

Assessment vs. appraisal of ethical aspects of health technology assessment: can the distinction be upheld?

Abstract

An essential component of health technology assessment (HTA) is the assessment of ethical aspects. In some healthcare contexts, tasks are strictly relegated to different expert groups: the HTA-agencies are limited to assessment of the technology and other actors within the health care sector are responsible for appraisal and recommendations. Ethical aspects of health technologies are considered with reference to values or norms in such a way that may be prescriptive, or offer guidance as to how to act or relate to the issue in question. Given this internal prescriptivity, the distinction between assessment and appraisal seems difficult to uphold, unless the scrutiny stops short of a full ethical analysis of the technology. In the present article we analyse the distinction between assessment and appraisal, using as an example ethical aspects of implementation of GPS-bracelets for people with dementia.

It is concluded that for HTA-agencies with a strictly delineated assessment role, the question of how to deal with the internal prescriptivity of ethics may be confusing. A full ethical analysis might result in a definite conclusion as to whether the technology in question is ethically acceptable or not, thereby limiting choices for decision-makers, who are required to uphold certain ethical values and norms.

At the same time, depending on the exact nature of such a conclusion, different action strategies can be supported. A positive appraisal within HTA could result in a decision on *mandatory* implementation, or *funding* of the technology, thereby making it available to patients, or decisions to *allow* and even *encourage* the use of the technology (even if someone else will have to fund it). A neutral appraisal, giving no definite answer as to whether implementation is recommended or not, could result in a *laissez-faire attitude* towards the technology. A negative appraisal could result in a decision to *discourage* or even *prohibit* implementation. This paper presents an overview of the implications of different outcomes of the ethical analysis on appraisal of the technology. It is considered important to uphold the distinction between assessment and appraisal, primarily to avoid the influence of preconceived values and political interests on the assessment. Hence, as long as it is not based on the subjective value judgments of the HTA-agency (or its representative), such an appraising conclusion would not seem to conflict with the rationale for the separation of these tasks. Moreover, it should be noted that if HTA agencies abstain from including full ethical analyses because of the risk of issuing an appraisal, they may fail to provide the best possible basis for decision-makers. Hence, we argue that as long as the ethical analysis and its conclusions are presented transparently, disclosing how well-founded the conclusions are and/or whether there are alternative conclusions, the HTA-agencies should not avoid taking the ethical analysis as close as possible to a definite conclusion.

Keywords: assessment, appraisal, ethical analysis, prescriptiveness, surveillance technology, persons with dementia

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Introduction and aim

Health technology assessment (HTA) should include evaluation of ethical aspects [2]. Research into such evaluations has become increasingly more systematic during the past decade, with the development of structured instruments or lists to aid ethical analysis and ethical evaluation [9], [10], [15], checklists for systematic reviews of ethical analyses [12] and, of course, the production of actual ethical analyses of different technologies. In this context, the question arises as to whether HTA-agencies should be limited to only assessment of ethical aspects of a technology, or if they should also engage in appraisal.

Assessment is here defined as the action of evaluating relevant aspects of the technology to form a basis for decision, while appraisal implies some form of recommendation about the implementation of the technology, based on this assessment. However, such a recommendation can lead to a number of different concrete actions (see below): funding, permission for implementation, encouraging, discouraging or even prohibiting implementation, etc.

Some HTA-agencies are restricted to assessments of the technology only and do not actually make recommendations on implementation in the healthcare system. In the United Kingdom, for example, there is a strict division between the HTA-agencies, which undertake assessments and The National Institute for Health and Care Excellence (NICE), which has an appraisal role [20]. [At the same time these HTA-agencies are commissioned by NICE to undertake assessments, hence these assessments are tailored to fit NICE's appraisal role.] In Sweden, The Swedish Council for Health Technology Assessment (SBU) is restricted by law to undertaking only *assessments* of technologies, while the county councils (and to some extent other government bodies) have the power to decide what healthcare is made available to the public (and thereby what funding is to be allocated) [18]. A major advantage, and one of the strongest arguments in favour of such a separation of tasks, is that it ensures that the evaluations are not influenced by political interests, i.e. the conclusions that the decision-makers would prefer. Hence, there is concern about “losing objectivity” in the assessment and allowing value judgements to influence the outcome (i.e. influencing how the assessment is skewed to arrive at results that are consistent with the preconceived value judgements of the decision-makers). This strict division of tasks has raised the question of how far-reaching the ethical analysis can be, without becoming an actual appraisal of the technology. The reason for this is that ethical evaluations are based on values or norms in a way that is perceived by many as prescribing or offering guidance as to how to act or relate to the issue in question. This lack of clarity may, in turn, increase the risk that the ethical assessment stops short of arriving at and presenting a full ethical analysis in the HTA-report. The aim of this article was therefore to analyse and discuss whether and if so, how, the distinction between as-

essment and appraisal can be upheld within the field of ethical analysis in HTA, without compromising the comprehensiveness and quality of that analysis. As an example, the ethical aspects of a specific technology are analysed, namely the use of GPS surveillance for people with dementia who tend to wander off [13], [16].

The analysis is conducted at different levels, progressing from a strict description of the arguments actually proposed in public debate, to a more fully-fledged ethical analysis of the technology (or rather an illustration of how such an ethical analysis could be undertaken and the features of such an analysis). The discussion focuses on the issue of whether the progressive stages towards a fully-fledged ethical analysis comprise an assessment or an actual appraisal of the technology.

The prescriptive nature of ethical values and norms

Within the field of ethics, distinguishing between assessment and appraisal is problematic. To state that something is ethically right or wrong, or ethically good or bad is not merely an assessment of a factual matter: a prescriptive component is implied [8]. [Here is not the place to enter into the vast field of meta-ethical discussion about how to understand ethical concepts and ethical values and norms. Suffice it to say that most meta-ethicists seem to agree that ethical concepts, values and norms are not only descriptive, but also prescriptive.] To take a simple example: If we say that lying is wrong, we have not just described another feature of lying, similar to that lying is characterized by communicating information, known to be false, to another human being. It seems that what we are in fact saying something which condemns or prescribes the action: “You should not lie (unless you have other, more compelling (ethical) reasons for doing so)”. In contrast, a statement such as “this is a red sofa” has in itself no inherent prescriptive component, unless some background information is added, for example, that the person being informed has expressed a wish to buy a red sofa. In HTA for example, if it is concluded that a certain technology reduces tumour size more effectively than an alternative method, there is still a need to question whether implementation of the new technology should be recommended. That the technology is more effective is of course a *prime facie* reason for adopting it, but in order to decide whether it should actually be implemented, further value judgments are required, based on answers to the following questions: Does reduction in tumour size have any effect on values that are important to the patient (e.g. quality of life and/or survival)? Are the costs of the technology reasonable in relation to the potential benefit to the patients? Are there other ethical reasons against using it, even if the above questions are answered in the affirmative – for example that there is a high mortality risk associated with the technology?

If however, it is concluded that use of a certain technology is ethically wrong or that there are grave ethical issues associated with it – and no corresponding ethical benefits or counter-arguments – this is in itself prescriptive: the technology should not then be recommended, regardless of whether it has proven to be effective and cost-effective. In such a case, it seems anomalous that a further norm or value judgement is required, claiming that we should not do what is ethically wrong. Given this feature of ethical aspects, the question arises as to whether it is possible to make an ethical evaluation of a technology, without it resulting in an appraisal, i.e. to make an objective assessment without implying any recommendations. If so, is this distinctly different from assessing the effectiveness or cost-effectiveness of technology? In this context it is important to clarify what is meant or implied by an appraisal.

Different implications of appraisal

The distinction between assessment and appraisal is made in a regulatory and organizational context, hence appraisal might have different organizational or regulatory implications. [We owe this idea to V. Dubljevic, one of the reviewers.] To return to the example of lying: arriving at the conclusion that lying is ethically wrong will have different implications, depending on the context. In normal, everyday life, lying is obviously not illegal, but can be morally sanctioned, e.g. by blaming or socially ostracizing the constant liar. Lying under oath, however, can lead to legal sanctions and lying to a patient could sometimes have repercussions for the healthcare professional (perhaps even to the point of losing his/her professional licence). Hence, in this context the implications associated with appraisal within HTA need to be specified. A positive appraisal could result in a decision on *mandatory* implementation, or allocation of *funds*, thereby making the technology available to patients; or a decision to *allow* and even *encourage* the implementation of the technology (even if someone else will have to fund it). A neutral appraisal, with no definite answer as to whether implementation is recommended or not, could result in a *laissez-faire attitude* towards the technology. A negative appraisal could result in *discouraging* or even *prohibiting* implementation. Moreover, encouraging and discouraging can be reinforced by imposing financial incentives or disincentives on the technology [3].

In many healthcare systems these different actions will be the responsibility of separate bodies. In the Swedish healthcare system, decisions about funding are generally made at county council level; decisions about mandatory implementation or permission for use (if an active decision is required) or prohibition of use are made at parliamentary level, in the form of legislation. Decisions to encourage or discourage the implementation of technology are often made by different government agencies (e.g. The National Board of Health and Welfare or The Public Health Agency of Sweden). However, cases in which financial incentives are involved to encourage or discour-

age use are handled at parliamentary or county council levels.

The case – surveillance technology for people with dementia and wandering behaviour

In dementia care, the question arises as to whether to allow people with dementia to move about freely. For those with mild dementia, who retain some degree of autonomous ability, this might not be a major issue, but there is a risk that they might get lost, with adverse consequences. A more serious problem is the so-called wandering behaviour of people with severe dementia, where the wandering cannot be said to be the result of an autonomous choice. Wandering behaviour may then lead to serious consequences. Not only may the person become lost and unable to find their way back: there is also the risk of more serious injury, and in the worst-case scenario even death. One way to reduce the risks associated with wandering behaviour would be the use of some form of surveillance technology that would alert carers (formal or informal) to situations in which people with dementia are at risk, so that they could intervene and prevent adverse effects.

A variety of such technologies are commercially available. In the present example the equipment is supplied in the form of a bracelet, which is difficult to remove. It has a GPS function, enabling the carer to identify the whereabouts of the wearer. The GPS function can be associated with virtual fences, i.e. if the GPS moves outside a certain physical space or geographical area, it will send a signal to the carer. Moreover, the bracelet can also have an alarm function, enabling wearers to signal to the carer that they are losing their way, or losing control of the situation. This alarm function can also be associated with a telephone function (see [7]).

Different levels of ethical evaluation – illustrated in relation to the example

In this section we will consider evaluation of the ethics of the GPS-bracelet undertaken at different levels of comprehensiveness and quality of ethical analysis, starting with a rudimentary evaluation.

Level 1 – repeating the ethical arguments in the actual debate

One form of ethical “evaluation” that would not risk being identified as an appraisal of the technology would be to repeat only the arguments raised against the technology in actual debate. There are degrees of complexity at this level, starting with the man in the street argument, but it could also include the more developed arguments found

in the research literature. For example, it has been argued not only that the bracelets constitute an unacceptable intrusion into the privacy of the wearer, but also that they are an offence to dignity, treating adults like children and criminals [5], [1], [11]. Healthcare providers have used these arguments to impede the introduction of such technologies. In contrast, the argument in support of the technology, as beneficial to people with dementia, is often presented without any acknowledgement of the disadvantages. In a recent review article, this dichotomous stand on surveillance technology for people with dementia was identified in actual debate [13].

Merely repeating these arguments without any critical scrutiny does not comprise an ethical evaluation of the technology and hence does not adequately fulfil the norms of ethical evaluation in HTA [19]. On the other hand, citing arguments for or against the technology does not entail any prescriptive content or conclusions. Hence, this is just an assessment of sorts and not an appraisal. However, as an assessment it is quite inadequate: it fails to provide grounds for better decision-making as to whether or not the technology should be implemented.

Level 2 – trying to identify all the relevant arguments in relation to the technology

The next level of evaluation would entail identifying and listing *all* the possible basic ethical arguments for and against the use of the technology, whether or not these have actually been raised in public debate (or any other context).

The following arguments *against* the use of GPS-bracelets for persons with dementia could be identified and listed [13], [16], [7] [This is not intended as a full list of arguments, just an illustration. In the review article by Niemeijer et al. [16] we find between 10 and 25 references for each argument.]:

- They constitute an intrusion of privacy.
- They are an offence to dignity.
- They can be an excuse to reduce staff and hence affect the quality of care.

In *support* of the use of GPS-bracelets, the following arguments could be identified and listed:

- They have a positive effect on patient safety and quality of life in reducing adverse events.
- They can enable the wearer to move about more autonomously than the alternatives.
- By minimizing the risk of adverse events, they might reduce the cost of search parties and medical care.

Such a relatively comprehensive list of arguments could be of some help to decision-makers and hence be seen as a form of ethical evaluation or assessment. As no appraisal is implied, there is no conflict with the task of agencies which are limited to undertaking assessments only. Although every single argument may of itself have

a prescriptive force, there is no mention of how these different arguments and their respective and differing prescriptive forces should be further understood and balanced against each other.

This is far from an ethical analysis of the technology. Firstly, apart from the fact that the arguments have not been balanced against each other, several vague, ambiguous concepts are used, which can expose the arguments to different, incompatible interpretations, including, for example, such concepts as privacy, dignity, autonomy, quality of life and quality of care. These concepts are central to how the arguments are understood. Secondly, the arguments in themselves are ambiguous and need further analysis to identify what they really amount to or claim. Thirdly, the arguments need to be analysed to determine whether they can be related to more basic values and norms. This implies yet another level of ethical evaluation and analysis, to examine what such clarifications would imply in terms of assessment vs. appraisal.

Level 3 – Level 2 plus conceptual clarification and relation to more basic values/norms

At this level, the above arguments require individual scrutiny, in order to understand them better and therefore also to better understand the prescriptive force of the argument (in itself). Let us take the argument about privacy as an example, i.e. that the GPS-bracelet constitutes an intrusion into privacy.

Privacy can be understood in several ways, depending on what aspects of personal life are affected. In the literature, privacy can refer to physical privacy, privacy of information, of each person's material belongings or of each person's close physical sphere [6], [17]. We can relate to privacy in different ways normatively: respecting, protecting, but also reinforcing or promoting privacy. "Respecting or protecting privacy" would imply a given personal sphere which should not be entered at all, or not lightly, or at least not without the permission of the person concerned. This interpretation seems to view privacy and our normative response to privacy more in deontological terms, i.e. in terms of rights or duties. This respect for privacy or right to privacy can be absolute and something which should never be overridden – but could also be seen more in terms of a *prima facie* right or duty that under certain circumstances can give way to other values or norms.

On the other hand, "strengthening or promoting privacy" implies that it is quantitative and might also imply that it is a (prudential) value: the greater the privacy, the better the quality of life. This seems to advocate a more consequentialist view: privacy has a final value together with other values, or at least a contributory value [4]. On the other hand, it could be argued that privacy is of instrumental value only to the extent that it protects or promotes other values, such as well-being, autonomy, etc.

In effect, claiming that GPS-bracelets intrude on privacy could refer to the fact that they are physically intrusive, in being impossible to remove, but would more likely refer to the fact that they collect information about the wearer (which he/she might not be willing to share). Moreover, claiming that the bracelets are intrusive can mean that they violate an absolute right of the patient, in which case it will always be wrong to use them (unless this is overruled by a more stringent right). Or, and in stark contrast, it can mean that they might compromise something that has instrumental value. If so, the extent to which their use is wrong depends on how the intrusion into privacy in turn affects the more basic final value, for which privacy is instrumental (an obviously more open question).

Moreover, the claim that the GPS-bracelet is an intrusion of privacy should be assessed in relation to the alternative of not using the bracelet. One possible alternative is to allow the person with dementia to wander freely, without restriction, obviously risking a number of potentially serious negative effects on their health and safety. From a deontological perspective, it might be argued that the rights to life and health override the right to privacy, while a consequentialist perspective could regard life and health as final values, or at least more closely related to final values than the value of privacy. Hence, if the protection of privacy is only of instrumental value and threatens health or life itself, then privacy should be overridden. Another argument is that there are fewer risks if instead of the GPS, a live carer always accompanies the person in his/her wandering. However, a live carer would be able to collect more information about the person with dementia i.e. not only where she is but also what she does, etc. – this would seem to be a relatively greater intrusion of privacy than the GPS-bracelet, from both deontological and consequentialist perspectives.

At this point, the ethical evaluation or assessment becomes fairly complex, especially when there are a number of arguments requiring clarification. It is also clear that there are different and to a large extent mutually exclusive normative interpretations of the arguments. Whether or not a certain argument will have prescriptive force depends on which interpretation of the argument seems to be most reasonable and in turn, which more basic normative perspective or theory (or combination of such) seems most appropriate. Hence, if the ethical assessment presents only a number of different interpretations, it will not be prescriptive and thus avoids the appraisal trap. However, in reviewing the argument about privacy in relation to alternative courses of action, it is difficult not to assess the strength of the argument also (and in view of the alternatives, the argument seems to lose some of its force, regardless of ethical perspective). This will have prescriptive implications (at least for whether this specific argument about privacy can be used to argue against the technology). On the other hand, assessing the effectiveness of a technology also involves comparison of the effectiveness of alternative technologies and a conclusion that one technology is more effective than another. It should also be possible to make a similar form of evalu-

ation of ethical comparisons, without it resulting in an appraisal.

Although the Level 3 assessment is probably more helpful to decision-makers than the Level 2 assessment, it is not a full ethical analysis of the technology, which requires balancing these different arguments against each other and assessing their respective and relative merits and strengths. Although this could be left to the decision-makers, it does require philosophical or ethical expertise, or at least competence in argument analysis. Not every decision-maker would be able to produce a reasonable analysis based on the Level 3 assessment.

Level 4 – conducting a full argument analysis based on the clarifications in Level 3

In the next step towards a full argument analysis, it will be necessary to examine how the different arguments (and the clarifications of these made at level 3) can be related to and countered by each other and whether it is possible to identify other relevant arguments to counter (or support) the advocated basic arguments.

With respect to the argument about whether or not the GPS is an intrusion into the privacy of the wearer, the degree of intrusion needs to be analysed in relation to other available technologies. There is also a need to analyse whether the intrusion-argument is strong enough, given, for example, the argument about empowering the autonomy of the wearer of the GPS. At level 3, analysis of the autonomy arguments would have required definition of the relevant group of people with dementia: not everyone with dementia would be affected by this argument, only those with adequate cognitive abilities. Is this a group of people with severe dementia, who it can reasonably be claimed has lost decisional competence? If so, the argument about autonomy seems to lose all of its force: it can in general be claimed that a person who lacks a minimal level of decisional competence cannot exercise autonomy. Hence, their autonomy cannot be enabled – at least not by a GPS-bracelet. However, other people with dementia retain sufficient decisional competence to be able to move about relatively freely (albeit at increased risk of the above-mentioned adverse effects) and can thus exercise autonomy. The GPS-bracelet could enable these people to exercise autonomy whilst at the same time reducing the risk of adverse events. In this case, unless it is claimed that privacy is an absolute norm or value, regardless of the person's attitude towards it, the argument about intrusion into privacy can be managed by requiring the person concerned to give informed consent to wearing the bracelet. Depending on the context of use being considered, the conclusion that informed consent would solve the issue might need further clarification and discussion. In a regulated, public healthcare system, use of the bracelet would be managed by health professionals who are familiar with obtaining informed consent; thus specific regula-

tions might not be necessary. If, on the other hand, the issue being considered is whether the bracelets should be sold on the open market, the informed consent requirement might necessitate other regulatory actions, e.g. special documentation or the need to provide individual information, etc. Under these conditions, the ethical analysis will give an answer as to *what* should be done, but not necessarily *how* it should be done. Nonetheless, this process, involving a more or less full ethical analysis, may lead to a situation where some arguments simply disappear, whilst others are further strengthened through the support of other arguments. If so, the prescriptive flair of ethical arguments will imply a certain action, i.e. the action supported by the arguments.

At level 4, points of controversy will be identified, where different arguments will provide support for and against using the GPS-bracelet. At this stage it may be necessary to acknowledge that there are different ethical intuitions in relation to this controversy, perhaps because there are basically different intuitions about which values should have priority. Is protection of a person's privacy a higher priority or more important value/norm than physical security, implying that intrusion into the privacy of the person is unacceptable, whatever the gain in terms of other values? A consequence of this standpoint is that not only is the GPS-bracelet unacceptable, but so is the more intrusive alternative of a physical person accompanying the person with dementia. Or is it the other way around? At this stage no definite prescriptive conclusion will be arrived at, although the analysing ethicist will probably have some intuitions.

On the other hand, in a specific healthcare system, more definite values might be expressed in the healthcare legislation or documents of similar standing. For example, in the Swedish Patient Personal Data Act, which regulates aspects of confidentiality of patient information, patient privacy does not have an absolute standing [14]. A person may have refused permission for information to be accessible to healthcare providers other than those who registered the information: if this person should subsequently become incompetent to make or communicate decisions, healthcare providers are permitted to access this information if the patient's life is at risk. It follows that the above interpretation of absolute priority of privacy over patient security and safety does not apply, unless it is argued that this specific healthcare legislation does not express a codified ethical standpoint in the particular healthcare context. If so, the ethical assessment leads to the conclusion that existing healthcare legislation is questionable, or in conflict with the assessment in this particular situation.

This is of course possible, and obviously there will at times be reason to question the ethics of the healthcare legislation. Nonetheless, legislation which has evolved through democratic process and is well-established and widely accepted by healthcare personnel and the general public should not be questioned lightly. Hence, in many cases it is reasonable to assume that healthcare legislation will provide some guidance in an ethical assessment.

To conclude, undertaking a full ethical analysis of a technology, without regard to the specific healthcare context in which it is intended to be implemented, will often result in hypothetical conclusions of the form: If we accept the value X or norm Y (or a specific set Z of such values and norms) it follows that the technology is ethically problematic (or unproblematic) – but if we instead accept another set Z* of values and norms it follows that the technology is ethically unproblematic (or problematic). At this point it usually remains an open question as to whether we should accept Z or Z*: there may be differing intuitions which cannot be fully resolved by rational argument.

Under these conditions, the analysis *per se* is not prescriptive in relation to the technology. On the other hand, in a given healthcare context, regulated by law etc., the scope of Z might not be as open – and the more guidance these regulations give, the more prescriptive the analysis will be.

At this level, it could be argued that the distinction between assessment and appraisal is more difficult to uphold. The assessment will limit possible recommendations. Hence, the decision-makers cannot, rationally, draw any conclusion they want. However, this is also the case when assessing the clinical effectiveness of a technology: if the assessment concludes that technology A is more effective than technology B, obviously decision-makers cannot preferentially select B on the grounds that it is more effective than A. That is, they need a further reason for preferring B. Hence, the possible recommendations based on the assessment will have been narrowed down in both cases.

An important difference between an ethical analysis and an assessment of the effectiveness of the technology is that in contrast to the assessment of effectiveness, a full ethical analysis should take into account all the values and norms relevant for evaluating whether or not the technology should be implemented. Hence, to the extent that the ethical analysis leads to a definite conclusion about whether the technology is ethically acceptable or not, it also answers the question of whether or not it should be implemented. Once again, this does not provide a definite answer as to how this conclusion should be applied: should it be by encouraging use, by funding use or even by making use mandatory?

This in turn might require separate ethical analysis because this regulatory or decisional step might have ethical implications of its own. The assessment of effectiveness does not in itself resolve the question about whether or not the technology should be implemented. There might be a definite conclusion that the technology achieves a more effective outcome than alternative technologies, but the decision as to whether or not it should be implemented will require a set of values or norms as to how to relate to that effect.

However, ethical analyses seldom achieve a definite conclusion. Hence, even a fully-fledged ethical analysis will in most cases leave room for different appraisals. Table 1 shows possible appraisal implications of conclu-

Table 1: Types of ethical appraisal and corresponding implications within the healthcare system (based solely on the ethical appraisal)

	Conclusion of ethical analysis	Possible appraisal implications
A	An intervention should or is ethically required to be used (for example since it is necessary to protect important or essential ethical values, etc.)	<ul style="list-style-type: none"> • Funding • Mandatory use • Encouraging use (through information, incentives, etc.)
B	An intervention should not or is ethically forbidden to be used (for example because it violates absolute ethical values or norms, etc.)	<ul style="list-style-type: none"> • Prohibition • Discouraging use (information, disincentives, etc.)
C	There are strong ethical reasons against using an intervention	<i>Prima facie</i> reason for discouraging use (information, disincentives, etc.)
D	There are strong ethical reasons supporting the use of an intervention	<ul style="list-style-type: none"> • <i>Prima facie</i> reason for funding • <i>Prima facie</i> reason for encouraging use (through information, incentives, etc.)
E	There are no strong ethical reasons for or against using an intervention.	<i>Prima facie</i> reason for a <i>laissez-faire</i> attitude

sions drawn from ethical analysis, without being an exhaustive list.

In the first two cases (A and B), the conclusions would determine the final appraisal as to whether or not the technology should be implemented, but this appraisal could result in different implications for how society should proceed with implementing the appraisal. If the technology is considered important enough, conclusive reasons for its implementation could result in legislation for mandatory use. If less crucial, there might be reasons to fund it or at least encourage use in other ways, and *vice versa* for reasons against use. In the other cases (C, D and E), the ethical conclusions will be an important complement to the decision as to whether or not to implement the intervention, but these conclusions will still only give a *prima facie* reason for a certain appraisal implication. However, unless it is generally claimed that ethical reasons should always predominate, in the latter cases these could be outweighed by other reasons, even when it has been concluded that there are ethical reasons against implementing an intervention.

The two former cases (A and B) would seem to be rare in most healthcare contexts but may still occur, given the extent to which strong absolute ethical values and norms are identified in such a context. Even so, it is probably more likely that the conclusion is that a certain norm forbids the use of an intervention (B) than requires its use (A). In any healthcare context, it is more likely that the other conclusions (C, D and E) would be arrived at and they obviously imply some form of recommendation (even if not finally settling the matter).

The distinction between assessment and appraisal revisited

So, what are the implications for the possibility of upholding the distinction between ethical assessment and ap-

praisal within HTA? And is this problematic, given the reasons for the divisions of tasks referred to above?

Firstly, it is important note the prescriptive nature of ethical considerations and standpoints, i.e. they are of themselves action-guiding and an ethical analysis could in principle lead to a conclusion that is, in itself, an appraisal or recommendation about whether or not to use the technology.

If the conclusion is that it is ethically wrong to use a technology because it violates established values and norms in the specific healthcare system, this will imply a definite recommendation against its implementation (regardless of other conclusions in the HTA). Exactly how this recommendation should be implemented through decision-making will depend on how important the matter is. If implementation of the technology would have far-reaching ethical implications, such conclusive reasons might warrant legal prohibition. If not as important, discouraging use through different disincentives may suffice. Here the ethical assessment differs from the assessment of other aspects of the HTA (effectiveness, cost-effectiveness, social consequences, etc.).

With respect to ethical analysis, strict application of the distinction between assessment and appraisal could then be interpreted to mean that full analysis should not be undertaken because of the risk of falling into an appraising role. In so doing however, the HTA agency fails to provide the best possible ethical basis for decision-makers. Moreover, it may be questioned whether an HTA-agency exceeds its role if such prescribing conclusions are drawn. If the ethical analysis has been conducted properly, i.e. by openly presenting and assessing all arguments and providing consistent and valid reasons for all statements made, it is not guided by preconceived value judgements or political interests. It is based instead on value judgements or interests that are explicitly agreed upon in the healthcare context. So, given that the conclusion is not ambiguous, and that the final conclusion is not based on possibly questionable interpretations or in-

tutions of the analysing ethicist – the HTA-agency would seem to be functioning within the rationale for the division of tasks.

The ethical analysis may result in a definite and therefore appraising conclusion, but will more frequently be open-ended. It will be up to the decision-makers to interpret the analysis or balance the remaining conflicting claims, etc. If the ethical analysis has been based on the ethical values and norms expressed in valid healthcare regulations, and the decision-makers also adhere to these, then given the prescriptiveness of ethical considerations, the conclusions which can be drawn from the assessment will be limited. It might be difficult for the HTA-agency to identify exactly where the ethical analysis should stop: unless the legislation (or other ethical guidelines for the healthcare sector) clearly sets out how a certain value or norm should be interpreted, this will be open to interpretation.

An HTA-agency concerned about clouding the analysis with the value judgements of the agency might prefer to abstain from adding such an interpretation, unless there is unequivocal support in legislation (or other statutes). This might be the case even when it is possible to provide good arguments for it. In the example above, Swedish legislation on the confidentiality of patient data formed a basis for refusing the absoluteness of the argument that GPS cannot be used because it threatens patient integrity. However, it is not explicitly stated in the legislation that this interpretation is valid for contexts other than the handling of patient data in electronic records or more generally valid for how to regard the integrity of the patient. It could still be claimed that this legislation refers specifically to information stored on electronic patient records. Hence, extrapolation to another field would be just one possible interpretation, and someone else could rationally claim that such extrapolation is not valid. On the other hand, it could be argued that it seems more reasonable that this interpretation is valid or substantiated, as nowhere else in Swedish legislation on privacy is there support for any alternative interpretation.

To take another example: an explicit interpretation of Swedish legislation is that it is wrong to cause the death of a patient by an active and intentional act. Hence a technology that does this explicitly would be prohibited under legal sanctions. Such a conclusion would be less open to interpretation and therefore less risky for the HTA-agency to put forward without being accused of basing their analysis on their own value perspectives. For an HTA-agency limited to assessment, but wanting to provide the best possible decisional basis for appraisal, the ethical analysis could be presented as well-founded interpretations that can be questioned, provided the analysis clearly states not only how, and to what extent, the different conclusions are supported, but also indicates other possible conclusions.

Summary and concluding remarks

The aim of this article was to analyse and discuss the distinction between assessment and appraisal with respect to ethical analysis within HTA. Given the prescriptive nature of ethical concepts and standpoints, a full ethical analysis could lead to a conclusion that is definite, and therefore prescriptive, indicating whether or not the technology should be implemented. However, it might not give a definitive answer as to how this conclusion should be processed in the healthcare system, e.g. through decisions on funding, or legal regulations, etc. In such cases, the conclusions of the ethical analysis will still amount to an appraisal; decision-makers will have difficulty deciding otherwise, without ignoring the ethical principles or norms underlying the analysis. HTA-agencies aiming to provide the best possible basis for decision-makers should not be concerned if this eventuates in an appraisal of ethical aspects. Otherwise there is a risk that the ethical analysis may be unduly limited, by being discontinued before it reaches the rationally required conclusions.

However, given the openness of ethical standpoints in a specific healthcare context, situations in which definite conclusions can be drawn will probably be rare. Hence, in most cases, ethical analysis will lead to conclusions which do not provide decision-makers with a definite answer as to whether or not the technology should be implemented. In these cases, the prescriptiveness of the conclusions that *can* be drawn will either be balanced by other considerations not appraised in the ethical analysis, or there will be an internal openness in the ethical analysis, because different arguments will support different conclusions and thus a final verdict cannot be arrived at. Nonetheless, some conclusions can be more well-founded than others. It is important that the ethical analysis clearly states to what extent a conclusion is well-founded and stipulates the limitations of these conclusions. The HTA-agency could still present such an analysis: while it might be regarded as an appraisal of sorts, it would still meet the requirement for separation of assessment and appraisal, i.e. limiting the risk that political interests and the preconceived value judgements of decision-makers will influence the objectivity of the assessment.

Notes

Competing interests

The authors declare that they have no competing interests.

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