Management in health
XXIII/1/2019; pp. 9-13

HEALTH TECHNOLOGY ASSESSMENT OF NONINSULIN HEALTH TECHNOLOGIES - ETHICAL ISSUES

Dima TSANOVA *, Associate Professor*
Medical University of Pleven,
Department of Public Health Sciences
Pleven, Bulgaria

OBJECTIVES. Health Technology Assessment (HTA) is a tool which measures the benefit of a new technology compared to existing ones. Unavoidably ethical issues within HTA should also be addressed especially in cases of very expensive technologies and need of prioritization.

Noninsulin health technologies for treatment of Diabetes Mellitus type 2 (DMT2) present such an example.

METHODS. A methodology developed by Hofmann and team and based on the Socratic approach was used with the original validated questionnaire including 7 main and 33 explanatory questions with respect to HTA.

RESULTS. DMT2 is a chronic disease. Basic human rights shall not be violated during the treatment. Issues of fairness and accessibility are distinguished due to the different price of therapeutic alternatives. Risk of inadequate diagnostics and treatment as about 25% of people in need of therapy are not diagnosed. The cost of health technologies has an impact on the image and status of individuals because people receiving treatment that is more expensive have better health prospects. Ethical challenges are related to the criteria for accessibility imposed by the National Health Insurance Fund (NHIF). These technologies have been selected for assessment due to the immense socio-economic importance of the disease and the expected increase in its incidence.

CONCLUSION. The main identified ethical problems are within the areas of autonomy of the physician when prescribing the appropriate therapeutic agent, physician-patient relationships in the course of disease therapy and fairness and accessibility of health technology when allocating resources.

Keywords: Ethical aspects, Socratic approach, Health technology assessment

INTRODUCTION

Chronic noncommunicable diseases are of increasing importance globally and are a public health issue not only for developed countries. Their burden is already greater than that of infectious diseases, even in low and middle-income countries, and will increase together with their integration in global economy, urbanization and ageing of population. The rapid growth embarrasses the reduction of poverty in these countries [1].

Diabetes mellitus (DM) is a chronic socially significant disease which importance is determined by its prolonged course, often causing disability, disrupting people's ability for daily activities and its main position in the leading causes of death [2]. DM has a huge effect on the socio-economic development of the countries; excessive prices for long-term and expensive treatment bring millions of people to extreme poverty. The Global Burden of Disease, Injuries, and Risk Factors Studies rank diabetes as one of the thirty leading causes of loss of years of life evaluated with years of life lost (YLLs) and disability-adjusted life years (DALYs) with fifteenth position for 2015 measured by YLLs and eleventh position – by DALYs [3-5]. Global healthcare expenditure for 2017 dedicated to diabetes treatment and related complications reached USD 727 billion which represents an 8% growth since 2015 [2].

All countries seek to provide universal health care and the decision-making process on health technologies and interventions is becoming more and more important. Governments face complex decisions how to target their limited health budgets to meet the priority health needs of their population and the choice between different technologies and interventions. Health technology assessment is a very useful approach for evaluation of properties, effects, and impacts of health technologies or interventions. World Health Organisation defines HTA as “The systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making” [6-8].

The aim of HTA is to improve health care and health system. The belief that health care and health policy must be evidence-based and decision-making must be transparent is a commonly accepted value within HTA.

In Bulgaria, since 19.04.2013, the first document, which regulates the normative base for health technology assessment - the Ordinance on the conditions, rules and procedure for regulation and registration of the prices of medicinal products has been introduced. It was in force until December 2015, when Ordinance No. 9 on the conditions and procedure for carrying out health technology assessment, issued on the basis of the Law on Medicinal Products in Human Medicine, was promulgated. The Ordinance regulates the requirements, the conditions and the procedure for conducting HTA in Bulgaria, as well as the structure and functions of the Health Technology Assessment Commission [9].

For a long time, moral aspects were not part of the HTA, but at the beginning of the century, the need for such issues to be included in the assessment has become more and more imperative. One of the reasons for this may be related to the characteristics of the technologies in question: some of them are morally contradictory, culturally and socially challenging, or extremely expensive, and would necessitate prioritization. Another reason for the interest in the integration of moral issues in HTA is the challenge of applying the results of good and thorough HTA in clinical practice [10-12].

According to the International Network of Health Technology Assessment Agencies INAHTA and the European Health Technology Assessment Network EUnet

HTA, ethics is an important part of the Health Technology Assessment. Integrating ethical issues into HTA is of great importance for disseminating the results of evaluations, facilitating decision-making, and developing health policy.

The importance of considering the impact of technology on "social, ethical, legal and other systems" was recognized early and was generally accepted. The role of ethics in HTA is based on several points:

- the application of health technologies can have moral consequences, which justifies the addition of ethical analysis to the "traditional" cost-effectiveness assessment;

- technology also brings values and can question some moral principles or public rules that should be addressed by HTA;

- HTA as an initiative is value loaded.

The approach to ethics aims to reveal and justify the basic legal structure of HTA to ensure the usefulness of the assessment [13-17].

There is a wide variety of methods for applying ethical issues, some of which are specifically adapted for use in health technology assessment. One of the most widely used approaches is the Socrates Approach. The goal of the approach is to inform decision makers about the values, views and arguments that are important in the context of decisions [18-21].

Our research objective was:

To see wider application of Socratic approach in healthcare decision-making.

To compare classical approaches of individual ethical decision-making per case to approaches of ethical decision-making within health technology assessment.

To identify specific ethic problems related to treatment of DMT2 with noninsulin health technologies.

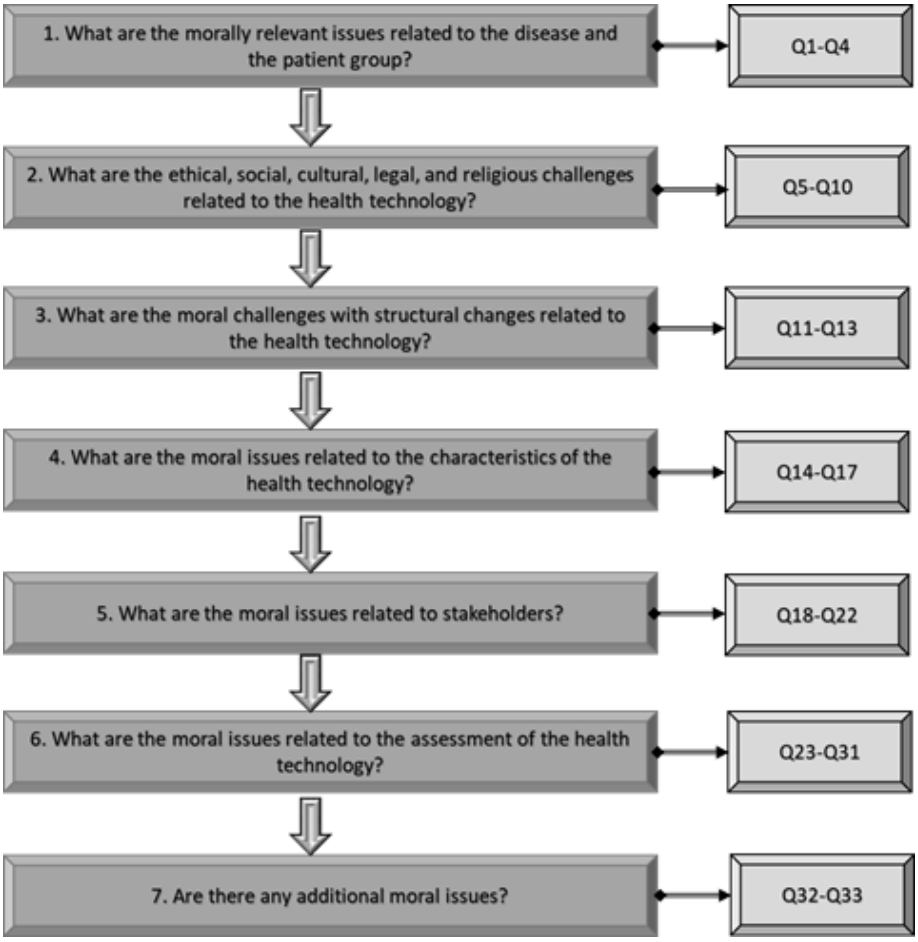
METHODS

A methodology developed by Hofmann and team and based on the Socratic approach was used to determine the ethical aspects of the HTA of noninsulin technologies for the treatment of DMT2. The original validated questionnaire of Hofmann was applied as expert assessment including seven main questions and thirty-three explanatory and guiding morally relevant questions with respect to HTA (Figure 1).

RESULTS

To fill the questionnaire, we analyzed the state of diabetes in Bulgaria and the health legislation in this area. Particular attention was paid to the regulation by the NHIF in the prescribing of the analyzed health technologies. The answers are shown below.

Figure 1. **Hofmann's questionnaire with morally relevant questions with respect to assessing health technology [19].**



1. What are the morally relevant issues related to the disease and the patient group?

Q1. What is the severity of the disease? May this change?

DMT2 is a chronic disease; the course of the disease is not subject to change. The disease can be very severe, especially when the patient is not being treated or given the unsuitable treatment.

Q2. What patient group is the beneficiary of the technology? (Are they particularly vulnerable, have low socioeconomic status or priority, or are they subject to prejudice? Are issues of underdiagnosis and undertreatment relevant?) Will any of these conditions change?

Patients are a heterogeneous group and none of then are particularly vulnerable. The issues of underdiagnosis and undertreatment are relevant because 25% of patients with DMT2 are not diagnosed and the drug therapy especially with more expensive drugs has a lot of restrictions and regulations.

Q3. Does the widespread use of this technology change the patient role? (Does it change the prestige or status of the disease, the conceptions, prejudice or status of persons with certain diseases?)

The use of the therapeutic alternatives under consideration will not alter the role of patients, their status and prejudices.

Q4. Does the technology involve healthy persons (screening, asymptomatic cases, disease prediction), and how are potential challenges addressed (false test results, overdiagnosis, futile or harmful treatment)?

These health technologies do not include healthy people and therefore do not suggest overdiagnosis, useless or harmful treatment.

2. What are the ethical, social, cultural, legal, and religious challenges related to the health technology?

Q5. Does the implementation, use, or withdrawal of the technology challenge patient autonomy, integrity, privacy, dignity or interfere with basic human rights?

The application of noninsulin health technologies for treatment of DMT2 does not violate basic human rights, nor does it conflict with patient autonomy, integrity, secrecy and dignity.

Q6. Does the technology challenge social or cultural values, institutions, or arrangements or does it affect religious convictions?

These health technologies do not affect social and cultural aspects and do not outstep religious beliefs, except for injecting forms of persons with specific religious beliefs.

Q7. How does the implementation, use, or withdrawal of the technology affect the provision of health care? (Justice in allocation, access, and provision).

The introduction and use of these health technologies affects the issues of fairness and accessibility in the distribution of health resources due to the large difference in prices between different therapeutic alternatives.

Q8. What are the morally relevant consequences (benefits and harms) of the implementation, use or withdrawal of the technology? (In particular from a patient perspective). How should the harms be balanced against the benefits? Are there alternatives?

The ethically relevant consequences - the benefits and harms of using these health technologies are balanced by the use of the so-called "patient-oriented" approach. The individual approach guarantees the most appropriate treatment for each patient, depending on the therapeutic outcome.

Q9. Can the implementation, use, or withdrawal of the technology in any way conflict with existing law or regulations or pose a need for altered legislation?

The use of these therapeutic alternatives is defined in the Requirements of NHIF for the treatment of DMT2 in outpatient care, which introduce a number of restrictions on the prescription of these medications. They must undergo at list three-month treatment with sulphonylurea and only after that and poor glycaemic control there is a procedure for more expensive therapy.

Q10. Will there be a moral obligation related to the implementation, use, or withdrawal use of a technology? (E.g., are there special difficulties with informing patients, with privacy, or confidentiality?)

The usage of these health technologies is related to ethical obligations to the patient, mainly with information about the different therapeutic alternatives, the expected outcome of the treatment.

3. What are the moral challenges with structural changes related to the health technology?

Q11. How does the assessed technology relate to more general challenges of modern medicine? (Underdiagnosis, undertreatment, medicalization, overdiagnosis, overtreatment, reduced trust)

Noninsulin health technologies are related to inadequate diagnostics and treatment in medicine, as about 25% of people in need of treatment are not diagnosed. A relatively large proportion of treated patients do not achieve the goals of glycaemic control, which gives rise to mistrust in medical professionals and in therapeutic behaviour.

Q12. Does the technology in any way challenge or change the relationship between patients and health care professionals or between health professionals?

Because of chronic course of the disease and the need of adequate treatment, the relationship between the doctor and the patient is of utmost importance in order to ensure mutual trust and respect. The success of the therapy depends largely on good relations and cooperation between them.

Q13. Are there morally relevant aspects with respect to the level of generalisation?

Regarding the generalization of health technologies, the ethical aspects are again related to the level of access to the particular group of medications, especially expensive ones.

4. What are the moral issues related to the characteristics of the health technology?

Q14. What is the characteristic of the technology to be assessed? (E.g., function, purpose, intention)

The function of analysed health technologies is to provide adequate glycaemic control to patients with DMT2. The reimbursement policy can assure better therapeutic outcomes and better health perspectives.

Q15. Is the symbolic value of the technology of any moral relevance? (Prestige, status?) May this change as a result of the health technology?

The cost of health technologies has an impact on the image and status of individuals as people receiving treatment that is more expensive have better health perspectives.

Q16. Are there moral challenges related to components of a technology that are relevant to the technology as such?

Ethical challenges are related to the criteria for accessibility to these health technologies imposed by the NHIF.

Q17. Are there any related technologies that have turned out to be morally challenging? (Are the same challenges relevant for this technology?)

Other alternative technologies are not related to ethical challenges.

5. What are the moral issues related to stakeholders?

Q18. Are there third party agents involved? (E.g. donors, relatives)

The application of the assessed health technologies is not related to the inclusion of indirect countries. The relatives are involved due to long-term and sometimes very expensive therapy that usually have huge impact on family budget.

Q19. What are the interests of the users of the technology?

The interests of users of noninsulin health technologies to treat DMT2 are related to achieving good glycaemic control, reducing the risk of disease-related complications, ensuring a good quality of life with the disease, reducing the financial burden of the disease on the patients and their families.

Q20. How does the technology contribute to, or challenge or alter health professional's autonomy?

The autonomy of the physician and the patient in the application of the assessed health technologies is to a certain extent limited by the above-mentioned requirements of NHIF imposing restrictions on the prescription of the drugs.

Q21. What are the interests of the producers of technology (industry, universities)?

The interests of pharmaceutical companies are to increase their market share, to increase the use of new, more expensive medicines, generating bigger profits.

Q22. Are the users of the technology in the studies representative of the users that will apply it in clinical practice?

In the selected clinical trials involving the four groups of health technologies, representative samples were used to cover the needs of the scientific interest.

6. What are the moral issues related to the assessment of the health technology?

Q23. Are there morally relevant issues related to the choice of endpoints, cut of values, and outcome measures in the assessment?

During the assessment of health technologies, there are no ethical problems about the choice of endpoints, the reading of values and outcome measures.

Q24. Are there morally relevant issues related to the selection (criteria) of studies to be included in the HTA?

No ethical issues have been identified in the selection of clinical studies included in the assessment.

Q25. What are the reasons that this technology is selected to be assessed?

Noninsulin health technologies were selected for evaluation due to the enormous socio-economic importance of the disease nowadays and the expected increase in the incidence of the disease associated with the large burden on public funds.

Q26. Are there morally relevant issues in the planning of the HTA (e.g., scoping process, expert group selection), in the structuring of the HTA work, and in selecting, synthesizing, and presenting the results?

During the planning, structuring the work, selection, synthesis and presentation of the results of HTA no ethical problems have been identified.

Q27. What are the morally relevant presumptions made in the economic analysis (e.g., on justice, equity (the quasi-egalitarian presumption that "a QALY is a QALY"), definition of a target population, as well as in the choices of analysis perspective, outcome measures, discount rates, and (p)reference value)

The target group in HTA is patients with DMT2 who have not achieved the goals of glycaemic control with first-line therapy with Metformin, the perspective is of the paying institution - NHIF, discounted by 5%, PSA sensitivity analysis.

Q28. What are the interests of the persons participating in the technology assessment?

Experts involved in HTA have no financial and any other interest related with assessed health technologies.

Q29. At what time in the development of the technology is it assessed (and what are the morally relevant consequences)? What morally relevant challenges follow from knowledge gaps?

The health technologies assessment is carried out after their introduction on the market and their reimbursement by NHIF.

Q30. Are there related or analogous technologies that have not been assessed? (Why not?)

There are similar health technologies - sulphonylurea used for treatment of DMT2, which are well known, with established efficacy and side effects that are not subject to this HTA.

Q31. What are the moral consequences of the HTA? (What are the results of implementing/not implementing the health technology? Will other non-effective technologies be abandoned? Will certain sub-groups benefit more than others? Are calling for further studies justified?)

The ethical consequences of HTA would be related to equitably allocate resources, increase accessibility to more expensive treatment, which can deliver better health outcomes and less side effects.

7. Are there any additional moral issues?

Q32. Are there moral issues in research ethics that are important to the HTA?

There are no problems in the research ethics, important for the HTA.

Q33. Are there morally relevant questions that have not been covered by this list, but that have been identified by the scoping process or literature search? (Which values and challenges do they pose?)

No other ethical issues except those described here have been identified.

CONCLUSION

The main ethical problems, identified through Hofmann methodology, are within the areas of:

- Autonomy of the physician when prescribing the appropriate therapeutic agent
- Physician-patient relationships in the course of disease therapy
- Fairness and accessibility of health technology when allocating resources

The Socratic approach used in our study introduce ethical conclusions and problems without showing particular position or presenting recommendations. The decision-makers have to use the conclusions for better and transparent assessment and reimbursement policy. Applying HTA with ethical issues can be a very useful approach for reduction or minimization of ethical problems in reimbursement policy in Bulgaria especially in the treatment of chronic diseases with their enormous burden on both the patient and his family as well as on society.

Financial support.

This research received no specific grant from any funding agency, commercial or not-for-profit sectors

Conflict of interest.

None declared for the authors

References

1. Grancharova G., Yankulovska S., Global public health issues, Publishing Center of the Medical University - Pleven, 2013
2. The International Diabetes Federation. Global Diabetes Atlas 8th edition, 2017, Available from: http://diabetesatlas.org/resources/2017-atlas.html
3. Global Burden of Diseases. General Evidence, Guiding Policy, Institute for Health Metrics and Evaluation, Washington, 2013, Available from: http://www.healthdata.org/sites/default/files/files/policy_report/2013/GBD_GeneratingEvidence/IHME_GBD_GeneratingEvidence_FullReport.pdf
4. Global Burden of Diseases Study 2015. The Lancet, 2016, vol. 388, Number 10053, pages 1447-1850
5. Murray CJL, Vos T, Losano R, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012; 380: 2197-2223
6. World Health Organization (WHO). Report of global survey on Health Technology Assessment by National Authorities. Geneva: World Health Organization; 2015, Available from: http://www.who.int/health-technology-assessment/MD_HTA_oct2015_final_web2.pdf
7. Skipper N., On the demand for prescription drugs: heterogeneity in price responses, Health Economics, 2013, 22, 7, 857-879
8. Foster M., Pertile P., Optimal decision rules for HTA under uncertainty: a wider, dynamic perspective, Health Economics, 2013, 12, 1507-1514
9. Ordinance №9 on the conditions and procedure for carrying out health technology assessment, Available from: https://www.lex.bg/index.php/bg/laws/ldoc/2136703288
10. Saarni SI, Hofmann B., Lampe K. et al., Ethical analysis to improve decision-making on health technologies, Bull World Health Organ, 86(8), 2008, 617-23
11. Ten Have H. Ethical perspectives on health technology assessment. Int J Technol Assess Health Care. 2004;20:71-76
12. Van der Wilt GJ, Reuzel R, Banta HD. The ethics of assessing health technologies. Theor Med Bioeth 2000;21:103-15. PMID:10927971 doi:10.1023/A:1009934700930
13. Beauchamp T, Childress J. Principles of biomedical ethics. New York: Oxford University Press; 2001
14. Autti-Ramo I, Makela M. Ethical evaluation in health technology assessment reports: an eclectic approach. Int J Technol Assess Health Care 2007;23:1-8. PMID:17234010
15. Burls A, Caron L, Langavant GC, et al. Tackling ethical issues in health technology assessment: A proposed framework. Int J Technol Assess Health Care. 2011;27:230-237
16. Droste S, Dintsios CM, Gerber A, R¨uther A. Integrating ethical issues in HTAs: More methods than applications? In: HTAi 7th Annual Meeting Dublin 2010. Maximizing the value of HTA. Book of Abstracts; Dublin: 2010;M5-02:169
17. Saarni S, Braunack-Mayer A, Hofmann B, van der Wilt GJ. Different methods for ethical analysis in health technology assessment: An empirical study. Int J Technol Assess Health Care. 2011;27:305-312
18. Hofmann, B. (2005). Toward a procedure for integrating moral issues in health technology assessment. International Journal of Technology Assessment in Health Care, 21(3), 312-318. doi:10.1017/S0266462305050415
19. Hofmann, B., Droste, S., Oortwijn, W., Cleemput, I., & Sacchini, D. (2014). Harmonization of ethics in health technology assessment: a revision of the socratic approach. International Journal of Technology Assessment in Health Care, 30(1), 3-9. doi:10.1017/S0266462313000688
20. Hofmann B. Why ethics should be part of health technology assessment. Int J Technol Assess Health Care. 2008;24:423-429
21. Hofmann B. On value-judgements and ethics in health technology assessment. Poiesis Prax. 2005;3:277-295.