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SCIENTIFIC CONTRIBUTION

Health technology assessment (HTA): ethical aspects

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Abstract "HTA is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused, and seek to achieve best value" (EUnetHTA 2007). Even though the assessment of ethical aspects of a health technology is listed as one of the objectives of a HTA process, in practice, the integration of these dimensions into reports remains limited. The article is focused on four points: 1. the HTA concept; 2. the difficult HTA-ethics relationship; 3. the ethical issues in HTA; 4. the methods for integrating ethical analysis into HTA.

Keywords Technology · Health technology assessment · Ethics · Health policy

Introduction

During the last four decades, technological innovation has undoubtedly yielded significant advances in health care. Breakthroughs in areas such as biotechnology, antivirals, surgical techniques, molecular diagnostics, diagnostic imaging, organ and tissue replacement, wound care, computer technology, etc. have helped to improve health care delivery and patient outcomes (Goodman 2004, pp. 9–10).

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As a first step, it could be useful to bear in mind that the expression 'health technology' does not refer just to medical technology. In fact, according to the *Health Technology Assessment* (*HTA*) *Glossary*, edited in 2006 by the International Network of Agencies for Health Technology Assessment (INAHTA), "it covers a wide range of methods of intervening to promote health, including the prevention, diagnosing or treatment of disease, the rehabilitation or long-term care of patients, as well as drugs, devices, clinical procedures and healthcare settings" (INAHTA 2006).

A rapid introduction and diffusion of technologies within healthcare systems has followed the technological innovation. For example, in the United States, the coronary bypass surgeries realized in non-federal hospitals were 53,000 in 1974, 137,000 in 1980, 284,000 in 1986 and so on, with a continuous diffusion during the years (Preston 1989).

The diffusion of health technologies has accompanied burgeoning health care expenditure, and the first has been generally considered as a 'culprit' for the second, although nature and development of this relationship are complex and evolving (Vanara 1998; Lucioni 1986).

In this age of increasing cost pressures, restructuring of health care delivery and payment, and continued inadequate access to care for many millions of people around the world, technology is—as C·S. Goodman has highlighted—the 'substance' of health care (Goodman 2004).

The use and implementation of technology is increasingly mediated by a widening group of policy-makers in the health care sector. In fact, health product makers, clinicians, patients, hospital managers, payers, political leaders and others increasingly demand well-founded information to support decisions about whether or how to implement technology, to allow it on the market, to acquire it, to pay for its use, and so on.

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The birth and diffusion of HTA in government and the private sector probably reflect this kind of demand (Cicchetti and Marchetti 1999; Cicchetti 2003): this research field has played a more and more important role in many European and North-American hospital organizations, to the point that nowadays it maybe represents the most functional support to the management in decisions regarding the implementation of technologies.

Moreover, HTA could represent also a new and stimulating field of bioethical reflection: although the ethical level represents a constitutive and not extrinsic element of HTA—as we will try to show in this contribution—until now it has been little debated in literature and in HTA reports.

HTA definitions, purposes, origin and diffusion

As HTA organizations and agencies are a large number, its definition is not univocal. For example, the INAHTA (2006) defines it as "the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences". Whereas, according to the European Network for Health Technology Assessment (EUnetHTA 2007), HTA can be defined as "a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner".

On the contrary, its general purpose is clear: to advise or inform technology-related health policymaking (INAHTA 2006) or, in other words, "to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value" (EUnetHTA 2007).

Instead, more particularistic and practical aims—as Goodman (2004) has underlined—could be, for example: to advise or to inform regulatory agencies "about whether to permit the commercial use (e.g., marketing) of a drug, a device or other technology; (…) clinicians and patients about the appropriate use of health care interventions for a particular patient's clinical needs and circumstances; (…) government health department officials about undertaking public health programs (e.g., vaccination, screening, and environmental protection programs); (…) health care product companies about product development and marketing decisions" and so on.

In short,—as R.N. Battista (1996) has noted—"health technology assessment is a bridge between the world of research and the world of decision making, particularly policy-making". Moreover, HTA seeks to couple evidence with decision-making, and thus has similarities to evidence-based health care and evidence-based policy making.

The expression HTA was first employed in the United States Congress in about 1967 and it was originally used in the areas of environmental issues and developments in the physical sciences; later, the attention was increasingly on health technologies.

In this regard, the U.S. Congressional Office of Technology (OTA) establishment in 1972 showed itself to be very important. Simultaneous with the beginnings of the OTA, Swedish researchers began to assess selected health technologies. The pressures were similar: high expenditure for health care, the new technologies' implementation and the necessity to begin to rationalize health care technologies (Banta 2003).

As the ideas of health technology assessment gradually spread to other countries, formal technology evaluation activities started. During its 40 years of existence, HTA has expanded enormously, both in terms of people involved and in importance. It has widened its scope and improved its arsenal of analytic techniques, attracting researchers from around the globe and leading to the establishment of several governmental and private agencies, some of them united under well-structured international networks as, for example, the INAHTA, the Health Technology Assessment International (HTAi) or, more recently, the EUnetHTA.

At a European level, three important projects contributing to the development of cooperation in HTA and to the establishment of a culture of evidence-based decision-making have been realized: the *EUR-ASSES* (1994–1997), the *HTA-EUROPE* (1997–1999) and the *European Collaboration for Health Technology Assessment/The European Collaboration for Health Interventions Project* (*ECHTA/ECAHI*) (1999–2001).

In the European Union (EU) Member States HTA activities are increasingly important, and at present almost all have a national focus for HTA associated with the Ministry of Health or its equivalent.

In 2004 the European Commission and the EU Council of Ministers targeted this research field as "a political priority", recognizing "(…) an urgent need for establishing a sustainable European network on HTA", that is the *EUnetHTA Project* (EUnetHTA 2007). Moreover, a Commission call was answered in 2005 by a group of 35 organizations throughout Europe, led by the Danish Centre for Evaluation and HTA (DACEHTA) in Copenhagen.

Nowadays, the EUnetHTA[1] coordinates the works of 29 European countries including 25 Member States of the European Union in assessing health technology in Europe.

[1] The *EUnetHTA Project* has concluded its work with a conference on "HTA's Future in Europe" held in Paris on November 20, 2008 and it is going to begin a permanent activity, named *EUnetHTA Collaboration*.

HTA and ethics

As S·I. Saarni et al. (2008, p. 617) have rightly noted within a HTA process, ethics is important for three fundamental reasons: "First, implementing health technologies may have moral consequences, which justifies adding an ethical analysis to a 'traditional' assessment of cost and effectiveness. Second, technology also carries values and may challenge prevalent moral principles or rules of society that should be addressed by HTA. Third (…) the whole HTA enterprise is value laden".

Within a HTA process, the ethical assessment could be considered as the evaluation of both the ethical issues raised by the technology itself and the ethical issues that are related to the HTA process.

Moreover, according to the useful E. Heitman's scheme (1998), the ethical questions in HTA can be arranged into five categories:

1. Issues related to 'concepts' and 'definitions' (inherent in HTA processes)[2];
2. Issues related to 'diagnostic procedures' (limits, risks, use, etc.);
3. Issues related to 'preventive strategies' (for example, risk management of pathologies) and 'therapies' (evidence, effectiveness, proportionality, etc.);
4. Issues related to 'research' (guardianship of subjects enrolled in trials, informed consent, etc.);
5. Issues related to 'resource allocation' (distributive justice, mechanisms of rationing, economic evaluations, etc.).

Even though the assessment of ethical aspects of health technology is listed as one of its objectives, in practice, the integration of these dimensions into HTA reports remains often limited (Ashcroft 1999).

H. ten Have (1995, pp. 13) affirms that such a situation is paradoxical: in fact "wishing to control the processes by which medical technology is developed, introduced, and used, and being concerned about the moral implications of new technologies, governments, agencies, and individual scholars have developed programs of technology assessment; however, such programs mainly focus on effectiveness and safety, and hardly address in a systematic way the moral concerns that were part of their genesis".

In confirmation of this, a search conducted by P. Lehoux and S. Blume (2000)—on the *1999 International Society of Technology Assessment in Health Care* (*ISTAHC*) *CD-ROM database* containing abstracts presented at its annual meetings (1994–1998) and all abstracts of papers published in the *International Journal of Technology Assessment in Health Care* (1985–1999)—showed that from a total of 2,906 records, 19 records contained the word 'ethical' in their title. A search of the abstracts was slightly more encouraging: 80 'ethical' (2.8%).

In 2003, the German HTA group, Deutsches Institut für Medizinische Dokumentation und Information (DIMDI), arrived at similar conclusions in their analysis of "short assessments on medical technologies" published worldwide (282): 25 reports (9%) described ethical issues, whereas 32 (11%) referred to such issues without defining them explicitly (Droste et al. 2003).

The reasons of the difficult ethics-HTA relationship are several (ten Have 2004): 1. Technologies are often considered by HTA producers as being ethically neutral and value-free; 2. the only questions perceived as relevant are technical and economical ones; 3. there are difficulties to integrating ethical considerations in HTA; 4. the training of HTA producers and available resources to conduct ethical analyses are often limited.

On the contrary, bioethics has shown enough that values are intrinsically connected with technology (Ellul 1954; Jonas 1987; Pessina 1999).

Furthermore, Lehoux and Blume (2000) have remarked that "because health technologies embody a variety of social and political implications for individual and society, technologies cannot be considered only through the narrow lens of cost-effectiveness (some more or less effective or affordable) (…). Evaluators can hardly ignore the growing claims made by and on behalf of consumer groups, and public policies need to be informed by the multiple values that prevail in a given society". In other words, costs and effectiveness of health technologies are extremely important dimensions to consider in public policy, but they are far from sufficient to exhaust all concerned questions.

So, ethical analysis must be considered a mandatory element of a HTA process.

The research methodologies

Once the importance of ethical analyses is admitted, the question of "how" to integrate ethical analyses in HTA reports comes up (Autti-Rämö and Mäkelä 2007; Hofmann 2005). In fact, they can be conducted very differently depending on the resources in the HTA organization, the technology in question and, above all, the research methodology.

A survey—started by the INAHTA and proceeded by the EUnetHTA—has underlined the variety of approaches for this type of assessment (Lampe and Mäkelä 2007).

[2] On this matter, A.J. Braunack-Mayer (2006) claims a distinction between ethical assessment *in* HTA ("it takes as its object of interest the analysis of ethical problems as they arise within the context of new technologies") and ethical assessment *of* HTA ("it is concerned with studying such as the organizational structure, role relationship, value system, rituals, and functions as a system of behaviour").

Casuistry, Coherence analysis, Principlism, Interactive, participatory HTA approach, Social shaping of technology and Wide reflective equilibrium have turned out to be the most used methods. Further approaches—defined as 'local'—are: Value analysis of the Norwegian Knowledge Centre for Health Services (NKCHC), Eclectic approach of the Finnish Office for Health Technology Assessment (FINOHTA), Promoting context-specific, integrated approaches of the French Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) and the Triangular model.

In short, the Triangular model[3]—based on a cognitivist aristotelic-thomistic ethical perspective—is founded on the concept of the human person as reference-value in the reality, into which all ethical judgements should be steered (Sgreccia 1986, 2007; Sacchini et al. 2005; Sacchini and Refolo 2007; Carrasco de Paula 2004; Maritain 1951; Seifert 1989).

Omitting the explanation of the theoretical aspects for the sake of brevity, this approach practically realizes ethical evaluations through three fundamental steps (Sgreccia 1986, 2007): 1. data collection (gnoseological level); 2. ethical/anthropological analysis (justifying level); 3. ethical evaluation (normative level).

First step (the point "A" of an ideal triangle) is an in-depth study of all factual data concerning the technology in question. In order to achieve it, putting these questions could be fruitful: a. what is it about?; b. how is it to be done?; c. why is it to be done?; *d.* what consequences?

Second step (point "B") is the ethical and anthropological understanding of facts or, in other words, the analysis of eventual values at stake or in conflict. In order to realize it, the following operating criteria/principles are utilized: *a.* the defence of human physical life; *b.* the contextual exercise of freedom and responsibility within the decision-making process; *c.* the safeguard of the therapeutic principle, according to which the human person has to be treated as a whole of body and soul; *d.* the principles of sociality and subsidiarity, for which public and private authorities are called to help all persons in need.

The third step (point "C") consists of the ethical evaluation that should guide the practical choices.

This approach intends to highlight a triangular connection among bio-medicine, anthropology and ethics. In particular, it affirms the importance to conduct ethical analyses referring to an anthropological view whose lack would make the process of analysis incomplete. Other methods (for example Casuistry or Principlism) do not take the anthropological factor into account in this manner.

[3] This approach is adopted by the Institute of Bioethics of the Università Cattolica del Sacro Cuore, Rome (Italy).

Conclusion

Nowadays, HTA, whose diffusion is almost worldwide, represents the most functional support to the management in decisions regarding technologies implementation.

From the beginning, this type of interdisciplinary research has also provided for the assessment of the ethical aspects of a certain health technology, even though, at the time, the integration of this dimension into reports remains rather limited.

Nevertheless, different research methodologies for the ethical analyses elaboration are already debugged. This heterogeneity could represent a further element of difficulty for integrating ethics into HTA.

On this matter, an interesting and promising attempt that could help to overcome such obstacles is represented by the EUnetHTA model on ethical analysis (Lampe and Mäkelä 2007).

It is formed by three elements: a set of questions that concern the fundamental issues for ethical assessment; a description of methods according to which the different issues could be approached; and the debate on the process of integration of ethical assessments into HTA reports" (Saarni et al. 2008, p. 618).

As Saarni et al. (2008, p. 618) have observed, "the model does not purport to solve the philosophical debate but to offer a tool usable by HTA organizations, irrespective of their resources (material, time and knowledge)".

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