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**OPERATION OF EUROPEAN NETWORK
FOR HEALTH TECHNOLOGY ASSESSMENT
(EUnetHTA) ON THE EXAMPLE
OF COLORECTAL CANCER**

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Operation of European Network for Health Technology Assessment (EUnetHTA) on the Example of Colorectal Cancer

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Abstract

INTRODUCTION: EUnetHTA was established in 2005, under the initiative of the European Commission and the Council of Ministers. EUnetHTA is currently active in Joint Action 2 (JA2), which started in 2012 and will last until 2015. Although JA2 includes several working packages (WP), WP4 represents one of the central ones. The main objective of this package is testing the tool (i.e. HTA core model), and to determine the optimal form of cooperation of all the partners in JA2 for the preparation of HTA studies.

METHODS: This chapter describes the whole concept of HTA Core Model. The chapter also provides information on partners, involved in preparation of the first pilot project, and on research strategy (research method was the literature review).

RESULTS: November 2013 represented one of the first major milestones within JA2 due to the closure of the first HTA pilot project, where two tests, which are used within colorectal cancer screening (i.e. gFOBT and FIT), were evaluated and compared.

DISCUSSION: The first results suggest that a methodological tool itself is not providing the efficiency and effectiveness within cooperation between partners. Nevertheless the first pilot project within JA2 demonstrates that core HTA model with its wide and comprehensive characteristics allows a comparison of HTA studies at the European level.

JEL Classification: I19

Keywords: Health technology assessment (HTA); EUnetHTA (European network for HTA); Core HTA Model; Colorectal cancer screening (CRC); gFOBT; FIT; systematic literature review.

1. INTRODUCTION

In 2004, the European Commission (EC) and the Council of Ministers defined the scope of HTA as one of the priority areas. Furthermore, a specific institutional organizational form of governmental and other organizations from the EU called EUnetHTA (European Network for Health Technology Evaluation), was set up in 2005 (EUnetHTA, 2013a).

EUnetHTA defines HTA as a multidisciplinary process, which systematically, transparently, objectively and robustly combines information on medical, sociological, economic and ethical issues related to the use of a certain medical technology. The purpose of the network is to connect the national HTA agencies, research institutions and health ministries, and enable an effective exchange of information (without overlap and duplication of efforts in the field of HTA) and support policy-making within individual countries (EUnetHTA, 2013a, Turk & Prevolnik Rupel, 2010; Kristensen et al., 2009b).

Therefore, the network should help to ensure reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and corresponding policy decisions within the EU. In this way, individual countries can more easily and effectively plan, provide and monitor health services at the national level (EUnetHTA, 2013a; Kristensen et al., 2009a).

EUnetHTA network is currently pursuing its core objectives and activities within the program Joint Action 2 (JA2, 2012-2015), whose general objective is to strengthen the practical application of tools and approaches developed in the previous program (JA1 - cross-border HTA cooperation). JA2 is based on the cooperation at a high level. Its central purpose is to develop a general strategy, principles and the proposal of an implementation for sustainable HTA collaboration at the European level. This should be in accordance with the requirements of Article 15 of the Directive on cross-border healthcare (EUnetHTA, 2013a).

Within the JA2 37 partners from 28 European countries (27 EU Member States and Norway) are involved, including two Slovenian partners: National Institute for Public Health (NIPH) and the Institute for Economic Research (IER). JA2 is primarily designed for evaluation and testing of HTA information at the national level and for preparation and use of HTA core model at European and national level. The JA2 activities are planned within 8 work packages (WP). The WP4 is one of the most important packages and Slovenia is extensively involved in it. Its main objective is to test the tools, i.e. the core HTA model, and determine the optimal form of cooperation among partners in JA2 for the preparation of HTA studies. Additionally, its purpose is to examine the capacity of national HTA bodies for production of common

structural HTA information, to further develop models and tools based on mutual cooperation, and to develop and test the methodological bases for European cooperation in the HTA field, including guidelines for various methodological issues and improvement of the quality of evidence for HTA (EUnetHTA, 2013a; EUnetHTA, 2013b; EUnetHTA, 2013c; Lampe et al., 2009).

A certain medical technology is assessed within the core HTA model. The technology is selected on the basis of proposals and the democratic voting process of the partners and the EC (DG SANCO). For the preparation of the first core HTA model the screening test for cancer of the colon and rectum was selected and evaluated, in which the gFOBT technology (Guaiac-based fecal Occult Blood Test) was compared with the FIT technology (Fecal Immunochemical Test).

The purpose of this article is through the experience of the preparation of the first core HTA model inform Slovenian health professionals about the activities of EUnetHTA network. Below the process of application of the basic HTA model and its results is described on the example of a screening test for cancer of the colon and rectum.

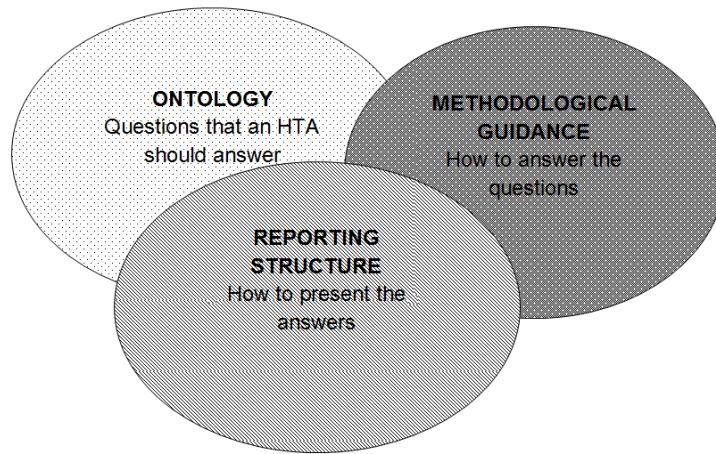
2. METHODS

2.1. The core HTA model

The core HTA model was developed in order to provide a common framework for gathering HTA information and standardized reporting. EUnetHTA defined the term "the core" as those relating to the allocation of the most useful and relevant information between countries and regions (Lampe et al., 2009). Moreover, various technologies require different assessment. On this basis, the three different applications of the HTA core model were currently developed, namely medical and surgical interventions, diagnostic technologies, and screening technologies (EUnetHTA, 2012).

The core HTA model is composed of three components (Figure 1, i.e. ontology, methodological guidelines and the common structure of reporting (EUnetHTA, 2012).

Picture 1: The Core HTA model



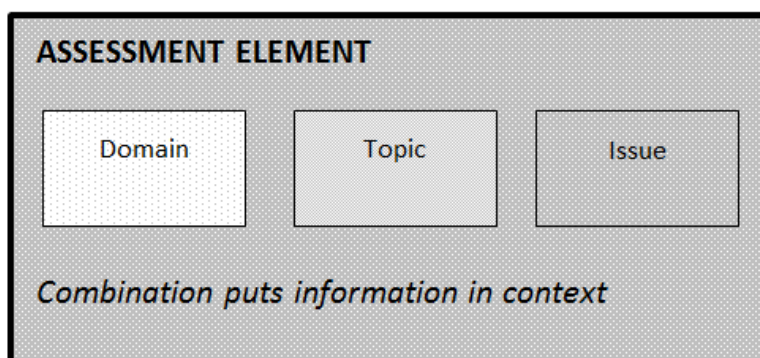
Source: EUnetHTA (8)

For better comprehension of the model it is necessary to be familiar with its composition.

HTA model structures HTA information within the framework of nine different and mutually equivalent domains: 1) health problem and current use of technology, 2) a description of technical features and technologies, 3) safety, 4) clinical efficacy, 5) costs and economic evaluation, 6) ethical aspect, 7) organizational aspect, 8), social aspect and 9) legal Issues (HTA Core model).

Each domain is divided into three or more topics and each topic is divided into several issues. The combination of the domain, the topic and the individual evaluation issues defines an assessment element (Figure 2) (EUnetHTA, 2012; HTA Core model; Pasternack et al., 2009).

Picture 2: Assessment element



Source: EUnetHTA, 2012

An assessment element provides the information that is relevant to the HTA and can be of national or international importance. If the information relates to the specific national or regional context, it is usually not useful in other environments. The core elements are defined by two key features: relevance and transferability of information (Lampe et al., 2009; EUnetHTA, 2012; HTA Core model; Pasternack et al., 2009). Completely or at least partially transferable is a valuable contribution exceeding the original environment of information. The term importance relates to the fact that the element contains information which is of a great importance in assessment of the individual technology. When deciding on the use of a particular issue / item within the HTA model the following matrix should be considered (EUnetHTA, 2012):

Picture 3: Core matrix

CORE MATRIX		Importance		
		1 <i>Optional</i>	2 / <i>Important</i>	3 <i>Critical</i>
Transferability	3 <i>Complete</i>	<i>Not core</i>	<i>Core</i>	<i>Core</i>
	2 <i>Partially</i>	<i>Not core</i>	<i>Core</i>	<i>Core</i>
	1 <i>Not</i>	<i>Not core</i>	<i>Not core</i>	<i>Core</i>

Source: EUnetHTA, 2012 & Lampe et al., 2009.

Therefore, the inclusion or exclusion of the element in the core HTA model is based on the usefulness of the information in an international environment. This does not mean that non-transferable data may not be useful and relevant; just the contrary - that information is very important in the national context (EUnetHTA, 2012).

Each evaluation element (non-core or core) appears on its element card, on which the evident information about this element is given, while the matrix also allows connections to other assessment elements (cards). Half of the generic issues in the model are mutually connected. Such a connection between the domains is a problem only in the case of raising the relationship raises into duplication of work and information (Iampe et al., 2009; EUnetHTA, 2012; HTA Core model; Pasternack, 2009).

2.2. The core HTA assessment

Preparation of the core HTA assessment requires a well-organized cooperation between partners. These voluntarily choose to participate and work on the selected domain. A primary investigator (PI) has a leading role in each domain, while investigators (I) and reviewers (R) participate with their roles (EUnetHTA, 2012).

The basis for the development of the core HTA model is a systematic literature review. This method is directly focused on the research questions, summarizes and synthesizes the results of known and unknown aspects of research, identifies areas where the literature is inconsistent and carries out the issues that still need to be explored (11). A literature review includes information gathering via a series of databases, such as medical databases (Medline, Cochrane Library, etc.), administrative databases (Science Direct, PubMed, EBSCO, etc.), various registers, international or national statistical databases, etc.. The information obtained by this means can be later supplemented by findings from gray literature or even the results of own surveys.

The process of making the first core HTA model in the framework of JA2 was launched in September 2012 and ended in November 2013. IER is participated in the process as PI on the organizational domain, as I on the economic domain and as R on the legal domain. Based on the HTA core model the national HTA will be prepared in 2014. It will represent the foundation for national HTA report. Implementation of national reports on the basis of HTA model is one of the tasks of a specific group within the WP4, the purpose of which is to test the appropriateness and transferability of information obtained by individual questions in the core HTA model from the European to the national level. IER participates in the group for national reporting as one of nine international partners.

3. RESULTS

In 2014 EUnetHTA JA2 project partners completed the first pilot project using the Core HTA Model. This project was focused on FOBT colorectal screening technology, where gFOBT (guaiac-based fecal occult blood test) technology and iFOBT (human haemoglobin immunochemical based FOBT) technology, also known as FIT technology, (Fecal Immunochemical Test) have been evaluated and compared. FOBT technology is non-invasive screening method with taking stool samples. Other methods of screening can be more invasive and are divided into endoscopic and radiological (e.g. colonoscopy). Target population within FOBT screening are asymptomatic individuals (both men and women), aged between 50 and 74 years, with an average risk of developing the colorectal cancer.

The results of all 9 domains of the first pilot project are presented by the individual domains hereinafter.

Domain 1: Health Problem and Current Use of the Technology (Huič et al., 2013a):

- Colorectal cancer is the third most common cancer which people suffers from around the world and the second most common cancer in developed countries.
- Colorectal cancer incidence increases after the age of 50.
- Most commonly cancer develops from malignant adenomas (that develops from adenomatous polyps).
- Screening test is a preventive method, which by removal of adenomas before they become malignant and by means of an early diagnosis (when colorectal cancer can be successfully treated) significantly reduces colorectal cancer morbidity and mortality.
- Screening has been already implemented in most of European countries in order to reduce the increasing trend of colorectal cancer.
- Some countries perform opportunistic screening, while a growing number of countries have already decided to introduce organizational and population based screening (because of the evidence of its effectiveness in reducing morbidity and mortality).

Domain 2: Description and technical characteristics of technology (Huič et al., 2013b):

- The difference between gFOBT and FIT technology: gFOBT is guaiac-based, while FIT technology uses antibodies that react on human haemoglobin (Hb).

- Common strengths of FIT and gFOBT technology: low price; simple distribution (via mailbox).
- Specific strengths of FIT technology: improved test characteristics with the same or comparable price to gFOBT technology; it is easier to use by the patient; does not require special diets; one stool sample is sufficient for the analysis; FIT test has several thresholds in terms of concentration of Hb that can result in a greater sensitivity level; reduces the proportion of false positive results of the test;
- Weaknesses of FIT technology: some studies demonstrate that FIT technology is slightly more expensive in comparison to gFOBT technology (although both of them remain within approx. the same price range); in addition, there is a greater instability of the sample in the device for collecting fluid;
- Specific strengths of gFOBT technology: samples are stable up to 21 days (within FIT technology the samples are significantly less stable).
- Weaknesses of gFOBT technology: it is not automated; requires a human factor and its subjective assessment; participants are required to prepare 3 samples of the test and before that adhere to special diets; because within this test threshold values of haemoglobin (Hb) cannot be adjusted, the test is less sensitive.
- Countries mostly use gFOBT technology, while on the other hand FIT technology is becoming increasingly relevant and popular in recent years.
- Colonoscopy is much more expensive than FOBT testing but represents a gold standard in the next phase (ie. in case of positive FOBT screening tests results), when the accurate diagnosis is required.

Domain 3: Safety (Maennik et al., 2013):

- The HTA model tried to detect the undesirable and harmful effects of FIT and gFOBT technology. As the colonoscopy is closely linked with the aforementioned tests, it is analyzed in the safety domain too.
- Non-invasive FOBT technology does not provide direct adverse effects, only some indirect harmful effects, which are associated with the occurrence of false-positive or false-negative results of the test. These may result in the occurrence of anxiety and stress at the individual, which can also lead to further undue investigation or cause delay in the detection of the potential occurrence of the disease. Therefore, indirect harmful effects can be overdiagnosis and excessive amount of treatment (overtreatment).
- Colonoscopy which is in most cases used for further detection of the disease can cause a number of direct complications, such as perforation of the colon, bleeding, infection, pain, and discomfort. These negative effects (psychological and

physiological) can occur immediately or later. There are no evidences that sensitive patients would be more disposed to negative influences. However, there are evidences that patients with more chronic diseases have higher probability to be subjected to the risks posed by colonoscopy.

- A certain degree of negative psychological impact can be reduced with good organization and implementation of screening, consistent consideration of instructions by patients and professionalism of the staff.

Domain 4: Clinical effectiveness (Gonzales-Enriquez et al., 2013):

- Studies that would compare the FIT and gFOBT technology in terms of mortality were not found.
- Studies that would compare each technology with the absence of screening show that screening reduces mortality and therefore is recommended.
- Evidences for a reasonable replacement of gFOBT with newer FIT technology: higher sensitivity of the FIT test for detection of advanced adenomas and cancer at the same specificity.

Domain 5: Costs and economic evaluation (Renner et al., 2013):

- Compared with the second technology the FOBT technology FOBT has lower price. Evaluated Technologies (FIT and gFOBT) belong to comparable price range.
- There are no studies that would directly compare only FIT and gFOBT technology; studies usually include information on other types of technologies, such as colonoscopy, sigmoidoscopy, fecal DNA test, etc. which are compared with the absence of screening.
- It is impossible to create a universal, simplified model of economic efficiency, because there are different types gFOBT tests (Hemoccult, Hemoccult II, Hemoccult SENSA), while the FIT test can be used with different thresholds, which affects both the sensitivity and specificity of each test .
- Economic studies do not distinguish costs incurred on patient level and of costs incurred outside the health care system. They address only the perspective of the payer of health care services. Nevertheless, certain cases indicate that the costs of screening procedure and the screening tests (screening kits) are cheaper in Europe than in the USA.
- The studies indicate that FIT technology is slightly more cost-effective compared to gFOBT technology.

- Within the discussion an incentive for the RCT study in the field of morbidity and mortality has been given and at the same time comparisons of gFOBT with FIT test, the absence of population based screening or opportunistic screening.

Domain 6: Ethical aspects (Endel, 2013):

- Comparison of FIT and gFOBT test does not involve any particular ethical problem.
- If the state decided for organized population screening and it is already being implemented, then ethical issues were already addressed in the stage of the strategy preparation.
- The key issues related to screening appear in the field of the individual's autonomy, which must be considered objectively.

Domain 7: Organizational aspect (Prevolnik-Rupel et al., 2013):

- Organized screening must follow a specific process involving various stakeholders (besides participants the administrative staff, epidemiologists, laboratory staff, general practitioners, nurses and experts in the field of public health). In further investigations and treatment experts in the field of endoscopy, radiology, pathology and surgeons should also participate and they must be well organized.
- The quality of screening is ensured through effective, quality communication, multidisciplinary collaboration of professionals and proper education of stakeholders.
- Despite the strong promotion of screening the participation rate by countries remains at a very low level.
- Link to economic aspects: there is no information on the impact of testing on a budget (BIA).

Domain 8: Social aspect (Lo Scalzo & Wilbacher, 2013):

- When using the test an individual may be faced with embarrassment, resistance to excrement testing, discomfort, fear of diagnosis, lack of information related to testing and similar.
- An individual as a member of society may be faced with peculiarities that require an adjustment of the testing process to the individual or affect his/her decision whether to accept the test (due to cultural, geographical and other reasons). It is therefore important that the planners of the national screening program at the time of its preparation take into account social, cultural and psychological factors.
- Women are more likely to participate in the testing than men.

- To assess the connection between participation in the testing and other factors, such as socio-economic status, age groups, etc. more in-depth researches should be done.

Domain 9: Legal aspect (Wilbacher, 2013):

- The regulation states that the voluntary participation in screening should be provided within each country.
- Protection of patient data is legally regulated on European level.
- There is a legal arrangement that an individual receives information on usefulness, harmfulness and realistic expectations when using certain technologies.
- There are some legal uncertainties relating to the responsibility of the individual false expectations within the screening.
- The obligation to protect the consumer when using medical devices and advertising health services: the aim is to achieve a complete freedom of choice of consumers of health services, based on complete, objective and unbiased information.

4. DISCUSSION

The core HTA model is based on secondary research. Since certain issues within the core HTA model are national-specific and because all of the data has not been possible to obtain (e.g. costs), it was not possible to give a complete answer to certain questions. To complement the information a survey among EUnetHTA network partners was carried out, which was due to low response rate (only 11 countries returned the survey) and incomplete answers, only partially helpful.

Despite the fact that certain information could not be obtained, the first core HTA model demonstrates that this extensive and comprehensive exercise leads HTA to the right direction. The key advantage of the model is that it includes and defines also some frequently overlooked areas that are important when deciding on a particular health technology. We are talking about the ethical, social, organizational and legal aspects, which by their nature are not the most visible part of HTA studies.

The collected studies were more or less focused on comparison between the tests in terms of medicine and technology (studies covering the ethical, social, organizational and legal aspects are rare). Studies were often focused also on cost-effectiveness. Therefore, some domains do not provide complete answers to specific questions. However, the advantage of the core HTA model lies in the fact that it highlights the points in which it is necessary to spend the effort for further and more in-depth research. Based on tool's testing it has become evident that the tool should be improved in order to eliminate duplication of questions and answers between the domains. That is exactly what happens in the first pilot HTA model in the framework of JA2.

Conclusions regarding cooperation are surprising - most of organizations have volunteered to participate in the evaluation; organisations were not active in the process (either as investigators or as reviewers); and other motives outweigh the original motives for the participation in the process. The division of labour within the first pilot project was ineffective – partners voluntarily chosen their roles within the core HTA model. Consequently, the number of investigators and reviewers was outsized and they did not respond appropriately or comment the contents. As well, the majority of involved organisations did not use the tools developed by EUnetHTA (e.g. communication between partners via the intranet) and therefore were not up to date with the progress of the project.

The exchange of information between partners within each domain was slow and uncoordinated, and between individual domains the communication was practically

nonexistent. For this reason, the project team decided to change the approach to work. In the second study in the framework of HTA JA2 (evaluation of intravenous immunoglobulins for Alzheimer's disease), which began in October 2013, the number of researchers and reviewers was limited to a maximum of four on each domain (i.e., a maximum of two researchers and a maximum of two referees).

Equally, a need for summary pages were brought up that would enable fast summary without reading the whole HTA report. Such summary would attract more readers – summaries could be made for the whole report as well for various assessment cards.

There are also certain issues that were open in the selection of the topic. The suggestion can be provided by all partners as well as by DG SANCO. In a process of democratic voting it turned out that no topic was given explicit priority – the voices were more or less equally distributed across all topics. Therefore a two-step voting process could be considered which would in the first phase eliminate topics with the least voices pushing into the second round only the technologies some technologies and hence provide a higher concentration of voices, from which real priorities would be seen.

5. CONCLUSION

In the current stage of the JA2 program implementation, when the first pilot project is nearly completed, and work continues on the second pilot project, it becomes apparent how important is the selection of technologies to be assessed. The results of the first pilot project indicate a weak collaboration and responsiveness among the partners, which means that the core HTA model is based merely on secondary research, precisely on a systematic literature review. The other options for obtaining information were not successful due to low response rate. If the area of the selected technology has not been studied yet, and therefore the studies are not available, the proposed system of cooperation among partners is not appropriate for the core HTA model preparation.

Despite many tools that EUnetHTA developed in 8 years of its operation, the cooperation between partners is not satisfactory. The communication has proved to be one of the crucial factors of poor cooperation. Poor co-operation is also affected by the working consciousness of the partners and, consequently, their actual (unsatisfactory and low-quality) practical contribution to the development of the model. Poor co-operation might also be a result of poor awareness of the importance of partners' joint work and their workload with other projects. It was difficult in both pilot projects to get the partners who would voluntarily accept the role of primary investigators on individual domains.

Therefore, the methodological tool enables cooperation between partners, but not the efficiency and effectiveness of cooperation within it. In any case, the organization and communication within field groups and between them could be strengthened and improved. The evaluation of the approach to the HTA core model is needed. Thereby, the EUnetHTA could determine whether the value of the information obtained on the basis of the first core model is greater than the value and time spent by all partners. For this purpose, partners already collected data and submitted them to the coordinator (i.e., the Italian organization AGENAS), but it is not clear how to evaluate the results of the accomplished work. Currently, the evaluation by AGENAS has not been made. If the effort put in an improvement of cooperation among partners contribute to changes, will show the next pilot project.

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