ORIGINAL ARTICLE

Evaluating facts and facting evaluations: On the fact-value relationship in HTA

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Abstract

Health technology assessment (HTA) is an evaluation of health technologies in terms of facts and evidence. However, the relationship between facts and values is still not clear in HTA. This is problematic in an era of "fake facts" and "truth production." Accordingly, the objective of this study is to clarify the relationship between facts and values in HTA. We start with the perspectives of the *traditional positivist account* of "evaluating facts" and the *social-constructivist account* of "facting values." Our analysis reveals diverse relationships between facts and a spectrum of values, ranging from basic human values, to the values of health professionals, and values of and in HTA, as well as for decision making. We argue for sensitivity to the relationship between facts and values on all levels of HTA, for being open and transparent about the values guiding the production of facts, and for a primacy for the values close to the principal goals of health care, ie, relieving suffering. We maintain that philosophy (in particular ethics) may have an important role in addressing the relationship between facts and values in HTA. Philosophy may help us to avoid fallacies of inferring values from facts; to disentangle the normative assumptions in the production or presentation of facts and to tease out implicit value judgements in HTA; to analyse evaluative argumentation relating to facts about technologies; to address conceptual issues of normative importance; and to promote reflection on HTA's own value system. In this we argue for a(n Aristotelian) middle way between the traditional positivist account of "evaluating facts" and the social-constructivist account of "facting values," which we call "factuation." We conclude that HTA is unique in bringing together facts and values and that being conscious and explicit about this "factuation" is key to making HTA valuable to both individual decision makers and society as a whole.

KEYWORDS

concepts, epistemology, ethics, evidence, facts, health technology assessment (HTA), philosophy, values

"Science is built of facts the way a house is built of bricks: but an accumulation of facts is no more science than a pile of bricks is a house" *Henri Poincaré (1854-1912)*

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1 | INTRODUCTION

In all types of evaluations and assessments, the fact-value distinction is of crucial interest,[1-3] so also in health technology assessment (HTA), which conveys between facts and values on several levels. First, HTA includes the assessment of ethical, social, legal, and cultural aspects, as expressed in many of its definitions, which are clearly value related.[4-6] Ignoring social values in assessing facts may render HTA analysis contentious or of questionable relevance, as illustrated by cases, such as prenatal screening, breast cancer screening, or cochlear implants, where social values have diverted from the outcomes valued by HTA. Second, there are many levels of values at play in the HTA process itself, for example, in the selection of end points and economic models.[7-10] Accordingly, value assessment frameworks, such as multi-criteria decision analysis (MCDA), have been developed for HTA.[11,12] Third, increased stakeholder involvement (with different value perspectives) on all levels contributes in forming and framing the fact-value relationship. Fourth, policy and decision-making level settings increasingly come to play on the information gathering and review level of HTA, potentially influencing the production (and framing) of facts. For instance, strong stakeholder groups and media attention may influence how different aspects are investigated, assessed, and presented. Additionally (fifth), a wide range of (epistemic and nonepistemic) values are in play in the outcomes research that form the input to and foundation of systematic reviews.[13-15] All in all, this makes what is considered to be putatively factual evidence, value laden.

These fact-value interactions are interesting in their own right but become ever more pressing in the so-called postfactual times, ie, times when the truth status of traditional fact producing and conveying institutions are questioned. Even though HTA can refer to a tradition of systematic, rigid, and transparent methodology, the issue of fact production in HTA becomes important in times of plentiful "fake facts." A thorough analysis of the fact-value relationship in HTA becomes more important than ever in order to maintain trust in HTA—with regard to both its process and its results. Even more, attending to this relationship can help ensure that policy decisions are both respectful and reflective of the values and preferences of those affected by the decision, thereby improving the likelihood that stakeholders will accept and commit to decisions based on it.

In this situation, HTA manoeuvres between 2 extremes: gathering and evaluating neutral facts on the one hand (the *traditional positivist account*) and "facting values" (the *social-constructivist account*) on the other. However, HTA does neither only assess existing value neutral facts (on the one hand) nor produce purely value-based facts (on the other). It evaluates facts that are produced because they are considered valuable. Accordingly, the objective in this article is to address where HTA can manoeuvre in this landscape. In particular, we investigate the role of *philosophy* and the importance of sticking to the *goals of HTA*.

2 | EVALUATING FACTS

According to what may be classified as a traditional positivist account, facts are given by observation of nature. Facts are objective and independent of observer and the observed. Whether a person is dead (eg, from acute myocardial infarction) is a fact in that can be verified by any reasonably skilled person. The relevance and importance of such facts are value issues, which are separate from the facts. It is a fact that colorectal cancer (CRC) screening with sigmoidoscopy reduces CRC-related mortality with 27% in Norway.[16] However, which consequences this should have for a CRC screening programme is an issue of value (and currently of significant debate). Correspondingly, the selection of mortality as the most relevant outcome with which to assess the effectiveness of CRC screening is also the result of a series of value judgements.[17]

Health technology assessment has traditionally been based on such a distinction between facts and values. The gathering, systematizing, and synthesizing of information has been considered as the factual (assessment) part and the appraisal of this information as part of or preparing a decision-making process has been considered to be an issue of value (evaluation). To some extent, such a view is based on the conception that technology is value neutral.[18] This distinction between facts and values is explicit within HTA in processes where facts and values are considered to be collected and analysed separately from one another and "integrated" through an appraisal process, for example, deliberation. In such processes, value judgements are considered to enter into HTA only at the point of recommendation development, when value judgements are made about the results of the various assessment domains.[19]

Figure 1 tries to illustrate the traditional divide between facts and values in the process of assessment and appraisal.

Against this traditional (and tenacious) conception, it has been argued that the fact-value distinction is difficult to maintain. From a philosophical perspective, it has been argued that how we see facts strongly depends on our preconceptions and our value system.[20-22] Whether
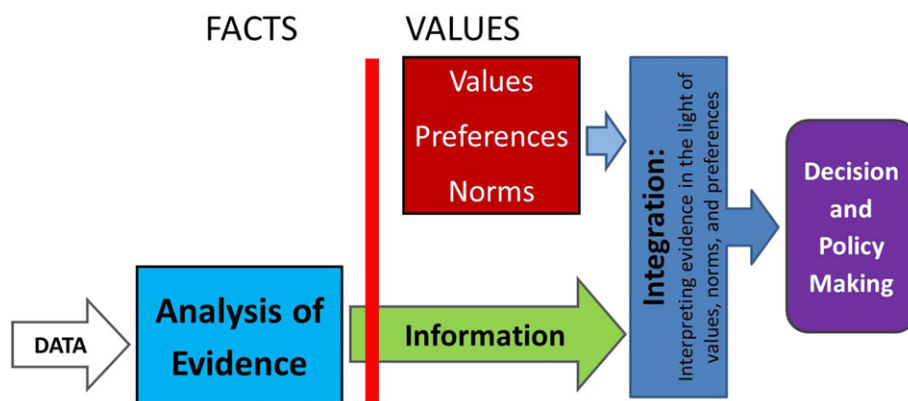

FIGURE 1 Distinction between facts and values in the health technology assessment process

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one sees a person's fatigue as a postviral reaction or as a behavioural (or psychological) condition, does not only depend on observations in nature. How we define death strongly depends on our social commitments (eg, prospective organ transplantation, respect for relatives) and on technology (brain angiogram, magnetic resonance imaging).

In manoeuvring between these 2 extremes in practice, HTA producers and users have implicitly, and sometimes explicitly, imported a view related to the traditional positivist account, and found traditionally in debates about the distinction between science and technology or between pure and applied science. This view is called "the myth of purity."[23] When imported to HTA, it holds that at least some domains of an HTA are "pure." One manifestation of this view is a distinction between "context-free" and "context-sensitive" evidence.[19] We are not implying that evidence cannot be of different kinds, rather our point is that some draw from this difference the (we think, incorrect) conclusion that some facts gathered for HTA are strongly influenced by value judgements or values, while others are not. The results of a randomized controlled trial provide "context-free evidence" while cost-effectiveness analyses provide "context-sensitive evidence." These and similar construals of the facts collected for HTA are perhaps the result of a focus on an insufficiently theorized notion of "objectivity" and a "continuum of objectivity" is a sensible and reasonable way to think about the relation between facts and values. For example, it is stated that Ontario Health Technology Advisory Committee in Canada "relies on reviews that systematically appraise the available evidence in a scientifically sound and objective manner."[24]

Common assessment and appraisal frameworks, such as Grading of Recommendations Assessment, Development and Evaluation, also adopt the "additive" approach displayed in Figure 1 (in which facts and values are "added" together between analysis and decision-making stages) and hence also reflect an assumption about the neat separation between facts and values.[25] An exception to the HTA processes that make this traditional assumption is arguably National Institute for Health and Clinical Excellence, which uses its Citizens Council to debate questions about substantive moral issues that will affect the conduct of its assessments and appraisals. (https://www.nice.org.uk/get-involved/citizens-council [Accessed November, 30 2017]). Another is the Swedish ethical platform for priority setting, decided by parliament and part of Swedish healthcare legislation to guide priority setting in health care and thereby the appraisal of health technologies in Sweden.[26]

Moreover, it has been argued that all the parts of HTA, from selecting a technology for assessment and deciding on end points, population, and comparator, as well as selecting economic models and how to present the results, are strongly value dependent.[7-9,27] Moreover, assessments of effectiveness depend on specific accounts of basic concepts, such as health and welfare, which have normative components.[15] Correspondingly, because HTA is meant to inform a health policy decision, the values of decision making may also influence the assessment and appraisal process.[28] Figure 2 gives an overview of some of the values involved in various parts of health care and its assessment.

In light of this value ladenness, it has been argued that "health technology assessment agencies (HTAs) presently employ value assessment frameworks that are ill fitted to capture the range and diversity of stakeholder values and thereby risk compromising the legitimacy of their recommendations."[29] Involved stakeholders, such as patients, providers, insurers, and citizens or taxpayers, hold a range

Decision making values	Legiti-macy	Justifi-cation	Robust-ness	Open-ness, Trans-parency	Sustain-ability	Partici-patory	Coher-ence	Afford-ability (Budget impact)
Values in HTA	Techno-logy selection	Framing assess-ment	Endpoint selection		Evidence assessment		Economic values	
Value of HTA	Dissemi-nation: Reaching out	Epistemic values:	Process values: Openness, clarity, transparency, systematic		Deliberation: Providing grounds, justification,		Functional value Improving health care	
Profes-sional values	Therapeutic values: Actionability • Intervention • Predictability • Reliability • Validity		Diagnostic values: -Accuracy (val.,relia) -Narrative < -Examination < -Paraclinical signs		Classificatory Values: -Simplicity -Exclusiveness -Exhaustiveness -Practical utility		Esthetical values: Beauty, symmetry	Functional values: Serving a purpose
Social values	Autonomy		Access		Equity		Solidarity	
Person-related values	Existential values, meaning	Empower-ment, Ability, Margin	Hedonistic values		Relational values	Moral values: Do good	Esthetical values: Beauty, symmetry	Functional values: Serving a purpose
Basic Human Values	Life		Pleasure	Pain (avoid)	Health		Reproduction	

FIGURE 2 Various forms of values involved in different aspects of health care and its assessment. HTA, health technology assessment

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of social, epistemic, and other values and may have very different conceptions of what makes specific health interventions valuable.[30,31] Accordingly, stakeholders in pluralist societies may have warranted disagreements on what values that should guide implementation of health technology.[32,33]

As a result of this, the HTA community itself has developed and applied a variety of value assessment frameworks, such as multi-criteria decision analysis.[11,12] Other approaches, such as accountability for reasonableness framework,[34] are procedural but still involve substantive moral judgements.[35] There are also combinations of various frameworks.[29] They try to include value issues in an open, transparent, and dynamic manner and thereby address some of the critique of value neglect in HTA.

3 | FACTING EVALUATIONS

However, some would argue that this may not be radical enough. Including and adding value aspects to factual information is not sufficient. The values of various health technologies are not revealed or discovered but are shaped, constructed, or (re)negotiated.[36] Whether we see obesity as a disease, a risk factor, or a controlling and stigmatizing categorization of human bodies strongly depends on our perspective and our goal.

This way of accounting for values in the assessment of technologies is associated with Science and Technology Studies (STS), where the fact-value distinction is rejected altogether.[3,37,38] Seeing something as a fact is already to make an evaluation. Science and Technology Studies contrasts traditional humanist analysis, which conceives technology as something given (black box) where the main objective is to scrutinize its relations to metaphysics,[39] the human condition,[40] human culture,[41] morality,[42] politics,[43] and the structure of society.[44] It studies how social, political, and cultural values affect scientific research and technological innovation and how these in turn affect society, politics, and culture. In particular, it investigates how technology influences people's perception of the world and human behaviour (in so-called scripts).[45-49] The strong influence of technology on society is sometimes analysed in terms of technology having some kind of moral agency.[46,50,51]

Various forms of technology assessments (TAs) are inspired by STS and other perspectives when assessing technologies. Parliamentary TA, participatory TA, interactive TA, and constructive TA take values into account in the process of assessing technologies, and values are acknowledged in the framing and forming of technologies.

Hence, social (and cultural) values and technology are intertwined and are mutually dependent and shape each other. An external (neutral or objective) assessment is impossible, as values are at play on every level. Facts and values have to be assessed together, according to this perspective. One challenge with many of the STS or TA approaches is how to assess technologies if every fact is a value issue and vice versa. There seem to be limits to what we can make technology do—how we can shape it—and how it can shape our values. Moreover, there seem to be some virtues in having a division of labour between innovation and assessment of technology. Hence, HTA may find some alternatives to adopting STS or TA.

4 | ALTERNATIVE ROUTES

In general, any HTA process that allows space for values to be identified, discussed, or formed will provide an alternative to the radical reconstructions offered above. One alternative is to apply parliamentary TA,[52,53] modified versions of expert TA, or modified versions of HTA.

Another alternative to addressing value issues in HTA is new modes of HTA, eg, integrated HTA for evaluating complex technologies (www.INTEGRATE-HTA.eu). In this model, (social, cultural, legal, and moral) values are addressed in every step of the HTA process, including stakeholder involvement.[54,55] The EUnetHTA Core Model was an early attempt to do something similar by framing the entire HTA against answers to a series of morally relevant questions.[56] While this was done explicitly to safeguard against unethical use of technologies and to provide information about how they can instead be used in a beneficial way, the authors advocated that every HTA process should be performed with consideration paid to 8 ethical issues:

1. The driving forces (and valued interests) behind the plan to perform the assessment at this particular stage should be identified, including the stakeholders and the whole HTA organization.

2. The morally relevant reasons for performing/not performing an HTA on the topic should be identified.

3. The interests of the technology producers should be identified.

4. Possible related technologies that are morally contentious should be identified.

5. The interests of the content expert group should be discussed openly in order for the work to be conducted in an objective and independent way.

6. The choice of end points in the assessment has to be carefully considered.

7. The morally relevant issues related to the selection of meta-analyses and studies the HTA means to include must be identified.

8. The scope of the HTA and the choice of research methods (eg, inclusion of other assessment aspects than effectiveness in the literature searches).

Nevertheless, the practical question of how this might be done and how it could facilitate discussion within a traditional HTA process remains.

One alternative for addressing the fact-value relationship is to scrutinize how technology enables and constrains certain human actions and goals.[57,58] This makes it possible to address the value ladenness of technology without claiming moral agency for technological artefacts. It has also been suggested to pay attention to value judgements in evidence production with respect to (1) choosing outcome measures, (2) balancing benefits and harms, and (3) tolerating uncertainty.[10] Other value judgements have been added elsewhere[8,9], and Figure 2 sums up a broader range of value issues.

Another approach can be to apply the framework from Responsible Research and Innovation, with emphasis on *anticipation* of the

application of technology, *reflexivity* on the innovation, *inclusion* of relevant voices, and *responsiveness* to emergent events.[59] A set of indicators for assessing Responsible Research and Innovation may be relevant for HTA, such as public engagement, gender equality, science education, open access, ethics, governance, sustainability, and social inclusion.[60]

Other relevant approaches take on a forward-looking responsibility in the development of technology.[42,61,62] It is beyond the scope of this article to explore all alternatives to address the fact-value relationship in HTA. Suffice it here to indicate that there is a great variety of approaches, and allow us to focus more particularly how philosophy can contribute.

5 | PHILOSOPHY'S CONTRIBUTION

In this situation, philosophical and ethical analysis can clarify the value landscape in which a specific technology is situated.

First, a basic assumption in much of value or normative analysis is the so-called Hume's law named after the Scottish philosopher David Hume.[63] This law states that we can never logically infer a value or normative statement exclusively from a set of facts or factual statements. Expressed in other terms, that we cannot infer a conclusion about what we should do or what is valuable in a given situation only from the facts about that situation. This implies that in all situations when facts are supposed to result in a normative implication about what to do or value statement about what is valuable, we need to analyse the underlying value assumptions associated with the fact. Or, viewed from another perspective, a fact always needs to be complemented by a number of value assumptions to work as action guiding. Hence, we cannot draw the conclusion that a certain drug should be used simply since it is evidenced to result in increased median survival. Such a conclusion requires that the fact is complemented by a normative statement, eg, that we generally should act as to promote increased survival in people.

Second, by observing the fact-value distinction or divide, and from the need to formulate a value or normative assumption that could complement the fact to result in action guidance, we can start to entangle the complex normative landscape in which this fact appears. Pondering the simplified normative statement above, that we generally should act as to promote increased survival in people, will soon make us realize that it is indeed simplified. What if the quality of life of the person using the treatment is very low, should we still promote survival? What if the person does not want to live any longer, should we still promote survival? Do we have as strong reasons to promote survival for a 90-year-old as for a 10-year-old? A reason why we ask these questions is that there are more or less established norms within the health-care sector where factors like quality of life, autonomy, and distributive justice are taken into consideration. In other words, a fact can thereby be related to different more or less consistent normative systems in play within the health-care system or suggested to apply for the health-care system. Several approaches of doing ethics in HTA try to tease out implicit value judgement in HTA, such as the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) approach, the Socratic approach, and the EUnetHTA Core Model.[56,64,65] More generally, how to evaluate uncertainty and risk is important in producing facts,[66] and risk and safety assessments may exclude other value judgements. For example, the (evaluation of) risks for cardiovascular diseases have directed cut-off values for blood pressure and cholesterol measurement and made hypertension and hypercholesteremia diseases.[67]

This leads us to a third contribution from philosophy and ethics, ie, the ability to analyse evaluative argumentation in relation to a set of facts about a technology. That is, when a certain fact about a technology is established (to the extent it is), we can start looking into whether there are justified grounds or arguments for using it, given these facts. Looking at established normative principles or general action patterns within health care, we can identify arguments in support of using the technology given these facts and counter-arguments not supporting use. These are then related to underlying and more general normative statements to see whether arguments can be consistently held. For example, if it is argued that we should generally promote survival in people, regardless of other features in the situation, this implies that however much suffering this causes in people or even if they do not want to live—we should promote survival. We might then discover that such a norm is not commonly or officially held within the health-care system where we are operating—hence, to uphold consistency, the argument from increased survival needs to be qualified. Such an analysis will also reflect the underlying values guiding which facts are collected about the technology. If only facts about outcome measures in terms of survival are collected, we seem to be operating on a norm that is not actually accepted within the health-care system—this should probably have us complement the assessment of the technology with other outcome measures, etc.

A further insight in philosophical or ethical analysis is the distinction between instrumental and intrinsic values, ie, something having an instrumental relationship to what is valuable or should be done, and that something should be done for principled reasons, regardless of consequences. Hence, a technology could be used since it promotes health, or it could be used since it is in line with respect for autonomy (simply since people want the technology). In the latter case, the actual effects of the technology might be irrelevant or rather, different levels of effects or side effects might be acceptable to different people.

Fourth, being trained in philosophical and ethical analysis, also means to be observant on different conceptual aspects and interpretations of value or normative statements. An interesting feature of value or normative concepts is that they are seldom purely evaluative or normative but often have an underlying descriptive content. However, if a concept has a positive evaluative content and especially if this is a strong positive evaluative content, it tends to be used almost universally within the system to provide argumentative support—but filled with different descriptive content. Few would argue, in favour of a technology, that it restricts autonomy. On the contrary, it might often be argued that it promotes and can be used in a way that respects autonomy. Still, such an argument can mean several different things dependent upon how the concept of autonomy is understood. Is it about decision-making capacity, about access to valued alternatives, about self-sufficiency or independence, etc.? Conceptual analysis, being part of philosophical and ethical analysis, can uncover such conceptual variations and differences, sometimes uncovering that what seemingly is the same argument reflects conflicting views.[68] One

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example of how conceptual analysis is valuable for the analysis of facts and values is the case of obesity: Is obesity a metabolic, a genetic, a social, or a moral condition (weakness of the will)?[69] Whether chronic fatigue syndrome or myalgic encephalopathy is a biomedical (postviral), a mental, or a bio-psycho-social condition is another.

Fifth, starting to analyse individual technologies in this way also provides grounds for a "self-reflective" approach on behalf of the HTA system or health-care system. Which are the general value and normative assumptions of the system? Are they internally consistent? How do they correspond to social or patient preferences in the population it is supposed to serve? Which are the long-term implications of such a system? Such systemic self-reflection will enable us to identify to what extent new innovative technologies can be fitted within the values and norms of the system and to what extent such technologies push the system into new grounds. In the latter case, further analysis of the potential arguments for and against such expansions will enable more justified assessments of whether such expansion of the goals or area of health care is ethically and socially acceptable or not.

Clarifying the value or normative landscape of individual technologies and the HTA system as such will thus provide grounds for transparency about the values and norms underlying decisions and goals. In line with the requirements of accountability for reasonableness,*[70] affected populations can assess whether decisions are made on relevant criteria and decision makers be made accountable. According to theoretical frameworks on what make for legitimacy of the system, this is an essential part. On the other hand, this in turn raises new interesting questions concerning the relationship between social preferences, social acceptance, and trust on one hand and ethical and normative justification on the other—unless we do believe that ethical justification simply amounts to social acceptance (something few ethicists and moral philosophers would agree on).

6 | GOALS OF HTA

Values come into HTA with goals and its methods (through function). The overall goals of HTA coincide with the goals of medicine and health care (ie, to reduce suffering and improve the health of individuals in a society).[71,72] However, the goals of medicine and health care are diverse. In the narrow sense, the objective is to cure or prevent disease, as well as palliate and postpone (where cure is not possible). In a wider sense, the goal is to promote health and well-being. In an even wider sense (policy level), it is "to make the system work." The fact-value

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*Accountability for reasonableness (A4R) is framework for procedural justice, according to which the procedure for how decisions on distribution of resources is relevant for assessing the ethical acceptability of such decisions. The fathers of A4R, Daniels and Sabin, have suggested 4 conditions of such a procedure:[77]

- Publicity—that the reasons for the decisions should be publicly available.
- Relevance—that the reasons for priority setting should be regarded as reasonable and be accepted as relevant by fair-minded people with the ambition to find common ground for cooperation.
- Revision and appeals—that there should be opportunity to appeal for decisions and in light of new evidence and argument revise decisions.
- Regulative—that there should be some form of process to enforce decisions made.

relationship may differ with these goals, in the sense that different goals give rise to the need for answering different factual questions. For example, the facts may support that something is a good health intervention on the level of specific patients but not support that it is so on a societal level or from a systems perspective and conversely. Recent examples of this are orphan drugs that might be effective but not cost-effective and due to high cost, a strain to the system.[73]

There have been several attempts to clarify the goals of and in health care.[71,72] Because of expansions of medicine and health care beyond treating disease and promoting health, eg, towards various forms of human enhancement,[74] this has not been an easy task. Nonetheless, it is possible to give an outline of various values involved in HTA, eg, as given in Figure 2. The figure illustrates how various values are relevant at different levels. For instance, hedonistic values are relevant on most levels, as health care aims at reducing suffering. At the same time, the awareness of various goals makes it possible to identify potential conflicting values. Hence, a focus on values can make it easier to anticipate, understand, and, hopefully, to handle some of the disagreeing values.

Moreover, the same facts may be interpreted differently on the basis of different goals in the health-care system. Correspondingly, different values may make us pursue different facts, eg, related to different end points. The awareness of the goals at play (ie, "the goal play") may be crucial for warranted assessment and for finding a balanced way between evaluating facts and facting values. In HTA, the various levels of evaluation may have different goals and involve diverse fact-value relationships. As indicated, the goals of decision making may conflict with goals of individual patients' preferences of access to treatment and care. This calls for addressing the question of which goals are most relevant for HTA? Is there a hierarchy of goals?

There are no easy answers to these questions; however, this analysis indicates that irreconcilable conflicts may occur when the goals of TA move too far away from basic human values. One way of maintaining a close focus on basic human values is ensure that patients, who arguably have the most to gain or lose from a particular assessment and its subsequent policy action, are involved in HTA. While patient involvement serves a number of goals (scientific, democratic, developmental, and instrumental), it is argued that if an HTA is responsive to and reflects patient values, the overall value judgement made regarding the technology will be better than it would be without this involvement.[75,76] It therefore seems reasonable to argue that higher-level goals, such as getting the systems working, are subordinated to the other goals or function as side constraints for these other goals. If HTA moves too far away from the core goal of health care, ie, to avoiding suffering of individuals, in its endeavour to evaluate facts and facting values, in what in a common term may be called "factuation," it may go astray. For example, if HTA pays more attention to specific goals, such as following evidence hierarchies, providing accurate systematic reviews, or providing policy-friendly reports than on what matters to people's health, it may go awry.

Moreover, the fact-value relationship may differ on the level of assessment and of appraisal. It may be argued that the relationship between facts and values is more specific in assessment than in appraisal, that is, facts relate to a more specific (or a narrower) range of values in the former than in the latter. One reason for this may be that the level of appraisal includes more explicitly acknowledged moral values (in addition to a wide range of epistemic values) than in assessment.

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Correspondingly, the facts relate to a more specific range of values (and thus be easier to define, identify, and delineate) in appraisal than in decision making. Assessment of facts connected to values such as survival, nonmorbidity, and safety—the so-called hard outcomes—is easier to define. When moving to other outcomes, such as quality of life (and other measures with a subjective component), the fact-value relationship gets more blurred. Moreover, values may be more pertinent in some fields than in others; eg, there are more (value-based) debates on facts in fields such as prenatal testing and reproductive technologies than in diabetes care.

In a decision-making and health policy setting, facts relate to an even broader range of values, eg, political values such as access to care and reelection. On this level, facts may be less rigorously related to relieving suffering and to safety and be valued more for their rhetorical effectiveness. No doubt, on this latter level, the fact-value relationship is different than on the first. We do not want to argue that the first is right and the latter is wrong. The point here is more that the fact-value relationship is different on the care provider level and the assessment level than on the decision-making and health policymaking level. It is important to be aware that a relevant fact on the first level might be different from a relevant fact on the last. Therefore, it is important to get the goals of evaluation straight when entering assessment and when producing facts.

It may of course also be interesting to address the issue of how far one on one level should pay attention to the goals on the next level, as the output of one (assessment) is the input on the next (decision making). Correspondingly, it is interesting to observe to what extent goals on a certain level might imply that you ignore facts from the previous level in the decision-making process—especially that negative facts on the assessment level are ignored at the policy level because it is expected that patient wants the technology and this is good for publicity and reelection. However, these issues are beyond the scope of this study and are pertinent topics of further research.

7 | DISCUSSION

In this study, we have outlined various relationships between facts and values and argued that the relationships vary across the diverse levels of health care—from basic human values, to the values of health professionals, and values of and in HTA, as well as for decision making. We have argued that philosophy (and in particular ethics) may have an important role in addressing the relationship between facts and values in HTA in 5 specific ways:

1. Following Hume's law, facts do not direct values. Hence, philosophy can help us to avoid fallacies and hinder us in hiding value issues in facts

2. To untangle the normative assumptions in the production or presentation of facts and to tease out implicit value judgement in HTA.

3. To analyse evaluative argumentation relating to presented facts about technologies.

4. To address conceptual issues of normative importance, as some concepts are strongly value laden.

5. To promote reflection on HTA's own value system in doing HTA.

We have also pointed out that the goals (ie, the values) may differ on various levels of the health-care system (including HTA and policymaking) and that this may result in (hidden) value conflicts and a variety of fact-value relationships. Figure 2 outlines some of these values. Therefore, we have argued that awareness of the value system, and the corresponding variety in relationships between facts and values that may occur, is key to HTA.

Our analysis of the values is by no means exhaustive. The values presented in Figure 2 are not exclusive either. They overlap. The specific values are certainly open for discussion. Hence, the intention with analysing and presenting them here has not been to end a discussion but rather to start it.

Correspondingly, perspectives on the relationship between facts and values are neither exhaustive nor exclusive. We have mainly indicated a span between 2 "extremes" and indicated some alternative routes in-between. Certainly, both the traditional positivist account and the social-constructivist account have strong defenders. Our middle-ground approach (focusing on competing goals in "factuation") may therefore be attacked from 2 sides. We do believe, however, that acknowledging both the pros and the cons of both these "extreme" accounts makes it easier for HTA to manoeuvre in the landscape between evaluating facts and facting values, ie, to make open and transparent "factuations."

Hence, we do neither claim that facts are value neutral (positivism) nor that they are totally produced by social norms and values (ontological relativism). There are limits to what technologies can do and what values they can have. We do not concede to the claim that values are given by facts (as part of a type of ethical determinism). Value-judgements are more than mere expressions of individual preferences (in the case of positivists) and social preferences (in the case of constructivists). They are part of a process of framing the relationship between our goals and aspirations and various constraints. How rational this process is, depends on how well we are able to assess the relationship between facts and values.

No doubt, philosophy, and in particular ethics, can have many other contributions to HTA in its endeavour to manoeuvre between evaluating facts and facting values than those mentioned here. We have only presented a few and focused on some ways that philosophy may contribute. Other contributions are most welcome.

Although we hope that attending to the fact-value relationship can help ensure that policy decisions are respectful of the values and preferences of those affected by the decision, thereby improving the likelihood that stakeholders will accept and adhere to decisions based on it, this does not automatically lead to acceptance of the actual values at stake. More may be needed. However, we do think that acknowledging this relationship is an important prerequisite.

8 | CONCLUSION

In our analysis of the various relationships between facts and values in HTA, we have investigated a variety of values involved and found that the relationship between facts and values may vary across the spectrum of values, ranging from basic human values, to the values of health professionals, and values of and in HTA, as well as for decision making. We have argued for a(n Aristotelian) middle way between the traditional

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positivist account of "evaluating facts" and the social-constructivist account of "facting values," (which may be called "factuation"). We have argued for sensitivity to the relationship between facts and values on all levels of HTA, for being open and transparent about the values guiding the production of facts, and for a primacy for the values close to the principal goals of health care, ie, relieving suffering. In doing this, we maintain that philosophy (and in particular ethics) may have an important role in addressing the relationship between facts and values in HTA. In particular, philosophy may help us to avoid fallacies of inferring values from facts; to untangle the normative assumptions in the production or presentation of facts and to tease out implicit value judgement in HTA; to analyse evaluative argumentation relating to presented facts about technologies; to address conceptual issues of normative importance, as some concepts are strongly value laden; and to promote reflection on HTA's own value system in doing HTAs.

Health technology assessment is unique in bringing together facts and values, and being conscious and explicit about this "factuation" is key to making HTA valuable to health policy decision makers and the health systems and societies that rely on them.

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CONFLICT OF INTEREST

All authors certify that there is no actual or potential conflict of interest in relation to this manuscript, and there are no financial arrangements or arrangements with respect to the content of this manuscript with any companies or organizations.

AUTHOR CONTRIBUTIONS

B.H. made the first outline and the first draft of this paper. L.S. revised the outline and contributed substantially to the content of the manuscript and to all revisions of the paper. K.B. revised the outline, provided important input, and contributed substantially to all revisions of the paper. All authors have improved the final version of the manuscript.

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