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Ethical perspectives on health technology assessment

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This study analyses why ethical aspects play a minor role in health technology assessment (HTA) studies, even when comprehensive approaches of technology assessment are advocated. Technology is often regarded as a value-neutral tool. At the same time, bioethics is dominated by an engineering model. Ethical contributions to evaluation of medical technology should go beyond issues of application in clinical practice and focus also on the definition of problems, the demarcation of technical and nontechnical issues, and the morally problematic implications of technologies.

Keywords: Health technology assessment; Ethics

Technologic advances over the centuries have substantially changed medical care and treatment. Modern medicine and technology have become so intertwined that the physician has become the prototype of technologic man (16). At the same time, it seems that technology and its concomitant changes in health-care approaches, particularly in the relationship between physician and patient, is also the origin of many ethical worries concerning present-day health care. The increasing public debates about potential and actual uses of technology and the differing views and values about human life suggested in individual and social judgments vis-à-vis scientific and technologic innovations, have given rise to bioethics as a discipline and discourse (12).

Although both have emerged from similar concerns with regard to health-care technologies, the relationship of technology assessment and ethics is not very transparent. On the one hand, it is stipulated, for example, in the Swedish study, that HTA is a form of policy research examining the short- and long-term consequences of the application of health technology; such a comprehensive approach includes the assessment of the ethical impact of the technology (4). It is also argued, as in the Dutch study, that mere technical and economic expertise is not sufficient; HTA suggests normative assumptions, and it can help to make explicit the implicit choices in priority setting and health policy (2). On the other hand, it is clear that ethical aspects play a minor role in HTA studies; the initially intended broad assessment soon becomes reduced to economic evaluations. The French study hardly mentions the ethical issues, although it indicates that they are implied in the complexity of issues (15). However, it is articulated that a broader view is necessary because "mere technical expertise is not enough." Normative considerations are often not addressed in the practice of technology assessment. In the English study, the distinction is made between assessment and appraisal, referring values to the realm of the political decision-making process (20). HTA essentially is assessment; it is the process of providing information; its output is knowledge, which then initiates the second stage of appraisal.

All four main studies show that HTA apparently oscillates between two conceptions: a narrow conception focussing on effectiveness, safety, and economic impact of technologies, and a broader conception taking into account the social and ethical consequences of technologies. The narrow conception dominates current practices, although a more comprehensive approach is advocated. The relationship between HTA and ethics is precisely at stake here. Should we view ethics to be an intrinsic or extrinsic dimension of technology assessment? And, if ethics is an intrinsic component of HTA, as I would like to argue, how can ethics research be incorporated into and contribute to HTA studies?

ETHICS AS A DIMENSION OF TECHNOLOGY ASSESSMENT

As the main studies show, technology assessment emerged in the 1970s because of cost considerations; these consideration have been a major stimulus to establishing assessment

agencies and procedures. Several concerns underlie the need for cost control. With the development of new and powerful technologies since the 1960s various concerns have been growing about the uncontrolled introduction of new technologies into health-care practice.

Policy Concerns

Technological innovations create a widening "gap between demand for health services and available resources" (4). This gap could lead to injustices; it demonstrates the necessity to determine health-care needs and priorities.

Clinical Concerns

Although innovations seem a priori beneficial, they are also associated with risks and harms. It was often not clear how to assess the benefit-harm ratio in advance, and how this would work out in applications to various patient categories. Even when a technology had been assessed in advance, it was difficult to control its expansion. Technologies that are useful in a carefully delineated context and for a demarcated patient category are not necessarily beneficial when introduced in a clinical context with an expanding set of indications. The example of dialysis demonstrates how renal technology, as soon as it was accepted in clinical practice, expanded its use to other patient categories (1). In vitro fertilization (IVF) is another example (14).

Social Concerns

Orvain et al. (15) observe that the same HTA topic can be viewed from different angles, satisfying different needs: patients' needs, professionals' needs, and policy needs. However, special efforts are necessary to obtain overviews of patients' expectations and preferences. The role of patient evaluations with regard to new technologies is often insignificant, or selective. In the early IVF literature, patient experiences of infertility are outlined as negative, requiring a technologic solution (19). Introduction of technologies requires public involvement in decision making; assessment should at least go beyond the particular perspectives of specific stakeholders (22).

Suggested in these concerns are moral considerations. Life and health are significant values for all human beings, and new technologies contributing to these values, therefore, are potentially relevant to everybody. A wide range of perspectives should be considered to evaluate the technologies, even more so because the introduction of new care options often impacts on other existing ones. Implicit prioritization could endanger the fairness principle. Moral justification for the use of new technologies, therefore, requires the articulation of as many values and stakeholders as possible.

The point is also that the benefits initially suggested by medical technologies are often different or transformed in practical application where harms to specific patient categories will appear. The promotion of consumer needs is often not as straightforward as assumed. The identification and interpretation of what exactly constitutes benefits and harms is not merely a technical issue but involves value judgments. Moral considerations, therefore, are implicit in the articulation of what are beneficial and harmful effects of technologies for particular patients or patient categories.

The introduction and application of new technologies in clinical practice is sometimes associated with explicit moral quandaries. It is argued that the current bioethics movement has emerged with the application of kidney machines (11;18). Although these were invented decades ago, clinical use was limited until the arteriovenous shunt was discovered; this enabled multiple use for terminally ill renal patients. However, the number of machines was limited, and allocation decisions had to be made. The selection of candidates was delegated by the clinicians to a special ethics committee. These so-called "God-committees" were faced with the impossible task of morally justifying selection of individual patients in the face of life or death. But since then, various selection criteria and mechanisms have been developed and analyzed (13).

Medical technologies also produce moral questions regarding appropriate use. In many cases—for example, life-supporting technologies—it is debatable when, how long and how intense interventions should be applied; the balance of benefits and harms is often fragile. The availability of a technologic intervention itself can dictate its applicability, leaving patients, and also sometimes health-care professionals, no choice. This was the issue with the new resuscitation technologies and the creation of intensive care units (27). The urge to attempt to save human life, even if the probability of success was rather low, was so strong that it became necessary to redefine the notion of death (because the traditional notion was obsolete when the new technology was applied). These technologies also led to debates on the limits of medical interventions, necessitating the development of nontreatment policies, and discussions on the notion of "futility."

The above examples show that moral considerations are implicitly or explicitly associated with the development and use of health-care technologies: value judgments are inherent in determining the effects, and moral problems themselves can be generated by technologies. If this is true, examination of moral aspects cannot be excluded from the evaluation of health-care technologies. It also implies that ethics should be an intrinsic component of the evaluation of technologies.

WHY IS ETHICS OFTEN NOT INCLUDED?

The Swedish study argues that we need to reinvent the concept of health-care technology assessment, transforming it into more comprehensive evaluation research (returning to the broader notion of HTA of the early days) (4). That is, we should go beyond the dimensions of safety, effectiveness, and cost-effectiveness. It also suggests that recommendations are not only science-based but also normative and require an examination of the relevant value judgments. Although this

proposal should be endorsed, it is important to explain why ethics thus far has not often been included in HTA studies.

Evaluating medical treatment is usually one-dimensional: selected parameters are limited in number and have a quantitative biomedical character. Evaluations tend to work within the domain of the dominant medical paradigm, proceeding with a well-defined benefit model. This model contains one or more well-defined measurable effect parameters or "output" parameters, scrutinized in terms of efficacy. The model also provides an explicit hypothesis describing the assumed relationship between the modifying parameter and what is being modified. It should also make explicit what risks and costs are involved. For example, in evaluating cochlear implants, the input will be the implant, the causal hypothesis the bypassing of a malfunctioning cochlea to a functional auditory nerve and intact central auditory pathways, the output is measured in terms of functional audiologic gain, and risks are quantified in terms of medical complications (28). When these implants were first used in children, the assumption was that, with the aid of implants, deaf children can learn to communicate; what could be more valuable than restoring hearing capacities in erstwhile deaf children? To the surprise of many, the deaf community itself protested against cochlear implants in children, by arguing that the new technology threatens the slowly obtained recognition of the specific culture of the deaf, namely sign language and communication systems developed within the world of the deaf. Now that it is accepted that the deaf are physically inconvenienced but not handicapped or disabled, implant technology may reintroduce the idea that deafness is a physical defect that is reparable. The point is that instead of being able to create their own world and instead of being accepted in a shared culture, the deaf will now be pressured into adapting to the world of hearing. This adaptation will be necessarily partial and incomplete. Learning to communicate with implants is more difficult than learning sign language, and the result of implantation is always imperfect. This result will continuously reinforce the marginality of those who cannot meet the standards of the hearing world without technical aids. This critical patient perspective illustrates that there is a dissimilarity between "effect" or "output" and "benefit." Identification and measurement of output presuppose some concept of benefit, which is often too restrictive because it is developed from the dominant medical paradigm. That we can improve hearing through cochlear implantation is easily equated with benefiting deaf children. From a medical perspective, restoration of bodily dysfunction is regarded as being beneficial to patients. However, this perspective not only gives priority to bodily functioning, but also to some level of social functioning: it assumes that oral communicative skills are necessary to realize a child's future opportunities. Precisely this normative assumption is contested by the deaf community itself: a deaf child's best interest is not determined by his or her future speech ability alone (17).

Similar controversies have arisen in the context of other technologies, especially life-sustaining technologies. Here, the assumed effect is also often equated with benefit. If human life is at stake, it is considered evident that making a treatment effort and running into failure is better than not attempting to treat and face certain defeat. This "no lose philosophy" drives health professionals into "activism," often disregarding a wider benefit perspective (21). "Being alive" does not necessarily suggest a "good life." Rather than asking whether a new technology brings immediate relief to a medical problem, questions should be asked about likely long-term medical consequences, the state of life that has been saved, and the meaning of the overall life of the patient (3). In other words, the value of medical treatments and interventions should always include the nonmedical context in which people live their lives.

Ethical analysis is rarely incorporated in HTA studies for two reasons. First, technology has a particular conceptualization in present-day evaluation research, demarcating it from ethical issues. Second, bioethics is often regarded as a specific technology itself, aimed at resolving or at least "pacifying" the moral consequences of the use of medical technologies.

The relation of ethics and HTA is first of all determined by the view of whether technology is value-neutral or value-laden (9). According to the first view, technology itself is neither good nor bad; it represents value-neutral means to an external end. It seems that this value-neutrality view is the most dominant one in the area of HTA (3;10). It is common to differentiate between direct and indirect effects of technology, or technology assessment in a narrow and broader sense. The moral dimensions of new technologies used to be considered as "second-order consequences"; they arise at the policy level when the data of evaluation studies must be implemented into health-care practice. This conception of HTA implies that ethics does not belong to the core processes of assessment. Values are not intrinsically connected with technology itself, but they are related to its application. Elsewhere, it is argued that this distinction originates from problematic presuppositions regarding the relations between technology and society, knowledge and its application, information and decision making, and the medical and nonmedical domains (25). A modified neutrality view also underlies the distinction made between assessment and appraisal (20). Assessment is the scientific analysis, gathering and summarizing information and producing knowledge. Appraisal is the political process of decision making, taking into account information as well as values. The evidence produced by assessment must be interpreted within a framework of values and preferences to generate a decision. Whereas Stevens and Milne restrict HTA to assessment, Carlsson (4) argues for a broader concept of HTA, combining the descriptive, scientific approach with the normative, pragmatic role of policy recommendations. However, Carlsson's argument presupposes the usual notion that technologies can be scientifically assessed without implicating values.

The second reason for the difficult relation between ethics and HTA is related to bioethics itself. Bioethics has

developed into an autonomous discipline assisting health practices, but it has also become a component of the technologic order (6). It is dominated by an engineering model of moral reasoning using the idea of technologic rationality in addressing a particular set of practical problems through the application of moral principles (in particular the principle of respect for autonomy). In this approach, bioethics is a sophisticated technology to make a particular set of (potential) problems manageable and controllable (25). Usually the focus of ethical analysis is narrow and not too critical. That technology confronts us with moral problems is, according to philosophers such as Habermas, Foucault, and Illich, basically related to the penetration, domination, or even "colonization" of our life and world by science and technology. The answer to such problems cannot be given by an ethics that is itself technologically orientated. In fact, a type of bioethics that is approaching moral problems in an engineering way, technically applying principles to cases and dilemmas, has become itself another manifestation of the same basic problem.

HOW CAN ETHICS CONTRIBUTE?

A repositioning of ethics will be necessary to uncover and analyze the moral dimension of practices of developing, testing and using technologies in the context of health care. The following distinction is helpful to specify the potential contributions of ethics in connection with medical technology assessment.

First, there is the category of moral questions arising within the framework of the particular technology. Examples are debates about the moral status of the embryo in the context of stem cell technology (examining whether the fertilized or "activated" egg is similar or different from the "traditional" embryo), or about the conditions for gamete donation. Questions of this type remain inside the framework of the technology; they proceed from the acceptance of the technology as a datum, trying to define its responsible and appropriate use. This type of question is usually addressed in HTA studies—in those studies that include any ethical analysis at all. The theoretical framework for these ethical studies is provided by the present-day conception of "applied ethics": this is, the application of general ethical theories, principles and rules to specific problems which may arise in health-care delivery, research, and therapeutic practice (26). The aim of the ethical contributions is to analyze these problems and to offer solutions that are morally justified. The main instrument of this approach is a set of moral principles. Usually three or four basic principles are used: respect for autonomy, beneficence, non-maleficence (which is sometimes included in beneficence), and justice. These principles are considered to be basic, because they are general judgments serving as justification for particular prescriptions and evaluations of human actions. Principles are normative generalizations that guide actions. From principles, ethical guidelines and rules can be derived. The advantage of the (four) principles is that they are defensible from a variety of theoretical moral perspectives. They provide an analytical framework, a universal tool, to clarify and resolve moral issues (8).

The principles approach in analyzing moral issues is usually very helpful in identifying and mapping out the relevant moral considerations regarding medical technologies and services; it is also instructive because it points out where further studies are required. For example, in transplantation of organs from living human donors, three fundamental issues are identified: the risks and harms affecting the donor, and questions about voluntary consent, and buying organs harvested from the living (5). The principles of beneficence and non-maleficence generate moral concerns about justifying harm to the donor. Is it justified to remove somebody's kidney when the removal harms the healthy person without producing any medical benefit to him or herself? Or is the donor more harmed by the loss of a family member or friend than by the loss of a healthy kidney? The principle of respect for autonomy generates concerns about consent. If an adult person is asked to give informed consent to surgery to remove a kidney for a family member, can the consent be truly voluntary in such circumstances? In the case of a child whose kidney is the best match for a sibling, can the parents give consent? A decision to "donate" is clearly not in the best interests of the child. Finally, the principle of justice generates concerns about the donation and transplantation systems. What kind of criteria are used to allocate donated organs within a particular area? At the same time, it seems that commercial arrangements are increasingly used, although the sale of organs for transplantation is prohibited in many countries.

The moral issues identified by using the principles approach show that two methodologic approaches need to be combined: empirical and theoretical studies (23). To know, for example, whether the autonomy of potential donors is compromised in practice, ethicists need to engage in empirical research. To evaluate the probability and extent of harms and benefits, ethicists need to use or produce quantitative data. Insights into the factual dimensions of a technology are required before these can be assessed from normative points of view. The moral principles identify not only which facts are relevant for further consideration from a moral point view, but they also provide a normative framework for further assessment. Theoretical research here requires analysis of the philosophical and ethical literature, articulating, for example, the implications of deontologic and teleologic ethical theories with regard to the problems at hand. Usually, this is intensive and innovative work, because the existing literature has rarely foreseen or addressed the moral issues arising in present-day medicine.

Ethics can also contribute to technology assessment by going beyond the framework of the technology itself. It then concentrates on a second category of moral questions. Within this category, analysis focuses on the question of whether the

technology, as such, is justified in the light of moral values. Here, ethical analysis does not, a priori, take the technology for granted. It starts from a critical perspective, assuming that technologies are not value-neutral but incorporate particular values themselves. Technologies are expressions of values, such as the values of searching for knowledge, having offspring, or relieving suffering. However, these values are often implicitly given and not articulated. Ethical research is now taking them as the starting point for a debate on (other) motivating values in society. This type of research focuses on values underlying or embedded in the development of technology itself. For example, studies in this category will not take for granted that the progress of transplantation technologies is beneficial. They will question the specific framing of notions such as personal integrity, altruism, death, and body, which is associated with these emerging technologies (7). They critically examine the implied notion of "body ownership," where the moral principle of respect for autonomy is indeed helpful to facilitate organ donation but at the same time reiterates the traditional dualistic image of the human person: an autonomous subject with a material body as its property (24). These studies will also explore the recent expansion of these technologies with cell and gene transplantation. They call attention to the claims of perfectibility and immortality, often implicit in the bewildering progress of stem cell technologies, and relate such claims to a philosophical, and sometimes utopian, body of knowledge. The methodology of such studies is historical as well as synthetic. They attempt to provide a diachronic and synchronic perspective: values embodied in current technologies are explained in connection to similar values in history, but they are also clarified in connection to developments in other scientific disciplines, thus looking beyond the framework of present times and existing disciplines. The presupposition of this type of ethics research is that ethics, first of all, is the philosophical and theologic effort to understand ourselves and our existence in terms of what is desirable or undesirable, supportable or reprehensible, good or bad.

The second type of research in this category of ethics contributions to HTA focuses on the values of the stakeholders involved or affected when the technology is introduced in the health-care system. Recent studies of the introduction of pediatric cochlear implants have set examples, although retrospectively. They have used a narrative ethical analysis of the "moral landscape," interviewing parents of deaf children and examining their experiences before diagnosis and some time after diagnosis when crucial decisions must be made regarding language and education (28). Some studies have tested the method of interactive evaluation to identify and analyze the multiple, often contradictory, perspectives of the different persons involved (17). Compared with the traditional biomedical model, these types of studies provide a much richer perspective of relevant values that need to be taken into consideration in the political decision-making process.

CONCLUSION

The country studies demonstrate that a gap exists between ethics and technology assessment. This gap is remarkable, because systematic assessment of technologies has originated from normative worries over the uncontrolled introduction of new technologies into health-care practice. On the one hand, this is due to the narrowing down of HTA to economic analysis. Insufficient impact on policy decisions and unwanted displacement of allocation decisions from the macro-level of prioritization to the relatively private context of individual physicians and institutions have initiated calls for a broader approach and reinvention of the concept of HTA (2;4). On the other hand, bioethical approaches are often themselves impregnated with technical rationality. However, in two ways, ethics may contribute to evaluating medical technologies. First, by mapping out the relevant moral issues that arise within the framework of specific technologies. Second, going beyond this framework, by recasting the way problems are defined, by exploring the interrelations of technical and nontechnical issues, and by accepting that the current technical framework with which technology is generally analyzed is problematic.

REFERENCES

1. Bayer R, Caplan AL, Daniels D. *In search of equity. Health needs and the health care system*. New York, London: Plenum Press; 1983.
2. Berg M, van der Grinten T, Klazinga N. Technology assessment, priority setting, and appropriate care in Dutch health care. *Int J Technol Assess Health Care.* 2004;20:35-43.
3. Callahan D. *What kind of life. The limits of medical progress*. New York: Simon and Schuster; 1990.
4. Carlsson P. Health technology assessment and priority setting for health policy in Sweden. *Int J Technol Assess Health Care.* 2004;20:44-54.
5. Devettere RJ. *Practical decision making in health care ethics. Cases and concepts*. Washington DC: Georgetown University Press; 1995.
6. Elliott C. *A philosophical disease: Bioethics, culture and identity*. New York, London: Routledge; 1999.
7. Fox RD, Swazey JP. *Spare parts. Organ replacement in American society*. New York, Oxford: Oxford University Press; 1992.
8. Gillon R, ed. *Principles of health care ethics*. Chichester: John Wiley & Sons; 1994.
9. Hofman B. On the value-ladenness of technology in medicine. *Med Health Care Philos.* 2001;4:335-346.
10. Hofman B. Technological medicine and the autonomy of man. *Med Health Care Philos.* 2002;5:157-167.
11. Jonsen AR. *The new medicine and the old ethics*. Cambridge, MA, London: Harvard University Press; 1990.
12. Jonsen AR. *The birth of bioethics*. New York, Oxford: Oxford University Press; 1998.
13. Kilner JF. *Who lives? Who dies? Ethical criteria in patient selection*. New Haven, London: Yale University Press; 1990.

14. Kirejczyk M. *Met technologie gezegend? Gender en de omstreden invoering van in vitro fertilisatie in de Nederlandse gezondheidszorg*. Utrecht: Uitgeverij Jan van Arkel; 1996.
15. Orvain J, Xerri B, Matillon Y. Overview of health technology assessment in France. *Int J Technol Assess Health Care.* 2004;20:25-34.
16. Reiser SJ. *Medicine and the reign of technology*. Cambridge: Cambridge University Press; 1978.
17. Reuzel RPB. *Health technology assessment and interactive evaluation: different perspectives*. Thesis. University of Nijmegen: Nijmegen; 2002.
18. Rothman DJ. *Strangers at the bedside. A history of how law and bioethics transformed medical decision making*. New York: Basicbooks; 1991.
19. Stephenson P, Wagner MG. *Tough choices. In vitro fertilization and the reproductive technologies*. Philadelphia: Temple University Press; 1993.
20. Stevens A, Milne R. Health technology assessment in England and Wales. *Int J Technol Assess Health Care.* 2004;20:11-24.
21. ten Have HAMJ, Kimsma GK. *Geneeskunde tussen droom en drama. Voortplanting, ethiek en vooruitgang*. Kampen: Kok Agora; 1987.
22. ten Have HAMJ. Letters to Dr Frankenstein? Ethics and the new reproductive technologies. *Soc Sci Med.* 1995;40:141-146.
23. ten Have HAMJ, Lelie A. Medical ethics research between theory and practice. *Theor Med Bioethics.* 1998;19:263-276.
24. ten Have HAMJ, Welie JVM, eds. *Ownership of the human body. Philosophical considerations on the use of the human body and its parts in healthcare*. Dordrecht, Boston, London: Kluwer Academic Publishers; 1998.
25. ten Have HAMJ. Medical technology assessment and ethics. Ambivalent relations. *Hastings Center Report*, 1995;25:13-19.
26. ten Have HAMJ, Gordijn B, eds. *Bioethics in a European perspective*. Dordrecht, Boston, London: Kluwer Academic Publishers; 2001.
27. Wackers GL. *Constructivist medicine*. Maastricht: Universitaire Pers; 1994.
28. Wever CC. *Parenting deaf children in the era of cochlear implantation. A narrative-ethical analysis*. Thesis. University of Nijmegen: Nijmegen; 2002.