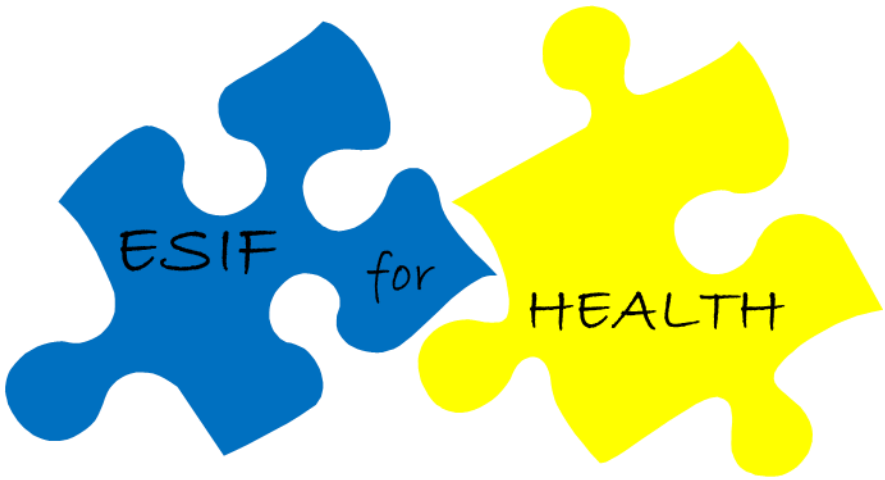
TECHNICAL TOOLKIT:

REFERENCE DOCUMENT ON THE APPRAISAL OF INVESTMENT

Developed under the project "Provision of support for the effective use of European Structural and Investment (ESI) Funds for health investments"



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List of abbreviations

CBA	Cost-Benefit Analysis
CCA	Cost-Consequences Analysis
CEA	Cost-Effectiveness Analysis
CER	Cost-Effectiveness Ratio
CHAFEA	Consumers, Health and Food Executive Agency
CQG	Cost per QALY gained
CUA	Cost-Utility Analysis
DG SANCO	Directorate General for Health and Consumers
ESIF / ESI Funds	European Structural and Investment Funds
EU	European Union
HIA	Health Impact Assessment
HTA	Health Technology Assessment
IAIA	International Association for Impact Assessment
ICER	Incremental Cost-Effectiveness Ratio
MoH	Ministry of Health
OA	Optional Appraisal
QALY	Quality-adjusted Life-year
WHO	World Health Organization
WP	Work Package

Introduction

This document "Reference document on the appraisal of investments" forming a part of the Technical toolkit supporting the Guide for effective investments in health under ESI Funds is developed in the framework of a tender action on the provision of support for the effective implementation of European Structural and Investment Funds (hereinafter "ESIF") for health investments, managed by the Consumers, Health and Food Executive Agency (CHAFEA) on behalf of the Directorate General for Health and Consumers (DG SANCO), being delivered by EY.

The Guide and its supporting documents (see the list of project outputs below) are based on broad analyses of collected case studies and EY expert opinion and do not represent official European Commission documents.

The project outputs developed within the framework of the tender action are as follows:

- WP 1 MAPPING REPORT ON THE USE OF EUROPEAN STRUCTURAL AND INVESTMENT FUNDS IN HEALTH IN THE 2007-2013 AND 2014-2020 PROGRAMMING PERIODS
- WP 2 GUIDE FOR EFFECTIVE INVESTMENTS IN HEALTH UNDER ESI FUNDS
- WP 3 TECHNICAL TOOLKIT FOR EFFECTIVE INVESTMENTS IN HEALTH UNDER ESI FUNDS with the following documents under the toolkit:
  - WP 3 (1) CATEGORIZATION OF THE 2014-2020 ESI FUNDS INSTRUMENTS AND MECHANISMS
  - WP 3 (2) REFERENCE CHECKLIST: ESSENTIAL AND SUCCESS FACTORS FOR CALLS FOR PROPOSALS AND FOR THE ASSESSMENT OF PROJECT APPLICATIONS
  - WP 3 (3) SET OF INDICATORS USEFUL FOR THE FINAL EVALUATION OF ACTIONS
  - WP 3 (4) COMPENDIUM OF (NEW) CONCEPTS AND MODELS FOR INNOVATIVE, EFFECTIVE AND SUSTAINABLE HEALTH CARE
  - WP 3 (5) MANUAL ON HOW TO PLAN, IMPLEMENT AND SUSTAIN CAPITAL INVESTMENT IN HEALTH AND HEALTH CARE
  - **WP 3 (6) REFERENCE DOCUMENT ON THE APPRAISAL OF INVESTMENT**
  - WP 3 (7) REFLECTION OF ADDITIONAL ISSUES RAISED BY MEMBER STATES

This part of the toolkit aims to analyze commonly used techniques for investment appraisal and, based on the analysis, to recommend useful techniques for effective investment appraisal of health projects with respect to the specifics of health care decision-making at all levels.

The document maps existing investment appraisal techniques and identifies which of them are relevant for health investments.

The document covers the following issues:

- Chapter 1 focuses on the **role and principles of an appraisal**.
- Chapter 2 addresses individual **appraisal techniques**.

1. Role and principles of an appraisal

1.1. Role of an appraisal in decision-making

One of the fundamental economic theses says that resources are scarce. Being responsible for public resources and their use, to satisfy the changing needs of the population, decision makers need to manage scarce resources in an effective way. The techniques of an economic appraisal introduced in this paper could help decision makers to:

- Identify and compare relevant alternatives
- Identify opportunity costs
- Avoid disregarding costs which are not expressed in monetary terms

An economic appraisal in health care decision-making is used to:

- Maximize the benefits from health care spending
- Overcome regional variations in access
- Contain costs and manage demand
- Provide bargaining power with suppliers of health care products

1.2. General principles of an economic appraisal

An economic appraisal generally refers to a set of techniques, used to weigh up the costs of specific action against the benefits that it provides. Various techniques exist, all of which represent a structured approach to supporting decision makers, responsible for allocation of public resources, in choosing between alternative recipients of these resources.

Regardless of the technique used, an economic appraisal is a process that should always comprise the following stages:

Step 1: Problem identification & definition	A starting point for any assessment is identification of a problem, rather than identification of a solution Problem is properly defined
Step 2: Definition of alternatives	Defining the different ways to deal with the problem Selection of the most relevant alternative(s) for problem solution
Step 3: Costs and benefits (outputs) assessment	**This stage always includes the following steps:** ▸ Enumeration: Development of a complex list of costs and benefits that are relevant for the case ▸ Measuring: Obtaining data to quantify / describe the levels of costs and benefits for different alternatives identified ▸ Valuation: Conversion of data gathered into a value of

	resources
Step 4: Calculation	Processing the data into results that will support the decision-making The exact nature of data processing will strongly depend on the type of appraisal
Step 5: Decision-making	An endpoint where a decision is made based on the results of an appraisal Must be taken by someone with appropriate responsibility to make the decision [usually a different person from the appraiser]

When carrying out an economic appraisal, it is always important to be aware of the viewpoint being taken, as different stakeholders may have different interests and concerns. This determines what constitutes benefits and costs and how these are to be valued, i.e. which type of appraisal is to be used.

2. Investment appraisal techniques

Those who plan, provide, receive or pay for health services face many recurring questions about who should do what to whom, with what health care resources and with what relation to other health care services. To answer these questions, a variety of methods could be used to appraise the efficiency and usefulness of actions or programmes. This chapter focuses on various types of appraisal and evaluation of the efficiency assessment of various approaches when used in health care.

The most complex and elaborated investment appraisal technique in the field of health is the **Health Technology Assessment (HTA)**. Nevertheless, there are more techniques introduced in this paper. The reason for this is twofold. First, as the HTA represents a complex approach, it actually contains and capitalizes on the other particular techniques. Second, as the nature of different health and health care projects varies significantly, it is not always necessary and even desirable to go through the whole complex process of the HTA, and merely the easier to carry out appraisal techniques are more appropriate to be employed. However, whenever a simple method is used, this has to be adequately justified.

Usual methods of appraisal before a project is approved are generally a feasibility study and cost-benefit analysis. The former aims to assess whether a project is performable, the latter weighs up the costs of a particular action against the benefits or outputs it provides. Most economic evaluations approach the identification of various types of cost and subsequent measurement in monetary units similarly, but they differ significantly in the nature of consequences stemming from the alternatives being examined. The overview on techniques further examined in this chapter provides the table below.

Table 1 Overview on approaches further detailed in this document

Investment appraisal technique	Page
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2.1. Feasibility Study

A Feasibility Study is an analysis of the viability of an idea. In general, a feasibility study helps to decide on the question: would this project idea work and what are the threats and risks connected with the project realization? In comparison to an impact assessment, a feasibility study aims at objective and rational assessment of the strengths and weaknesses of the idea on which the assessed project builds, and identification of opportunities and threats present in the environment, the resources required to carry it through, and ultimately the prospects for success.

A Feasibility Study evaluates primarily five areas of feasibility: technical, economic, legal, operational, and scheduling. Other feasibility factors that could be recommended to be included in the assessment are: resource feasibility and financial feasibility.

The conclusions of the Feasibility Study should outline in depth the various scenarios examined and the implications, strengths and weaknesses of each one. Based on findings resulting from the analysis, the go / no-go decision is made.

Feasibility studies are appropriate when there is a strong evidence to justify a larger study, and where the nature and structure of the study are known, but where critical practical information is needed to convince the investor and make the potential study fundable. Putting it simply, the two main criteria to judge feasibility or to decide to fund a project or an action are the cost required and the value to be obtained.[1]

2.2. Cost-Benefit Analysis (CBA)

A Cost-Benefit Analysis is one of the most popular methods of appraisal used widely by public institutions.

CBA is a technique which attempts to **value the consequences of investments** in monetary terms so as to make them commensurate to costs. Within this technique, all costs and benefits are measured in monetary terms. Thanks to the same comparative base, within this type of analysis one can easily ascertain whether the beneficial consequences of an investment justify the costs, and therefore decide if a health care programme should be implemented or not.

The rationale of the decision-making based on CBA is constructed as follows. An **activity should be undertaken** if its net benefit is positive, i.e. if the sum of benefits exceeds the sum of costs related to the investment. Provided that a given number of activities should be realized (most commonly a sole activity), activities with the highest net benefit are always selected.

However, there are some limitations that need to be considered when deciding whether the CBA technique is the right one to be used in a specific case. **CBA assumes that all benefits can be expressed in monetary terms**. However, in case of health investments, this might be sometimes very difficult, if possible at all. As a result, many cost-benefit analyses conducted in practice are more restricted than the other types of appraisal techniques and are limited to a comparison of those costs and consequences that can be easily expressed in monetary terms. Obviously, this limitation of the approach could significantly compromise the quality of the results.

[1] Young, G.I.M.: Feasibility studies. Appraisal Journal Vol. 38, No. 3, pp. 376-383.

CBA is a method widely used by public authorities for its relative simplicity. On the other hand, there are significant limitations in the proper use of this method for appraising health and health care projects. Specifically, the assumption about the ability of the valuation of all benefits in monetary terms plays a crucial role in this sense. **CBA shall** therefore **not be** recommended to be **used as the sole source for decision making in a case of complex programmes or large scale investments.**

2.3. Option Appraisal (OA)

The Option Appraisal technique helps decision makers to choose between different options for meeting an objective which is determined for the purpose of filling a public need. OA is therefore appropriate in the cases where meeting a public need is a priority.

OA follows CBA as the process in which, first, different options for meeting a public need objective are generated, and then, the best solution is selected on the basis of the CBA results. Nevertheless, OA exceeds the range and scope of an economic case study for a project. The economic case (evaluated by CBA) constitutes only a single part of a more complex project appraisal containing affordability and achievability and different kinds of impact assessment, e.g. the environmental and safety aspects.

The fact that OA focuses on the objectives defined by a public need predetermines it to be a **suitable tool for health programmes financed from public funds.**

2.4. Cost-Consequences Analysis (CCA)

A Cost-Consequences Analysis is a kind of cost-benefit analysis in which costs and effects are calculated but not aggregated. The entire set of the costs and benefits is not measured in the same units which represent the main differences between the appraisal techniques of CCA and CBA.

CCA systematically defines and measures a set of the activity's attributes which should be considered. It should cover all possible health outcomes and consequences, but it does not prescribe the weighting system. The advantage of listing all the resource use, costs and health outcomes in a transparent manner is that it allows the decision makers to choose whatever resources are used; costs and health outcomes are of particular interest for them to be included in the economic analysis.[2]

A problem with CCA is that the weighting of the relative importance of different costs and benefits is left to each decision maker which can lead to an increase in the decision makers' welfare, but might not always be in the patients' or society's best interest. Therefore, CCA is not recommended for use as the sole source for decision making. The weighting system should be set on the basis of a broader discussion, and preferably agreement.

[2] Mauskopf, J. A. The role of cost-consequence analysis in healthcare decision-making. PharmacoEconomics. 1998, vol. 13, issue 3, s. 277-88. DOI: 10178653.

CCA is considered of particular interest in public health because it respects diversity in forms of health and health care investment outputs. It provides information to the decision makers in a simple and disaggregated format. Since information is provided in such way, the decision makers has to design their own weighting system to decide whether any health benefits associated with the activity are worth any extra costs that might arise.

2.5. Cost-Effectiveness Analysis (CEA)[3]

A Cost-Effectiveness Analysis is most convenient when benefits cannot be reasonably measured in monetary terms. It is usually carried out by calculating the cost per unit of non-monetized benefit and is required to quantify benefits but not to attach a monetary price or economic value to the benefits.

CEA is a comparison of alternative activities with a unique common effect which may differ in magnitude. Its results are useful for those activities whose benefits are very difficult, if not impossible, to evaluate, while costs can be predicted more confidently. CEA is less helpful when a value, even an indicative one, can be given to the benefits and not just to the costs.

The results, defined as costs divided by benefits, are expressed in the form of a cost-effectiveness ratio (CER) (e.g. $10 000 per life-year gained). The CER most often used in health economics is called an incremental cost-effectiveness ratio (ICER). This ratio is based on comparisons of incremental costs to incremental outcomes, since this gives information on how much it is necessary to pay in order to add an extra, more beneficial, measure. In particular, when the alternative activities are mutually exclusive, an incremental analysis is required in order to rank the activities and single out the one that is most cost-effective. This is preferred to the average CER since the latter can hide the often high price for achieving incremental health care goals, potentially causing decision makers to choose interventions with poor cost effectiveness.[4]

While the measurement of costs is the same as in the financial analysis of CBA, the measurement of the effectiveness depends on the type of outcome chosen. Some examples of measures of effectiveness used in CEA are:

- Number of life-years gained
- Days of disability avoided

[3] This subchapter is based on, and some passages are adopted from, the European Commission's texts: European Commission: Evaluation methodology, Evaluation tools: Cost-effectiveness analysis. [Dec 4 2014] Available at: http://ec.europa.eu/europeaid/evaluation/methodology/tools/too_cef_en.htm

European Commission: Guide to Cost-benefit analysis of investment projects. Structural Funds, Cohesion Fund and Instrument for Pre-Accession, 2008. Available at: http://ec.europa.eu/regional_policy/sources/docgener/guides/cost/guide2008_en.pdf

[4] Hershey, J. C., Asch, D. A., Jepson, C., Baron, J. and Ubel, P. A. 2003. Incremental and Average Cost-Effectiveness Ratios: Will Physicians Make a Distinction? Risk Analysis, 23: 81–89. DOI: 10.1111/1539-6924.00291

In health-care programmes, the life-years saved, sometimes also adjusted by their quality, can be considered a comprehensive social welfare measure. In fact, **when the planner assigns a conventional money value to the statistical life**, or the quality-adjusted statistical life, in health care, **CEA turns back to standard CBA**.

If an activity is both more effective and less costly than the alternative, there is no need to calculate the CER, because the decision on the activity to select is clear. However, mostly, the activity under examination is contemporaneously both more costly and more effective (or less costly and less effective) than the alternatives. In this case, ICER allows decision makers to rank the activities under examination and to identify, and then eliminate, cases of extended dominance.[5]

In practice, CEA allows decision makers to exclude those options that are not technically efficient while for the remaining activities, the choice will depend on the size of the budget. The treatment with the lowest incremental cost-effectiveness ratio should be the first to be implemented and then other strategies should be added until the budget is exhausted.

Cost-Effectiveness Analysis is a tool for activity comparison when only a single dimension of outcome matters. This limits significantly its field of application as, in most circumstances, activities have impacts not falling into a unique effectiveness measure. Also, without valuation of benefits, CEA can only measure technical efficiency rather than allocative efficiency. **The only case for which CEA is perhaps close to CBA is when the effectiveness measure captures all the social benefits delivered by a certain project, but this is a very difficult task.**

2.6. Cost-Utility Analysis (CUA)

Cost-Utility Analysis differs from the techniques that have been introduced so far. It is sometimes considered to be a specific kind of CEA in which the measure of effectiveness is a utility or preference adjusted outcome. In any case, **CUA** is the first technique introduced in this paper that also **enables qualitative evaluation of the outcomes obtained**. Within CUA, the consequences of programmes are adjusted by health state preference scores or utility weights, i.e. resulting statuses are valued relative to one another. Thus, it also enables decision makers to involve qualitative aspects in the evaluation.

The most common measure of consequences in CUA is the quality-adjusted life-year (QALY), which is a composite measure of gains in life expectancy and health-related quality of life. The distinctive outcome of CUA is the calculation for each alternative of ICER in terms of the extra cost per QALY gained (CQG). The ceiling ratio is the amount reasonable to pay to gain QALY. It is sometimes referred to as the CQG threshold, because it is a dividing line between health care that is regarded as cost effective and that which is not. In terms of national health care systems, the so-called shadow price of QALY determines what can be afforded. Alternatively, the social value of QALY shows what the population is willing to pay for health gain. If both values are known, it can in principle be used as a means of converting costs to QALYs or vice versa, which puts costs and benefits into the same units and enables the calculation of net benefits in the same way as for CBA. [6]

[5] Extended dominance is where ICER for a given activity is higher than that of the next more effective alternative.

[6] Health Knowledge: Techniques of economic appraisal. [Dec 4 2014] Available at: http://www.healthknowledge.org.uk/public-health-textbook/medical-sociology-policy-economics/4d-health-economics/economic-appraisal

Besides the possibility of evaluating the qualitative aspect in evaluation, **CUA is particularly useful when comparing alternatives with already identified side-effects**. QALYs are regarded as a better outcome indicator than the natural units of the Cost-Effectiveness Analysis when appraising therapeutic alternatives for the same condition. This is because they deal with efficiency in the production of health itself rather than simply of health care. **Its biggest value added is the possibility of comparing across treatments even for different conditions**: an example being comparison of treatment for cancer with physiotherapy, to determine which is the most efficient at producing health gain in the form of QALYs.

Furthermore, CUA has the general ability to compare all health interventions, producing an even more contentious implication which is that it can be used to allocate health care resources, and therefore determine health care priorities. In this point, CUA overcomes the principal problems of CBA, because it would indicate whether or not the health care benefits from a particular type of health care should be realized, rather than simply which the best way of achieving those benefits is.

CUA is a method that overcomes the limitations of some of the methods introduced earlier. As it is designed, it is a method suitable for the determination of health care and health priorities. A typical question CUA could help to answer might be presented as: **"What is a health care priority and how to allocate health care resources between health interventions?"**

Nevertheless, there is a certain controversy about CUA since it is problematic to set the value for a health status or an improvement in health status as evaluated by different individuals.

2.7. Health Impact Assessment

Health Impact Assessment (HIA) is a technique developed by the International Association for Impact Assessment (IAIA) together with the World Health Organization (WHO) to identify and evaluate how development induces unintended changes in health determinants and subsequent shifts in health outcomes.

As it is defined, HIA represents a combination of procedures, methods and tools that systematically judges the potential, and sometimes unintended, effects of various policies, plans, programmes or projects on the health and population and the distribution of those effects within the population. HIA identifies appropriate actions to manage those effects.[7]

Based on the definition of HIA, it is obvious that this technique could be applied to any development programme or project to identify and assess its potential effects on the health of the population. This therefore represents a different point of view and approach to the techniques described in the previous subchapters.

HIA provides a systematic **process through which health hazards, risks and opportunities can already be identified** in the development planning process **to avoid the transfer of hidden costs connected to unconsidered obstacles**. HIA uses quantitative, qualitative and participatory techniques. Its aim is to maximize a proposal's positive health effects and minimize its negative health effects.

HIA attempts to clarify health implications by disaggregating the determinants of health and well-being. HIA investigates the pathways of how the inter-related determinants may be affected by a proposed policy, programme or project. It aims to trace the changes through to their impact on health status. Some of the pathways are direct (such as pollution and asthma admissions to hospitals); others may be indirect (such as traffic density and community severance, leading to changes in several health outcomes etc.)[8]

The purpose of all HIAs is to inform and influence decision-making on proposals and plans, so **health protection and promotion** are effectively integrated into them.

Key steps in the HIA process, with involvement of stakeholders in brackets, are as follows:[9]

- **Screening** – deciding what scale, if any, HIA is required (desk exercise, MoH or Managing Authority)
- **Scoping** – setting the boundaries in time and space for the assessment (MoH and key stakeholders)
- **Full scale HIA** (HIA team)
- **Public engagement and dialogue** (initiated by MoH or other relevant authority)
- **Appraisal of the HIA report** – feasibility, soundness and acceptability of its recommendations (MoH or independent consultants assigned by MOH)

[7] World Health Organization (WHO): Health Impact Assessment, Guides. [Dec 4 2014] Available at: http://www.who.int/hia/about/guides/en/

[8] Quigley, R., L. den Broeder, P. Furu, A. Bond, B. Cave and R. Bos 2006 Health Impact Assessment International Best Practice Principles. Special Publication Series No. 5. Fargo, USA: International Association for Impact Assessment. Available at: http://www.iaia.org/publicdocuments/special-publications/SP5.pdf?AspxAutoDetectCookieSupport=1

[9] Ibid.

- Establishment of a **framework for cross-sectorial action** (MoH and relevant ministries)
- Negotiation of **resource allocation** for health safeguard measures (Ministry of Finance and relevant ministries)
- **Monitoring, evaluation** and follow-up – monitoring of compliance and health indicators (MoH)

HIA is a tool to make adjustments that will **maximize the beneficial effects of any development programmes** or projects **and minimize any harmful effects on health**. It is a tool developed for qualitative health assessment to be provided before, during or after the implementation of a plan and thus offering an up-to-date appraisal of a project in its course. Given its complexity, wide range of actions and professionals included and public engagement, HIA is more suitable for big projects and programmes.

2.8. Health Technology Assessment

Health Technology Assessment (HTA), similarly to Health Impact Assessment (HIA), is a technique to support informed policy and decision-making. It is defined as a multidisciplinary field of policy analysis. HTA studies the medical, social, ethical and economic implications of the development, diffusion and use of health technology.[10] The overall aim of HTA is to systematically and objectively assess evidence to inform decision makers in their formulation of national / regional / local health policies to provide patients with equitable and timely access to safe, effective, high quality health technologies that achieve best value.[11]

HTA is promoted and used by the European Commission, the WHO and many national authorities.

In order to maximize the relevance of HTA for decision making, it needs to be undertaken within the policy context of the country rather than at the European level. Policy context takes into account national priorities and systems, as well as cultural and social differences. Despite the differences in structure and priorities of health care systems across Europe, **reducing unnecessary duplication of HTA activities, developing and promoting good practices in HTA, and facilitating local adaptation of HTA information have been considered essential for the efficient use of HTA resources.**[12]

In Europe, collaboration in HTA has been ongoing for more than twenty years through EU co-funded projects which started to facilitate cooperation at the scientific and technical level. Today, up to 2015, cooperation between national and regional HTA bodies is supported by the Joint Action EUnetHTA. EUnetHTA is active in producing and

[10] The term health technology covers a wide range of interventions used in health care and health promotion including methods for prevention, diagnosis, treatment and rehabilitation (such as vaccines, pharmaceuticals, medical devices, medical and surgical procedures), and the systems within which health is protected and maintained.

[11] EUnetHTA Strategy 2012 and beyond. JA-WP8 EUnetHTA Joint Action (2010-12). Available at: http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20Strategy%202012%20and%20beyond.pdf

[12] Ibid.

testing common tools for HTA and is placing significant priority in developing joint work that is expected to be taken up and used by interested national or regional bodies for their national decision-making.[13]

EUnetHTA performs the function of the scientific and technical support of the HTA Network which is a voluntary network, set up by Directive 2011/24 (Article 15)[14] gathering all Member States. It also associates (as observers) stakeholders representing industry, payers, providers and patients.

The Network acknowledges that European cooperation in HTA can:[15]

- Promote a more consistent approach to HTA as a health policy tool to support evidence-based, sustainable, equitable choices in health care and health technologies
- Increase efficiency, optimize use of resources and avoid duplication when performing HTAs
- Further develop national know-how and capacities for HTA and developing shared know-how among national bodies working together to produce and apply shared methodologies
- Facilitate joint work in HTA, and enhance the exchange of experience and good practices

The Network aims at implementing a vision which reflects that methodologies and evidence used to assess technologies are often global and can and should be shared, as appropriate, while decisions made on the basis of the assessments are local and within the responsibility of national and regional authorities.

However, EU financial support cannot be taken for granted. It will only be useful if Member States will commit to joint work in a future Joint Action and agree on a proposal for a sustainable model for the next phase of cooperation, once the Health Programme funding ends. According to the EU Financial Regulations, the Health Programme cannot fund recurring activities. Its support will be limited in time and cannot be extended beyond 2020. In the longer term scenario, it is expected that the scientific activities necessary to deliver joint work will continue to be carried out by national and regional HTA agencies or bodies. Administrative coordination and other supporting functions may be performed within suitable structures and possibly be supported by the EU budget.[16]

EUnetHTA has developed a **core model for HTA** to serve as a generic framework to enable international collaboration for producing and sharing the results of HTAs. For further information, not covered in this document, see the EUnetHTA's *HTA Core Model Handbook*[17] or *The HTA Core Model*[18] documents.

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[13] European Commission, DG Health & Consumers: Strategy for EU Cooperation on Health Technology Assessment (HTA). HTA Network, Adopted documents, Oct 10 2014. Available at: http://ec.europa.eu/health/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf

[14] Article 15(2) Directive 2011/24/EU on the applications of patients' rights in cross-border healthcare. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

[15] European Commission, DG Health & Consumers: Strategy for EU Cooperation on Health Technology Assessment (HTA). HTA Network, Adopted documents, Oct 10 2014. Available at: http://ec.europa.eu/health/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf

[16] Ibid.

[17] HTA Core Model Handbook Version 1.5. JA2-WP8 EUneHTA, Apr 8 2014. Available at: http://meka.thl.fi/htacore/ViewHandbook.aspx

[18] The HTA Core Model Version 2.0. JA2-WP8 EUneHTA, Nov 28 2013. Available at: http://meka.thl.fi/htacore/BrowseModel.aspx

HTA has been developed to **evaluate the impacts of health technology**. In the assessment, HTA may involve the investigation of one or more of the following impacts, or other effects of health technologies or applications, forming the EUnetHTA Core Model Domains:[19]

- Health problem and current use of technology
- Description and technical characteristics of technology
- Clinical effectiveness
- Safety
- Costs and economic evaluation
- Ethical analysis
- Organizational aspects
- Social aspects
- Legal analysis

As indicated at the beginning of this document, the cost and economic evaluation domain of **HTA usually contains most of the individual investment appraisal techniques listed formerly.**

The basic steps involved in most of the HTAs can be depicted by the EUnetHTA Core Model Phases:[20]

- Project definition
  - Project scoping
  - Technology and its intended use
  - Target condition
  - Target population
  - Technology comparison
- Protocol Design
  - Selecting relevant issues and translating them into research questions
  - Relations between issues and possible overlaps
  - Domain framing
  - Viewing and locking protocol
- Research
- Results
- Review and publishing

[19] HTA Core Model Handbook Version 1.5. JA2-WP8 EUneHTA, Apr 8 2014. Available at: http://meka.thl.fi/htacore/ViewHandbook.aspx

[20] Ibid.

Given the variety of impacts addressed and the range of methods that may be used in an assessment, multiple types of experts are needed in HTA. Depending upon the topic and scope of assessment, these may include:

- Physicians, nurses, dentists, and other clinicians
- Managers of hospitals, clinics, nursing homes, and other health care institutions
- Radiology technicians, laboratory technicians and other allied health professionals
- Biomedical and clinical engineers
- Pharmacologists
- Patients and patient affairs representatives
- Epidemiologists
- Biostatisticians
- Economists
- Lawyers
- Social scientists, Ethicists
- Computer scientists / programmers
- Librarians / information specialists

Due to its complexity, HTA is able to cover a wide range of medical, social, economic, and ethical issues, such as:

- Drugs: e.g. aspirin, beta-blockers, antibiotics
- Biologics: vaccines, blood products, cellular and gene therapies
- Devices, equipment and supplies: e.g. cardiac pacemakers, CT scanners, surgical gloves, diagnostic test kits
- Medical and surgical procedures: e.g. psychotherapy, nutrition counseling, coronary angiography, gall bladder removal
- Support systems: e.g. electronic patient record systems, telemedicine systems, drug formularies, blood banks, clinical laboratories
- Organizational and managerial systems: e.g. prospective payment using diagnosis-related groups, alternative health care delivery configurations, clinical pathways, total quality management programmes

HTA is a wide-range tool given the scale of examined attributes of health technologies or applications and the variety of impacts addressed. Therefore, complex projects can be evaluated with this method. On the other hand, multiple types of experts are needed to draw up the HTA.

HTA contributes in many ways to the knowledge base for improving the quality of health care, especially for supporting the development and updating of a wide spectrum of standards, guidelines, and other health care policies. Thanks to its various orientations, HTA can assess emergent projects or work as the initial tool for tackling a particular problem.

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European Commission sources:

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