Health Technology Assessment

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Health Technology Assessment

Introduction

Health technology assessment (HTA)

The International Network of Agencies for Health Technology Assessment (INAHTA) defines health-care technology as: “…prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained.” Technology assessment in health care is defined as: “…a multidisciplinary field of policy analysis. It studies the medical, social, ethical and economic implications of development, diffusion, and use of health technology”. The EUnetHTA Project has added the following explanatory clarification that emphasizes the process and aims of an assessment: Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method. The practice of HTA within this definition varies considerably across national settings. It informs policy- and decision-making in specific political, economic and institutional contexts. In order to be useful HTA has to be designed with processes and outputs that fit the relevant context.

HTA and Health Services Research

HTA is a field that connects clinical research with health services research (HSR) in order to provide a broad based input to policy-making and to the development of an evidence-based health care practice. HTA is not in itself research, but is building on both clinical research and on health services research. However, HTA is sometimes combined with clinical research and/or HSR to answer policy questions satisfactorily.

The working definition of HSR used in this report is:

HSR is the multidisciplinary field of scientific investigation that studies how social factors, financial systems, organisational structures and processes, health technologies and personal behaviours affect access to health care, the quality and cost of health care and, ultimately, the health and wellbeing of citizens.
In the field of HSR HTA is obviously related to analysis of health technologies, but with strong links to the full field of HSR in order to analyse different prerequisites for and consequences of the use of health technologies.

Objective

This chapter provides an overview over health services research (HSR) of relevance for health technology assessment (HTA) in Europe. Based on review of published research we identified the trends in health services research in relation to HTA so far. In addition we provide input to a future research agenda by describing the research called for in the existing literature. In order to give input to a future research agenda we focus on development of: 1) the content of analysis in HTA (e.g. analysis of economy, organisation, ethics, legal aspects and social aspects), 2) the ‘HTA products’ developed to adequately meet the needs of policy-makers (e.g. early warning/horizon scanning, rapid assessment, mini-HTA, core HTA), 3) themes/problems where HTA should be developed to be able to address them more comprehensibly in future (e.g. fast evolving technologies, information and communication technologies, the life cycle of technologies, and link between policy and HTA), 4) development of HTA in relation to specific technologies, and 5) development of HTA capacity and of HTA programmes. To give input to a future research agenda we discuss need for development in relation to theoretical approaches and in research methodologies in relation to HTA. Basically these themes concerns two different contributions:

- HSR as part of HTA methods to analyse consequences of use of technologies
- HSR as analyses and improvement of HTA as a tool to provide input to policy-making

Methods

This section describes the methods we applied in this literature review presenting existing research and input for a future research agenda. At this stage the draft report builds on a literature review. Later input from the conference will be used in the report.
Literature review

In this section, the methods used in the literature review concerning HSR of relevance for HTA are summarised, including search strategies and inclusion/exclusion criteria used for the selection of relevant literature.

Initially we piloted different search strategies to find the strategy with the largest sensitivity and specificity. In general it was difficult to define a strategy which captured relevant articles without losing too many. Based on these pilot literature search we decided to search exclusively in PubMed. This decision was made since the search seemed to catch a large majority of the relevant literature. However the consequence of this strategy is that we have not specifically searched in specialised databases for articles concerning the ‘HTA disciplines’ e.g. health economy, organisation, and ethics, and we therefore risk losing the specialised research within each discipline. To compensate for this we decided that the only Mesh term used for the literature search was ‘technology assessment’. This ensured a high sensitivity but a low specificity of the search, and therefore allowed us to find the large majority of relevant articles included in the rather broad search. The search was conducted on the 19th February 2009 and was limited to include articles dating back ten years. The Literature search included 3360 references. These references were scanned at title/abstract level by two researchers and were in this process reduced to 555 articles. The next step was to review each article and to decide whether to include or exclude the article. This process reduced the number of relevant articles to 195 articles. These articles were supplemented with articles from a recent volume of International Journal of Technology Assessment in Health Care (vol.25, 2009, SUPPL. 2) which contain 14 articles summarising the findings from the EUnetHTA project. Not all articles are directly cited in this draft version of the report.

Criteria to select the relevant articles were the following:

Inclusion:
Articles containing HSR within the area of HTA or debating future needs for HSR within HTA. All languages included.

Exclusion:
Articles which did not include HSR within HTA (clinical research, health impact assessment, assessment of specific technologies, articles from outside Europe, priority-setting within health care not specifically concerning HTA).
Articles from outside Europe were excluded from this systematic review, but some were still used to show the state-of-the-art, to put the European HSR into perspective, and to give input to the section on future research agenda. Within HTA the European and non-European research is closely related and it is useful to take the non-European research into account when providing input to a future research agenda.

The systematic literature search was supplemented with grey literature. This includes all products from the EUnetHTA project [www.eunethta.net](http://www.eunethta.net) and a number of recent reports commenting on the development of HTA. These reports were selected because they are examples of the most recent research within HTA including HSR and because they specifically address the need for development within HTA including need for research. The included grey literature is listed in appendix 1.

The articles and the grey literature were analysed and distributed into relevant categories reflecting the following themes:

- The content of analysis in HTA
  - Economic evaluation
  - Ethics
  - Legal aspects
  - Organisational aspects
  - Social aspects
  - Best practice in undertaking HTA

- HTA products
  - Horizon scanning/early warning
  - Rapid assessment
  - Mini-HTA
  - Core HTA
  - Adaptation toolkit
• Life cycle perspectives of technologies

• HTA and specific technologies
  o Pharmaceuticals
  o Screening

• Development of HTA capacity and HTA programmes
  o HTA capacity
  o HTA programmes
  o Priority setting within HTA programmes
  o Links between policy and HTA

Overview over the literature

This part of the report will give a descriptive, graphical overview of the literature included in the literature review in relation to selected variables. The variables chosen for classifying the articles included in this review were: 1) the nationality of the first author, 2) the number of nationalities involved in the research, 3) the institution(s) involved in the research, 4) the topics of the research, 5) the journal where the research was published, and 6) the distribution of articles in the decade 2000-2009. Overall this overview intend to provide a visual overview of characteristics of the body of research undertaken in relation to HTA.
This diagram provides an overview over which countries are active in publishing research in relation to HTA, and it is a clear tendency that British research are very active within HSR/HTA. Also it is shown that a large number of European countries are involved in this field. The Canadian, US, and Australian articles are included, because there are European co-authors.

Number of nationalities involved in the research
This diagram shows to what extent the research is based on collaboration between researchers from different countries. Even if most research is based in one country, it is still clear that collaboration between researchers from different countries is established. This is partly due to a long tradition of (EU-supported) projects among HTA institutions in Europe.

Types of institutions involved in the research
This diagram provides an overview over the scientific environment in which the research was undertaken. Mixed scientific environment is identified in 88 of 215 cases. Even if the universities are most active it is remarkable that research in relation to HTA is characterised by involvement of other actors – primarily HTA institutions. However, also private consultancies and industry has published relevant research.

**Topic**
This diagram provides an overview over the research topics identified in the analysis of the literature. The diagram shows the especially research in health economics and in the links to policy have been conducted during the last 10 years. However, a broad field of topics have been covered.
Not surprisingly, the International Journal of Technology Assessment in Health Care is the most used journal for publication of HSR in relation to HTA, but also other journals or programmes are represented in the list of publishers.

Year of publication
This diagram provides an overview over the number of articles published and the year of publication of research in relation to HTA. The number of identified articles varies between 12 and 30 pr. year.

**Existing Research**

This part of the report has the purpose of presenting the content of the identified research. As earlier indicated the research is categorized into different topics of relevance to HSR in the area of HTA.

**The content of analysis in HTA**

This part includes research within the ‘HTA disciplines’ and articles concerning best practice in undertaking HTA.
Economic evaluation

Economic evaluation is the comparison of two or more alternatives courses of action in terms of both their costs and consequences. Economists usually distinguish several types of economic evaluation, differing in how consequences are measured:

- Cost minimisation analysis
- Cost benefit analysis
- Cost effectiveness analysis
- Cost utility analysis

Economic evaluation is a well established research discipline with lots of different methods available. However, in spite of the great amount of research, there is still disagreement concerning the methods to apply when conducting an economic evaluation as part of an HTA. Hence, even though the economic aspect might have well established methodologies available, there is still lack of clarity about recommendations and best practice concerning economic evaluation in relation to HTA.

This literature review revealed that a lot of research is being done in the area of health economics in relation to health technology assessment. This was the area in which the greatest body of literature was identified. In total 60 articles were identified to provide an overview of the European research in this area. Among these articles 37 reported specific studies and were relevant to provide an overview of the current research activity in this area, while the rest solely point to or debate areas of future research.

14 studies concerned different aspects of economic modelling (1-14). 4 studies concerned different aspects of guidelines of how to carry out economic evaluations and how to present them (1-4). 5 studies concerned cost-effectiveness analysis or different aspects of such analysis (10, 15-21). 3 studies concerned methods of how to estimate learning effects, that is the consequences of increasing effectiveness over time (22-24). 4 studies concerned the assessment of effects. One study concerned the assessment of utility (25-28), one study concerned the assessment of quality of life (5), one study concerned assessments of willingness to pay (6), and one study concerned discrete choice experiments (29). Finally, 4 studies concerned the use of economic evaluations and the influence on decision making (30-33).
In addition EUnetHTA has contributed to analysis of how provide core elements of an economic analysis which can be used to adapt to different settings (7-11).

Thus, this literature review showed, that economic modelling, guidelines, cost-effectiveness analysis, the effects of learning curves, estimation of effect and utility, the use of economic evaluation, influence on decision making, and use of economic analysis in different settings were the themes that make up the majority of the current research activity dealing with economic evaluation in relation to HTA.

Other studies dealt with the use of systematic reviews and evidence and the assessment of uncertainty.

The studies primarily applied quantitative methods or review quantitative methods. Those studies, that concern the use of economic evaluations and the influence on decision making, were the only studies that apply qualitative methods or a combination of qualitative and quantitative methods.

The studies were predominantly conducted in university environments. Also, the research activity was most prevalent in the United Kingdom.

Additionally, this review revealed that a lot of research is also undertaken in especially Canada and US. This body of research overall reflected the same research themes as the current European research.

Ethics

The ethical domain of HTA deals with prevalent morals, values and behavioral models of the society relevant for the technology. It has been argued that ethics should be part of HTA since its inception in the beginning of the 1970’ies. However, today there is still little agreement on the methods for integrating ethics in HTA, and only few HTAs report on these issues.

A variety of methods to integrate ethics in HTA exits, e.g. causistry, coherence analysis, and principlism. Both qualitative methods taken from existing research disciplines and methods developed specifically for the integration of ethics in HTA were applied.

Working groups within both INAHTA and HTAi have tried to come to some agreement of which methods that are most appropriate to approach the ethical issues, and most recently EUnetHTA
developed methodology to address the ethical domain as part of the Core model. However, still only few HTAs address these issues.

6 articles relevant for the ethical domain were identified in the literature search.

4 articles were methodological articles that provided and addressed specific methods of how to include the ethical issues in HTA (12-15). Also relevant for the consideration of ethics, 2 articles address criteria for how qualitative research should be evaluated (16, 17). 2 articles discuss why ethics should be part of HTA and the reasons for the lack of its inclusion (18, 19). In EUnetHTA, ethics were included in the core model (7-11).

Several articles addressed ethics and discussed the opportunities and challenges in relation to specific technologies that are considered controversial or ethically complex (e.g. genetic screening).

All of the articles use qualitative methods or discuss qualitative methodology.

The research is mainly undertaken at universities.

In addition, this literature search revealed that research and debate concerning the ethics in HTA is undertaken in Canada and Australia.

**Legal aspects**

The legal aspects of HTA address legislation questions concerning the technology under assessment. For an issue to be considered a legal one, one must be able to point out the legal source (stipulation, convention or agreement) that makes the issue legally relevant. Also, this is what separates the legal domain from domains concerning ethics, social issues and safety.

No articles explicitly focusing on the legal aspects were identified in the literature review. Only one European article address the role of legal aspects in relation to genetic screening. The article proposes an Internet citizens’ jury as a method to address ethical, societal and legal implications (34). Additionally one Canadian study also focusing on the legal aspects in relation to genetic screening was identified in the literature (35). EUnetHTA included legal aspects in the core model (7-11).
Organisational aspects

The organisational aspect of HTA focuses on the delivery modes of the assessed technologies. This includes aspects of e.g. the management, financing and controlling issues, and can thus contribute to assessments by clarifying challenges and barriers in implementing health technologies.

One European article identified in the literature search addressed the organisational aspects of HTA. The authors aimed to make a case for a greater emphasis in research on how health services are managed, organised and delivered, and discuss the theoretical differences between and within disciplines, and discuss their implications for research methods (20). In addition organisational issues are incorporated into the EUnetHTA core model (7-11) and the adaptation tool kit (21-25).

One article underlined the future need for inclusion of organisational analysis in HTA due to demand from policymakers (36).

Social aspects

The literature revealed a great deal of mixing of different concepts such as social aspects and patient perspective under this heading. According to EUnetHTA the social domain of HTA takes the patient as a point of departure in the analysis of the manifold social implications of a health technology. The analysis should reveal the resources needed when using a technology and the consequences of its use in the life of the patients.

No European articles focusing explicitly on the assessment of social aspects were identified in the literature review. One Danish study presented a research design including a citizens’ jury that aims at exploring ethical, social and legal implications (34).

However, two Belgian studies concern the use of qualitative research in HTA, how knowledge of the nature of this type of research can be improved, become more trustworthy and how the contribution can be increased and criteria for judging this type of research (16). EUnetHTA has included social aspects as part of the core model and introduces a broader range of literature on this topic, which has not been included in this review (7-11).

EUnetHTA included social aspects in the core model (7-11).
Additionally, three Canadian studies, two American studies, and one Australian study focused on the social aspects, how to assess the social issues, how to incorporate the assessment in HTA and how to evaluate methods (26-29).

**Best practice in undertaking HTA**

Seven articles analysed and debated best practice in undertaking HTA in general. One article from the ECHTA/ECAHI project describes the current best practice in undertaking and reporting HTA (37). One articles described the time-trends in health technology assessment from 1989 to 2002 and thereby gave an overview over the content of HTA reports (38) Another gave en overview over cross-national HTA processes (39), while a further article gave an international comparison of the definition and practical application of HTA (40). An statistical analysis analysed what factors that influenced assessment methods in HTA (41). On article discussed key principles for the improved conduct of HTA (42), while the last identified article debates advantages and disadvantages of standardization of evidence requirements for HTA (43).

In addition the EUnetHTA products – mainly the core model - could be seen as a further implementation of the conclusions from the ECHTA/ECAHI project, and contributed to developing a more standardized form for reporting HTA (7-11).

**Transparency**

As part of the discussion on best practice, a lot of attention has been given to transparency issues – both in relation to use of methods and to reporting of HTA. An example of this is the INAHTA checklist which promotes different requirements for creating increased transparency in the reporting of HTA (30).

As the implementation of HTA in EU member states increased, this led to a series of EU funded projects from 1993-2002, including EUR-ASSESS and the ECHTA/ECAHI. The recommendations of these projects are currently being implemented through the EUnetHTA project, and include a core model of HTA reports and an adaption toolkit to expand proper sharing and production of information – including promoting transparency.
Five articles dealing with issues of transparency were identified. In one article two HTA reports on the same topic are compared in order to address issues of transparency and variations in HTA methods (31). The authors concluded, that efforts to guarantee transparency in the original studies, and in the HTA reports themselves, needed to be taken, as such lack of transparency may affect policy decisions. Another article presents the INAHTA checklist for HTA reports (30). The three latter articles were debating articles. One article reviewed and discusses the issues associated with standardisation taking into account the perspectives of multiple stakeholders (32), while two articles debates issues of transparency in NICE technology assessments in the case of drug evaluations (33, 34).

Three reports debated and critiqued the lack of transparency in HTA reports in general and opted for more focus on transparency issues (44-46)

**HTA products**

A variety of different types of health technology assessments have emerged, typically from the work of HTA agencies. A lot of literature addresses HTA production in general. However, a more limited literature addresses specific ‘HTA products’ which have been developed to meet the needs of users of HTA.

Mini HTA and rapid assessments are two types of assessments that have emerged as responses to the existing conflict between traditional thorough HTAs and the need to produce input to decision making in a timely fashion. Political and administrative decision makers require a faster production of HTA.

Horizon scanning/early warning is a HTA product that was developed in response to the needs of assessing technologies in the early phases of adaption before thorough research have been undertaken.

Core HTA and an adaptation toolkit for ‘translation’ of foreign HTA reports has been develop as part of the EUnetHTA project with the aim of reducing duplication of work and promoting already existing foreign reports.
Horizon scanning/early warning

Health technologies in an early stage of its life cycle sometimes spread rapidly in a health care system despite lack of convincing evidence. Also, new technologies exist, that may be underused resulting in lack of benefit for the patients.

Horizon scanning systems/early warning systems is a method evolved from the work of HTA agencies. The International Information Network on New and Emerging Health Technologies (EuroScan) is an international collaboration established in 1999. EuroScan defines the focus of horizon scanning as those technologies that are not yet adopted by the healthcare system and those that are in the phase of adoption. The purpose of horizon scanning is to provide input to decision making that is timely and relevant.

The members of EuroScan have agreed on a common terminology, classification and understanding of their activities. Their activities consist of five main components which are the identification and filtering of technologies, prioritization, early assessment, dissemination, and monitoring the assessed technologies.

Nine articles concerning different aspects of horizon scanning were identified. One of these articles reported from a workshop and subsequent discussions, that reviewed the achievements and progress of Euroscan (35), and one article provided an overview of processes and practices of horizon scanning (36). Six articles evaluate different aspects of what constitutes a proper horizon scanning. This includes the use of selection criteria in horizon scanning, the sources to search in the process of identifying technologies, and the effectiveness and accuracy of HSS (37-40). Two articles explore aspects of adaption of established horizon scanning to Danish horizon scanning (41, 42). Finally, one article explores the intrascientific citation (bibliometric impact) of the Swedish early warning reports (SBU Alerts) and the science base of these reports (43).

EUnetHTA produced a newsletter on new and emerging health technologies for European policy makers in collaboration with Euroscan (44). The process was reported in an article which described the process of producing a newsletter (45).
Rapid assessment

Rapid assessment is a tool to produce input to decision making in a timely fashion. The rapid assessments are typically carried out by HTA agencies within a timeframe of 6 months or less. A number of programs exist. However, they vary in scope and methods. At this point, no common definition and methodology of rapid assessment exists and the quality of the assessments varies.

The literature review identified only two European articles concerning rapid assessments. One German article compares different rapid assessment programs with respect to scope, methods and time to complete assessments, and introduces and discusses a model for processing rapid assessment in the German context (46). Likewise, a British study describes a method for the rapid appraisal of new interventional procedures and compares its conclusions with those derived from a slower, more thorough method (47).

Additionally, one Canadian article and one Australian article were identified concerning the impact and methods of rapid assessments (48, 49).

Mini HTA

Mini HTA is a tool mainly used in hospital settings when making decisions about the uptake of new technologies. It typically consists of a form containing a number of questions corresponding to the domains of a thorough HTA. This tool aims at providing input to decision making within few weeks adjusted to the local settings.

Only two articles concerning mini HTA were identified in the literature search (50, 51). Both studies were Danish studies undertaken by Danish University Hospitals. Both studies evaluated the use of HTA and the attitudes of decision makers towards the tool. The studies revealed that different versions of the tool, and with varying quality, are commonly used in hospital settings in Denmark.

Core HTA

Core HTA built on recommendations from previous European HTA projects and developed a specific structure for undertaking and reporting HTA. The main aim was to avoid duplication of
HTA reports in Europe since there are many examples of reports on technologies produced synchronically across Europe – and also across the rest of the world.

The core model was reported in five different publications. One model for medical and surgical procedures (7), and one for diagnostic technologies (8). A handbook introducing the model was published (9), and two articles presented the idea behind the core model (10), and the testing of the model during the development phase (11).

**Adaptation toolkit**

EUnetHTA also developed an adaptation toolkit. This product was a further development of an already existing activity among the HTA agencies, which used foreign HTA reports and ‘translated’ them into the relevant setting. The aim to avoid as much works as possible by reusing e.g. the systematic review from the foreign report. EUnetHTA worked to structure the activity by publishing a glossary of HTA adaption terms (22, 23). Also the adaptation toolkit itself (21) and two additional articles described the development of the toolkit (24, 25).

**Life cycle perspectives of health technologies**

Many existing healthcare interventions diffused before the establishment of the current assessment and evaluation procedures. Assessment of ineffective or inappropriately applied practices is growing as a priority for international health policy, both for improved quality of care and sustainability of resource allocation. It might be difficult for assessments to have an impact on an established practice (52). On the other hand, assessments of resource consuming technologies that remain in use are needed in order to determine disinvestments and to improve the overall quality of care and sustainable resource allocation (53-55).

The literature review identified four articles concerning aspects related to the assessment of technologies already in use including disinvestments. One of these articles introduced a method of constructive medical technology assessment that aim to change the development and diffusion of a medical device to improve its later clinical effectiveness, illustrated by the case of heart assist devices (52). The three other articles discussed disinvestment in relation NICE evaluations. These articles pointed out, that NICE had a tendency to focus on the assessment of new technologies while the assessments of existing technologies are given less priority (55).
This concerned the aim of the establishment of NICE which partly was to ensure the overall best use of resources in the NHS so that patients receive the greatest benefit (54). Hence, NICE recommendations may not necessarily increase the overall efficiency of resource allocation decisions in the NHS due to lack of focus on the full life cycle of health technologies (54). This dilemma called for an overall increased focus on the assessment of technologies already in use (55). One article added to this debate by exploring the policy options available to NICE as it prepared to launch a programme to meet the NHS request for guidance on disinvestment. All of the possible options present different challenges, as NICE will need to collaborate in new ways with partners inside, and perhaps outside, the NHS (53).

EUnetHTA also focused on the life cycle perspective in relation to assessment of technologies, but so far concentrated on the earlier stages of the life cycle by focusing on evidence generation on promising health technologies (56-58). However the core model encouraged that new technologies should always be compared to existing technologies, and the model can also be used to assess possible obsolete technologies.

**HTA and specific groups of technologies**

In this section two groups of technologies are addressed. The first group concern primarily pharmaceuticals that possess challenges to HTA in terms of the ability to provide input to decision making in a timely matter and address the literature that concern Coverage with Evidence Development (CED) as an option to overcome this obstacle. The other group concern screening methods that represent a group of technologies that in many cases by practitioners and to the general public is received as harmless.

**Pharmaceuticals**

To provide assessments of technologies as an input to a rational decision making process in a timely matter is always a challenging task. A sufficient amount of studies for thorough assessments are usually not available until the technologies already are in use. On the other hand technologies that are in early phases of their lifecycle may lack sufficient studies for thorough assessments which affect the quality of assessments. Hence, the balance between
too early and too late assessment of technologies is a challenge for HTA (see also paragraph on life cycles).

The cases of pharmaceuticals often make up a great body of this discussion especially in relation to the evaluation of the economic benefits of new pharmaceuticals. Resulting from this discussion, the possibility of providing pharmaceuticals while ongoing evaluation is still undertaken has been put forward. This has been referred to as Coverage with Evidence Development (CED) and refers to the reimbursement of pharmaceuticals given that an ongoing evaluation of the benefits is undertaken.

Even though the possibilities of providing pharmaceuticals in terms of CED, the issue can be generalized to other health technologies, as the challenge to provide assessments of technologies as an input to a rational decision making process in a timely matter relates to all new technologies. CED gives an opportunity to provide an input to the decision making process, but with certain reservations.

4 articles concerning CED were identified in the literature search. One article address the tension between pharmaceutical regulators and healthcare reimbursement authorities and CED as an option to overcome this issue (59). One article discusses CED as a possibility for NICE recommendations to the NHS (60). One study explores the conceptual and policy issues in general relation to CED and discusses issues involved in operationalizing CED in practice and presents criteria for which technologies may be most suitable for CED (61), and finally one article comments on this study (62).

**Screening**

Screening is the application of a test to detect potential disease or condition in a person who has no known signs or symptoms of that disease or condition. The goal of screening is the early detection of disease or risk factors of disease so that intervention can reduce morbidity and mortality from the involved disease (63). Methods of screening represent a group of technologies essentially different from clinical practice. The main issues being that screening is carried out in apparently healthy persons, so the moral duty is essentially different from that of typical clinical practice (64). Also the technologies are typically received as harmless by practitioners and the general public resulting in a growing demand for and uncontrolled use of
these technologies. In some cases traditions of use of screening technologies is a challenge (65).

In the literature review a series of articles concerning HTA and screening were identified carried out as a specific theme in IJTAHC. The objectives of these articles were to explore the impact of HTA on health policy and practice in the case of preventional technologies in nine different countries illustrated by three cases of screening: Mammography screening for breast cancer, screening for prostate cancer, and the use of ultrasound screening in pregnancy (63-71).

Mammography screening represents a technology with a surprising lack of active policies concerning implementation despite the weigh of evidence that indicates benefits. Only Sweden, UK and The Netherlands had at the time of the publishing of the articles implemented such policies (64, 65, 67, 68).

Ultrasound screening in pregnancy represented a technology that had spread despite lack of assessment showing benefit. The technology was perceived as an appealing, apparently safe and relatively cheap technology resulting in a pressure on demand side from both patients and physicians (65).

Screening for prostate cancer presented a technology that (despite no assessment program supported such screening so far) was supported by many physicians resulting in a growing use of the technology (65).

An overall concern was the case of opportunistic screening that is when screening tools is used as diagnostic tools outside the context of a national screening program. This practice was reported extremely difficult to control (65).

**Development of HTA capacity and HTA programmes**

An always important issue for the HTA community is to build capacity and develop existing programmes to ensure sustainability of HTA in Europe. Related themes are 1) how to ensure that an HTA programme prioritises assessment of the right technologies to ensure as much benefit of HTA as possible, and 2) how to improve the links between policy and HTA to improve the impact of HTA.
HTA Capacity

Internationally there is a growth in HTA activities. However, despite this growth many European countries have none or only limited HTA capacity, especially low and middle income countries.

There are several obstacles to the introduction of HTA. In many countries, there is a general lack of awareness of HTA and the manpower to conduct assessments is insufficient. Hence, an important aspect of capacity building is the establishment of educational programs to promote training and knowledge in HTA. Moreover data availability in these countries is low and the quality and validity of morbidity and mortality data is questionable. For these reasons, developing countries are dependent on studies carried out in other countries. However, while some data might be transferable, such as clinical and epidemiological data, resource utilization, costs, cost-effectiveness data, prices, ability and willingness to pay vary from country to country.

These issues are particularly relevant due to the recent uptake of several new member countries in the European Union. The literature review revealed, that some efforts, European and international, are undertaken in areas of capacity building. Furthermore, one of the main goals of the EUnetHTA Collaboration is to increase transparency and transferability of HTAs.

The literature review revealed that European initiatives of capacity building are undertaken in the case of Hungary (72, 73) and Estonia (74).

As a part of the ECHTA project, Working Group 5 provided an overview of current HTA education and training programs in Europe revealing that education programs are limited in the EU12 countries. Additionally, the working group developed a curriculum of a European Master of science in HTA (75). Likewise, the Ulysses Program, a training program developed in corporation between Canadian, Spanish and Italian HTA agencies, aimed at evaluators who will produce HTA and decision makers who will use HTA (76).

EUnetHTA published a handbook on capacity building to support the development of HTA in Europe (77).

HTA Programmes

Also the description and analysis of different organizational aspects of HTA programs seem to be of increasing interest. The particular organizational features of the body producing HTA
reports may influence the diffusion of knowledge and the effect of those activities on policy making.

The literature search revealed two European articles concerned with the performance and description of HTA programs. One article focused on the differences and similarities of HTA agencies (448), the other article analyse what constitutes an “optimal” HTA program (3070).

EUnetHTA published a survey on characteristics of existing HTA organisations to provide information on how to develop vigorous HTA organisations in Europe (78).

**Priority setting**

The resources for HTA within existing HTA programmes fall short of that needed to evaluate all health care technologies. Therefore, for resources to be used cost effectively, priorities are set by the HTA agencies concerning which technologies to assess. Several methods exist to make this prioritization, and some are more transparent and systematic than others. Different HTA agencies apply different methods for priority setting.

In total four European articles concerning different aspects of priority setting were identified in the literature search. Two articles evaluated the methodology of two priority setting approaches in UK and the Netherlands respectively (79, 80), and one article described and evaluated the relative importance of the different sources used for priority setting by the NHS HTA Programme (81). Finally one study aimed at developing a method (PATHS) for economic evaluation and at the stage of research prioritization (82).

**Policy-HTA links**

The development of links between policy-making and HTA has been a built-in theme in relation to HTA since the first HTAs were produced in the 1970ties. This was a result of the fact that HTA was ‘invented’ to give input to policy-making at different levels. Thus development of and research in the policy loop - ‘policy-HTA-policy’ - is an important theme since the utilisation of HTA is necessary to justify the use of resources on production of HTA. In short…. if policy-makers do not see the benefit of HTA and find it useful when making decisions, HTA is not viable. Therefore researchers and HTA institutions has shown a growing interest in developing
HTA so that it is useful to policy-makers and in documenting the impact of HTA on policy-making.

44 contributions (articles, reports, book chapters) were identified which deal with the links between policy and HTA.

A total number of 11 publications addressed the policy-HTA links in a UK setting. In one comprehensive report the impact of the NHS HTA Programme was assessed (47). The overall conclusions were that the programme has had considerable impact on knowledge generation, perceived impact on policy and to some extend on practice. One article evaluated the impact of a technology appraisal process in the South and West Development and Evaluation Committee by measuring awareness, influence, and quality of reports among clinical and managerial staff and concluded that the process was perceived to have an impact on policy decisions among the staff. However, impact on practice could not be identified with routine data (48). Another article debated the use of evidence (mainly economic evidence) in the development of local health policies, and based their conclusions on an in-depth study of Health Improvement Programmes in England. The questionnaire based study concluded that the main ways of increasing the use of evidence were to produce more evidence-based national guidance and to disseminate summaries to local decision makers (49). In addition to these three publications a total of eight articles analysed the policy-HTA links specifically in relation to NICE processes. Two articles analysed the implementation and impact of NICE guidance. One looked at impact on GP prescribing and found only little impact unless the guidance coincided with information from other sources (50). The other studied the extent and pattern of implementation using multiple methods and concluded that implementation of the guidance has been variable. However, guidance was more likely to be implemented when there was strong professional support, a strong, stable evidence base, no increased or unfunded costs in organisations with good systems for tracking guidance implementation, and where the professionals involved was not isolated (51). Two article discussed the general procedures of NICE (52, 53), while two other article analysed the use of cost-effectiveness analysis/economic appraisal and discusses the consequences for the use of NICE appraisals (54, 55). One examined concerns from patient groups in relation to NICE decision-making processes (56), and finally did one article analyse NICE’s use of cost effectiveness as an exemplar of a deliberative process which include both scientific context-free evidence about the general clinical potential of a technology, scientific context-sensitive evidence about particular evidence in realistic scenarios, and colloquial
evidence to into a context and to supply the best evidence short of scientific evidence to fill in any relevant gaps (57).

A series of articles analysed HTA and its influence on health-care priority setting based on case studies in England/Wales, France, the Netherlands, and Sweden (58-62). The overall conclusion on this 2004 overview was that translating HTA into policy is a highly complex business, and that its influence on policy making remains marginal (58).

Two articles investigated the usefulness and impact of HTA in hospital settings in France and Italy, and the French article concluded positively that HTA has had significant impact on the implementation of technologies (63, 64).

Six different articles addressed the questions of impact (65, 66), priority setting for adoption of health technologies (67), integration of HTA recommendatons into organisational and clinical practice (68), needs of decision makers (69), and lessons learnt from a user perspective in relation an HTA programme. These studies took place in different European countries.

Furthermore seven articles investigated different themes in relation to the policy HTA link (70-76).

A series of articles, letters and replies debated the links between policy and HTA by focusing on why HTA reports building on the same methods and material in relation to PET in oncology led to different conclusions and policy decisions (77-79). Further the authors discussed the requirement for documentation in relation to future HTAs of diagnostic methods.

Finally EUnetHTA published a book containing eight separate chapters analysing the policy-JTA links in Europe. This included reviews of e.g. the impact of HTA on policy-making, the needs and demands of policy-makers, and an overview of the producers of HTA in Europe (80).

**Stakeholder involvement in HTA**

Five European articles concerned stakeholder involvement in HTA processes. Two articles specifically focused on the involvement of consumers. One article gave an overview of consumer involvement in processes of INAHSTA member organisations (81), while the other describes consumer involvement in the NHS HTA program (82). Both articles described current status of involvement and particularly the second article emphasized the need for explicit, inclusive and reproducible methods for supporting consumer involvement. The same theme is
dealt with in a Canadian article which identified what consumer organisations considered meaningful involvement, what the current practices in Canadian HTA processes were, and developed a model for involvement based on priorities and needs (83). Two articles analysed stakeholder involvement more generally in NICE processes (84, 85). The articles analysed the processes where NICE was created and discusses the unique way of involving stakeholders, but also concludes that there is a need for more flexible approaches to stakeholder involvement in order to ensure legitimate and transparent processes. Two Canadian articles also analysed stakeholder involvement – one as a means to improve the impact of HTA (86), and one a involving the values and judgements of stakeholders in policy coverage decisions (87). The final article described the processes developed in the EUnetHTA project with the purpose of involving stakeholders in the further development of European collaboration in relation to HTA. The article focused on stakeholder involvement in common processes across a large number of HTA institutions and included European umbrella organisations in the development of a stakeholder policy (88).

**Input for future research agenda**

Several inputs for the future research agenda concerning HTA in relation to health services research in Europe were identified in the literature review.

Some research themes relate to the methodology relevant to the specific elements of HTA, some relate to ways of improving the influence of HTA on health policy making while others relate to the assessment of technologies at different stages in their life cycle and assessment of technologies that challenge the current methodological framework of HTA.

In addition to the outcome of the literature review that is presented in this report, the achievement of the Health Services Research Europe Working Conference the 8th and 9th of April will provide even more insight and result in further inputs to this research agenda.

A thorough presentation of the input for future research agenda concerning HTA in relation to health services research in Europe will thus be provided after the Conference.

However, to provide a basis for the parallel session concerning HTA at the conference, three agendas will be presented and discussed in more detail at the conference. These are:

- Assessing the wider impact of health technologies (e.g. organisational aspects)
Improving the links between HTA and policy
Assessing technologies which challenge the common HTA methodology

Closing remarks
This version of the report should be considered a draft version of a final report on Health Technology Assessment in relation to Health Services Research in Europe that will be provided after the Health Services Research Europe Working Conference in Hague.

The final report will provide a thorough presentation of the future research agenda concerning HTA in relation to health services research in Europe incorporating the result of the literature review, the achievements of the Working Conference and finally the results of the stakeholder survey undertaken as a part of the project.

Literature


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