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HTA IN GERMANY: BASICS IN PRACTICE AND EDUCATION

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The aim. *The aim of the investigation was to elucidate the HTA system's development process and its educational component by studying the basic functions and options of services that are responsible for its functioning in Germany.*

Material and methods. *Official sites of government and non-government non-profit organizations and government publications in specialized open sources have been used. Research methods include mostly descriptive approaches and methods for collecting data: observation, generalization data, graphics and methods for analyzing data: qualitative content analysis.*

Results. *The creation of the HTA system in Germany has been ongoing since 1994. State institutions responsible for HTA have changed, and their areas of responsibility and control have been reformatted. Today, 5 institutions/organizations that ensure the effective functioning of the HTA in Germany are presented. A basic training program aimed at training executors (reporters) and decision-makers is presented. A grid of 7 basic competencies in HTA education in Germany is presented. The program is presented in 10 modules, which are grouped by the authors into three cycles: fundamental (modules 1–6), methodological (modules 7–9) and final cycles (modules 10).*

Conclusions. *To build or improve the HTA system, attention should be paid to the periodicity of updating information, which will contribute to a more accurate identification (satisfaction) of the needs of the country's HTA, both from the standpoint of implementation and ensuring applied functioning, and for the educational component of the HTA process. Constant review and assessment of the need/basic scope of the national HTA and stakeholders. The best way to do this is to study existing models and mechanisms of HTA in countries with the most developed and advanced healthcare systems*

Keywords: *healthcare, health economy, health assessment, health technology, health technology assessment (HTA), HTA curriculum, HTA authorities, competence grid, HTA stakeholders, target groups in HTA*

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1. Introduction

The health system's strengthening is the ground strategic aim of the health technology assessment system (HTA), which is expected to lead to an increasing the health level and economic resource usage.

Significant effort and political commitment, in addition to human and financial resources, are the basic requirements for building an efficient HTA system. Expectations of what HTA can offer are continuously rising, which drives health policymakers to raise the question of whether HTA could help secure the financial sustainability needed to implement universal health coverage [1]. HTA is a transparent and accountable process that can be used by decision-makers and other stakeholders to support the decision-making process in health care at the policy level by providing evidence about given technologies. WHO has described HTA as a bridge that connects the world of research to that of policy-making [2]. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods [3]. As HTA bodies and processes vary from country to country (and sometimes region to region), there is no common (harmonized) approach to HTA. However, in recent years, the fundamentals of good HTA processes have become more standardized.

It is important to use basic standardized aspects for building and developing the HTA system and its components because standardization provides a grouping of basic identical (similar) components of the system for their better understanding and application in similar conditions. Countries implementing or improving the HTA process have a great opportunity to use the acquisition in this aspect of other more developed countries, i.e. their achievements, which can be taken as a basis for building one's own HTA system characteristic of a specific region under certain conditions.

High-developed countries' experience where the HTA concepts were used testifies to the veracity of the specified expectations. Scientific and government publications point to HTA effectiveness in EU countries and OECP (The Organization for Economic Co-operation and Development) [1–6].

Germany is one of the EU countries where basic HTA principles are used simultaneously, considering national features. Therefore, the aim of the investigation was to elucidate the HTA system's development process and its educational component based on studying the basic functions and options of Services which are responsible for its functioning in Germany.

The publications presented the results of the study of the comparative characteristics [5] of HTA systems according to various parameters, mainly in European countries. Also, professional literature partially highlights the issue of differences in HTA practice in different countries [6] and their impact on the results of technology approval. The publications pay much attention directly to the educational component of HTA and the analysis of existing educational programs and training courses on HTA [3, 7–10]. At the same time, publications on the HTA system in Germany include mainly the results of report analyses and the assessment of accepted or rejected technologies according to published reports; in addition, the information is mainly presented in German. Therefore, the purpose of the study was to briefly outline and describe the main services related to or directly representing the HTA systems in Germany, with a description of their main functions and characteristics, as well as to present the search results regarding the educational component of HTA in Germany, namely, a description of the existing current basic curriculum, which was developed specifically for German-speaking countries, and also provides for periodic updates [11].

2. Planning (methodology) of research

The study was conducted using the following methodology, which consists of four main stages:

I. Preparatory.

II. Analytical.

III. Generalizing.

IV. Final.

Preparatory. Studying and displaying sources of official and reliable information regarding the organization of state and non-state administration in the system of HTA in Germany

Analytical. Forming a list of stakeholders and their basic functions based on the results of the preparatory stage. Open sources regarding the existing educational programs were analyzed, because of which a single, updated educational (educational) program with HTA in Germany was selected, which, in fact, is the basic one for other German-speaking countries as well.

Generalizing. The obtained result allowed:

– to identify the main target groups for training under the programs of the HTA in Germany;

– to separate and describe the basic competencies of specialists in HTA in Germany;

– give a concise description of the basic competencies of the program's students.

Final. Structuring and presenting the form of the existing basic training program in HTA, indicating the main modules of the Colloquium by describing their main objects and content (for each module). Determination of features, advantages and limitations of the presented curriculum has been conducted.

3. Materials and methods

As materials of investigation, official sites of government and non-government non-profit organizations, as well as government publications in specialized open sources, have been used. Research methods include mostly descriptive approaches and methods for collecting data: observation, generalization data, and graphical and methods for analyzing data: qualitative content analysis.

4. Research results

4. 1. Health technology assessment development process in Germany

One of the positive aspects of globalization is the possibility of adopting experiences between countries in defined aspects that have been implemented and effectively applied in practice. Concerning Health Technology Assessment (HTA, engl.; Medizintechnik-Folgenabschätzung, germ.), the example of Germany is expedient, where politics is significantly promoting HTA development. HTA is a systematic and multidisciplinary evaluation of the properties of health technologies and interventions covering both their direct and indirect consequences. In 1994, the Office for Technology Assessment was founded at the German Bundestag. An HTA program was set up in 1995 as part of a funding initiative by the Federal Ministry of Health (germ.: Bundesministeriums für Gesundheit, BMG). In 2000, the German Institute for Medical Documentation and Information (Deutsche Institut für Medizinische Dokumentation und Information (DIMDI, subordinate to the BMG) took over the German HTA program, which was also anchored in the state social security (coding) system (germ.: Sozialgesetzbuch, SGB). For this purpose, the German Agency for Health Technology Assessment (DAHTA) of DIMDI (DAHTA@DIMDI) was founded. Until now, the Institute for Quality and Efficiency in Health Care, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) has been preparing reports on health policy problems and evaluations of evidence-based guidelines since 2004. The IQWiG publishes HTA reports on behalf of the Federal Joint Committee. However, since 2016, a public proposal procedure for HTA topics, commissioning and publishing corresponding HTA reports in the Social Health Insurance Care Improvement Act (germ.: Gesetz zur Stärkung der Versorgung in der gesetzlichen Krankenversicherung, GKV-VSG) has been developed and had done under the name «ThemenCheck Medizin». Thus, the preparation of the HTA report followed standard operating procedures to ensure high quality, transparency and verifiability of individual work steps. Additionally, HTA reports were subject to an internal and external peer review process. Transparency and availability of the HTA results are provided by the fact that completed HTA reports are available free of charge and can be updated at any time upon request. One of the most progressive steps in the development of an effective HTA system in Germany was the commission of qualified scientists to DAHTA@DIMDI, who evaluate the technology based on experimental effectiveness, effectiveness and efficiency in social, legal and ethical aspects. From 2020 DIMDI was integrated into the Federal Institute for Pharmaceuticals

and Medical Products (germ.: BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte), whose core tasks include the licensing and registration of medicines and medical devices, recording and assessment of risks their usage, monitoring of the legal traffic in narcotics and precursors, as well as the publication of medical coding systems for healthcare sectors. Since 2000 there has also been a German specialist society for HTA, the Association for the Promotion of Technology Assessment in the Health Care System. The list of basic HTA stakeholders and their priority activities are presented in Table 1.

It may be concluded that the German HTA process has been developing during the last three decades and has successfully passed implementation in the health system, especially to the SGB, by insignificant modifying of the structure and functions of the HTA practice and by introduction of fundamentally new and important principles of HTA, which appeared in the course of development by improving the international methodology of HTA, in particular, cross-assessment and involvement of scientists. The data may be useful for countries where HTA is in the initial implementation stage, probably including Ukraine.

Table 1

Stakeholders in the German HTA system and their tasks

Stakeholder in HTA		Main tasks	E-Recourse	Notes
Abbrev.	Full name			
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)	– decides on and publishes binding regulations (=directives) on what is covered by the SHI funds. Thereby, the G-BA specifies which services in medical care are reimbursed; – assesses new pharmaceuticals, i.e. conduct HTAs according to the regulations laid out in AMNOG law; – investigates new examination methods and medical technologies; – defines quality standards for hospitals; – designs disease management programs for chronic diseases; – determines reference price groups	www.g-ba.de	The BMG oversees the work of the G-BA. The G-BA has 13 voting members
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Healthcare)	– examines benefits and harms of medical interventions; – provides information about the advantages and disadvantages of examination and treatment methods; – produces independent, evidence-based reports by conducting systematic searches of international scientific literature	www.iqwig.de	–
GKV-SV	Gesetzliche Krankenkassen- Vereinigung-Spitzenverband (National Association of Statutory Health Insurance [SHI] Funds)	– votes in G-BA meetings; – is responsible for price negotiations with pharmaceutical companies for new pharmaceuticals; – sets maximum reimbursement price for pharmaceuticals and medical devices in reference price groups; – develop framework contracts and reimbursement agreements for hospital, outpatient and dental care; – represents interests of statutory health insurance (SHI) funds at the federal level (at G-BA and BMG) and European/international level; – supports SHI funds and their subnational associations in fulfilling their tasks	gkv-spitzenverband.de	On 1 Jan 2021, 103 SHI funds were registered in Germany. On 1 Jan 2024 – 95
EMA	European Medicines Agency	– evaluates applications for marketing authorization of pharmaceuticals, i.e. it is the regulatory authority at the EU level; – facilitates development and access to pharmaceuticals; – monitors the safety of pharmaceuticals across their lifecycle; – provides information to healthcare professionals and patients	www.ema.europa.eu	–
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute of Medicines and Medical Devices)	– evaluates applications for marketing authorization of pharmaceuticals, i.e. it is the regulatory authority at the German level; – collects and evaluates reports of adverse drug reactions and takes the necessary measures for patient protection; – collects, analyses and evaluates risks arising from the use or application of medical devices and co-ordinates the necessary measures to be taken; – publishes official medical classifications and maintains medical terminologies, thesauri, nomenclatures and catalogues	www.bfarm.de	It has roughly 1,250 employees: physicians, pharmacists, chemists, biologists, lawyers, engineers, technical assistants, administrative staff etc.

As mentioned above, HTAs provide relevant information for numerous decisions in the healthcare sector. The preparation of HTA reports requires well-trained, interdisciplinary specialists, and the appropriate interpretation and implementation of decisions requires understanding on the part of the decision-maker. Therefore, an important step was to ensure the specialized education of specialists involved in the HTA. That is, a few years after DAHTA was created, the Association for the Promotion of Technology Assessment in the Health Care System (Health Technology Assessment) eV (HTA.de) and the German Network for Evidence-Based Medicine eV (DNEbM) first developed the HTA curriculum.

Specialists who needed additional professional knowledge of HTA formed two main groups: creators and users/decision makers. Based on the purpose of using HTA for the specified groups, it is a mandatory condition. When creating the colloquium, it is necessary to ensure the knowledge and skills of each of the specified groups of people involved. Thus, the curriculum is primarily aimed at two target groups (Fig. 1).

The basic functions and skills of specialists who are already working or are preparing for the German HTA system can be easily understood by familiarizing yourself with the basic competencies that are the goal of training HTA specialists in Germany. The competencies grid for the HTA curriculum was formed with the COMETT-ASSESS project (1996, modified in 2003, 2005, 2017) (Table 2) [3]. The given grid describes competencies which are mandatory today for both users of HTA information and HTA authors (creators). We have tried to present them as accurately as possible, as in the colloquium, but in a somewhat abbreviated/simplified form.

A. Decision-makers or Order-makers

Persones who want to use information from HTA for decisions in the healthcare or who place HTA orders themselves

- In curriculun **the focus is** on **knowledge** acquiring

B. Creators (of HTA reports)

Persones who want to create HTA reports themselves or who are or will be involved in the creation of HTAs

- In curriculun **the focus is** on **specific skills and abilities** receiving, through training tasks, case studies and internships (in addition to acquiring knowledge)

Fig. 1. Target groups in HTA

Table 2

Competence grid for advanced training in the field of HTA, version 2.0

Competence	Training goal	Specific ability (skill)
1	2	3
History and development of HTA	Understanding of the HTA´s origin, status and international character of HTA the place of HTA in the context of the EvB health system. Current development in Europe and all over the world, as well as knowledge of professional international societies and networks. Relevant terminology, terms and definitions in HTA and related areas (epidemiology, health economics, ethics) in English and mother language	Knowledge of historical milestones, knowledge of international aspects, relevant terminology
Overview of the entire HTA process and preparation of an HTA report	Overview of the entire process of an HTA (submission of topic proposals/ identification of needs for an HTA, prioritization, awarding of contracts, preparation of the HTA report, dissemination. Overview of the procedure and work steps in the concrete preparation of HTA reports (policy question, background, research questions, methodology, implementation, discussion, recommendation), project management	Knowledge and understanding of the entire process of HTA, from the identification of relevant issues to the dissemination and implementation of results from HTA reports, basic principles of HTA, structured preparation of HTA reports, and knowledge of the range of methods
Diffusion of technologies, life cycle, timing of HTA	Understanding diffusion research of technologies, life cycle and parts and disadvantages of the timing of implementation of HTA at different stages of the life cycle innovation-related HTA activities: horizon scanning, managed entry agreements, coverage with evidence development and similar programs, consulting for manufacturers, disinvestment	Knowledge of the health care system, the legal framework and system-specific incentive structures, analytical skills, approaches and possibilities of innovation-related HTA activities
Selection and application of adequate HTA methods	Selection of relevant aspects for the evaluation of specific technologies as well as determination of the appropriate assessment methodology in each case Approaches to standardization [best practice] I and Harmonization of practices (consensus, guidance, EUnetHTA-Core Model, etc.)	Epidemiology, in particular clinical epidemiology, including clinical and epidemiological study designs (RCTs, other intervention studies, observational studies such as cohort or case-control studies), fundamentals of biostatistics, fundamentals of decision sciences, benefit-harm assessment

Continuation of Table 2

1	2	3
Critical evaluation of HTA reports and other secondary literature	Assessment of quality, validity and transferability of systematic reviews, HTA reports, evidence-based guidelines and other secondary literature	Clinical epidemiology, methodology of systematic reviews incl. Meta-analyses and indirect comparisons, assessment of bias, health economic evaluation/budget-impact analysis, modelling, qualitative methods Models such as GRADE and Multi Criteria Decision dna/ys/s (MCDA)
Dissemination and implementation of HTA outcomes	Understanding of the effectiveness of different strategies for dissemination and implementation of HTA outcomes to different target groups; Target group-specific preparation of HTA results Stakeholder Involvement Impact Assessment	Qualitative, social science methods, communication, psychology, methods of empirical social research; DECIDE, GRADE, layman's versions
Relationship between HTA and industry and politics	Understanding of the exploitation contexts and possible consequences of HTA information at the various decision-making levels in health care, (health) politics and industry. Definition of conflicts of interest and good practice/rules for their disclosure	Knowledge of the health care system, knowledge of relevant legal bases, understanding of health policy Dealing with conflicts of interest

Note: +GMS Health Technology Assessment 2017, Vol. 13, ISSN 1861-8863.

One of the educational objectives of this article is to familiarize interested parties with the curriculum, which is used as a basis by all educational and state institutions for training under the HTA program in any interpretation. The curriculum includes 10 basic modules, presented in Fig. 2–11. The structure for the HTA curriculum builds on several existing international courses that have been developed and tested in recent years [7–9, 12–14]. However, courses geared towards an international audience are only suitable to a limited extent for considering the specifics of the healthcare system in German-speaking countries. For this reason, the conditions for decision-making in Germany, Austria, Switzerland and Luxemburg have become inclusive legal ones [11, 15]. The European perspective was also included since this is becoming increasingly important for the HTA methodology and decisions of individual European countries.

The current curriculum has been the basis for German language courses with HTA and has been revised in cooperation of The Association for the Promotion of Technology Assessment in the Health Care System (Health Technology Assessment) eV (HTA.de), the German Network for Evidence-Based Medicine eV, the Austrian EbM Network, Institute of Clinical Epidemiology, Switzerland and Social Security Inspectorate General, Medical Expertise Unit (CEM, *Medical Examiner Certification*) in Luxembourg [11, 15].

Parts of the EbM curriculum for critical study evaluation are adopted. (The evidence-based medicine curriculum was developed by the EbM network and the German Medical Association in 2005. It is, among other things, the basis for the certification of courses by DNEbM. The EbM curriculum was also updated in 2017 [1, 16–18]. The current version can be found on the official EbM site [11]. Each module is first introduced with an overriding learning objective and supplemented with specific content. The number of hours is not specified so that the curriculum can be adapted to different settings [11, 19–22]. According to the developers, apart from the first module, the order of the modules is not mandatory. The modules are listed in the article in the order presented in the Curriculum. However, in some cases, in the author's opinion, it is advisable to transfer module 10, block "Legally ethical foundations" to study after module "General Information", or module (block) No. 2. A detailed description of the modules: general title, basic objects and key points of content, is presented in Fig. 2–11.

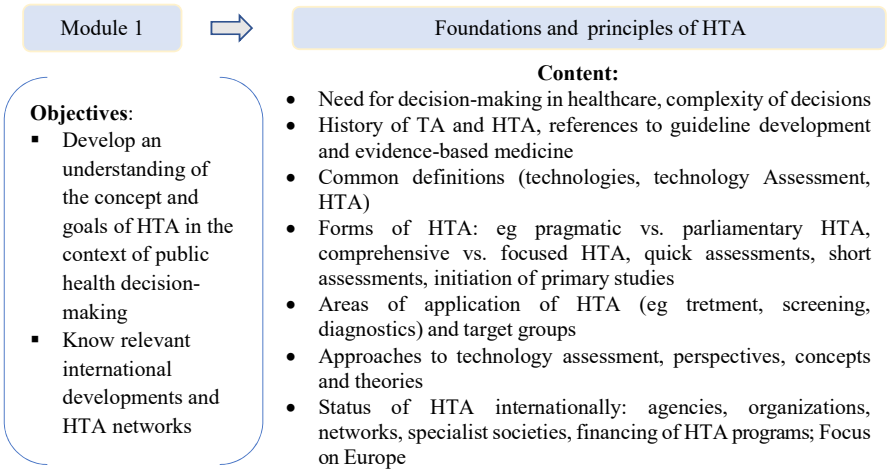

Fig. 2. Curriculum in HTA (module 1)

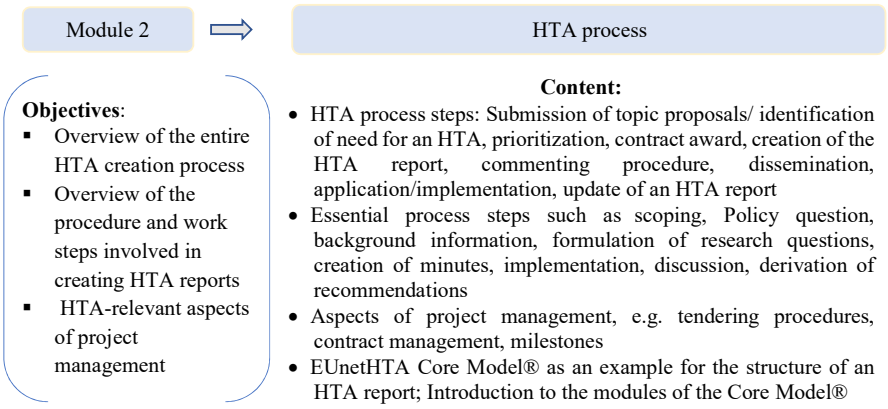

Fig. 3. Curriculum in HTA (module 2)

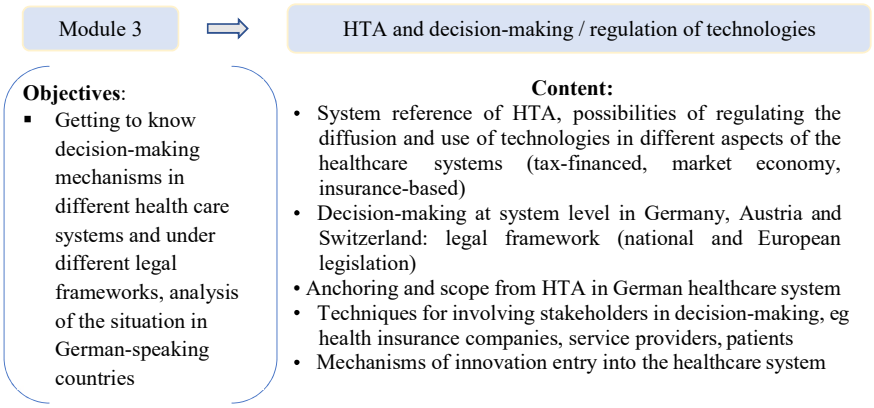

Fig. 4. Curriculum in HTA (module 3)

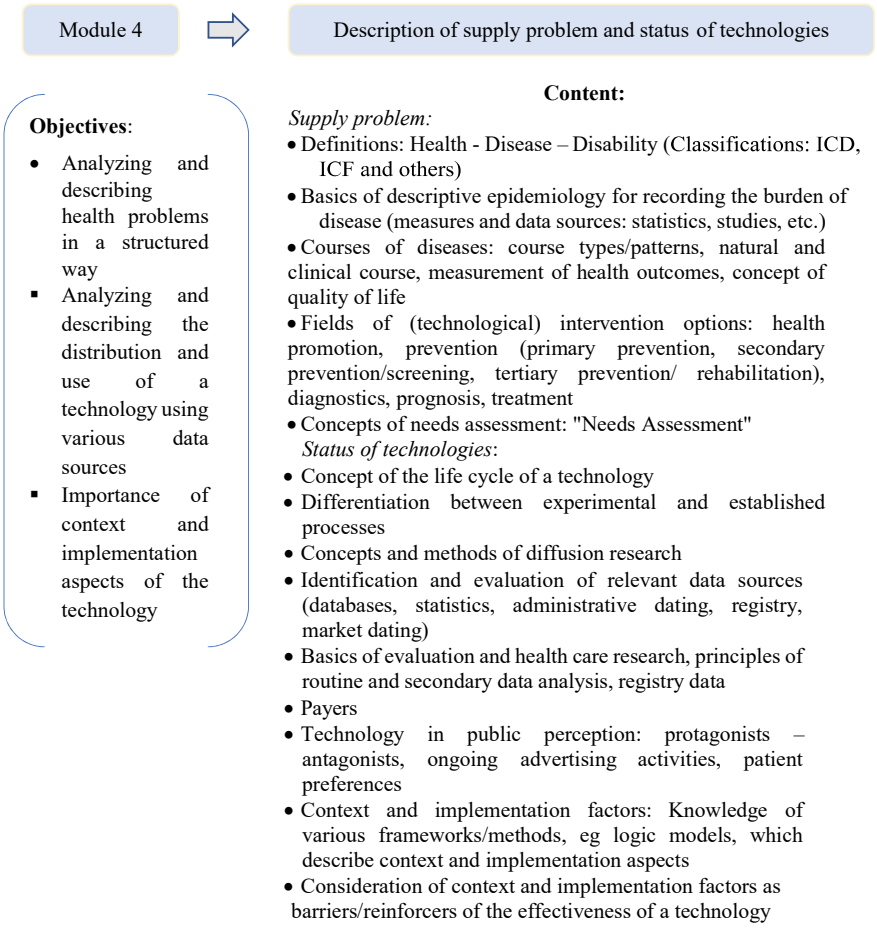

Fig. 5. Curriculum in HTA (module 4)

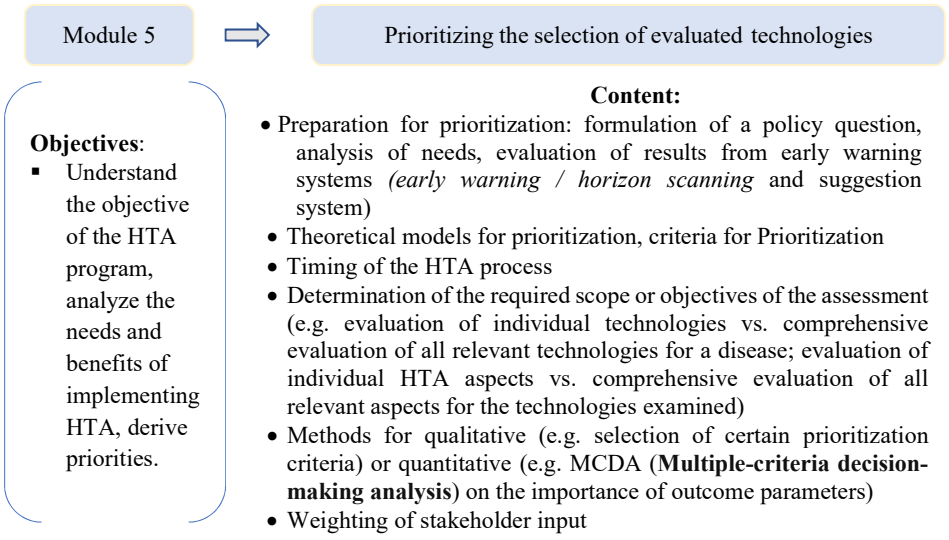

Fig. 6. Curriculum in HTA (module 5)

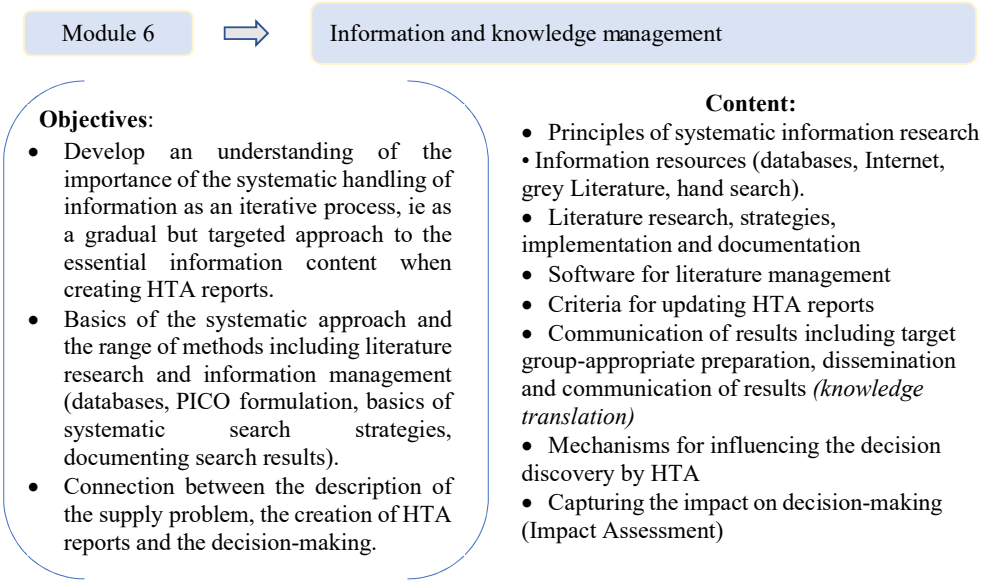

Fig. 7. Curriculum in HTA (module 6)

At the same time, it is fair to point out that, as noted above, dynamism is a feature of modern healthcare and, therefore, of modern HTA. Therefore, the review of existing approaches is periodic, which contributes to the ability of the HTA system to respond to modern healthcare challenges, social needs and the capabilities of economies (countries).

In our opinion, the fact that, having a basic curriculum, each of the training programs can differ in content – the content and volume of the proposed material – is positive and, at the same time, worthy of special attention. It is this mode of "autonomy" that will determine the competitiveness of each of the trained specialists in the field of NTA, and, as a consequence, the effectiveness of the health system as a whole, where we include in "effectiveness", among other things, the following concepts: the level of satisfaction of health needs, the effectiveness of therapy/management of the disease (condition)/diseases (conditions), the level of health of the population of the country/region, the level of quality of life, etc.

Description of the modules. All modules are separate and independent (this is why it is possible to choose their different order creating curriculums). At the same time, all modules are strictly important to be presented in training plan (curriculum).

Conditionally, we would single out three cycles of the curriculum, which can still be changed and reformatted by the authors of the curricula. However, we conditionally single out the first – the basic "Fundamental cycle", to which it is natural to include modules 1–6. This cycle as a whole reveal to the students the basic concepts of HTA (M 4), priorities, sequence of the HTA process (M 2, 3), prerequisites and conditions under which the HTA process will be maximally effective (M 4, 5, 6), and also provides specifications of the HTA process and its implementation at the level of the country (Germany)/ region (German-speaking countries).

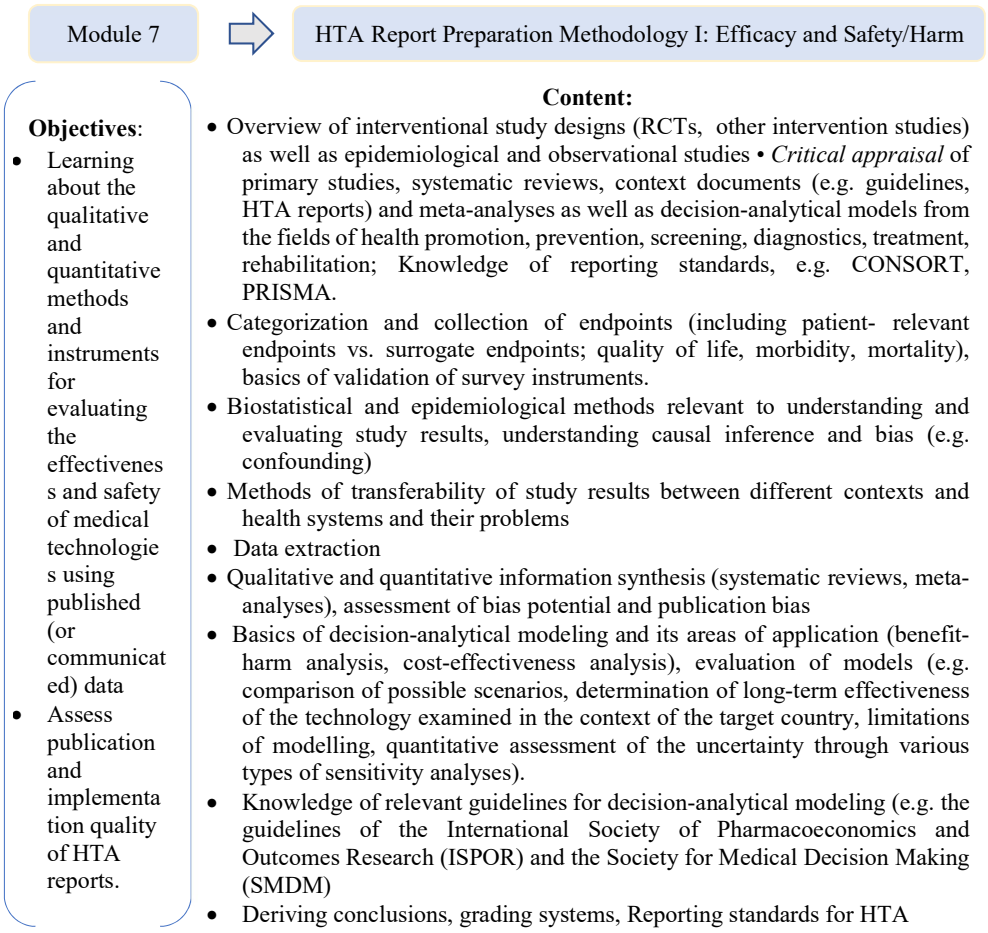

Fig. 8. Curriculum in HTA (module 7)

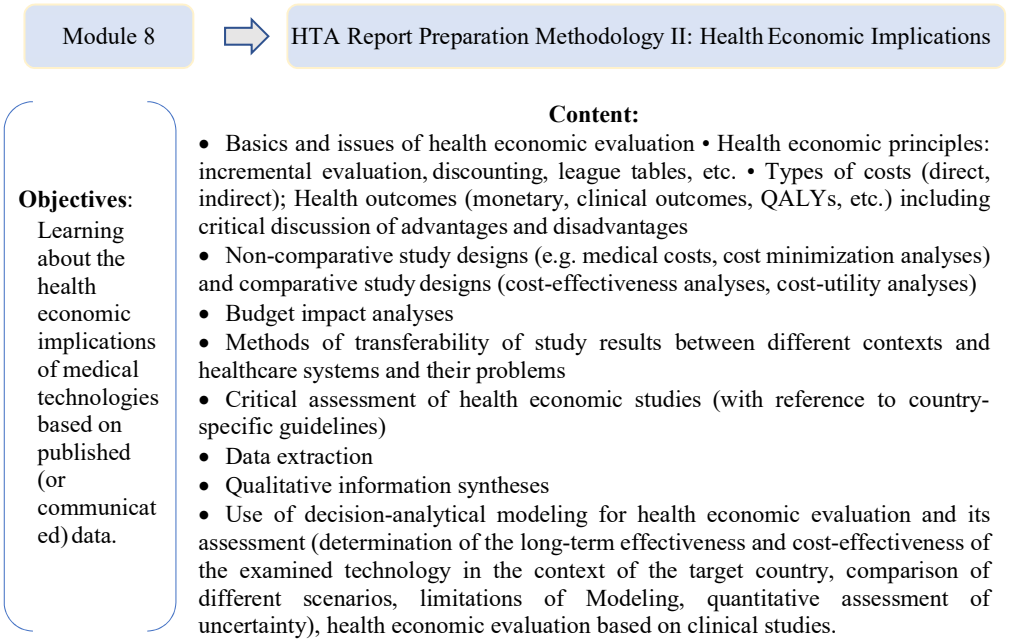

Fig. 9. Curriculum in HTA (module 8)

The second cycle combines modules that reveal the HTA methodology – "Methodological cycle" – modules 7–9, namely: indicators of effectiveness, safety and harm that are appropriate to use when assessing technology (M 8), ethical and cultural features (M 9), where aspects specific to the country/region should also be given.

The final cycle is impartiality of the result(s) (M9), where the independent status of HTA entities is described.

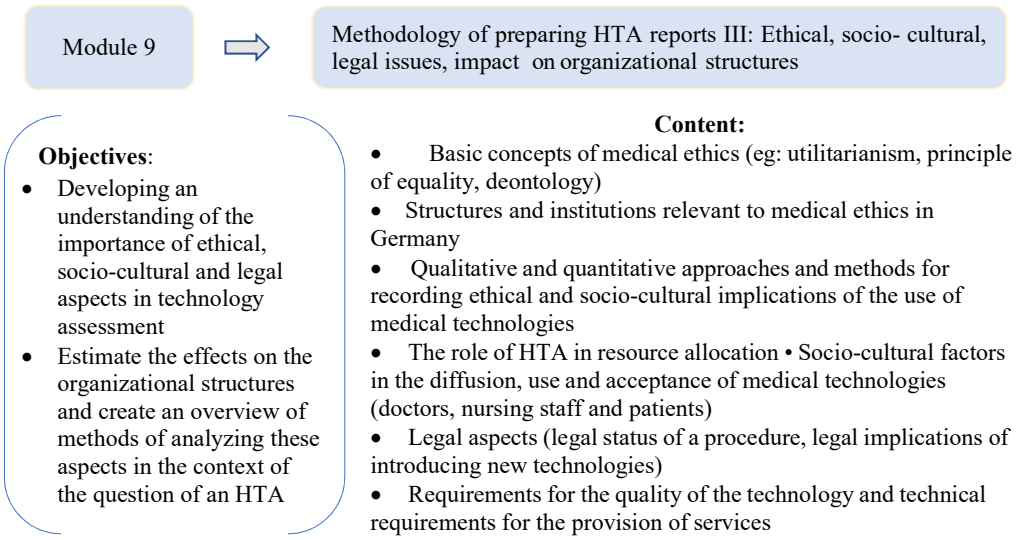

Fig. 10. Curriculum in HTA (module 9)

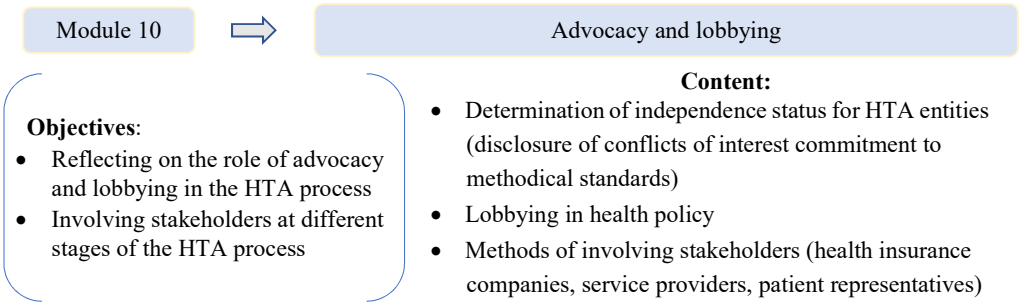

Fig. 11. Curriculum in HTA (module 10)

It should be noted about highest regional specification for two Modules – 3 and 9, where regional features should be not only tacking into account also describe in detail.

5. Discussion

Other authors' results of the study of the technology assessment system in European countries and in Ukraine are presented in open sources [3, 5, 16, 23]. The issue of the educational component in European countries has also been studied by scientists [7, 9, 10, 13, 19, 24, 25]. However, to date, there are no open access publications on a brief generalization and analysis of the authorities that carry out HTA in Europe, namely in Germany, as well as the insufficiently covered issue of content analysis of the EU's current core HTA curriculum. Therefore, the presented research results can be attributed to relevant and timely.

Thus, as shown by the study of interaction between the main participants (performers, regulatory authorities), the HTA system in Germany, dynamism is a positive sign of the development of the health system. In the process of improving the functioning of the HTA, new institutions changed and appeared, the boundaries of responsibility of the institutions involved were reformatted, which in turn contributed to the creation of a transparent HTA system.

The educational component presented in the article aims to clarify and disseminate the achievements of German-speaking specialists in the field of training specialists in HTA, which may be of importance for other countries in the European region that are in the process of creating/developing HTA. Among the research questions that need discussion, we can mention proposals regarding the consideration of expediency in the prioritization of competency grid, by target groups described in the article.

An additional positive factor, among those contributing to the successful assimilation of the basics of HTA and their practical use, could be a recommendation/requirement to have a knowledge of a foreign (English) language, basics of statistical analysis and economics (programming) and statistics.

Optimization of the process of the HTA basics studying as an optional approach, may also include detailing the curriculum according to target groups, or offer students to choose a general or prioritized (according to a specific target group) HTA curriculum.

An unresolved issue in the HTA process remains uncertainty – to what extent and in what way the information presented in reports and processed by experts influences decision-making, i.e. the level of correlation (impact). As well as to what extent the existing factual information (based on factual data) is fully reflected

in the process of preparing reports (unfavorable information may not be covered).

The current question that needs descriptions – the approaches to AI applying. We think, regarding last NICE politics in AI issues and popularization of AI methods among researchers and stakeholders it should be recognized its level of presents in the Curriculum and basics that will be proposed for students as well as coding and Python/R programming usage.

Practical significance. The results obtained will contribute to the process of creating and/or improving HTA system for developing countries. Presenting material can also be used in researching and modeling of HTA curriculums or in training process of HTA professionals in general.

Research limitations. Limitation of the investigation may be including only German-language Curriculum for analyses and only German official resources.

Prospects for further research. Considering the current geopolitical situation, which directly affects Ukraine, future research it's going to pay attention to proposals for the creation and implementation of HTA curriculum for developing countries and countries that are/were in a war condition.

6. Conclusions

The article lists and describes the stakeholders of the HTA system in Germany. Based on an information search of certain reliable sources of official information on the German HTA system, the source and content of the current basic program on HTA are presented. Based on the results of the analysis of this program, the main target groups are summarized and listed, basic professional competencies are highlighted. The structure of the modules and their brief characteristics are presented. The authors raise the issue of the utility of using basic training programs based on existing ones with the need to interpret and adapt to the needs of the country implementing/improving the HTA system, in particular its educational component. As study resulted, the context and structure of German HTA systems reflect health system priorities and underpin a country's history, culture, values and preferences. Therefore, HTA is a concept with many facets and may differ in its focus and method, its governance and role, scope and remit, the assessment method employed and its impact on coverage decisions [4, 5]. These variations make HTA processes unique, resulting in different levels of use, implementation and impact on the decision-making process and final coverage decision [4, 5].

We, as authors, draw attention to the fact that the materials presented are neither a proposal for a prepared solution, but rather a review of the existing German system and educational program in HTA. To build or improve the HTA system, attention should be paid to the periodicity of updating information, which will contribute to a more accurate identification (satisfaction) of the needs of the country's HTA, both from the standpoint of implementation and ensuring applied functioning, and for the educational component of the HTA process. Constant review and assessment of the need\ basic scope of the national HTA and stakeholders. The best way to do this is to study existing models and mechanisms of HTA in countries with the most developed and advanced health care systems.

Conflict of interest

The authors declare that they have no conflict of interest in relation to this research, whether financial, personal, authorship or otherwise, that could affect the research, and its results presented in this paper.

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Data availability

Manuscript has no associated data.

Use of artificial intelligence

The authors confirm that they did not use artificial intelligence technologies when creating the current work.

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