethical issues and to reduce the tendency for the ethicist to be viewed as the "moral conscience" of an HTA panel.
3. Though "checklists" may be imperfect, the fact that checklists in other aspects of HTA have been developed and refined while in use in other aspects of HTA could be a model for ethics.
4. Prioritization criteria for HTA currently in use may select those technologies that ought to have an ethics analysis already, obviating the need for a "needs assessment checklist" because every HTA would, by virtue of making through the prioritization process, require an ethics analysis
5. The perspective of the ethics checklist is important and ought to reflect the needs of the person/group using it.
6. It is unclear how specific a "checklist" ought to be in order for it to appropriately assess the "need for" an ethics analysis.

IHE Workshop Day 2: October 19, 2013

Aim of Workshop Day 2

This session aims to address general issues in the critical appraisal of ethics analysis such as how to assess the reasonableness of premises, relevance of premises to conclusion, and the extent to which the premises provide good grounds for the conclusion in ethics arguments.

Objectives for Workshop Day 2

Part 1. Workshop attendees will learn about and discuss the use of quality assessment of the ethics literature, focusing in particular on *normative* ethics literature, and potential tools for quality assessment. A checklist and scoring system drafted by Anna Stoklosa (University of Sydney, Australia) and Ken Bond (Institute of Health Economics, Edmonton, Canada) will form the basis for this part of the session.

Part 2. Develop a checklist, with a strong logical justification, that might be used by HTA agencies either as-is or as the basis for the development of their own checklist, and provide guidance with respect to how agencies ought to modify or develop such checklists. The developed checklist will be reviewed by decision makers (e.g. of some INAHTA member agencies) prior to the development of a manuscript.

Schedule for Workshop Day 2

Saturday, October 19, 2013: Workshop Day 2: Tools for assessing the quality of ethics analyses in HTA		
Time	**Topic**	**Method / Speakers**
8:30-9:30	What are the goals of using a quality assessment tool for ethical literature or analysis in HTA?	Introduction: **Katherine Duthie** Group discussion and consensus building
9:30-10:30	What items ought to be included in a checklist for assessing the ethics literature? Critical examination of the proposed checklist	Introduction: **Glenn Griener** Group discussion and consensus building
10:30-11:00	Tea/Coffee Break	
11:00-12:30	What approaches are used to synthesize the ethics literature? Critical examination of the "systematic review of reasons" approach.	Introduction: **Ken Bond** Group discussion and consensus building
1:00-2:00	Lunch	
2:00-3:00	Should the same quality assessment tool be used in descriptive and prescriptive approaches to synthesizing ethics literature? For example, should there be a separate section to assess empirical research that informs the ethical deliberation using tools from quantitative and qualitative methods?	Introduction: **Lisa Schwartz** Group discussion and consensus building
3:00-3:30	Tea/Coffee Break	
3:30-4:30	Next Steps	Introduction: **Ken Bond** Group discussion and consensus building
	Closing	

Discussions on Day 2:

Day 2, Item 1: What are the goals of using a quality assessment tool for ethical literature or analysis in HTA? Introduced by Katherine Duthie (Fraser Health Authority)

Presentation Summary

Katherine Duthie began her introduction to the session on goals with a reflection on the previous day's discussion. She noted that, at times, the content of a checklist envisioned by participants varied and remained underexplained. There was also an issue over the correct terminology and whether "checklist" captured the kind of work that needed to happen. In turning to thinking about quality assessment of ethics analysis, Katherine observed that there are at least three levels of focus for our assessments: assessing ethical arguments, assessing the ethical literature (see McCullough' paper), and assessing an ethics analysis that has been prepared for an HTA process. Underlying each of these are larger questions about what it is that we're doing when we do ethics analysis, what we ought to be doing, and how we know when ethics work is good. As commonly understood in research, "rigour" says something about the means by which we produce trustworthy findings. Quantitative and qualitative research use different indicators of rigour. Qualitative research examines internal and external validity. Qualitative research will look for transparency, credibility, reliability or dependability, comparativeness, and reflexivity. Understanding rigour in ethics work enables us to do and recognize good work and to explain the value and robustness of our work to others. Katherine posed the following questions to the participants:

1. What are (or ought to be thought of as) our core methods in ethics?
2. What constitutes rigorous ethics analysis?
3. Are there similar constituents for rigour in process, as well as for the doing and description of analysis?
4. What about rigour in empirical work in ethics (simply a matter of study design)? Relatedly, what are the indicators that a piece of ethics work is rigorous?
5. How can our understanding of ethics rigour serve us within the broader HTA project?

Issues Raised in Discussion

- From policy-maker perspective, answering questions about rigour are paramount because rigorous work ensures that results can be trusted and allows the level of uncertainty to be gauged.
- Question was raised about who will use a quality checklist and for whom the answers to checklist questions are intended.
- A checklist that determines whether an analysis meets a "threshold" of good or bad doesn't seem to make sense for ethics work because we need to understand what is important and then design the response to maximally align the results with these values.
- Concern about linear vs. lateral process. A checklist ought to be able to capture the fact that an ethics conversation needs room for debate and negotiation.
- Checklist proposed by Ken Bond and Katherine Duthie focuses on form, on domains to structure discussion, rather than on substance. Need also to evaluate how ethically meaningful the arguments are. A participant noted that we seem to be in need of two tools: an ethics literature review tool and guidance or handbook for the ethicist engaged in HTA.
- In terms of quality assessment, several issues with respect to synthesizing ethical issues were identified:
  - It was unclear what ought to be done if multiple papers addressing the same ethics question use different frameworks for assessment of the issues.
  - A role for ethics more broadly may be in explaining some of the weakness of empirical findings because of generalizability can be related to matters of ethics.
  - Though decision makers may be very interested to know what the majority opinion is with respect to an issue, ethicists recognize that majority opinion is not an acceptable reason for adopting an ethical position.
- Including multiple perspectives important to reducing the potential for bias or prejudice.
- Ethicists need to be aware of the history of a technology and be able to situate themselves within the context of existing arguments and build from there.

- Ethicists engaged in a particular HTA should be familiar with the debates already. We see ethics articles where people without this expertise write using a narrow view of ethics and produce work that is not valuable.
- Conceptual analysis is another important skill that ethicists have, but it can be disvalued because there is a sense that the process is getting bogged down in the conceptual analysis.
- Importance of adequately describing and understanding context was highlighted.
- Difference between literature synthesis as conceived in evidence-based medicine and as it is conceived in ethics was noted. Ethicists go for a slower pace, one that involves dwelling on the literature. They do not simply describe the literature; they are committed to thinking very hard through the issues.
- Motivations for scientific comprehensive systematic review were contrasted with the need to synthesize issues in ethics. With time there is progress of a certain kind in science; hence, capturing recent scientific literature is important. Nevertheless, the same kind of progress does not hold true in ethics.
- May be more constructive to think of ethics in HTA as more akin to systems-level consultation in that the upfront work matters a great deal and that there are process criteria for rigour.

Day 2, Item 2: What items ought to be included in a checklist for assessing the ethics literature? Introduced by Glenn Griener (University of Alberta)

Presentation Summary

Glenn Griener introduced the topic of what items ought to be included in a checklist for the ethics literature with a distinction between the various kinds of research that might be considered. Papers in empirical ethics can be considered empirical papers and evaluated using the criteria that has been developed to assess that form of research. Normative ethics papers present arguments (in the sense meant in informal logic) and there is little reason to further develop checklists for the assessment of arguments. We have neutral ways of assessing the logic of a paper. The paper authored by Ken Bond and Katherine Duthie also suggests we consider thoroughness, but there is a question about what "thoroughness" means. There are two ways to ensure thoroughness: by means of a checklist and "ticking off" items to ensure they are covered, e.g. the "four principles," or by means of a systematic review of the literature. A systematic review will give the HTA community the assurance they are seeking in terms of comprehensiveness.

Issues Raised in Discussion
- Similarity noted between synthesizing the ethics literature and thematic analysis in qualitative research.
- Might learn from other approaches/disciplines to improve thoroughness.
- Methods in ethics should not be seen as mystical---they are simply more refined and rigorous methods for argumentation. We can explain how we get from our premises to our conclusions in the way that researchers in other disciplines do.
- Though comprehensiveness is important, a comprehensive review of the literature does not ensure comprehensiveness in argumentation. The literature has blind spots and gaps, but literature review may be a way to identify what may have been missed. There may be times, for example when stakes are high, that we will need to commission a study or analysis to fill in the gap.
- Because ethicists cannot guarantee thoroughness, there is an opportunity for public consultation in the process to help identify relevant issues.

<u>Presentation Summary</u>
Ken Bond provided participants with the article by Daniel Strech and Neema Sofaer that employs the "systematic review of reasons" approach. *Reference:* Sofaer N, Strech D. Reasons Why post-trial access to trial drugs should, or need not be ensured to research participants: A systematic review. Public Health Ethics 2011;4(2):160-84. After reading the article, participants were asked to reflect on 4 questions:

1. What do you think about the authors' systematic review?
2. What are your thoughts on the demandingness of the methods?
3. Do the authors' stated aims and methods align?
4. How does this fit with what we're aiming to do in HTA?

<u>Issues Raised in Discussion</u>
- Because approaches and orientations in moral philosophy are strongly influenced by culture, systematic reviews in ethics may be especially subject to bias if literature is restricted to that published in English.
- Being aware of the context of the HTA is crucial. For example, an HTA conducted in Quebec would likely want to be especially diligent in searching the French-language literature to ensure that the culturally relevant issues are identified.
- Reviewers would need to be sufficiently well trained in identifying reasons. Reviewers with different skill levels in doing this may have selected a different set of literature. Philosophers are well-trained to identify reasons, but it is still difficult and takes time.
- Despite its limitations, e.g. no quality assessment of reasons, which are for the most part acknowledged by the authors, the approach proposed by Strech and Sofaer has the potential to provide a good starting point for ethics analysis. Rather than narrowing the conversation toward a research question (as a systematic review on effectiveness might do), this approach seems to offer a way to broaden the conversation and offers a role for the ethicist in facilitating this broadening. The reasons identified through a systematic review of this nature would serve as some of the "raw data" for an ethics analysis.
- Considering the length of time a review of this nature takes, there is a question of how feasible this might be as a standard or regularly used approach. However, it was noted that the effort may be proportional to the jurisdictional level of the issue.
- The particular issue being addressed was international in scope; lower-level questions may be less demanding. Policy makers may find the results difficult to digest. However, it would ensure that a minister could have some confidence that the background work has been done.
- The review appears to draw a strong divide between empirical and philosophical issues and this raised the question of whether the same quality assessment tool should be used in descriptive and prescriptive approaches to synthesizing ethics literature.
- Quality piece was missing (a fact acknowledged by the authors); however, the authors seemed to have done quality indirectly by noticing and screening out those articles that were not considered to have provided reasons.

Day 2, Item 4: Should the same quality assessment tool be used for descriptive and prescriptive literature? Introduced by Lisa Schwartz (McMaster University)

<u>Presentation Summary</u>
Lisa Schwartz introduced the topic by observing that, although the quick answer to this question is "probably not," there needs to be sufficient understanding about how the two kinds of literature connect. Both types of literature are very relevant to the HTA process: descriptive work helps us understand the implications of the technology; the normative literature helps us sort out how we ought to react toward it given those potential implications. Descriptive ethics is most often empirically produced evidence and, as noted previously, we have the tools to assess this work. However, approaches are not always sufficiently critical; they don't often acknowledge standpoint analysis or answer the question about what qualifies as good evidence in the first place. Tools for normative analysis are less well known outside of philosophy. There are systematic ways of assessing this normative work (literally hundreds, if not thousands, of books on informal logic). The domains described in paper by Ken Bond and Katherine Duthie (available upon request from the report authors) are well-known concepts and techniques described and used in introductory courses in formal and informal logic. Lisa emphasized that, while it is significant to translate arguments into logical notation, the importance of formalizing arguments in this way is not to identify what form the structure of the argument takes, but to identify what is left over. While we may see some value in checklists—and one very useful potential checklist is the traditional structure of logical argument and list of fallacies—we should also be aware that using this set of components to measure the adequacy of the structure of argument could be misleading, if it does not also engage us in thinking about what is left over.

We ought to be explicit about the importance of valid structure and of empirical verifiability to ensure soundness. These two aspects of arguments are relatively straightforward and deceptively simple to turn into checklists. The danger, then, would be in being lured into complacent reliance on a checklist of these sorts (because they look like other tools for HTA), and forget that we also need to be attentive to the substance of what is being argued for and what is implicitly valued therein. Arguments can fulfill all the criteria for validity and not be sound, but, perhaps more pressing for ethics in HTA, they can also fulfill the criteria for soundness and still not be ethical. Since validity and soundness can be more readily measured through accepted and HTA-palatable tools, it is this dimension of ethical argument that may be missed. The moral content of the arguments is not as easily measured and so may be left to languish without consideration because the other, more easily identified and assessed elements are satisfied.

<u>Issues Raised in Discussion</u>
- Don't have to redo the work of talking about standards for normative analysis because that is well done.
- Recent experience of conducting an ethics analysis was described and the difficulties that resulted when two peer reviewers felt the analysis was of poor quality and drew the wrong conclusions. This issue again raised the concern about the potential narrowness of checklists.
- Need to understand the needs of the decision maker (health minister). In a pluralistic society, a minister or government has to understand why a specific group or cultural tradition has a special attachment to a norm.
- Pluralism highlights importance of engaging in public consultation; however, the feasibility of this kind of activity was questioned. Not only is public engagement time consuming and resource intensive, but every time the public is engaged, the goals and intentions of the discussion need to be focused and clearly articulated.
- HTA researchers are typically aiming to answer a research question whereas the ethics analysis is (rightly) more concerned with the policy question about whether the technology is right for the particular context. However, this way of viewing the difference may not be entirely correct as the HTA aims to inform the policy question rather than answer it.

Day 2, Item 5: Next Steps

Presentation Summary

Ken Bond and Anna Stoklosa remarked that they were committed to providing workshop reports and they volunteered to take on the administrative roles developing and circulating these reports. Everyone would be listed as a workshop participant, and would be eligible authors.

Issues Raised in Discussion
- Value and possibility of establishing an ethics working group was explored. There is a model for the ethics working group that informs Health Technology International (HTAi) and the question was raised whether participants were interested in forming a Canadian working group.
- Establishing a working group would require a clear sense of the goals.
- A working group might be a valuable way of sharing information. People involved in the work generally do so in isolation, so a working group would provide an opportunity to engage with others in a similar situation. It would also allow an opportunity for people who are not already hooked in to the current conversations of ethics and HTA to become engaged (networking).
- A working group would provide a pool of people who could engage in educational work in Canada around ethics in HTA. There was agreement that funders may be supportive of this direction, too.
- Other opportunities to promote the work of ethics in HTA may be with WHO and in an educational program being developed for the international HTA community.
- Day's conversations show clearly that ethics has a role to play in HTA and this role is underdeveloped. Ethics involvement needs to be formalized sooner rather than later.
- An article could be written to call upon all Canadian health care systems to bring in ethics in HTA. Don Juzwishin indicated that he would be happy to forward this message to the Canadian College of Health Leaders (CCHL).

Summary of Day 2 discussions and issues raised

Key Issues and recurrent Themes from Day 2:

1. Ethicists need to clearly articulate what it means to do rigorous work in ethics in a way that can be understood by non-ethicists.
2. Though a systematic review of the literature can be a helpful way to gather information on potential ethical issues, it seems that a systematic review in ethics does not serve the same function as does one of the scientific evidence.
3. Because of the importance of cultural context in ethics, systematic reviews for ethics need to pay especially close attention to the potential for bias, e.g. in emphasizing issues of autonomy over those of solidarity.
4. A systematic review of reasons may provide useful "primary data" for an ethics analysis, but there are questions about the feasibility of this approach (in terms of time and expertise) and its utility for non-ethicists.
5. Any checklist of the quality of ethics analysis must be able to assess not only the soundness of ethical argumentation, but also the ethical relevance and force of the argument, morally speaking.
6. A systematic review of reasons may help an ethicist to broaden the conversation within and about an HTA.
7. The quality of descriptive/empirical ethics research can be evaluated using tools that have already been developed to assess this form of research.
8. The quality of normative ethics work can be assessed using existing philosophical tools, but these are not well known or understood outside of philosophy (see point 1 above).

Acknowledgements

Appendix 1 to IHE workshop: Steps in an HTA Process

1. Identification of technology or health care problem
2. Prioritization of possible assessments
3. Assessment
4. Appraisal and decision
5. Dissemination of findings and conclusions
6. Implementation of findings and conclusions
7. Impact assessment

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), Cologne, Germany: October 25-26, 2013

IQWiG Workshop Day 1: October 25, 2013

Aim of Workshop Day 1

The goal of this session is to compare the existing approaches that have been developed to help HTA producers and decision makers determine if an ethics analysis might assist with decision making regarding a candidate technology. Checklists are currently being used by several HTA agencies, and researchers from these agencies will present the checklists and discuss their experiences with them.

Objectives for Workshop Day 1

Part 1: Describe the debates regarding the appropriateness of these checklists, describe the checklists currently in use by HTA agencies, and discusses their potential benefits and drawbacks.

Part 2: Develop a checklist, with a strong ethical foundation, that might be used by HTA agencies either as-is or as the basis for the development of their own checklist, and provides guidance with respect to how agencies ought to develop or modify such checklists.

Schedule for Workshop Day 1

Friday, October 25, 2013: Workshop Day 1: Assessing the need for an ethics analysis in HTA		
Time	**Topic**	**Method / Speakers**
8:30-9:00	Welcome and Introductions	**Sigrid Droste, Ken Bond, Anna Stoklosa**
9:00-10:00	What goals does the use of an ethics checklist aim at?	Introduction: **Emelie Heintz**
10:00-11:00	Under what conditions might the use of an ethics checklist in HTA be appropriate or inappropriate?	Introduction: **Clémence Thébaut**
11:00-11:30	Tea/Coffee Break	
11:30-12:30	Ethics checklists currently in use in HTA: how were they developed, what are the components of these checklists, and what has been the experience of those who use them?	Presentation: **Iñaki Gutiérrez-Ibarluzea** Presentation: **Sigrid Droste** Presentation: **Lars Sandman/Emelie Heintz**
12:30-1:30	What components ought to be included in a standard or basic checklist?	Introduction: **Björn Hofmann**
1:30-2:00	Lunch	
2:00-3:30	Tour of Cologne Cathedral	
3:30-4:30	Should different checklist be used for different health technologies (screening vs. intervention vs. diagnostic technologies, pharmaceuticals vs. non-pharmaceuticals, etc.)?	Introduction: **Lars Sandman**
4:30-5:00	Summary of day's discussion	
7:00-9:00	Workshop dinner	

Organizers

Sigrid Droste, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, GERMANY

Ken Bond, Institute of Health Economics, Edmonton, CANADA

Anna Stoklosa, NHMRC Clinical Trials Centre, The University of Sydney, AUSTRALIA

Recorder

Anna Stoklosa, NHMRC Clinical Trials Centre, The University of Sydney, AUSTRALIA

Participants

Kristin Bakke Lysdahl, University of Oslo, NORWAY

Eva-Maria Bitzer, University of Education, Freiburg, GERMANY

Annette Braunack-Mayer, University of Adelaide, AUSTRALIA

Hans-Peter Dauben, Institute of Medical Documentation and Information (DIMDI), Cologne, GERMANY

Elisabeth Giesenhagen, Institute of Medical Documentation and Information (DIMDI), Cologne, GERMANY

Iñaki Gutiérrez-Ibarluzea, Basque Office for HTA (OSTEBA), Basque Country, SPAIN

Emelie Heintz, Swedish Council on HTA (SBU), Stockholm, SWEDEN

Björn Hofmann, University College of Gjøvik and University of Oslo, NORWAY

Dagmar Luehmann, University Medical Center Hamburg-Eppendorf, GERMANY

Mirella Marlow, NICE, London, UK

Alric Rüther, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, GERMANY

Dario Sacchini, Institute of Bioethics, A. Gemelli Catholic University, Rome, ITALY

Lars Sandman, University of Borås and Linköping University, SWEDEN

Clémence Thébaut, Haute Autorité de Santé (HAS), Paris, FRANCE

Gert Jan van der Wilt, Radboud University/Nijmegen Medical Centre, THE NETHERLANDS

Discussions on Day 1:

Day 1, Item 1: Welcome and Introductions
The workshop began with participants introducing themselves, describing their connection with ethics and HTA, and providing an indication of to what extent ethics is incorporated in HTA in their jurisdiction.

Day 1, Item 2: At what goals does the use of an ethics checklist aim? Introduced by Emelie Heintz (SBU)

Presentation Summary

Emelie Heintz provided reflections on the experience of SBU on its work in addressing ethical aspects of health technology assessment (HTA). She reported that SBU does not have the resources to hire an ethicist for every project; hence, ethicists are not always involved in SBU's HTAs. When ethicists were not involved, the following issues have arisen: project managers did not know what method to use for the ethics analysis, a variety of approaches to the analysis was chosen, and there were concerns about the lack of project managers' experience in this area. Conversely, in those instances when ethicists were involved, the following issues have arisen: the content and structure of the ethics analysis was contingent on who the ethicist was; the analysis was not always relevant; the analysis produced was too reminiscent of a chapter in an ethics textbook, which limited its usefulness for HTA purposes. It was suggested that, for these reasons, an ethics checklist could provide a more structured approach both for the projects in which ethicists are involved and for those for which no ethicist is involved, ensure that no important elements of an ethics analysis are left out, make the ethical chapters more relevant, and build up in-house ethical competence.

Issues Raised in Discussion[2]

Further goals for ethics checklists identified in the discussion:
- To inform those conducting the HTA and the decision-makers about ethical issues
- To assist agencies with resource allocation (a decision whether to bring an ethicist into the process, or whether this is not required)
- To provide a structured approach, which increases readability of the subsequent analysis
- Checklists are used to facilitate and systematize the analysis in other areas of HTA (e.g. quality assessment)—the same goal applies in context of ethics checklists
- To make the HTAs more robust and potentially preclude subsequent legal challenges to the policy decisions made on the basis of the HTA
- To serve a communicative function—an initiation and structuring of the dialogue between the various participants in the HTA process (clinicians, epidemiologists, ethicists, patients, carers, etc.). This may increase the ethical issues identified as salient to the particular technology
- To divest the ethicist of responsibility (in case of conflict, the disagreement regarding the quality of ethics analysis is between the users and the checklist, not between the users themselves)

Other issues raised:
- There are various ethics checklists (a trigger checklist assessing the need for an ethics analysis, a checklist for conducting the ethics analysis itself). The goals of such checklists will differ.
- The "checklist" vernacular suggests a "ticking boxes" exercise; another term is needed here. [This point is well taken; however, "checklist" is retained throughout the report for ease of reporting and consistency.]
- Is it worth having a checklist if an ethicist is not participating in an HTA?
- At what stage should an ethics analysis be initiated? Prioritisation? assessment? appraisal? other?
- Some reservations about the usefulness of checklists in an ethics context were expressed, but a pragmatic consideration is that they allow us to introduce ethics issues in a structured way.

---

[2] Points are amalgamated from both the small and large group discussions.

- A checklist should be structured as a set of open-ended questions rather than yes/no answers, because this forces the person using the checklist to reflect on their answers.
- An HTA assessment is incomplete without a careful identification/assessment of personal and social values at stake around the technology—hence, the question is not whether an ethics assessment is necessary, but of identifying how thorough/in-depth that assessment should be.
- An ethics checklist does not prescribe a particular decision; it identifies salient ethical issues.
- An ethics checklist should be context-specific, i.e. targeted to the ethics environment of the particular jurisdiction.

Day 1, Item 3: Under what conditions might the use of an ethics checklist in HTA be appropriate or inappropriate? Introduced by Clémence Thébaut (HAS)

Presentation Summary

Clémence Thébaut provided reflections on when using an ethics checklist might be appropriate or inappropriate in HTA, based on HAS's experience in producing (April 2013) a methodological guideline which includes a checklist for identifying HTAs likely to raise ethical issues, and a method for producing ethics analyses ("L'évaluation des aspects éthiques à la HAS"[3]). HAS includes ethical analyses in its full HTA reports (completed in 12 months); however, there is a question of whether ethics analyses are required for its rapid assessment reports and efficiency appraisals (completed in 90 days).

HAS evaluates the need for an ethics analysis at the project scoping stage. The need for an ethics analysis is identified when one or more of the following criteria obtains: health technology has specific features (e.g. it's regulated by bioethical laws – e.g. stem cells, equality issues); a conflict exists between the technology and fundamental human rights (e.g. human dignity, integrity), or controversies exist around the technology (e.g. in the media). The ethics analysis consists of identification of ethical arguments through literature review and discussion among stakeholders, presenting the ethical arguments in the report (typically although not always based on Beauchamp and Childress' framework), and the identification of the main ethical disagreements.

Issues Raised in Discussion

Further goals for ethics checklists identified in the discussion:
- Are ethical analyses needed in an efficiency appraisal (90 days) or similar short timeframe assessments that are utilized by other HTA agencies?
- By law, in France, reimbursement request must be resubmitted every 5 years (as an "efficiency appraisal" which is to be carried out in the 90 day timeframe). Given these time constraints, a checklist in these instances might be a practical tool to highlight the salient ethical issues. This issue is also salient for other jurisdictions which utilize assessments other than full HTAs and short time-frames for assessment (e.g. Spanish "therapeutic analyses" or Australian "submission-based assessments")
- It was argued that a checklist for identifying the need for an ethics assessment should always be used; whether a full ethics analysis should be used (relying on a checklist or another methodology) is contingent on the result of that checklist.
- The number and nature of categories to be included in the "needs for an ethics assessment checklist" is an open question – HAS uses 3 criteria (as discussed below, IQWiG uses 4 categories of criteria).
- Further evolution of HAS's methodological guideline for ethics analysis is planned, and will take into consideration issues identified both in the French context, and internationally.
- Development of further guidelines and checklists is also planned by HAS (on gender issues, social inequalities issues).
- Different fields involved in health technology assessment (public health, economics, ethics) adopt different methods to highlight the same issue (e.g. the impact of a health technology on social inequality), and have different epistemic commitments (what is knowable, and through what methods).

---

[3] Available at: http://www.has-sante.fr/portail/jcms/c_1525743/en/levaluation-desaspects-ethiques-a-la-haute-autorite-de-sante

Day 1, Item 4: Ethics checklists currently in use in HTA: how were they developed, what are the components of these checklists, and what has been the experience of those who use them? Introduced by Iñaki Gutiérrez-Ibarluzea, OSTEBA; Sigrid Droste, IQWiG; Lars Sandman and Emelie Heintz, SBU

Presentation Summary: Iñaki Gutiérrez-Ibarluzea (OSTEBA)
OSTEBA developed its checklist on the basis of EUnetHTA's "HTA Core Model" and UETS's "Lain Entralgo report on needs for ethics analysis." The checklist is intended to help to decide whether a formal ethics analysis is needed, and to identify the dimensions that need to be considered in cases where an ethics analysis is required. The checklist consists of 32 questions, falling into the following categories:

- Questions about the technology itself and its characteristics (questions about diagnostics, questions about preventives and therapeutics)
- Questions about general ethical issues (including: Autonomy, Human Dignity, Human integrity, Beneficence/non-maleficence, Justice and Equity, Rights, Legislation)
- Questions about the HTA process itself
- Question about the life-cycle stage that the technology is at

Staff interviews have found that the checklist makes the process easier, enables staff to raise ethical questions and include them in all HTA reports, is considered by staff a mark of quality, and lengthens the HTA process. Internal testing revealed a high degree of agreement and concordance among staff using the checklist. The main barriers to use included the lack of ethics knowledge and increased workload. A formal evaluation of the checklist's impact is planned for 2014.

Presentation Summary: Sigrid Droste (IQWiG)
Since May 2012, 5 reports have been (or are currently being) piloted applying IQWiG's "ethics check." The objectives of the procedure are to assess the potential for ethical issues to arise around the technology being assessed (this justifies subsequently preparing/not preparing a systematic review of ethical issues), and to review the ethical issues around the technology being assessed by reflection and literature analysis.

The "ethics check" utilizes 4 criteria to identify an elevated potential for ethical issues to arise:

A. Conditions which don't allow an autonomous decision-making or an appropriate judgment of the implications of an intervention
B. Screening / Diagnostics in diseases/health disorders which are not treatable or (may) cause consecutive interventions with significant risks
C. Screening tests, which don't fulfil the criteria of the UK National Screening Committee on introducing a population screening program.
D. Interventions in several specific areas (including: palliative care, prenatal interventions, transplants, etc.)

The approach is currently being piloted on 5 reports. Preliminary experience is that the method works and is acceptable to the project coordinators; the time expenditure is also regarded as acceptable. The checklist is planned to be modified – a 5th category will be added: "10 or more questions from Bjorn Hofmann's list of 33 questions are fulfilled." It is perceived that the criteria list and a list of Hofmann's 33 questions should be completed for every HTA report.

<u>Presentation Summary: Lars Sandman and Emelie Heintz (SBU)</u>
Unlike OSTEBA and IQWiG, which are already using and evaluating their checklist, the SBU checklist is still in development. The checklist is intended to be used by project managers, as a departure point for discussion on ethical issues. Using the checklist, the project group identify ethical issues that are relevant to the project; if ethical issues are deemed to be complex, an ethicist is involved in the ethics analysis. The SBU checklist comprises 5 categories: aim of care, ethical side-constraints, structural factors with implications for the implementation of the intervention, long-term consequences, and summary of evaluation. Each category includes between 1-6 further sub-questions which aim to adapt the questions to the legal context of Swedish health-care.

In June 2013, the checklist was reviewed for content validity by 7 ethicists; in November 2013, a revised version will be sent to government agencies (the National Board of Welfare, The Pharmaceutical Benefits Board, etc.). Testing of interpretability and reliability with focus groups is planned. Preliminary feedback indicates that the checklist's usefulness consists in ensuring that the right questions were asked, and that no important issues were left unaddressed. The feedback from both experts and project managers has generally been positive. A few warnings have been raised as to whether such a checklist would end up in superficial and shallow ethics evaluations. Outstanding issues that remain to be considered, include methodology for answering the questions included in the checklist (e.g. literature search, patient/stakeholder involvement, other?), concern about the potential to over-focus on the checklist questions at the expense of thoroughness of ethics analysis, identifying the kind of competence that is needed in-house, and establishing when an ethicist should be involved.

<u>Issues Raised in Discussion</u>
- Answers to the questions contained in these checklists are contingent on the goals, remit, and organisational structure of the HTA agency
- Checklists may be more necessary in instances where ethical issues are not immediately obvious, in order to identify those issues
- Who are these checklists targeted at – the ethicists or the project managers? It may be both (to ensure thoroughness/completeness)
- "Trigger" checklist could be a means of establishing whether an ethicist's involvement is required
- Question 1 in the SBU checklist appears to force the ethics analysis to be carried out after the completion of the HTA, as it focuses on risks/benefits (which are not known until after the HTA has been completed)---c.f. comments in previous sessions, which suggested completion of the ethics analysis in earlier stages, and discussion of the IQWiG approach, above
- What ought to be done if the need for an ethics analysis is identified, and a literature search is conducted, but no literature exists? Proposals included: documenting the search and its outcomes, extrapolation from literature on related technologies, involvement of an ethicist. Methods for conducting ethics literature searches already exist (e.g. Sigrid Droste's paper)
- A more general worry was raised about the tendency to dichotomise in these discussions between "ethics experts" and "everyone else"--- in reality, this is a continuum, and most people will fall somewhere in between
- Ethics checklists facilitate familiarity with ethical issues on the part of HTA report-writers
- Tools that assist with the structuring of the analysis are considered to be desirable in HTA – e.g. guidelines for how to structure an HTA (e.g. CRD's). This suggests that a tool for structuring an ethics analysis could also be desirable.
- Reiteration of the need to be clear about the kinds of checklist that is under consideration: "trigger"checklist (whether an ethics analysis is necessary), checklist for completing the ethics analysis itself (identifying the elements/domains to consider in the analysis), and a checklist or quality assessment tool for evaluating an ethics analysis conducted as part of an HTA
- There is a need for establishing a clear guidance or set of criteria for when an ethicist ought to be involved in the ethics analysis

Day 1, Item 5: What components ought to be included in a standard or basic checklist? Introduced by Björn Hofmann (University of Oslo)

<u>Presentation Summary</u>

When considering what components ought to be included, it is important to keep in mind that "components" can mean many things, e.g. questions, tasks, guideline items, checkpoints, issues to discuss or address. Components can also refer to formal aspects, such as the procedure for applying the checklist, the procedure for procuring relevant information to assess the ethical issues around the health technology in question, the procedure for synthesizing the ethics information identified in the procurement process, and the procedure for drawing conclusions from the synthesized information.

Björn concentrated on "components of a checklist" in terms of the content of the checklist and argued that the following issues ought to be included among basic components:
- Goal definition/selection
- Endpoint definition/selection
- Disease / condition
- Technology
- Ethical aspects
- Religious and cultural aspects
- Legal aspects
- Framework
- Stakeholders' interests
- HTA process and values/goals (NB: this is contestable)

In addition to the issue of which components to include, an issue to consider is how those components are framed by the various stakeholders involved in HTA: patients, health professionals, industry, health policy makers, etc. It was suggested that stakeholders ought to have an input into the elements (issues) of each of the components of the checklist.

<u>Issues Raised in Discussion</u>
- How (if at all) should the components above be grouped to facilitate navigating them?
- What logical sequence should these elements be organized into to provide the best guidance for structuring the analysis?
- Who the relevant stakeholders are needs to be clearly explicated and their interests need to be clearly described (descriptive dimension). The prescriptive dimension arises around decisions regarding what to make of these and how to take them into consideration.
- Some categories described above are more relevant at the scoping or prioritisation stages, than at other stages; perhaps different checklists are required for use at different stages.
- To what extent (if any) should macro-economic considerations be taken into account (e.g. evaluation of a technology produced in that jurisdiction, employing large numbers of people)?
- Should environmental/sustainability issues be considered as part of an ethics analysis?
- Preferability of the deductive approach (starting with components) to the inductive approach (starting with the issues/questions)?
- In some jurisdictions, safety of a health technology is assessed as a condition for market entry. However, it was noted that this sort of safety assessment may be too general – issues around safety/willingness to accept risks may depend on disease stage, disease type, etc.
- Some ethical questions are (almost?) strictly ethical, whilst others overlap other domains (social, legal, cultural, etc.) How best to handle this issue, so as to minimise the duplication of work in the HTA process? How to address the fact that frequently, these domains are poorly discussed or altogether absent?
- The greater context (of how an HTA agency operates, what its priorities are, how it was established – whether at political initiative or academic – etc.) will influence the policy goals, and hence, what is contained in these checklists. Various 'contexts' can be differentiated (HTA agency structure/remit, health system structure/setup, greater political context, etc.)

- Such checklist may have the benefit of preventing controversy from arising (e.g. Gardasil case)

Day 1, Item 6: Should different checklist be used for different health technologies (screening vs. intervention vs. diagnostic technologies, pharmaceuticals vs. non-pharmaceuticals, etc.)? Introduced by Lars Sandman (University of Borås)

Presentation Summary
Lars argued that a skilled user may be able to adapt the checklist to the particular situation, but a less skilled user may require a pre-adapted list (or assistance in adapting the list); pre-adapted lists (with examples) are likely to be easier to use for clinicians and others. If adapted checklists are being produced, checklists may require adaptation for: different technologies, different stages in the HTA process, and different evidentiary situations.

Whether checklists require adaptation to different technology types (screening vs. intervention, for example) depends on the checklists themselves. More detailed checklists may require adaptation, whilst more general ones may require no or minimal adaptation. If checklists are being adapted to stages in the HTA process, a checklist adapted to the prioritisation stage of an HTA should be fairly condensed. Checklists assessing for potential investment (assessing interventions for potential use) and for potential disinvestment or rationing may require different elements or different ways of posing questions. Finally, checklists may also need adapting for different evidentiary situations – cases where evidence is adequate, and cases of knowledge gaps (more or less extensive) regarding the technology.

Issues Raised in Discussion
- It was re-emphasised that who the checklist is aimed at will impact on the structure and level of detail of the checklist
- Checklist needs to be targeted both to the stage of assessment (prioritisation, assessment, etc.), and to jurisdictional/HTA agency-context
- What is the best method for modifying checklists – e.g. in collaboration with the team using the checklists?
- Evidentiary gaps may be empirical or theoretical. They may arise due to gaps in the clinical evidence, and large costs and/or ethical issues around filling those gaps.
- How should we deal with evidentiary gap situations that may never be filled, for whatever reason?
- Should evidentiary gap situations that may never be filled be disclosed to patients?
- Three main advantages of using these kinds of checklists are: for an ethicist, to structure their own analysis; for an HTA agency, to raise awareness about ethical issues; and to convey thoroughness of an HTA to the agency/decision-maker requesting the HTA.
- The checklist enables an HTA agency to show an ethicist being brought into the HTA process: what is expected (content) and how it's expected to be done (method). This will aid in ensuring consistency in the process (HTA to HTA).
- What is the appropriate approach to answering the questions/items on the checklist? Literature, textbooks, background knowledge/training, patient input, etc.? This will impact resources required to obtain the answer, as well as the quality of the answer.
- Checklists serve to make the ethical issues (and dealing with them) more transparent.

Summary of Day 1 discussions and issues raised

Key issues and recurrent themes discussed on day 1 of the workshop:

1. Some ethics checklists/tools already exist, and seem to work well (although they are still being assessed)

2. Context (of the remit and goals of the HTA agency, as well as the organisation of the health system, greater political context, etc.) will shape the content of the checklist. Context-sensitivity requires that jurisdictions adapt checklists/tools to their own needs, although some elements may be common across jurisdictions and thus not require changing.

3. A guidance document, describing the contextual issues that structure the lists produced (e.g. legislative requirement that chronological age not be taken into consideration as is the case in Sweden), would facilitate adaptation of the tools and checklists between jurisdictions.

4. There is a need for clarity on which checklist is being discussed (the "trigger" checklist assessing the need for an ethics assessment, the checklist assessing the ethical issues around a particular technology, the quality assessment checklist for evaluating extant ethical analyses in HTA). These checklists have different goals, and will contain different elements.

5. Checklist needs to be specific to the need of the user of the checklist (ethicist, systematic reviewer, project manager, decision-maker, etc.). Different structure and level of detail may be required by each of those users.

6. Checklist needs to be adapted to the stage at which it is being used (prioritisation, assessment, appraisal); different checklists may be required at the different stages.

7. Checklists themselves will need to be evaluated for appropriateness to purpose, enablers of use, barriers to use, unnecessary elements, missing elements, etc.

8. Some of the main goals of the various checklists, include: communicating potential ethical issues to users, means of identification of relevant ethical issues, providing a structured approach to analysis, establishing whether an involvement of an ethicist in the HTA is required, convey to the ethicist what is expected (content-wise) and how it is supposed to be presented (method).

9. The "checklist" label may not be ideal, as it connotes a "box-ticking" exercise.

10. Should the checklist be structured in a yes/no format, or open-ended question format?

11. The structure of the checklist should be logical and easy to follow; questions should be grouped appropriately.

IQWiG Workshop Day 2: October 26, 2013

Workshop Day 2: Tools for assessing the quality of ethics analyses in HTA

Aim of Workshop Day 2

This session aims to address general issues in the critical appraisal of ethics analysis such as how to assess the reasonableness of premises, relevance of premises to conclusion, and the extent to which the premises provide good grounds for the conclusion in ethics arguments.

Objectives for Workshop Day 2

Part 1. Workshop attendees will learn about and discuss the use of quality assessment of the ethics literature, focusing in particular on the *normative* ethics literature, and potential tools for quality assessment. A checklist and scoring system drafted by Anna Stoklosa (University of Sydney, Australia) and Ken Bond (Institute of Health Economics, Edmonton, Canada) formed the basis for this part of the session.

Part 2. Develop a checklist, with a strong logical justification, that might be used by HTA agencies either as-is or as the basis for the development of their own checklist, and provide guidance with respect to how agencies ought to modify or develop such checklists. The developed checklist will be reviewed by decision makers (e.g. of some INAHTA member agencies) prior to the development of a manuscript.

Schedule for Workshop Day 2

Saturday, October 26, 2013: Workshop Day 2: Tools for assessing the quality of ethics analyses in HTA		
Time	**Topic**	**Method / Speakers**
8:30-9:30	What are the goals of using a quality assessment tool for ethical literature?	Introduction: **Ken Bond**
9:30-10:30	What items ought to be included in a checklist for assessing the ethics literature?	Introduction: **Gert Jan van der Wilt**
10:30-11:00	Tea/Coffee Break	
11:00-12:00	Should the same quality assessment tool to be used in descriptive and prescriptive approaches to synthesising ethics literature?	Introduction: **Annette Braunack-Mayer**
12:00-1:00	Evaluating the proposed checklist and scoring system.	Introduction: **Ken Bond, Anna Stoklosa**
1:00-2:00	Lunch	
2:00-3:00	Guidance on reporting for ethics analysis	Introduction: **Ken Bond**
3:00-3:30	Tea/Coffee Break	
3:30-4:30	Summary of Day 2 discussion. Next Steps and Wrap Up	**Sigrid Droste, Ken Bond, Anna Stoklosa**

Discussions on Day 2:

Day 2, Item 1: What are the goals of using a quality assessment tool for ethics literature? Introduced by Ken Bond (Institute of Health Economics)

Presentation Summary

Goals of a quality assessment tool for assessment of ethics literature depend on who the intended user of the tool is (e.g. ethicist vs. non-ethicist) and what is being assessed for quality (e.g. single argument vs. totality of ethics literature vs. an ethics analysis included in an HTA).

Whether the ethics quality assessor is an ethicist or a non-ethicist, a quality assessment tool will aid in facilitating the assessment and communication of the ethics analysis, consistency in terminology, and facilitating comparison of judgements amongst different technologies. For non-experts, the quality assessment tool will also aid in familiarization with the work of experts, familiarization with the process of ethics analysis, management of expectations about both the process and the outcome of the analysis, and fostering of dialogue about quality.

Additional issues worth considering here are the elements that constitute "quality" in ethics work and how to characterize indicators of "rigorous" work in ethics.

Issues Raised in Discussion

The following goals were proposed:

- Promoting transparency and clarity of ethics analysis
- Guidance for an ethicist (especially one unfamiliar with HTA) on how to structure an ethics analysis
- Verification (by an HTA agency) whether the ethics analysis is of appropriate standard and can be included in an HTA report
- Standardization of structure of an ethics analysis between jurisdictions
- Management of differing expectations between the ethicist conducting the analysis, agency commissioning the analysis, and decision-maker relying on the HTA report containing the analysis
- Improved communication between the ethicist, agency, and decision-maker
- Divestment of responsibility, i.e., in conflict cases, disagreement regarding the quality of ethics analysis is between the users and the checklist, not between users themselves

Other issues raised in discussion:

- Checklists can be misused as just a "box-ticking" exercise
- Utilization of a checklist at the beginning of the HTA may stifle deeper reflection about the issues
- A possible sequence of proceeding here may be (1) generate a list of questions (rather than a checklist) to structure thinking about ethics issues at the initial stages of HTA, (2) perform the ethics analysis, and (3) deploy a checklist to assess the quality of ethics analysis
- How can someone who is not an ethicist identify a poor quality ethics analysis?
- Methodology for generating the quality assessment tool: start with an example of a poor quality ethics analysis, identify its problems, and from those generate a "what not to do" tool
- There is a need here for a definition of core competencies of an "HTA ethicist" so that we know who is an expert/non-expert in this context
- In standard HTA methodology, it is typical to use several experts to assess the HTA itself; perhaps a parallel consideration could be given to ethics analysis?
- Checklist should be primarily targeted at ethicists/ethics experts; however, some additional description of methodological approach could make it useful for non-ethics HTA personnel, as well

Day 2, Item 2: What items ought to be included in a checklist for assessing the ethics literature? Introduced by Gert Jan van der Wilt (Nijmegen Medical Centre)

<u>Presentation Summary</u>

Using an HTA of extra corporeal membrane oxygenation (ECMO) as a case study, Gert Jan focused on addressing the issue of what researchers can – and should – do to adequately address ethical issues associated with the use of health technologies. This includes consideration of methods for:

- Identifying potentially morally significant issues
- Establishing their actual moral significance
- Justification of particular conceptions of norms
- Practical deliberation: deciding what ought to be done

Considerations of quality of the ethics analysis will depend on the type of analysis: descriptive, normative, or transformative. Different standards for quality assessment apply to different analytical approaches. As no set of necessary and sufficient criteria for a correct explication of a moral concept exists, "correctness of explication" will depend on what is selected as relevant paradigmatic cases, and the comparison that is drawn between those and the health technology under assessment.

In order to be useful in a policy-setting context, the ethics analysis needs to explore the full range of potentially morally significant issues. Research strategies conducive to this end include interviewing stakeholders and participant observation. For the purposes of quality assessment, research quality criteria can be applied here. The analysis may need to show both that a particular moral norm is applicable, and to justify a specific conception of the moral norm being deployed. (Wide reflective equilibrium may be more appropriate here than foundational approaches.) A suggestion for resolving value conflicts is required.

<u>Issues Raised in Discussion</u>

- One could rely on casuistry to justify the particular conception of norms
- Is there a danger that adoption of a particular moral stance (e.g. casuistry) will be seen as biased from other perspectives (e.g. utilitarian)? It was proposed that this could be countered by a transparent description of the standpoint adopted.
- Health care policy and legislation are not strictly utilitarian, so that approach may not be viable
- Conceptual clarity is often absent in these analyses – this is a particular problem around "autonomy" but also other salient concepts. Conceptual clarification is required here.
- Assessment of quality should look at the entire picture (all the steps) rather than just the snapshot
- Context-sensitivity is crucial; there may be normative considerations that are not permitted to be taken into account in context of particular health systems.
- Those conducting the ethics analysis must be aware of the context in which that analysis will be used. E.g. an assessment of ethical issues around cochlear implants in the Netherlands proceeded as follows:
  o Interview with the various stakeholders
  o Reconstruction of their moral judgements, reconstruction of the problem (is it deafness? Or something else?) reconstruction of the background theory underlying the judgement (what moral theory underlies the judgement), the normative preferences (what action is acceptable, desirable)
  o Mapping and identifying the relationships between these elements

Day 2, Item 3: Should the same quality assessment tool to be used in descriptive and prescriptive approaches to synthesising ethics literature? Introduced by Annette Braunack-Mayer (University of Adelaide)

Presentation Summary
Ethics literature is traditionally categorised as descriptive (how things are) and prescriptive (how things ought to be). Descriptive literature describes actual judgements regarding health technologies, policies concerning them, documents outcomes of technology use. Its sources include assessments of the technology's purpose, clinical need and burden of the disease, treatment alternatives, and clinical outcomes. It usually describes broader patient, community and societal perspectives – what does the community think, is there a variety of views in the community and if so, what are they, etc. Prescriptive literature focuses on the implications of ethical concepts, theories, principles for technologies, and provides rationale for the use of technology. It is frequently found in professional standards statements (e.g. review articles, clinical opinions, codes of ethics, or professional guidelines) or in normative ethics literature (books, journal articles).

These are very different bodies of literature, and consequently, it would seem that we should use a different tool to assess their quality. However, the descriptive and prescriptive do not divide up so simply a lot of the time, i.e. the descriptive and prescriptive ethics elements are often intertwined in the literature, which was demonstrated using an example of the use of MRI for foetal abnormalities. For the purposes of a quality assessment checklist, the following grouping of items might be advisable: items that are more descriptive, items that are more prescriptive, items that are both.

Issues Raised in Discussion
- The descriptive and prescriptive are always connected
- We should also look to what is "standard" for a particular technology (e.g. high sensitivity or specificity for a diagnostic test). The underlying standard will determine what sort of empirical information about the technology is considered to be relevant
- Key questions to ask: is x true, does x matter
- Tendency in HTA to think of facts as "value-neutral" is likely to pose a challenge here
- As many of the other relevant issues were already discussed under the previous topic, the discussion was kept brief

Day 2, Item 4: Evaluating the proposed checklist and scoring system. Introduced by Ken Bond (Institute of Health Economics) and Anna Stoklosa (University of Sydney)

Presentation Summary

A checklist and scoring system drafted by Anna Stoklosa and Ken Bond formed the basis of this session (checklist is reproduced in Appendix 1). The checklist and scoring system are intended as a starting point for generating an assessment tool for evaluating the quality of the normative ethics literature. Key elements raised for consideration, included domains to include on the checklist, elements within each domain, approach to rating, and justification for the rating assigned.

Issues Raised in Discussion

The participants suggested that the following issues ought to be considered when modifying the checklist:

- Include information about the process: who was involved, in what way, were various stakeholders' perspectives taken into account, was the search strategy to identify literature a comprehensive one. These elements merit consideration because they inform the quality of the analysis.
- Assess the quality of the evidence search: a comprehensive search ought to include not only a literature search, but also a consultation with relevant stakeholders
- "Conclusions" element requires a consideration of support for the claim (i.e. moral norms/standards, their source, their justification, empirical support)
- Transparency and explicitness about methods used to answer items on the checklists are desirable
- Explicitness about the norms and standards supporting the rating and justification for rating of each element (what norms/standards underlie the rating, their source, justification, empirical support, appropriateness to context in which the checklist is being used) is desirable
- Definition of concepts are required
- Explicitness about the perspective/position adopted is required.
- The assessment of assumptions' "reasonableness" may be a problem and perhaps ought to be replaced with an assessment of their consistency with the perspective adopted. (E.g. if an argument is made from a utilitarian perspective, the assumptions ought to be consistent with this).
- The "bias" element ought to be replaced with a "balance" element, due to potential for confusion. "Balance" element should be described as a consideration of opposing or conflicting positions
- Methods should be described clearly enough to allow replicability. There was a debate whether the term "transparency" would be preferable here (as "replicability" is value-laden) but it is not clear whether "transparency" quite captures what is intended here.
- Conflicts of values should be identified explicitly.
- The "completeness" element ought to be replaced with "evidentiary gaps" element. The "evidentiary gaps" element can be described as, e.g. prescriptive arguments relying on empirical claims where empirical evidence is missing. In context of descriptive work, identification of a gap would involve identification of an ethical issue on which no ethical literature has been produced (although there was a discussion about whether that would ever be the case, and what the role of the person conducting the analysis would be in such an event).
- The logic of the arguments requires assessment of explicitness about values relied on, whether justification for those values was offered, whether conclusion logically follows from those values, whether the empirical evidence cited in support (if any) is relevant
- A further "coherence" element was proposed – requiring a consideration of whether the reasoning about the appropriateness or desirability of a particular health technology is consistent with decisions previously made about similar technologies.
- Conflict of values (where present) is clearly identified and described

- "Premises" element ought to be changed to "moral arguments" element; this will also require a change to the "relationship between premises/conclusions" element.
- "Objections" element should be moved up the list, and considered in conjunction with the "moral arguments" (previously: "premises") element
- Assessing the reasonableness or unreasonableness of premises raises concerns about reliance on majority opinion
- There is a need to provide space in the checklist to give a reason for the rating assigned. This is also something that could be included in a guidance document attached to the checklist

Other issues raised in the discussion:
- It was suggested that one of the key roles of experts in HTA/ethics is to indicate whether particular methodological choices are preferable to others
- An issue in need of settling is whether it is actually possible to amass the totality of ethics arguments relevant to a particular health technology
- In context of evaluating an ethics analysis, one must bear in mind the difference between the assessment of a conclusion of a final recommendation vs. the assessment of the analysis underlying it
- Proposed presentation format for the executive summary of the ethics section, e.g.: 10 arguments were identified, of which the following two are the most relevant (describe). Value preference A supports adopting the position following from argument 1; value preference B supports adopting the position following from argument 2.
- The checklist requires a companion guidance document, to assist those completing the checklist. The guidance document should contain worked out examples.
- A substantial glossary may be required for this checklist (particularly as some terms – e.g. validity – are terms of art in logic, but are also used commonly, to mean something else)
- Analogies are quite frequently used in ethics arguments – this is something worth considering in more detail, and potentially including
- A properly conducted ethics analysis may yield a new ethical argument that subsequent analyses will need to consider
- Should the checklist or the guidance document include a set of criteria for when an involvement of an ethicist in the analysis would be beneficial?
- The resulting instrument will require trialling and revision
- Members of the various HTA agencies (or working in collaboration with the various HTA agencies) should be queried for best/worst case examples

Presentation Summary

A reporting guideline can be defined as an "explicit text to guide authors in reporting a specific type of research, developed using explicit methodology" (Moher et al 2010)[4]. Such guideline documents are common in other areas of HTA (e.g. EQUATOR network, CONSORT, STARD, MOOSE, etc.), although it is worth noting that these documents are aimed at publication of research in academic journals. Nevertheless, as they clarify what is required, foster consistency and transparency, a question arises whether similar guidelines for reporting could be adopted and adapted for reporting on ethics analyses?

Reasons to put together a reporting guideline in this space include the lack of clarity, transparency and completeness of reports, which undermines assessment of transferability and ability to replicate, incomplete picture of what was done, difficulty in assessing the quality and reliability of results.

First steps toward generating a reporting guideline is establishing consensus on the following items: identification of the need for a guideline, development of a new guideline, review of literature, search for evidence on quality of reporting, identification of participants, Delphi procedure, generation of a list of items for a face-to-face meeting.

Key questions to consider are whether there is a need for reporting guideline(s) for ethics analysis, whether such a guideline would promote the production and/or use of ethics analyses in HTA, and whether a list of potentially plausible items could be generated.

Issues Raised in Discussion
- If we have already reached the point where we are assessing quality of ethics analyses (i.e. they already exist), is producing a guideline for ethics analysis really required?
- One of the often-cited reasons to put together a reporting guideline is to seek evidence on quality of reporting. But this is something that the present workshop is already aiming at.
- A concern was raised about the various methods and formats adopted by the various HTA bodies. However, in spite of those, various guidance documents *do* exist (e.g. CRD guidance for undertaking systematic reviews), so by itself, diversity of method is not a decisive argument against producing a guideline
- A concern was raised about a potential race to the bottom – e.g. stipulating a set of minimum criteria to be met may have the result that this "minimum" will become "the standard"
- The guideline has the potential to be utilized as a "wedge strategy"
- The guideline could serve as an educational tool both for ethicists who are not familiar with HTA, and for HTA personnel not familiar with ethics
- Guideline documents may stipulate indexing standards, which would have the benefit of making searches easier
- Assessing whether a guideline is needed could be carried out after the checklist is trialled and finalised. This is because the use of a checklist will allow us to assess the quality of reporting, and thus identify examples of good/bad analyses. If the majority of identified analyses are good, then there is no/limited need for a guideline
- It is not clear whether a reporting guideline can be successfully disseminated via ethics journal, as the format is unlikely to map onto the structure that ethics journals (read by ethicists) require

---

[4] Moher D, Schulz KF, Simera I, Altman DG (2010) Guidance for developers of health research reporting guidelines. PLoS Med 7(2): e1000217.

Summary of Day 2 discussions and issues raised

Key issues and recurrent themes discussed on day 2 of the workshop:

1. The main goals for the quality assessment checklist are: transparency, clarity, methodological guidance, standardization of method/approach, management of expectations, improved communication. However, we must be cautious to structure it such that the checklist does not become simply a "box-ticking" exercise,[5] or stifle further reflection about ethical issues.

2. Questions around the notion of "ethical expertise" kept recurring. Main issues raised included who counts as an expert, what is their role (both vis-à-vis the checklist, vis-à-vis non-ethics experts in HTA, and more generally in HTA), what are their competencies supposed to be, and whether it is the ethicist at whom the checklist is targeted. This issue also raises a cognate question of who counts as a non-expert in ethics in HTA.

3. What is the appropriate methodology for generating the checklist? Is it preferable to start from good examples and expand or start from poor examples, and identify gaps?

4. It was proposed that rather than producing the checklist as a stand-alone document, a companion guidance piece also be produced (similarly to PRISMA or CONSORT).

5. The checklist requires clear definitions of concepts and worked out examples, possibly to be provided in the aforementioned companion document or a glossary.

6. Numerous helpful amendments to both the structure and the content of the proposed checklist were offered by the participants (noted under "Day 2, Item 4").

7. Trialling the checklist across a variety of technologies and in variety of contexts will be crucial; context-sensitivity of the checklist will require that checklist be flexible enough to be amended for different contexts

8. Whether reporting guideline for ethics analyses in HTA (analogous to something like the CRD guidance for systematic reviews) is required generated some debate. Concerns were raised that such a document would generate a potential race to the bottom, although on the other hand, it was acknowledged that such a tool could be used as a "wedge strategy" and a means of educating both ethicists unfamiliar with HTA, and HTA personnel not familiar with ethics.

---

[5] This is an empirical question. A consideration of whether similar checklists in other areas of HTA suffer from these problems would shed some light here.

Next Steps

Plans for subsequent work emanating from the workshop include:

Publications:
Several journal submissions are proposed. These will include:
- A more general discussion around the role of checklists, as well as the various types of checklists that can be used (and useful) in ethics in HTA, and the various stages (topic prioritization, assessment, appraisal) where they can be used;
- A review of the existing checklists, the experiences of those using them, their content, challenges around their adoption, etc.;
- The proposed ethics checklists (assessment of individual arguments, assessment of the totality of ethics literature, assessment of an ethics analysis included in an HTA);
- Companion document to the proposed ethics checklists, containing their justification, conceptual definitions, etc.

Subsequent Conferences:
Preliminary discussion of some of the workshop's findings (particularly regarding the issues around the assessment of quality of ethics evidence in HTA) already took place at the 2nd Annual Australian Health Technology Assessment Conference, which took place in Sydney, in December 2013. With support of the Ethics Interest Sub-Group of the Health Technology Assessment International (HTAi), two panel proposals (including several of the workshop participants) to both present the findings of the workshops to the greater HTA community and to build further on those findings, were submitted to the HTAi Programme Committee. Workshop material is also being included in the Ethics in HTA 101 workshop to be held at HTAi 2014 meeting (including 4 of the workshop participants). Further panel and abstract submissions are proposed for the CADTH symposium (April 2014), and the Canadian Bioethics Society conference (May 2014).

Educational Module:
The content of the workshop will be re-organized as a module for an online course in Ethics in HTA that is convened by the Ethics Interest Sub-Group of Health Technology Assessment International (HTAi) under the leadership of Gert Jan van der Wilt and Wija Oortwijn.

Appendix 1 to IQWiG workshop: Checklist discussed in Day 2, item 4

A checklist and scoring system below was drafted by Anna Stoklosa and Ken Bond, and formed the basis of Day 2 item 4 session of the Cologne workshop.

1. Internal quality assessment			
Domain	**Element**	**Rating**	**Grounds for rating**
Perspective	Does the argument identify from whose perspective it is offered (e.g. patients, health system, health care professionals, etc.)	Clear Partly clear Unclear Not applicable	Explicit identification Implicit identification No identification ---
Assumptions	Are assumptions identified?	Clearly Partly clearly Unclearly Not applicable	Explicit identification Implicit identification No identification ---
	Are assumptions reasonable?	Reasonable Partly reasonable Unreasonable	***needs grounds for rating***
Premises	Are premises identified?	Clearly Partly clearly Unclearly	Explicit identification Implicit identification No identification
	Are premises reasonable?	Reasonable Partly reasonable Unreasonable	*Unreasonable* premises include appeal to brute biological facts, majority opinion, legality, or historical tradition; *reasonable* premises include appeal to current practice standard, ethical principles and theory, casuistry, reflective equilibrium. (See McCullough et al. 2004).
Conclusions	Are conclusions identified?	Clearly Partly clearly Unclearly	Explicit identification Implicit identification No identification
	Are conclusions reasonable?	Reasonable Partly reasonable Unreasonable	***needs grounds for rating***
Premises / conclusion relationship	How strong is the relationship between the premises and conclusions?	Strong Weak Does not obtain	***needs grounds for rating***
Objections	Are objections to the argument identified?	Yes Partly No	***needs grounds for rating***
	Are objections to the argument addressed?	Yes Partly No	***needs grounds for rating***
2. External quality assessment			
Domain	**Element**	**Rating**	**Grounds for rating**
Transferability	Is the argument transferable to the context of assessment?	Yes Partly No	Judgement regarding whether the argument is made within similar health/ethical context
Implications	Are policy implications of the argument identified?	Clearly Partly clearly Unclearly Not applicable	Explicit identification Implicit identification No identification ---
	Are implications differentiated by stakeholder (e.g. patient, health professionals, policy-makers, health system, industry, etc.)	Clearly Partly clearly Unclearly Not applicable	Explicit identification Implicit identification No identification ---
Completeness	Does the analysis acknowledge gaps in the ethical literature?	Clearly Partly clearly Unclearly Not applicable	Explicit identification Implicit identification No identification ---
Bias	Are possible sources of bias identified?	Clearly Partly clearly Unclearly Not applicable	Explicit identification Implicit identification No identification ---
	Are steps taken to address possible sources of bias?	Yes Partly No	***needs grounds for rating***