
ОРГАНІЗАЦІЯ ТА ЕКОНОМІКА ФАРМАЦІЇ

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METHODOLOGICAL APPROACHES TO DEVELOPMENT OF THE NATIONAL GUIDELINES ON THE HEALTH TECHNOLOGY ASSESSMENT

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Key words: healthcare system; health technology assessment; clinical analysis; economic analysis; analysis of the impact on the budget

On the basis of scientific processing and compilation of the literary sources data reflecting the methodology of creating the guidelines for the system of health technology assessment the main stages of the informative components of the National guidelines in health technology assessment have been determined. The informative components of the guidelines developed have the following four stages: description of the task in the technology assessment, clinical analysis, economic analysis, and analysis of the impact on the healthcare system. The first stage of the research is determination of the technology to be estimated – diagnostic, preventive or therapeutic interventions, which is used in a specific clinical situation. At the second stage the clinical analysis, which concerns the medical consequences of using the health technologies estimated, is carried out. It also provides information about its efficacy and safety in a particular group of patients compared to the similar technologies. The third stage provides the performance of the economic analysis consisting of comparison of the technology to be estimated with the reference one based on the cost and health effects. There are three strategies for conducting the economic analysis of the medical technology: relevant; cost-effectiveness; and carried out again. At the fourth stage the analysis of the impact on the health system, the budget impact and assessment of the organizational consequences, as well as estimation of the ethical and social consequences has been conducted.

The system of Health Technology Assessment (HTA) has become one of the most effective systems used by almost all European countries, except for the former Soviet Union, to substitute the choice of priorities in health technologies (HT) and decision-making. Prevalence of HTA reflects the increased demand for reliable information required to confirm the efficacy of HT considering evidence-based medicine [4, 5, 6, 10].

In recent studies of HTA among a fairly wide range of problematic issues of the HT assessment the methodology is of particular importance [2, 9]. Currently HTA bodies of different countries set the task to create the methodological framework or standard instructions in HT conducting that would summarize the best practices [1, 3]. These developments are relevant and useful for national health systems (healthcare), especially for countries that begin implementing HTA, and it fully refers to Ukraine.

Experimental Part

Analysis of the national legislation and regulations has shown that at this time there is no methodology that would comprehensively evaluate HT in terms of clinical and economic feasibility. In this regard, the aim of

the research was the study of approaches to create guidelines to assess HT in Ukraine. The object of the study was the methodology used by developers to create guidelines of HTA in the EU.

Results and Discussion

The purpose of the guidelines for HTA, as a rule, is to determine the basic principles and methods of the HT assessment in order to provide high quality of analysis and reliable results. They should focus on patients, as well as to provide the efficacy and safety of treatment, the best results and the rational use of resources. The systemic HT assessment should include the following methods: analysis of clinical efficacy, economic analysis, analysis of the impact on public health. The scientific study and generalization of the literature [1, 2, 3, 7, 8, 9] reflecting the methodology of creating guidelines for HTA allowed to determine the informative components of the national guidelines on the assessment of HT (hereinafter – Guidelines), they are presented in Fig.

The first stage of the study is to identify clearly the technology to be estimated: diagnostic, preventive or therapeutic interventions used in a specific clinical situation. According to the guidelines the full description of

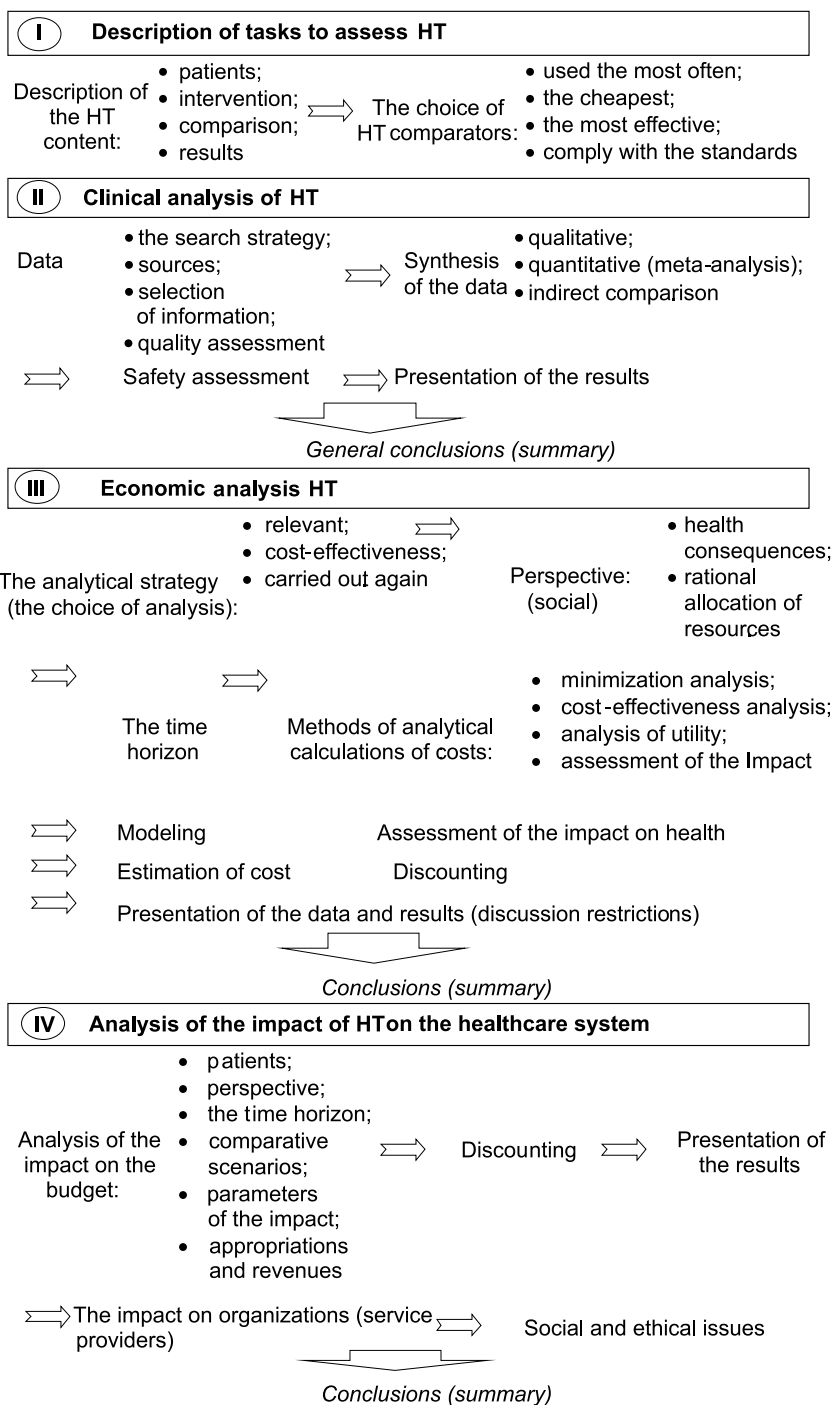


Fig. The informative components of the National guidelines in health technology assessment (HT).

the HT content should be carried out by the following scheme: patients who will use the intervention, characteristics of the intervention offered, comparison with similar interventions, medical outcomes, i.e. the endpoints of the clinical research.

If technologies are not approved in Ukraine, it is advisable to specify the date and place of their approval in other countries, particularly in the following recognized organizations such as the EMEA (European Medicines Agency) and FDA (Food and Drug Administration, USA). It is recommended to compare with other comparators, i.e. the technologies shown in Fig. It is important that the comparators chosen meet domestic re-

alities, it is expedient to explain their choice, it should be also noted the data source. Medical outcomes represent analysis of health consequences of HT introduction.

At the second stage the clinical analysis concerning the health effects of HT to be estimated is carried out. It also provides the information on its efficacy and safety in a particular patient group compared to the similar technologies. In the analysis it is necessary to develop a strategy for data searching that is relevant to perform the clinical task. It is generally recommended to use the most highly sensitive search strategy.

The data collected during the clinical analysis are related to experimental and practical efficiency of HT.

It is advisable to select data based on a protocol that contains the specific criteria for their inclusion and exclusion in the research. Further it is expedient to find independent reports and systematic reviews of the technology assessment, in particular, including those that can be found in the Cochrane library, databases of Medline, EMBASE and the Centre for reviews and dissemination.

Selection of information reduces itself to the question whether the scientific reports found are suitable for analysis, including selection based on the summary of the content, and therefore, the analysis of text publications. It is advisable to carry out the process of selecting information for systematic review of HT by at least two analysts working independently. Finally, it is necessary to determine the degree of consistency between analysts conducting the analysis.

Assessment of data quality allows to determine their authenticity. Synthesis of the data is intended to obtain information and to provide estimates of variability. It includes a systematic review of the literature (with or without meta-analysis). Meta-analysis is the preferred method of results processing. When conducting a meta-analysis is not possible, the analysis can be narrowed down to the quality inspection. In case of the absence of direct comparative studies where the estimated and alternative technologies are directly compared it should be recommended to perform indirect comparisons. When estimating the technology the results of the safety analysis should be taken into account.

The third stage involves the economic analysis consisting of comparison of the technology to be estimated with the corresponding reference subject based on the cost and health effects. There are three strategies for economic analysis of the medical technology: relevant, cost-effectiveness, and carried out again. The primary prospect of analysis is financing of healthcare organizations services (government, patients and other payers). The social perspective is recommended when deciding on funding HT. The time period of the economic analysis should be sufficiently long to determine the costs and

health outcomes. The time horizon for the short-and long-term results should be presented separately.

The method of analytical calculations of costs involves the use of various types of analysis: cost minimization, cost-effectiveness, utility costs, costs consequences. In certain situations it is recommended to use simulation, namely the need to assess the outcomes in practice, extrapolate the results beyond the time period of the clinical trials, etc. The economic analysis aims to assess the impact on health conditions for introduction of this technology in the current clinical practice. The cost of the product unit used in the analysis must be conditioned by the choice of the method for measuring the resources used: standard costs, published studies, local pricing grid elements, direct calculation.

The acceptable level of discounting is 5% of the value and 3.5% of the results of medical and pharmaceutical care in the main analysis. It is advisable to introduce the results of the economic analysis in the presentation clearly enough for proper interpretation and the possibility of using the data in future.

The fourth stage is the analysis of the healthcare system, which includes analysis of the impact on the budget and assessment of organizational outcomes, as well as estimation of the possible ethical and social consequences.

General conclusions made at each of the three stages should be summarized. The main element here is the presentation of conclusions based on the summary of the material.

CONCLUSIONS

In order to evaluate HT the methodological approaches have been proposed to make informed decisions concerning the implementation of effective technologies in healthcare and pharmacy, which should be used in development of the national guidelines. The informative components of the guidelines, namely description of the task in the technology assessment, clinical analysis, economic analysis, and analysis of the impact on the healthcare system have been developed and scientifically grounded.

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МЕТОДОЛОГІЧНІ ПІДХОДИ ДО РОЗРОБКИ НАЦІОНАЛЬНОГО КЕРІВНИЦТВА З ОЦІНКИ ТЕХНОЛОГІЙ ОХОРОНИ ЗДОРОВ'Я

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Ключові слова: система охорони здоров'я; оцінка технологій охорони здоров'я; клінічний аналіз; економічний аналіз; аналіз впливу на бюджет

На основі наукового опрацювання та узагальнення даних літературних джерел, що відображають методологію створення керівних вказівок щодо системи оцінки технологій охорони здоров'я, визначені основні етапи формування змістовних складових Національного керівництва з проведення оцінки технологій охорони здоров'я. Розроблені змістовні складові керівництва мають чотири етапи: опис завдання з оцінки технологій, клінічний аналіз, економічний аналіз, а також аналіз впливу на систему охорони здоров'я. Встановлено, що на першому етапі дослідження є визначення оцінюваної технології: діагностичного, профілактичного або терапевтичного втручання, що використовується у певній клінічній ситуації. На другому етапі проводиться клінічний аналіз, який стосується медичних наслідків застосування технологій охорони здоров'я, що оцінюється. Він також надає інформацію про її ефективність та безпечність у певній групі пацієнтів у порівнянні з аналогічними технологіями. Третій етап передбачає проведення економічного аналізу, що складається з порівняння оцінюваної технології з референтною, виходячи з вартості та наслідків для здоров'я. Виділяють три стратегії проведення економічного аналізу медичної технології: релевантний; економічної ефективності; наново проведений. На четвертому етапі проводиться аналіз впливу на систему охорони здоров'я, що охоплює аналіз впливу на бюджет та оцінку організаційних наслідків, а також оцінку ймовірних етичних і соціальних наслідків.

МЕТОДОЛОГИЧЕСКИЕ ПОДХОДЫ К РАЗРАБОТКЕ НАЦИОНАЛЬНОГО РУКОВОДСТВА ПО ОЦЕНКЕ ТЕХНОЛОГИИ ЗДРАВООХРАНЕНИЯ

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Ключевые слова: система здравоохранения; оценка технологий здравоохранения; клинический анализ; экономический анализ; анализ влияния на бюджет

На основе научной обработки и обобщения данных литературных источников, отражающих методологию создания руководящих указаний по системе оценки технологий здравоохранения, определены основные этапы формирования содержательных составляющих Национального руководства по проведению оценки технологий здравоохранения. Разработанные содержательные составляющие руководства имеют четыре этапа: описание задания по оценке технологий, клинический анализ, экономический анализ, а также анализ воздействия на систему здравоохранения. Определено, что на первом этапе исследования дается определение оцениваемой технологии: диагностического, профилактического или терапевтического вмешательства, используемого в определенной клинической ситуации. На втором этапе проводится клинический анализ, касающийся медицинских последствий применения оцениваемых технологий здравоохранения. Он также предоставляет информацию об ее эффективности и безопасности в определенной группе пациентов по сравнению с аналогичными технологиями. Третий этап предусматривает проведение экономического анализа, состоящего из сравнения оцениваемой технологии с референтной, исходя из стоимости и последствий для здоровья. Выделяют три стратегии проведения экономического анализа медицинской технологии: релевантний; экономической эффективности; проведения заново. На четвертом этапе проводится анализ влияния на систему здравоохранения, охватывающий анализ влияния на бюджет и оценку организационных последствий, а также на оценку этических и социальных последствий.