

HTA REPORT | VOLUME 9 | EXECUTIVE SUMMARY**Methods for the assessment
of ethical aspects and moral
concepts in society in short
HTA reports – an interna-
tional survey****Droste S, Gerhardus A, Kollek R**HTA Schriftenreihe, Band 9, Hrsg.: Dauben,
Rüther, Warda, Köln, 2003. ISBN 3-89906-732-0.**BACKGROUND**

To do a health technology assessment means evaluating a medical technology complete and comprehensive. For coping with this, it demands – besides the consideration of medical effectiveness and economic efficiency – to look at the patients' perspective, at psychological and last but not least at ethical aspects. In conclusion, ethical aspects and moral concepts of society are playing a meaningful role in many medical technologies: for example in oncology, in genetics, in transplantation medicine, in prenatal diagnostics or in screening tests. Questions of autonomy, beneficence, maleficence, proportionality and justice are to be carefully examined according to the individual and the social level. It particularly demands rapid assessments, because they were done more often for newer or up to now little evaluated technologies.

Thus, there are to exercise in the following analysis of existing rapid health technology assessments the questions:

- whether and to what extent ethical aspects and moral concepts are discussed,
- which ethical aspects are presented and discussed and
- whether there are introduced methods for systematic acquisition and the consideration of ethical aspects.

METHODS

A systematic search for short assessments on medical technologies is carried out in common databases, like the Cochrane Library, MEDLINE, EMBASE, Sociological Abstracts etc. and on websites of worldwide HTA institutions. Included were all publications stated as rapid, short or brief assessment in title or abstract. Furthermore, the publications had to be written in German, English or French. No exclusion criteria have been defined.

But only those rapid assessments have been included which have been available as complete document. The identified assessments were analysed by means of a self-developed working definition on ethical aspects and moral concepts of society (there are many existing, partly very extensive definitions, but in the context of the analysis they are not workable concerning ethical aspects and moral concepts of society.).

RESULTS

By means of the described methods, there could be identified 513 rapid assessments. Overall 282 of these rapid assessments were included in the analysis. 231 rapid assessments were not available as complete document for different reasons and have not been considered. The ethical principles of bioethical principlism and interrelated terms are widely-used in evaluation-oriented discussions and therefore they are well suitable as subheadings in medical databases. Using them, there could be identified ethical aspects which are requiring an appraisal in evaluations of medical technologies. For this, the ethical principles were consulted for developing a working definition on ethical aspects. This working definition – described as follows – is the basis for the analysis of identified and available rapid assessments.

"Ethics is – in short – the theory of right action. It reflects and reviews the correctness of human action, which is stamped by moral concepts and rules in specific cultures have obtained social worth. In the context of this study ethical aspects and moral concepts of society are understood as that parts of an HTA report, which evaluate human action and explicitly or implicitly refer to ethical principles and/or definitions or categories which are derived from these principles or are based on them. These principles are e.g. autonomy, beneficence, proportionality, justice and non-maleficence."

In application of the working definition on ethical aspects the included 282 reports were assigned to the four following categories:

Category 1: Assessments whose authors are describing ethical aspects of the evaluated technology and name these explicitly ethical aspects (25 assessments).

Category 2: Assessments whose authors are describing ethical aspects of the evaluated technology, but do not name them ethical aspects (32 assessments).

Category 3: Assessments whose authors do not describe ethical aspects – neither explicitly nor implicitly (208 assessments).

Category 4: Assessments where ethical aspects are not of relevance, because the technology of concern is not an application to a person, e.g. the impact of HTA (seven assessments).

Only a few of the identified rapid assessments (nine percent of the included reports) explicitly named ethical aspects and comparably few reports (eleven percent of the included reports) implicitly named ethical aspects. Most of the reports do not gather or deal with ethical aspects. Furthermore, not any of the analysed rapid assessments of category 1 performs a systematic evaluation on ethical aspects. Only a few conceptional considerations or methodological proposals for gathering such aspects in rapid assessments could be identified.

DISCUSSION

The results of the analysis show a very subordinated role of ethical aspects in existing rapid assessments. This is to consider against the background of less evaluated medical technologies with rarely known risks and side effects in rapid assessments. Also ethical aspects are taking an important role in the application of medical technologies and their social rating in the discussion of such technologies. This impact will grow in future.

Hence, it is desirable and meets the self-conception of HTA to gather systematically ethical aspects in (rapid) HTAs, too. Against the background of missing concepts and standardisations for evaluation on ethical aspects in HTA reports the authors of the present report introduce a conceptional proposal for the consideration of ethical aspects and moral concepts of society in rapid assessments. On the basis of the ethical principles, there has been developed a search strategy - containing a group of subheadings and search terms in databases of interest for ethical aspects. However, the absolutely reasonable application of the ethical principles in the search strategy results in a collection of information and findings which have to be systematised, synthesised and evaluated.

The concept introduced by the authors includes on the one hand systematically the effects of medical acting in different dimensions (the effect dimensions have been structured in form of the application possibly affected by individuals or by groups). On the other hand the concept allows to summarise respectively to synthesise the results of the evaluation of consequences in evaluation-related categories. Therefore, it should be able to make up the balance systematically to the manifold consequences of medical acting essential for a differentiated evaluation. Thereby, the empiric-related

funding of this concept advises that it is rationally applicable in practice. Nevertheless, it still has to be examined its suitability in practice by examples.

CONCLUSIONS

On account of the analysis of existing rapid assessments and of the development of a conceptual proposal on further consideration of ethical aspects and moral concepts of society in rapid assessments there result the following conclusions:

- Despite the demand of a health technology assessment to be comprehensive and to consider not only scientific-medical, but also non-medical dimensions of consequences and ethical aspects in evaluation, it is in practice – at least in rapid assessments – rarely implemented.
- By assistance of the subheadings for standardised searching (developed in this study) probably there might be identified a reasonable and sufficient sample of publications in the biomedical and ethical databases in established technologies.
- A first step in the systematic consideration of ethical aspects could be the admission of a chapter "ethical aspects" in the structure of rapid assessments. This integration in the structural concept is reasonable and necessary, but it is not sufficient.
- The insufficient consideration of ethical aspects in rapid assessments may be due to the lack of conceptional and methodological basics for systematic gathering and evaluating of ethical aspects.
- A systematic, comprehensive consideration of ethical aspects and moral concepts of society in technology assessment is able to appoint and discuss the existing ethical problems, but cannot solve them – independently from, the fact whether they are on individual or social level.
- There will be used almost ethical principles for measuring the quality of medical acting in the medicoethical und social discussion on the consequences of a medical technology and its validation. But searching of publications accordingly in a collection of information and of statements which have to be systematised, synthesised and assessed.
- The concept on ethical aspects introduced by the authors systematically takes into account the consequences of medical acting in different dimensions. It is divided in individuals or in groups which possibly might be applied by the technology. It also allows summarising and

synthesising the results of follow-ups in assessment-related categories. The concepts usability of the concept still has to be checked in practice.

- More difficult than systematically gathering and balancing relevant medical and non-medical results and consequences of medical interventions, is their assessment. Frequently, there are not enough data and often there have not been developed and validated criteria by which such an assessment could be made comprehensive and valid.
- Health technology assessment also has to deal – concerning the ethical assessment of medical technologies – with a different evaluation of the result or consequences of the technology by different groups. For this, the potential of the evaluation processes which include the different concerned populations or perspectives have to be examined systematically.

RECOMMENDATIONS

The following recommendations for the consideration of ethical aspects and moral concepts of society are resulting from these conclusions:

- Ethical aspects should be integrated in the conceptual framework of rapid assessments.
- Suitable activities of education and of training should be undertaken to mediate the terminology of ethics to the producers of HTA reports and the seriousness of these ideas.
- In established medical technologies there should be used the developed subject headings in the called databases. The developed subject headings should be used in exemplified studies to verify for which technologies they are ideally applicable to gather information on ethical aspects.
- It is assumed that in more recent, uncommon or few evaluated technologies the available literature often is not sufficient to identify all relevant ethical aspects. In this case, there should be studied further examples. By this way there could be identified technologies in which the presented methods are promising.
- In technologies without existing studies on their consequences – which could add to their ethical assessment – this shortcoming should be named explicitly.
- It is to develop a methodology and a standardisation respectively it is necessary to process a methodological and conceptional advancement for health technology assessments concerning ethical aspects and moral

concepts of society. This must also be applicable to others than professional ethicists. The authors of the present report submit a proposal for this idea.

- Quality measures for assessing ethical aspects of a medical technology could be the classical principles of the bioethical principlism. They could be implemented as an approach to a systematic, comprehensive assessment.
- The application of the ethical principles in search strategies results in a collection of information and findings which have to be systematised, synthesised and assessed. For this, the introduced concept could be a method of resolution.
- To consider the usability of the developed concept for gathering, systematising and synthesising ethical aspects of a medical technology the developed concept should be used and developed further in exemplified studies.
- The greatest shortcoming persists in the lack of availability of transparent and validated criteria and concepts for the ethical evaluation of risk-benefit-balances. The (advanced) development of such concepts appears to be needed badly.

All HTA reports are available for free as full texts in the HTA database (only in German). (www.dimdi.de – HTA)

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