

# Horizon Scanning System (HSS)

An Overview



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WP7 Strand B – 1 Deliverable Overview on Horizon Scanning System (HSS) for Priority Setting on emerging/new technologies

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An Overview



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# Inhalt

	Summary	. 7
1	Presentation of the project	. 9
2	Horizon Scanning System (HSS) – An Overview	11
3	Origins of Horizon Scanning Systems	13
4	Context of Horizon Scanning Systems	17
5	Identification       7         5.1       Differences of Identification among HSS	
6	Priority setting	25 27 27
7	Early Assessment and Monitoring.       7.1         7.1       Conditions of Early Assessment.         7.1.1       Lack of Evidence.         7.1.2       Technology Development.         7.1.3       Socio-Political Issue         7.2       Differences in Early Assessment .	32 33 34 35
8	Dissemination and Implementation       8         8.1       Target Group(s)         8.2       Characteristics of the Message         8.3       Time of Dissemination         8.4       Differences of Dissemination among HSS	37 38 38
9	References	41
Appendix		

#### Abbildungsverzeichnis

Figure 3-1:	Field of Work for Horizon Scanning according to Stevens et al. [10]	14
Figure 4-1:	Functions of HSS	20
Figure 5-1:	Potential Information Sources of HSS	22
Figure 6-1:	Factors Determining Priority Setting in HSS	25
Figure 7-1:	Area of Operation of Early Assessment	31
Figure 7-2:	Impacts of a New Technology on average Length of Stay[43]	

#### Tabellenverzeichnis

Horizon Scanning Systems and Their Operating Level,		
Host Organization, Staff and Costumers	15	
Components and Work steps of HSS	19	
Classification of Healthcare Technologies by Types	22	
Selection Criteria formulated by EuroScan	28	
Most frequently used Selection Criteria among EuroScan Members[3]	29	
Types of Target Groups for HSS		
	Components and Work steps of HSS Classification of Healthcare Technologies by Types Selection Criteria formulated by EuroScan Most frequently used Selection Criteria among EuroScan Members[3]	

## Summary

**Introduction:** All western healthcare systems are confronted with a rising number of new health technologies. These new technologies bring particular challenges, not only in terms of financial burdens but they also raise questions concerning managed introduction, reimbursement, organizational requirements, changes in medical practice or social and ethical problems. Decisions have to be made not only concerning degree and time of adoption and/or reimbursement but also concerning treatment policies. To support these decision making processes with sound information about new health technologies, some countries have established "Horizon Scanning", "Early Warning" or "Alert" Systems. Currently there are 13 government-funded organizations that undertake substantial activities in this field. Since 1999 they have been collaborating in the EuroScan network. This report presents an overview of methods, processes, similarities and differences between the many Horizon Scanning activities.

**Objective:** Within EUnetHTA, it is the task of WP 7 (Strand B) to develop a European-wide newsletter on emerging technologies. This review aims at supporting the newsletter development with transparent criteria for the selection of new technologies that will be reported on.

**Method:** The report is based on a literature review, on unpublished information gathered from the relevant agencies (Horizon Scanning Systems/HSS) and on personal e-mail contacts with staff members. It was reviewed by Carla Douw/CAST.

**Results:** As a first step towards a broader understanding, EuroScan agreed on a common terminology, classification and understanding of their activities. Definitions refer to the object and components of HSS. The harmonization of the criteria to select and prioritize new technologies is another activity of international co-operations.

Definitions of subject: HSS is concerned with new or emerging technologies, but also established technologies with new indications or technologies that are part of a group of developing technologies that may as a whole have an impact. A new technology is one that is in the phase of adoption, has only been available for clinical use for a short time and is generally in the launch or early post marketing stages. In contrast an emerging technology is defined as 'not yet adopted to the health care system'. In the case of pharmaceuticals it will be in phase II or phase III clinical trials or pre-launch. Medical devices will be prior to marketing or within 6 months of marketing or marketed but <10 % diffused or localised to a few centres. The time horizon is 0-5 years before introduction.

*Function:* The fundamental function of HSS is to support policy makers by providing them with timely information on new health technologies and possible consequences for the healthcare system. Their need to control the adoption and diffusion of new technologies in health care by pushing or slowing down the speed of diffusion process is the objective of HSS.

Horizon Scanning for early identification and assessment of important new health technologies

objektive: supporting development of newsletter on emerging technologies

method: review of literature and information

subject could be new, emerging and established technologies with new indications

to support policy makers with timely information

All HSS activities consist of 5 sequenced main components:

*Identification* is the process of filtering out new and emerging technologies which may have an important impact. The challenge is to gather information of sufficient quality from a huge quantity of data. In the information gathering process sector specific searches – pharmaceuticals, surgical procedures etc. – proved to be most effective for identification. While primary sources, basic research journals, provide very early information, secondary sources already give hints on medical, financial and social aspects.

*Prioritisation* in HSS is the process of decision-making on the technologies in which further resources for investigation are to be invested. The target group and the data available on specific technologies determine the priority setting. The selection is either delegated to experts or is based on agreement by consensus within the HSS or HTA agency. Since this process is susceptible to subjectivity, formal prioritisation and ranking along selection criteria are being used for objectification.

*Early Assessment* aims at presenting information on anticipated impact on health care and health services. The challenge is to deal with lack of evidence, technologies still in development and issues other than health related (organisational, political, social). Accordingly a balance between timeliness and accuracy has to be found. Some quantifiable parameters to assess significance of impact are the relevant patient-group, the performance in relation to gold standards or the costs over time.

*Dissemination*: The impact of HSS is determined by reaching the target audience and decision-makers that influence regulation or introduction of the relevant technologies. Close links to the system and knowledge of the policystructure are prerequisites for dissemination and effective implementation.

*Monitoring* the assessed technologies and updating the reports with new information is the final component in the HSS cycle.

**Conclusion:** The established Horizon scanning systems are similar in that they go through the same processes, but they differ in terms of size, resources, operational level, mandate, customers, and organisational embedding and therefore there are some differences in methodology of identification, filtration and prioritisation, assessment, dissemination and monitoring. The most obvious difference is that they serve different target groups and therefore prioritise and select different technologies. Additional the weight that is given to expert suggestions and the use of implicit or explicit measures for identification and selection of technologies are characteristics of the different HSS.

Horizon Scanning comprises identification, prioritisation, early assessment, dissemination and monitoring

similar task – differences in terms of organization and methodology

## 1 Presentation of the project

This document concerns a work package that is part of the project to set up a European Network for Health Technology Assessment – EUnetHTA.

#### European Network for Health Technology Assessment – EUnetHTA project

In 2004 the European Commission and Council of Ministers targeted Health Technology Assessment (HTA) as "a political priority", recognising that there was "an urgent need for establishing a sustainable European network on HTA". In 2005, an invitation to tender by the European Commission was answered by a group of 35 organisations throughout Europe, led by the Danish Centre for Evaluation and HTA (DACEHTA) in Copenhagen (www.eunethta.net).

The European network for Health Technology Assessment (EUnetHTA) coordinates the efforts of 27 European countries, including 24 EU Member States, in the evaluation of health technology in Europe (www.eunethta.net). The strategic aim of the Network is to link up public national/regional HTA agencies, research institutions and health ministries, thus encouraging exchange of information and providing support for policy decisions made by Member States (www.eunethta.net).

Between 2006 and 2008, EUnetHTA intends to develop:

- an organisational framework for a sustainable European HTA network
- practical tools to feed into this framework

to ensure timely and effective production, dissemination and transfer of HTA results into useful policy advice to Member States and the EU (www.eunethta.net).

Initially, the project will be co-financed by the European Commission (DG Sanco) and contributions from Network members (www.eunethta.net).

The project is divided into 8 work packages, each with its own milestones and deliverables (see www.eunethta.net for details). Work package 7 (WP7) is "Monitoring development for emerging/new technologies and prioritization of HTA".

Since the actual effectiveness and cost-effectiveness of many of the approved health technologies cannot be evaluated before broader application under real conditions, many countries either release technologies that are not fully assessed or require post marketing follow-up studies. An alternative is the requirement to monitor the use and the outcome of a technology. For this reason some countries have started to set up "registries" or "application-protocols" in order to keep some health technologies (often surgical or costly interventions) under surveillance before broader diffusion takes place and until final evidence is proven.

It is the objective of WP 7 to provide tools that enable countries to monitor the development of (emerging, new or established) health technologies and to share data and results of this monitoring. Another objective is to support prioritisation for HTA and for health care decision makers with policy relevant information. EUnetHTA was initiated by the European Commission in 2005

within the network, the efforts of 27 European countries are coordinated

aim: sustainable European HTA network

co-financed by the European Commission

project is divided into 8 work packages

work package 7 refers to emerging/new technologies work package 7 comprises two Strands (A/B)

Strand B is about information services on new/emerging health technologies To fulfil these objectives WP 7 is divided into two Strands with the following aims:

- Strand A: Development of manageable monitoring instruments
- Strand B: Development of frequent information services on new/emerging health technologies

The results of this work can be used within WP6 to show concrete use of information from selected and monitored technologies by local health policy makers in member states.

# 2 Horizon Scanning System (HSS) – An Overview

All western healthcare systems are confronted with the spread of a rising number of new health technologies. The development and supply of new health technologies is, alongside changing demography and growing expectations of the population, one of the great challenges for policy making and research in health care[1]. New technologies affect health care systems in various ways (improved care, rising costs, changes in treatment). Therefore decisions have to be made not only concerning the degree and time of adoption and/or reimbursement but also to change current treatment policies (i.e. immunization)[2]. To support these decision-making processes with preferably sound information about new health technologies, some countries have established formal organizational units. They are usually called Horizon Scanning Systems (HSS), but also Early Warning Systems or Alert Systems[3, 4].

The aim of this paper is to examine the issue of horizon scanning conceptually and to point out several differences and similarities between some of the organizations working in this field. We focus on specific functions, targets, methods and challenges as a means of acquiring a deeper understanding of the issue.

The literature review started out with an extensive list of literature in the field of horizon scanning provided by EuroScan[5]. Additionally, internet and hand search was conducted, and all member agencies of EuroScan were contacted by e-mail to provide unpublished descriptions of their methodology or to give any other useful information. Contact information was taken from the Euro-Scan website. Where personal communication with HSS staff was used as a reference, contact details appear in the list of references.

The development of this report was conducted as a part of the EUnetHTA project.

Horizon Scanning to support decision-making processes about new and emerging health technologies

aim is examining the issue and point out differences and similarities

## 3 Origins of Horizon Scanning Systems

The issue of horizon scanning first appeared on the agenda in the mid-1980s[4]. A Norwegian and a Dutch study had identified health care technologies that were predicted to become important to their respective healthcare systems [4, 6]. The Dutch study concluded that it is not satisfactory to react to technological developments only when confronted with their consequences[3]. Therefore the authors called on the government to develop a permanent system for identifying new health care technologies before they were widely used kind of. This led to the first Horizon Scanning System, established in 1985-86 at the Dutch Health Council. Since then efforts have been undertaken in several countries to develop systems which are capable of providing relevant decision makers with timely information about potentially important new health technologies.

Currently there are 13 government-funded organizations which undertake substantial activities in the field of ,scanning the horizon' of [their respective] healthcare systems. Alongside them several non-profit (ECRI, U.S), forprofit (Hayes Inc., U.S) or academic (AHFMR, CAN) organizations also operate in the field of horizon scanning.

The countries with HSSs that are 100 % publicly funded are Canada, Denmark, Norway, Sweden, The Netherlands, The United Kingdom, Israel, Spain, France, Australia and New Zealand (which co-operate in a network) and Switzerland[3].

Since 1999 these 13 HSS have been collaborating in an information network called EuroScan, which is hosted at NHSC, the British HSS. The primary aim of EuroScan is to share information on selected emerging health technologies or new applications of existing ones in order to address their effects and anticipated consequences[7]. For this reason EuroScan provides a database of new and emerging health technologies available only for member agencies. Since its start in June 2001 750 topics have been put into database. EuroScan additionally offers an open database of different kinds of technology reports produced by member agencies. Another aim of EuroScan is to support the exchange of information and experience, and research in the field of HSS.

As a first step towards a broader understanding among the HSS, EuroScan members have agreed on a common terminology, classification and understanding of their activities[7]. Definitions refer to the object and components of HSS. Another aim of EuroScan concerns harmonization of the criteria for selecting and prioritizing new technologies (see Chapter 6).

According to EuroScan, HSS focuses on health technologies that are either:

- new technologies,
- emerging technologies,
- established technologies with new indication or
- technologies that are part of a group of developing technologies that may as a whole have an impact.

The difference between new and emerging technologies is defined such that a **new** technology is in the adoption phase, has only been available for clinical use for a short time and is generally in the launch or early post marketing stages. In contrast, an **emerging** technology is defined as 'not yet adopted to the health care system'. In the case of pharmaceuticals it will be in phase history of Horizon Scanning Systems goes back to mid 1980s

currently 13 publicly funded HSS + some private initiatives

countries with HSS

HSS network: EuroScan

common terminology, classification and understanding among EuroScan members

emerging technologies are not yet adopted, new technologies are technologies in the early phase of adoption II or phase III clinical trials or perhaps pre-launch. Medical devices will be prior to marketing or within 6 months of marketing or marketed but <10 % diffused or localised to a few centres[8]. This comes down to a time horizon of 0-5 years before introduction[3, 9]. Figure 1 shows the field of work of HSS in relation to a stereotyped diffusion process.

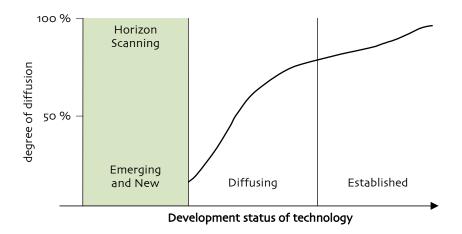


Figure 3-1: Field of Work for Horizon Scanning according to Stevens et al. [10]

Generally, a system which aims at the early identification and evaluation of new and emerging health technologies consists of 5 sequenced main components[7]:

- 1. Identification (& Filtering)
- 2. Prioritisation
- 3. Assessment
- 4. Dissemination
- 5. Monitoring.

The stage of priority setting is sometimes described as a two phase procedure[1, 3, 11]. The first phase is called filtering and comprises the (mainly implicit) rough selection of technologies. The second phase, which is the actual priority setting, comprises of a choice of selected technologies on the basis of preliminary evaluations.

Throughout this report (see also Table 4-1) filtering is assigned to the identification stage. Douw and Vondeling[3] found in their review of selection processes in HSSs that in some systems filtering virtually coincides with identification. In such systems, HSS staff filter technologies that are deemed unimportant while scanning sources for potentially significant health technologies. In other systems, filtering is a step that can be clearly distinguished from both identification and priority setting[3].

Nevertheless, from a functional perspective, filtering appears to be more a part of identification than priority setting, even if filtering is an organisationally distinguishable step between identification and priority setting. Overall, the goal of identification and filtering is to generate a list of technologies which will be used as the basis for prioritisation, the next step of horizon scanning. Therefore, the assignment of filtering to the identification stage seems appropriate to further define the term priority setting

the authors of this review assign filtering as part of identification. For EuroScan Filtering is part of prioritisation. Despite having the same objective there are some differences among HSS. They differ in terms of size, resources, operational level, mandate, customers, organisational embedding and therefore in their specific methodology of identification, filtration and prioritisation, assessment, dissemination and monitoring. despite the same object systems collaborating at EuroScan differ significantly

An overview of all current HSS is given in Douw and Vondeling[3] highlighting some differences among them.

		National/ local/		
HSS	Country	regional	Host organization	Customer
Basque office for HTA (SorTek) (OSTEBA)	Spain	Regional	HTA agency	Regional Department of Health
Agencia de Evaluación de Technologicas Sanitarias de Andalucia (DETECTA)	Spain	Regional	HTA agency	Regional Department of Health
Sistema de Información de Tecnologías Sanitarias Nuevas y Emergentes (SINTESIS)	Spain	National	HTA agency	A network of health professionals
Health Council (Gr)	The Nether- lands	National	Governmental advisory body	Department of Health
Committee for Evaluation & Diffusion of Innovative Technologies (CEDIT)	France	Local	HTA agency	Hospital group: Assistance Publique- Hôpitaux de Paris (AP-HP)
National Horizon Scanning Centre (NHSC)	England and Wales	National	Department of Public Health and Epidemiology at University of Birmingham	Department of Health in England and Wales
Swiss Federal Office of Public Health (SFOPH)	Switzerl and	National	Federal Office of Public Health	Department of Health
Norwegian Health Services	Norway	National	HTA Agency Norwegian	Government, health
Research Center (NOKC)	·		Knowledge Centre for the Health Services	professionals
The Swedish Council on Technology Assessment in Health Care (SBU-ALERT)	Sweden	National	HTA agency	Health care professional, decision maker at all level
Danish Centre for Evaluation and Health Technology Assessment (DACEHTA)	Denmark	National	HTA agency	Health professionals, interested public
Canadian Emerging Technology Assessment Program (CETAP)	Canada	National	HTA agency	Health professionals, interested public
Division of Medical Technology Policy (DMTP)	Israel	National	Department of Health	Department of Health
Australia and New Zealand Horizon Scanning Network (ANZHN)	Australia New Zealand	National	HTA agency and the Australian Safety and Efficacy Register of New Interventional Procedures–S (ASERNIP-S)	HealthPact (Health Ministers)

Source: Dow and Vondeling 2006[3]

Most of the institutions collaborating at EuroScan operate at a national level. Exceptions are the three Spanish HSSs working for regional departments and the French HSS operating at a local level. The majority of the HSSs are part of an HTA agency. Other forms of organizational embeddings are affiliation to a university as in the case of the British NHSC, to a federal insurance office as in Switzerland, to a hospital group like in France or to governmental bodies as in the Netherlands and Israel. Whereas principally all HSS could be rated as small units, there tend to be differences in personnel facilities (between 1-9 FTE). These variations could be interpreted as indicators of the different relevance of horizon scanning within the healthcare systems. What is common to all these HSS is that they are 100 % governmentally funded.

## 4 Context of Horizon Scanning Systems

New technologies bring particular challenges to all healthcare system. These are not only in terms of financial burdens due to the fact that all systems face budgetary constraints. New technologies can also raise questions concerning managed introduction, reimbursement, organizational requirements, changes in medical practice or social and ethical problems[2, 12].

For this reason the potential HSS target groups are diverse. They can basically be distinguished into 4 groups, leading to different functional needs. These groups are:

- Decision makers and health service planners
- HTA agencies
- Medical professionals
- ✤ Public.

They all face the overall condition of a growing rate of new health technologies[13]. Douw et al.[14] illustrated this on the basis of the numbers of new drugs that were brought to market in the U.S., which increased from 239 in the 1980s to 370 in the 1990s. According to Pharmaceutical Research and Manufacturers of America (PhRMA) today there are over 2,000 medicines in development[15]. The number of new devices and procedures has also increased. Trindade et al.[16] stated that at least 20 medical innovations of some significance appear every week. At the same time there is an increasing technology demand from patients and an increasing interest in health care issues among the public[17].

Various trends at the medical industrial market and the public demands were observed by ten Velden[18]. Areas of intensified development are thus diagnostic technologies, information technologies, less invasive technologies, population screening technologies, outpatient and home-care-related technologies, smaller and more sophisticated medical devices, biotechnology-related technologies and organ-replacement-related technologies.

Both developments, the growing supply of and increasing demand for new health technologies, are outpacing health systems' ability to effectively rationalize the introduction of new health technologies, because there are mostly insufficient data on safety, effectiveness and cost-effectiveness before technologies are widely diffused[17, 19].

Differences between types of target groups can be assumed in respect of their specific needs. Decision-makers and health service planners are the main target group of HSS. As Douw and Vondeling[3] show, decision-makers in health care are operating under several – in part contrary – pressures, generating needs for information.

*Firstly* a growing pressure to accelerate decision making on new health technology can be identified in order to ensure that beneficial technologies are made available as quickly as possible. Health technology developments however, hold the promise of improving care, health service quality and economic benefit. Alongside the danger of inappropriate enthusiasm among health care professionals in the face of a new technology, public enthusiasm and expectations affected by mass media have an increasing importance[12].

*Secondly* there is simultaneously the pressure or expectation to protect consumers of unsafe and ineffective technologies.

new technologies can cause various questions ...

... which leads to different target groups

there is a growing rate of developments in healthcare ...

... especially in some areas

new technologies diffuse often on the basis of insufficient data about their benefits

decions makers are the main target group of HSS ...

... operating under several pressures HSS function is to produce timely information on new and emerging health technologies

HSS establishes formal communication mechanisms between stakeholders

HSS can affect diffusion processes differently

sometimes it is necessary to slow down the process of diffusion, ...

... and sometimes HSS work push the diffusion of health technologies

HSS can increase the awareness of emerging ethical or political controversies *Thirdly* a pressure or need to concentrate scarce resources on the most beneficial technologies has arisen. Today, variations in health care practice indicate unnecessary or inappropriate use of technologies. Premature introduction of new technologies could increase this variation and contribute to inefficiency and inequity in health care[18].

To manage these situations, decision makers and health planners need above all timely and high quality information on new health technologies[3]. The fundamental function of HSS is therefore to support policy-makers in controlling and rationalising the adoption and diffusion of new technologies in health care practice by providing them with timely information on new health technologies and possible consequences for the healthcare system[14].

In the face of the high political risk related to new health technologies, HSS could be understood as a means by which policy makers try to buy time[12], enabling them to enhance their planning horizon[4]. To meet these requirements, an HSS has to connect policy makers with experts in the field of new health technologies (developer, early user, relevant scientific communities) and can therefore be understood as a formal mechanism to allow communication between parties who are in other respects isolated[4].

In accordance to the diffusion context described above, an HSS may affect the diffusion process of new health technologies differently. Carlsson and Jørgensen[17] differentiate in this respect between the need to push and the need to slow down the speed of the diffusion process.

The slow down function has traditionally been perceived as the function of an HSS, controlling health technologies that are pushed into health service by stakeholder or media enthusiasm. An historical example for this kind of threat to public health is DES (Diethylstilbestrol), described by Douw et al.[14]. DES (a synthetic female hormone to reduce complications in pregnancy) was approved for marketing in U.S. 1941 on the basis of several uncontrolled studies carried out by the advocates of the drug. Although 7 controlled studies carried out from 1950 to 1955 showed that DES was ineffective, it was frequently used worldwide until cases of a rare cancer of the vagina appeared which were attributed to DES in the 1970s.

To push or support a technology is necessary when there are attributes that discourage an effective diffusion, irrespective of the relative advantage of the technology[17]. This refers to the fact that a technology needs a compatible social and political environment to operate effectively[12]. The need to push is given e.g. if a new technology has a low degree of compatibility with adopters' values, or its' use and understanding is difficult and requires special qualification. According to ten Velden[18] one of the main purposes of an HSS is therefore to support the distinction between technologies which need particular policies and those which do not. Thus HSS may trigger planning and configuring health services or developments of standards and training[17].

Alongside an inappropriate diffusion process, decision makers may be confronted with controversial ethical, social or political consequence related to a new or emerging technology as xenotransplantation or pediatric cochlear implants[12]. Controversies may be triggered by major risks that are difficult to assess, profound ethical dilemmas or groups of actors who feel threatened in terms of power or resources[12]. HSS is therefore also an instrument to increase the awareness and preparation for emerging political or ethical controversies on new technologies. To meet all these functional requirements, the aim of HSS is to provide timely reports about important new and emerging health technologies and their anticipated impact on health care and health services before they diffuse too extensively[4].

Based on HSS components, the following work-steps comprise the work of HSSs:

5 work-steps to scan the horizon of health technologies

<i>Table 4-1:</i>	Components a	and Work steps	of HSS
-------------------	--------------	----------------	--------

Components	Work Stepps
Identification	identify new and emerging technologies
(& Filtration)	gather basic information on the technology and its applications
	<ul> <li>filter out unimportant technologies as well as worthless information</li> </ul>
Prioritisation	<ul> <li>select most important technologies for assessment (priority setting)</li> </ul>
Early Assessment	perform assessments of selected technologies
Dissemination	<ul> <li>disseminate information on important technologies</li> </ul>
Monitoring	monitor assessed technologies
	update reports if new information is available

An additional aim should also be to evaluate the effectiveness of the HSS itself, i.e. to what extent it fulfils its various purposes. Actually there is still a lack of evidence concerning effectiveness and efficacy of HSS components and the system in general [20-22]. Simpson et al.[23] compared some results of prioritisation made by the British NHSC between 1997 and the end of 1999 with expert opinions on the importance of those technologies 3-5 years later. They concluded that NHSC performed acceptably, i.e. they prioritized 5 of 7 technologies that were rated as important by experts and predicted 80 of the 110 technologies that were rated as unimportant. As Simpson et al. emphasize, such a gold standard is imperfect and complete evaluations of HSS have to consider more outcome parameters (e.g. to identify potentially important technologies that turn out to be ineffective after assessments or technologies that could have a significant negative impact).

Alongside decision makers there are other potential target groups for information produced by HSS. Firstly, HSS may enable HTA agencies to identify and prioritize objectives of further medical research and technology assessment. Earlier identification of technologies could allow cost-effectiveness research prior to marketing and introduction[9]. HSS can therefore be seen as the first stage of a comprehensive HTA process. Accordingly most HSS units are part of a HTA agency.

Furthermore, medical professionals may benefit from timely information to rationalize practice and by being spared improper expectations. The public may also profit by an increased awareness of new technologies and stimulated debate on potentially controversial consequences[17].

performance of HSS is hardly evaluated

Horizon Scanning as first stage of a comprehensive HTA-process

other target groups: emerging medical professions, public

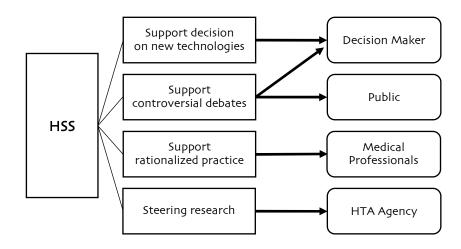


Figure 4-1: Functions of HSS

methods of Horizon Scanning are highly affected by the specific purposes of an HSS The specific purposes of a Horizon Scanning System determine to a high degree the particular methods of identification, priority setting, early assessment and dissemination. The specific conditions and challenges which are associated with the components of horizon scanning and various differences among the member agencies of EuroScan in this regard are the topic of the following sections.

# 5 Identification

The task of this first component of HSS is to identify new and emerging technologies which may have an important impact on health care service if widely diffused. Furthermore, basic information like indication, number of patients, cost or clinical effectiveness must be gathered to enable subsequent priority setting. To fulfil this task the gap has to be bridged between basic science, industry, medical experts and those engaged in horizon scanning[17].

There are many scientific developments which appear on the horizon but never reach market entry. Others, seemingly from nowhere, diffuse rapidly within the health care system. The challenge of identification new technologies is therefore to gather information of sufficient quality from a huge quantity of data. Thus identification may be perceived as the first part of filtering before the prioritisation process.

Data can be obtained from different sources, however all of them are associated with advantages and disadvantages, dependent on the respective information needed. Generally, a distinction can be made between sources appropriate for identifying interesting topics and sources that are suitable for gathering further information on interesting health technologies.

To validate findings and to increase the likely accuracy of any predictions as well as the amount of useful information, a combination of sources is recommended[9, 14].

The specific process and kinds of sources used in particular HSS depends on:

- the purposes of HSS determining what technologies have to be observed and what information is required for priority setting
- resources available
- individual preferences of local information specialists[14].

To assess different identification procedures it is necessary to recognize that health technologies differ considerably in terms of their diffusion context. Some technologies have to pass regulatory hurdles resulting in a delayed market entry, as in the case of drugs which must be approved by FDA and EMEA before diffusion into healthcare systems. Other technologies, like surgical procedures emerge mostly within medical professions without any formal admission[1, 24].

Similarly, the speed of diffusion varies among different types of technologies[25].

In accordance with these different diffusion conditions one can assume that distinct information sources will be used for different types of technologies[9], i.e. FDA database for drugs and surgical experts for surgical procedures. Robert et al.[9] therefore developed a classification of health technologies to explore the most useful sources for the identification of new ones. They decided to classify them according to the sectors in which they are most likely to originate, highlighting specific sources for identifying. This resulted in the following list:

task: identify new technologies and gather basic information

there are several sources of various benefits for identification

combination of sources is useful

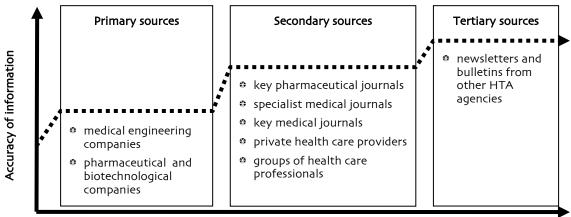
technology-specific diffusion contexts have to be considered

speed of diffusion varies as well

different sources for different types of technologies

Table 5-1:         Classification of Healthcare Technologies by Types
---

	Pharmaceuticals
	Diagnostic strategies
	Procedures
	Procedural devices
	Other medical and assistive devices
	Healthcare settings or treatment delivery systems
	Information technology
	New professions
	Other forms of classification were presented by Robert et al., e.g. distinguish- ing between product characteristics (product diversifying/product enhanc- ing/cost saving) or between origins of the technology (cognitive/mechanical/ biological/informational).
it is common to classify sources for identification into	There are also several attempts to classify the huge number of sources offer- ing information on health technologies. The most common is the classifica- tion into primary, secondary and tertiary sources, determined according to the proximity to the origin of innovation.
primary,	Primary sources provide information from developers or manufacturers like patents or FDA licensing applications.
secondary	Secondary sources provide – mostly published – information concerning the technology in use from a medical, financial or social perspective, like drug information services, conference abstracts, journals, but also expert groups or patient interest groups.
and Tertiary Sources	Tertiary sources provide information from other organizations engaged in the identification of new health care technologies. These are mainly other HSS or EuroScan.
trade off between time and accuracy	The separation into primary, secondary and tertiary also highlights a trade off between earlier 'warning' and greater accuracy of the information pro- vided. Figure 5-1 presents this trade off, together with the sources which were recommended by Robert et al.[9] as the minimum when developing a compre- hensive HSS. As already indicated, the use of sources is primarily determined by the specific purposes of an HSS.



#### Earliness of information

Figure 5-1: Potential Information Sources of HSS

Primary sources are likely to provide earlier 'warning' but suffer in terms of reliability of predictions and detailed data, while secondary and tertiary sources are likely to investigate technologies later but with greater detail and more accurate predictions.

In addition, sources face advantages and disadvantages in terms of their different importance throughout the identification process. Blume[12] states that technologists, biomedical scientists and clinicians directly involved with new technologies have lost some of their ability to estimate the future course of an innovation during the last decades because the role of government and consumer groups has made innovation and diffusion of health technologies more complex and unpredictable.

Using experts to identify technologies in an open survey is likely to produce a long list of potential new technologies but with little detail. On the other hand, experts are sometimes the main or sole source for identifying new technologies, their applications, and their relevance, which is important for subsequent prioritisation. Experts are therefore a key source to any HSS[9, 10]. Another advantage of experts is that data can be collated quickly and cheaply. However, a central and challenging question is who is to be classified as an expert and how to access them in horizon scanning.

The advantage of regulatory bodies like the FDA and the EMEA for drugs or the EU marketing approval for medical devices (CE markings) is the high number of hits possible and in the case of drugs the predictable time horizon. Additionally data via internet is easily and cheaply accessible. The high rate of hits makes it simultaneously difficult to identify more important candidates.

The benefit of industry-related sources depends on the time horizon. It is assumed that information concerning long-term planning of future technologies is more easily accessible than information concerning a product ready to market[17]. The main barrier for reliable information from companies might be the commercial sensitivity of such data. Nevertheless collaborations with suppliers of health technologies are important for the work of HSS but also may involve conflicts of interest. EuroScan has therefore developed some guidelines for collaboration between industries and individuals in HSS[26].

General scientific journals like Nature posses the same disadvantage as primary sources, informing too early and possibly unreliably. Specialist medical journals are in contrast one of the best sources for identifying diagnostic strategies, procedures and other medical and assistive devices but need huge time resources due to their high number[9]. When using tertiary sources, one must consider that different priorities may be applied by these organizations.

Resource restrictions and the huge quantity of data instigate the use of the ... and the internet internet for identification [13, 14, 16, 27]. It was observed that the control of the huge amount of data on new health technologies offered by a great number of web sites is the biggest challenge to HSS using this media. All studies present various web sites of different importance. However, they emphasize that, to perform effectively and efficiently, it is necessary to develop specific internet search strategies. Such strategies have to depend on categories of technologies and the specific kind of information needed. Appendix I lists several important web sites mentioned by these studies and staff of HSSs.

all kind of sources face specific advantages and disadvantages this applies to developer, ...

... experts, ...

... regulatory bodies, ...

... companies, ...

... journals, ...

# 5.1 Differences of Identification among HSS

there are differences in terms of	Generally there are a lot of similarities of identification methods but also some differences among EuroScan member HSS, mainly reflecting differences of purposes and resources available.
scope of scanning,	<i>Firstly</i> there are differences regarding the scope of scanned technologies. The majority of HSS consider all kinds of technologies and specialities. Exceptions are the systems of Norway, Australia and New Zealand, the Basque and Andalusia agencies.
	The Norwegian agency is constrained by disease considering only cancer treat- ments[28]. Others, by contrast, focus on different types of technologies. The Australia and New Zealand Horizon Scanning Network (ANZHN) observes no drugs but directs its attention with NET-S particular towards surgical health technologies (ANZHSN Homepage). OSTEBA (Basque) also excludes drugs and focus on devices and procedures[29].
sources that are used,	Secondly there are differences in sources used for identification. The major- ity of HSS combine the scanning of various sources like journals, websites and other HSS and EuroScan, with active (i.e. permanent co-operation) or passive (i.e. information on inquiry) use of experts and health professionals. A Special case in this respect is the Israeli HSS, which works on the basis of a list of 400 candidate technologies for the basket of publicly funded health technologies[30], the Norwegian HSS which uses tertiary sources and a clini- cal network exclusively, the Spanish SINTESIS, which mainly uses expert suggestions and the French CEDIT, which identifies potential topics mainly by requests from representatives of a huge organization of hospitals in the Paris region[31].
and specific methods that are used for identification	<i>Thirdly</i> there are a few features concerning the method of identification. The Danish HSS has at one time developed a specific Internet search strategy for new health technologies in oncology.
	The British NHSC collates the scanning of sources with a speciality based work program to ensure an in-depth investigation in every medical speciality. The SINTESIS attracts attention because it has developed a complete inter- net and intranet-based program to manage the issue of horizon scanning.
two systems established an explicit filtering process, using external expertise	According to Douw and Vondeling[3] a subsequent filtering of identified but trivial technologies to narrow down their number is undertaken within two systems using individual experts or groups of clinical experts. For this pur- pose, these systems use a form with predefined questions concerning the nov- elty of the technology, the time horizon of introduction and the likely impact. In the other systems, which declared that they undertake filtering, this proc- ess is completely implicit.

# 6 Priority setting

Through identification HSS usually finds a certain number of health technologies that are appearing on the ,horizon' of health care service. As resources are limited the subsequent task of HSS is to decide in which of those technologies further assessment resources are to be invested. This task is labelled as priority setting and constitutes the second component of HSSs. Priority setting in HSS differs to some extent to the similarly labelled issue of priority setting in health care. The objective of the latter is to select the technologies which should become part of healthcare basket.

In contrast, the objective of priority setting in horizon scanning can generally be described as to define the potentially most significant new and emerging technologies[3] in order to invest the scarce assessment resources on those technologies.

Obviously the term ,most significant' is ambiguous and requires further efforts in operationalization. Selection criteria fulfil the purpose to define the characteristics of a new or emerging health technology that indicate its significance. Generally, in this stage of horizon scanning a choice will be made whether a technology will be assessed or onwardly observed (monitored)[18].

It is not surprising that selection criteria differ among HSSs, albeit slightly, reflecting differences in terms of values, target groups and specific purpose. Before criteria used among HSS are presented in more detail, some comments shall clarify the general conditions and constrains of the priority setting issue for new and emerging health technologies.

task: prioritize technologies for further evaluation

defining those which are most important

importance can be operationalized by selection criteria applied

selection criteria have to reflect values, target groups and purposes of an HSS

## 6.1 Conditions of Priority Setting

Three factors seem to affect the selection of criteria and the mode of decision making to define candidates for profound assessment. As Figure 6-1 shows, priority setting depends on the target groups and the data and resources available.

target groups, data and resources available determine the choice of selection criteria

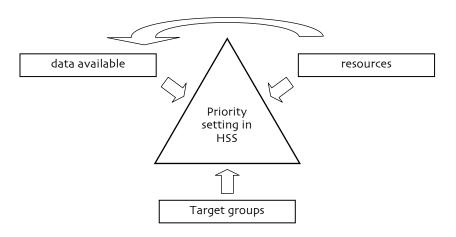


Figure 6-1: Factors Determining Priority Setting in HSS

#### Firstly, priority setting on new and emerging technologies is fundamentally target groups define the purposes of an HSS dependent on the target group(s) of the prevailing HSS[17]. The definition of target group(s) determines the specific purpose of an HSS. This defines simultaneously the most interesting aspects of new and emerging technologies. According to the pilot study for the Swedish SBU Alert, only 10 % of the target groups were interested in all the technologies assessed[27]. Different interest-structures among users of health technology assessment (HTA) are presented by studies examining the different use of such reports. As Luce and Brown[32] observed for the U.S., hospital based decision makers are particularly interested in financial or economic aspects of a new technology, whereas decision makers in payer organisations focused more on evidence of clinical and cost-effectiveness. In contrast to that, political decision makers might be more interested in social, legal or ethical consequences e.g. technologies that affect a small number of patients but require administrative decisions[33]. Others such as strategic planners might be interested in detailed information about those technologies with the most organizational impacts. For clinicians, on the other hand, the potential patient outcome might be most important. only those criteria with Secondly the setting of priorities for Horizon Scanning is largely constrained data available can be by the data available. Thus the data available at the time of decision making considered defines the possible range of selection criteria. It is, for example, more difficult to use ,value for money' as a criterion, as long as there is no sound data on the effectiveness and costs of a technology[3, 11, 34]. Obviously the availability of data increases with the stage of development and diffusion. In this context the specified time horizon of the HSS is of importance. Therefore, priority setting faces also the known dilemma of accuracy and timeliness. Thirdly, efforts towards the issue of priority setting in HSS are limited by the there is a link between availability of resources resources available. This refers mainly to staff time for gathering informaand availability of data tion on technology candidates. For that reason there is a link between availability of resources and that of data. Resources are furthermore necessary for the process of decision making, applying the selected criteria Work time either of external experts or HSS staff - also increases with the number and complexity of the criteria and with a more explicitly organised decision making process [33]. priority setting can be The extent to which the priority setting component of an HSS fits its goals evaluated by sensitivity can be retrospectively described in terms of outcome parameters known for diagnostic tests[23]. The primary goal of priority setting in HSS is to select and specificity as those technologies for further assessment that will truly become most signifioutcome parameter, ... cant (in terms of selection criteria) to a health service. This can be described as sensitivity or the extent of true positive or avoidance of false negative predictions. As assessment resources are scarce, it is secondly important to avoid

... but this is not unproblematic

t However, specificity is a precarious outcome parameter because, thanks to the work of HSS, technologies may possibly not become as important as they would be without assessment triggered by HSS. Therefore some prioritized technologies that appear ex post as not so significant and must be counted as true negative predictions owe this to the work of an HSS. To put it in a nutshell, good performance of prioritisation comprises not only the selection of those technologies which truly turn out to be most significant, but also those which would gain unjustified significance or inappropriate use without assessment.

assessments of less important technologies or false positive predictions. The extent of false positive predictions is incorporated in the term specificity.

## 6.2 Differences of priority setting among HSS

Prioritisation of technologies is not used in every HSS, either. Systems which exclusively assess technologies on request do not need this stage. This is the case in the Israeli and French systems.

#### 6.2.1 Process of Priority Setting

Concerning the process of priority setting Douw and Vondeling highlight that all HSS select technologies on agreement by consensus – either by the HSS or the HTA agency that hosts the HSS or it is delegated to experts. The process of prioritisation in HSS is therefore more susceptible to subjectivity. According to Douw and Vondeling[3] subjective means that it is not clear if all criteria are taken into account and if the same process is followed for each technology. The description "an on-back-of-our-mind exercise"[3] typifies this process well.

As Douw and Vondeling[3] note, two HSS tried to objectify the selection process by using formal priority setting methods, where criteria were scored and weighted and a final ranking was achieved on the basis of decision rules. Both systems stopped using those formal methods, because the associated efforts exceeded their means[3]. Up to now the specific conditions of priority setting in HSS, particularly the limited availability of data and corresponding resources, complicates the establishment of an explicit and transparent selection process.

Nevertheless, there are some tools capable of enhancing the accountability of the selection process. Besides the use of explicit criteria it might be advantageous to operationalize, if possible, individual criteria to improve common understanding. Another tool would be a formal checklist of the selection criteria and their indicators, which is intended to enhance the likelihood that all criteria are taken into account. Finally the documentation of the decision process might substantially enhance accountability and transparency.

The more implicit the selection criteria are used, the more important other factors may become for priority setting on new and emerging health technologies that do not necessarily correspond to the selection criteria in use. According to qualitative case studies on the issue of priority setting in health care, decision making under such circumstances is affected by the following factors[35]:

- organizational context in which the decisions are made
- people who make the decision
- factors they consider
- specific reason for the decisions
- characteristics of the process of decision making (procedure, appeal mechanisms).

The more implicit the prioritisation, the more likely are the results biased by influences concerning the factors which do not reflect the chosen selection criteria. The latter factor refers to the special relevance of the chairman for decision making within a collective player. The significance of the chairman in collective bodies for decision making is also addressed in the study by Douw and Vondeling[3].

not every HSS prioritizes technologies

those, which prioritize, select all on agreement by consensus

to objectify the selection process is challenging

several tools can enhance accountability of priority setting

if priority setting is implicit, other factors become more important ...

... and selection can be biased ...

... and depends on individual skills The second factor highlights the fact that the more implicit the process of decision making, the more important individual knowledge and experience in fields of medicine, HTA and health care system becomes for the sensitivity of the HSS[33].

#### 6.2.2 Selection Criteria in Use

majority of HSS use criteria explicitly Selection criteria in HSS define which characteristics of a new and emerging technology are crucial to trigger further assessment efforts. According to Douw and Vondeling[3] the majority of the examined HSS use selection criteria explicitly, which means that they are internally documented. Hence only one system prioritizes implicitly, i.e. without defined criteria, whereas two systems declared that they use explicit and implicit criteria.

overview of criteria show extensive congruencies and specific varieties Among those HSS using explicit criteria somehow, extensive congruencies as well as specific differences regarding the composition of criteria can be observed. EuroScan developed a list of criteria comprising the central criteria used by its member agencies. Table 6-1 displays the criteria, which are in patches further specified by EuroScan.

Priority setting criteria	Specifications
major uncertainties	regarding health benefit
	regarding cost-effectiveness
health benefit if diffused widely	innovative therapy for a disease or disorder with no satisfactory standard treatment
	a new, potentially more effective therapy, measured by relevant outcomes, than standard treatment
	a new therapy with significantly fewer known side effects or long term adverse effects than the standard treatment
potential for <b>inappropriate</b> <b>diffusion</b> or <b>use</b> of the technology	
Major <b>cost impact</b>	because of moderate to high unit costs
	because of patient numbers
	because of service re-organisation requirements
other major impacts	like staff retraining needs
significant legal, ethical, political, environmental or social issues with regard to the use of the technology	

Table 6-1: Selection Criteria formulated by EuroScan

costs and possible health benefits of a new technology are most considered criteria As Douw and Vondeling[3] show, costs related to an emerging technology are the most frequently considered characteristic among HSS (Table 6-2). Similarly broad consideration is given to the possible health benefit or uncertainty on this issue as criteria to legitimate further assessment. These leading criteria are followed by the organizational consequences of a technology (73 %) and fears in the diffusion rate as well as ethical, legal or social issues (both 64 %). Other criteria used by a number of HSS were the number of patients (55 %), the innovativeness of the technology (36 %), cost-effectiveness (27 %) and severity of illness (18 %). The fact that only a minority use cost-effectiveness seems to affirm the assumption that this indicator is mostly not yet available for this issue.

Table 6-2: Most frequently used Selection Criteria among EuroScan Members[3]

1. Costs

- 2. Health benefit and/or uncertainty according to health benefit
- 3. Organizational consequences
- 4. Rate of diffusion
- 5. Ethical, legal, social issues
- 6. Number of patients
- 7. Innovativeness
- 8. Cost-effectiveness
- 9. Severity of illness
- 10. National policy relevance

Douw and Vondeling[3] observed additionally eight other criteria, mainly unique to one HSS, reflecting specific fears concerning new technologies. The British NHSC e.g. considered if a technology is of policy relevance or rather concerns clinical guidance or government priority areas. The Danish HSS considered the grade of interest of investors, clinical experts and decision makers for a new technology.

The number of selection criteria used varies highly, ranging from three to thirteen. However, there are no explicit decision rules or weighting tools used among HSS which would assign different importance to the selection criteria of an HSS. Such an approach would only be preferable as long as the weighting criteria reflect the needs of the target group(s). Therefore selection criteria are not an instrument for managing priority setting in HSS, but instead for facilitating a systematic and informed decision making process.

several HSS use agency specific selection criteria

number of criteria used varies highly

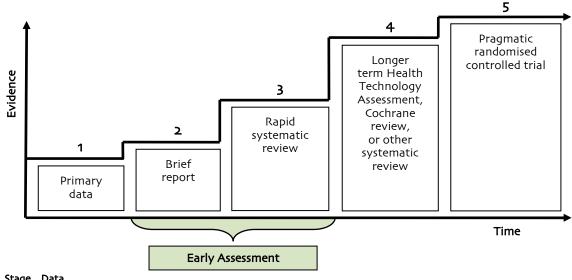
priority setting is more than defining selection criteria

#### Early Assessment and Monitoring 7

The task of early assessment is to gather and present information on a new or emerging technology, that was identified - whether by formal identification and priority setting or by commission – as potentially relevant for future health care service.

task: gather and editing information on new technologies

Stevens et al.[10] noted that the evaluation process accompanying the introduction of new important technologies appears to follow a pragmatic fivestaged sequence of events, which illustrates the area of early assessment (Figure 7-1, Table 8-1).



#### Stage Data

- Primary data sufficient for launch or licensing, assembled by the manufacturer 1. or pharmaceutical company
- Brief report on the advantages and disadvantages of the new technology, who 2. might prescribe it, and the need for research
- Rapid systematic reviews (based on published and unpublished primary з. research) and cost effectiveness modelling (making various assumptions on cost and longer term outcomes)
- Longer term systematic review, Cochrane review or other systematic review 4.
- Pragmatic randomised controlled trial (the result should be set in the context of 5. updating existing systematic reviews

Figure 7-1: Area of Operation of Early Assessment

The aim of early assessment is to produce timely reports on such technologies and their anticipated impact on health care and health services[4].

These reports comprise first of all descriptions and explanations of the technology in question. This is followed by information concerning the clinical, economical and societal impacts.

## 7.1 Conditions of Early Assessment

3 challenges of early	In fulfilling this purpose, HSS have to deal with a number of issues. Based on
assessment in HSS	the literature reviewed the following three can be differentiated:

- lack of evidence
- technology development (change of its subject)
- consideration of non health-related issues (political, social, organisational).

accurate information is rare and ... It is quite natural that the earlier a technology is in its life-cycle the less information on the technology is available. At the same time, it is advisable to begin assessment as early as possible, because the earlier in the diffusion process a technology is assessed, the easier it might be to start assessments undistorted and to influence decision making and further diffusion[17, 36]. Early assessment thus faces the same dilemma of all Health Technology Assessment (HTA), to balance timeliness and accuracy. In the case of early assessment the timeliness of such information is associated (bought) with less accuracy of data.

... technologies can<br/>develop while<br/>assessment, ...Another challenge for early assessment is that its objective is a moving entity.<br/>Technological changes are possible between first identification and market<br/>entry, but also after introduction. As Gelijns and Rosenberg[37] stated, health<br/>technologies may change in terms of indication or patterns of application<br/>through an iterative interaction between users and manufacturers. These<br/>changes often help to improve outcome or reduce costs but may invalidate<br/>the results of previous evaluations[38].

... this requires monitoring efforts to steer reassessments Given the limited availability of sound information and the dynamics of technological change, early assessments must be perceived as part of an iterative evaluation process. Its rationale is to present the best available information at each stage of this iterative process[17]. To steer this process, it is important to monitor assessed technologies. Monitoring is therefore to be rated as an integral part of early assessment. Ideally reassessment should be carried out when sufficient new data is available or when a technology has changed enough[4, 36]. The issue is here to find reliable triggers or thresholds.

questions concerning<br/>non-health-related<br/>consequences require<br/>broader methodological<br/>effortsThe third issue of producing early assessment is not only to assess in terms<br/>of clinical effectiveness, costs or cost-effectiveness, but also according to the<br/>political, social and organisational consequences. As Rosen and Gabbay[39]<br/>argue, the extension to these aspects entails complex methodological prob-<br/>lems. According to Carlsson and Jørgensen[17] it is essential to involve the<br/>social sciences in early assessment to incorporate the perspectives of patients<br/>and consumer.

Broader understandings of these three challenges to early assessment and approaches to better deal with are presented separately below.

### 7.1.1 Lack of Evidence

Usually no randomised controlled trials or even systematic reviews are available when horizon scanning systems start to assess emerging technologies. It's therefore seldom possible to fully analyze effectiveness or cost-effectiveness[17]. According to clinical effectiveness, expert opinions or other methods from a lower level of evidence are the basis of early assessments[4].

The persons possessing the greatest knowledge are the researchers who have contributed to the development of the technologies, or medical experts in the field. However, it must be assumed that anyone who has participated in the development and early testing work is especially optimistic about the bene-fits and the further usage of the technology in question[27, 40].

As reliable data on effectiveness is normally unavailable, early assessment concentrates on the topic to aggregate the available data, which is necessary for a future complete assessment. Information that is available earlier to consider cost-effectiveness is for instance costs or alternative treatments. Efforts in preliminary economic evaluation may also help to clarify what the impact of a new technology might be, what effectiveness it must reach or where critical thresholds of efficacy in relation to extra cost lie[17, 41].

A general assessment of the impact of an emerging technology on a health care system needs more than effectiveness or cost-effectiveness. Blume[12] specifies a few quantifiable parameters capable of assessing the significance of an emerging technology for a healthcare system. These are:

- For which patients will it work?
- Will it be more cost-effective than existing procedures?
- What is the spread of costs over time likely to be?

Indeed, these parameters are potentially more difficult to estimate than it appears at first glance. A technology that promises cost saving and improves quality at an individual level may lead to an increase in total expenditures caused by growing use of the technology[37, 42]. Predictions of other outcome parameters like length of stay or work time saved are also difficult. Handling such complex estimations requires a number of theoretical steps.

One example of such steps is the framework for predicting the impact of new health technologies on average length of stay, developed by Simpson et al.[43]. The framework distinguishes three main categories of mechanisms affecting the average length of stay. According to this, a technology may influence the length of stay directly, through its influence on patient characteristics, and through the impact on organization and clinical practice (Figure 7-2). Each new technology somehow associated with inpatient stay could thereby be considered separately according to these categories by early assessors.

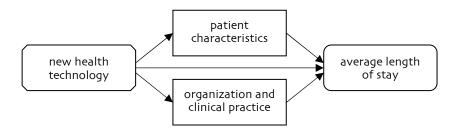


Figure 7-2: Impacts of a New Technology on average Length of Stay[43]

early assessments are seldom based on RCTs, ...

... but rather lower levels of evidence like expert opinions

it should aggregate the available data and open parameters to ease future assessments

assessment of impact of a technology contains some difficulties ...

... and require theoretical efforts The development of such prediction frameworks, by identifying key variables, ensures that various facets of a new technology are taken consistently into consideration[41, 43].

other approachesOther approaches suggested for managing the 'data gap' of early assessmentsuggested the use of<br/>estimates ...Other approaches suggested for managing the 'data gap' of early assessment<br/>are "retrospective forecasts", where the forecasts of a new technology are com-<br/>pared with actual evidence or rough preliminary estimates concerning the re-<br/>sults from major clinical trials to compare former predictions and actual re-<br/>sults[17, 41].

... or HSS own research A different approach would be to equip HSS with the mandate and funding to collect the data which is not available.

decisions on the base of<br/>early assessments imply<br/>high degree of<br/>uncertainty, ...However, no methodological approach is able to completely eliminate the un-<br/>certainty of early assessments. When decisions must be made on the basis of<br/>early assessments there is always the risk of recommending a technology that<br/>later proves to be unfavourable or of rejecting a technology that later proves<br/>to be favourable[17].

... which must be reflected and labelled Therefore the presentation of early assessments has to reflect the nature of uncertainty, labelling possible variations of key variables and the methods used[27, 41]. Basically the variety of bias requires a systematic and explicit procedure in early assessment. To manage the danger of unreliability from primary sources, the Swedish HSS SBU-Alert lays down that assessments must be made with reference to existing data, documented experience, and general considerations. The use of primary data is merely tolerated in exceptional cases[27]. Furthermore, SBU-Alert reports state the evidence level on which their statements are based to communicate the extent of uncertainty concerning their messages.

some technologies are<br/>easier to assess than<br/>othersAs always, there are various differences among health technologies according<br/>to early assessment. Some technologies are easier to assess than others. Es-<br/>pecially those technologies that present a substitute or a replacement for ex-<br/>isting technologies or that are already established but are to be developed for<br/>a new application are easier to assess[17].

The lack of evidence is an unavoidable condition of early assessment. Therefore early assessments have to be considered as an iterative process comprising assessment, dissemination, monitoring and reassessment components[17].

fications in design and use after licensing. Generally it is easier to manage the

### 7.1.2 Technology Development

technologies may As the time horizon of horizon scanning systems spans up to 5 years before introduction, early assessment has basically to deal with technological develchange through improvement and opments. Even after introduction, health technologies are by no means stable entities. Instead, introduction constitutes the beginning of a prolonged procredesign processes ess of redesigns and improvements triggered by feedback mechanisms[37]. In consequence, it has to be added that the earlier an assessment is conducted, the greater is the probability of irrelevant data (For example, through further developments of the technology or changed indications for its use)[38]. The basic challenge for assessors is the appearance of different variations of one particularly devices are subject to frequent generally innovative treatment approach, generating a form of treatment fammodifications ily[44]. This concerns particularly devices, which are subject to frequent modidevelopment issue for highly regulated health technologies like pharmaceuticals, as regulation hurdles require a more formed? kind of technology[36].

Greer[45] distinguishes dynamic technologies from formed technologies by considering their different diffusion patterns. According to her, formed technologies are more or less completed products such as CT scanners or automated blood analyzers. In contrast, dynamic technologies develop as they diffuse. Greer names coronary surgery, fiberoptic or neonatal intensive care as examples for those technologies. As formed technologies have stable characteristics, allowing concluding assessments, their diffusion happens faster and is more predictable compared to dynamic technologies.[45].

Lilford et al.[44] have proposed a modified type of trial – the 'tracker trial' – which would enable researchers to begin collecting high quality randomised trial data, although there are various examples of the new type of technology in progress. The idea of the tracker trial is to compare the standard treatment at the beginning with all available versions of the innovation in question and to modify experimental subgroups, protocols and research questions as the trial proceeds. This would comprise the inclusion of new promising applications and the exclusion of versions which show significant disadvantages. The disadvantage of the tracker approach is that it would require more complex and resource-intensive commissioning, management and analysis. Although this approach seems broadly disregarded, it is also clear that the challenge of the technological development of new health technologies requires a multifaceted approach and more complex research efforts on trial management[1].

HSS should take into account the possibility of important developments not only before introduction, but also afterwards. It would be advantageous to identify different stages of development of a health technology with respect to the possibility of significant changes. As Mowatt et al.[36] argue, such a theoretical model of a linear process towards technological stability is only appropriate for highly regulated technologies. Less regulated technologies may develop in a more complex manner during diffusion. This makes it more difficult to identify phases of technological modification.

The issue of changing developments additionally aggravates the object of monitoring and reassessment, as reassessment is not only indicated when new important data is available, but also when a technology has changed to some extent. The question is again, what are appropriate indicators for starting reassessment[36].

### 7.1.3 Socio-Political Issue

The purpose of horizon scanning systems is to provide timely information not only to medical professionals, but also to decision makers and the interested public. These aims necessitate broadening the focus for information to issues that are not directly related to health care service but rather to its societal embedding. Next to information on the possible impact of a health technology on health service in terms of costs, patient group, effectiveness or alternative treatment, HSS should also focus on social, organizational and political (comprising ethical and legal questions) issues[17, 39].

Such a claim sounds reasonable and understandable, but operationalization is difficult to deal with. A main problem is again the lack of sound data before a new technology has come into use in everyday health care. It may be complex to assess or even measure the organizational impact (i.e. concerning basically, one can distinguish dynamic technologies from formed technologies

technological developments concerns trial management as well

identification and theoretical modelling of stages of development is restricted

monitoring should be sensitive to new data as well as to technological changes

early assessment comprises organizational, social and political consequences of health technologies

the problem is to operationalize these issues ...

and to find adequate sources	staff time saved) as this depends highly on local circumstances and is hard to generalise[39]. Also ethical and social concerns may change as patient groups or applications of a health technology change during early adaptation. The specific problem of this task is that the ordinary information sources for health technology assessment might be unable to cope with this challenge. Early Assessment principally relies on scientific and clinical literature and on the views and judgements of well-informed senior professionals[12]. Carlsson et al.[27] emphasize that medical experts may be unsuitable to assess effects on health care organization or economy and researchers may not perceive the	
	ethical problems of relevant groups within society.	
other perspectives must be considered,	The task is therefore to consider, alongside scientific feasibility and clinical usefulness, desirability or potential consequences in politics and society. Such an approach requires consideration of different perspectives, especially those of users and parties possibly affected.	
which require involvement of different scientific expertise	Early assessment needs therefore the involvement of scientific expertise in the field such as political science, sociology or law. Such an approach leads to a number of consequences. The more and deeper an early assessment considers these not (directly) health related issues, the more informational benefit for the specific case but the less the transferability to different contexts (e.g. countries, patient groups) is to be expected[12].	
and methodological approaches	As Rosen and Gabby[39] indicate, this may lead to concerns among assessors about a dilution of the well-known data-orientated methodology with the more diffuse study of organisational systems or ethical doubts.	

## 7.2 Differences in Early Assessment

#### early assessments differ in terms of format, style and size

Differences in early assessments among HSS can be identified concerning the format in which information on new and emerging technologies is produced and the style of assessments. The latter appears to be essentially dependent on who is commissioned to make the assessment. According to Douw et al.[11], who compared assessments of CETAP and SBU, assessments written by clinical experts are more detailed, are clinically oriented and require some insights into medicine. If the assessments are written by HSS staff, reports might be more concise and understandable even for non medical target groups.

HSS also differ in terms of size. Some produce short reports without dedicated recommendations, like the Swedish, the Danish or the Norwegian. Others, such as the Dutch, the Israeli and the Swiss HSS, produce partly comprehensive reports to enable profound decision making. The French CEDIT again produce early assessments in the format of dedicated recommendations.

The Canadian HSS and the HSS of Australia/New Zealand state that they generate different formats of emerging technology messages. Whereas the latter published short prioritising summaries as well as more detailed horizon scanning reports, the Canadian CETAP produces a bulletin on new and emerging technologies, a newsletter and a list of emerging drugs.

# 8 Dissemination and Implementation

Having identified, prioritized and subsequently assessed new or emerging technology, the final stage is to disseminate the findings. The dissemination and implementation of reports about emerging technologies faces a special challenge in so far as the findings so early in the life-cycle of a technology most likely involve great uncertainty.

It must also be considered that early messages concerning a new technology may sometimes be commercially sensitive and require therefore restricted dissemination as in the case of the British NHSC[46].

As long as the available evidence does not allow the deduction of any recommendations on the introduction of a technology, the aim of these reports should be to enhance the awareness of the development of the technology and to influence further research efforts.

As Carlsson et al.[27] noticed, the development of internet HSS today enables their dissemination needs to be arranged according to emerging technologies with the need to update information quickly and often.

The specific dissemination strategy is essentially determined by the relevant customer or target group of an HSS[17, 21, 39, 47]. As Hailey et al.[33] note, it is also decisive for the benefit of horizon scanning systems that decision makers have appropriate machinery for using information of this sort[33]. If horizon scanning is to facilitate and rationalize the provision of healthcare it is therefore necessary to have an organization to receive and react to such information[27, 38].

Furthermore the literature highlights the characteristics of the message and the timing of dissemination as important factors for the success of dissemination and implementation[21, 47].

## 8.1 Target Group(s)

According to Carlsson and Jørgensen[17], the potential target groups of horizon scanning reports are regulatory bodies, policy makers, research funding agencies, health insurance organizations, physicians, other health professionals, hospital administrators, patients' organisations, the public and perhaps industry.

As Mowatt et al.[21] stress, it is initially important to direct horizon scanning messages at those target audiences that have been identified as powerful in influencing introduction and diffusion.

It may also be necessary to consider that the respective powerful target audience depends on the type of technology[48] and the purpose of the message[21]. It therefore makes a difference if the technology is a highly regulated new drug or a non-regulated new procedure, if it recommends the stopping of the use or the promotion of the technology. dissemination is the final stage of Horizon Scanning

commercial sensitivity may restrict dissemination

enhancement of awareness as basic aim

development of internet did facilitate work of HSS effective dissemination depends on characteristics of target groups, ...

... message characteristics and timing of dissemination

there is a wide range of potential target groups ...

... with different impact on introduction and diffusion

there is no evidence for a universal dissemination approach	Regarding the effectiveness of alternative dissemination strategies, the Eur- Assess Subgroup[47] observed that there is some evidence about effective dis- semination strategies to change the behaviour of health professionals, but only limited evidence concerning decision makers or patients. Different pat- terns of incentives as well as social or cultural factors make it impossible to recommend a universal approach.
the establishment of close links to the target groups	Nevertheless, it is regarded as worthwhile for the dissemination of horizon scanning findings to establish close links to the system for knowledge dissemination and implementation[1] as well as to the information system within the policy-making structure[33].
and consideration of their information system is worthwhile	As opinion leaders (i.e. well respected peers) might play a big role in these systems, it is important to identify and reach them[39]. Alongside the information needs of the specific target groups, other determinants of their practice and competing resources of information should be considered before dissemination[47].

### 8.2 Characteristics of the Message

credibility of the researcher, content and style of the message are important for its impact The source, content and style of emerging technology reports may also influence its impact. As Rosen and Gabby[39] emphasize, clinicians and managers rate the findings of health technology reports differently to how the HTA or HSS might do.

Whereas assessors are more focused on methodological stringency, target audiences pay more attention to the credibility of the researchers or the types of outcome associated with the technology (e.g. risk or benefit). Both, HSS and HTA agencies have to consider the complexity (i.e. the knowledge background and language they presuppose) and the quantity of information in their messages[17, 21].

Of equal relevance is the credibility and appreciation of the source among target group members for the acceptance for the message[39]. Of particular importance is therefore the plausibility of the independence of the HSS conducting early assessments[48].

## 8.3 Time of Dissemination

best Horizon Scanning Report is futile when it comes too early or too late In addition to appropriateness and selectivity of the message concerning the target group, the timing of dissemination is termed as a key factor for its impact[47]. The task in this respect is to attune the process of dissemination to the process of decision making on a new technology. Potentially influential research may be ignored if it matches the decision making process too early or too late[39, 48]. The challenge as to the timing of these messages is to connect the need for flexibility (e.g. if a policy maker urgently needs quick information) with the necessity of a sound scientific foundation for such messages[17].

## 8.4 Differences of Dissemination among HSS

As stated above, dissemination activities depend primarily on the specific target group(s) of an HSS. On the basis of the differences among HSS concerning their customers presented in Table 1, a distinction can be made between three types of target groups (Table 8-1).

HSS can be classified by types of target groups

<i>Table</i> 8-1:	Types of Target	Groups for HSS
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Department of Health (national, regional)	Health Professionals	Systems without dedicated customer
NHSC (GBR)	CEDIT (FRA)	NOKC (NOR)
SorTeK (ESP)	SINTESIS (ESP)	SBU-Alert (SWE)
DETECTA (ESP)		DACEHTA (DEN)
ANZHN (NZL/AUS)		CETAP (CAN)
Health Council (NED)		
DMTP (ISR)		
SFOPH (CH)		

In the first group, national or regional departments of health are the customers of horizon scanning messages. The second group comprises those HSS which primarily inform health professionals about new and emerging technologies. HSS which have not got a dedicated customer for their early assessments form the third group.

Although the first two groups might have a specific target groups, the products might also be available to a wider audience, as a number of the

HSSs publish their assessments on the web (e.g. CEDIT, NHSC). Some of the assessments are also made publicly available through the EuroScan web site[49].

On the one hand systems without a dedicated customer might have the greatest need for developing a specific dissemination strategy as there is no direct link to the target groups. On the other hand Douw and Vondeling[3] examined different 'risk groups' in terms of priority setting among HSS in Euro-Scan and found that those systems which do not have a customer but inform a wide variety of decision makers, experience only a moderate need for priority setting. This was explained by the fact that there is not a lot of pressure/demand from the outside[3].

However, the missing direct link to the customers in such systems demands the establishment of certain communication channels. One example documenting such efforts is the Canadian newsletter 'Technology Update'[50]

Studies examining the impact of HTA messages emphasize that simply publishing is often not enough[48, 51]. Therefore, some HSS undertake efforts to communicate their messages more directly to people viewed as important. The Swedish SBU Alert, for example, established a network of nearly 4,000 people working in the healthcare sector, who receive new assessments or revisions by e-mail[52]. Likewise, SorTek at OSTEBA is working on establishing a Spanish network to provide information to the Spanish Health Service and the Ministry of Health [29]. systems without dedicated target group should have the highest need to think about dissemination strategies

simply publishing is often not enough

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# Appendix

Regulation Units	European Medicines Agency (EMEA)	http://www.emea.eu.int/
	Food and Drug Administration (FDA)	http://www.fda.gov
	Medicines and Healthcare products Regulatory Agency	http://www.mhra.gov.uk/
Information on new drugs	PharmaLive	http://www.pharmabusiness.com
	Pharmaceutical Research and Manufacturers of America	http://www.phrma.org
	PJB Pharmaprojects Online	http://www.pjbpubs.com/pharmaprojects/web.htm
	Pharma Times	http://www.pharmatimes.com
Information on new medical devices	Medical Device Daily	http://www.medicaldevicedaily.com
	Association of European Medical Technology Industry	http://www.eucomed.be
	Association of American Medical Technology Industry	http://www.advamed.com
Information on new digital health technologies	Future Health Bulletin	http://www.headstar.com/futurehealth/
Information on	Science Daily Magazine	http://www.sciencedaily.com
Developments in Science	British Medical Journal	http://www.bmj.com
Science	Journal of American Medical Association	http://www.jama.ama-assn.org
	The Lancet	http://www.thelancet.com/journals
	Nature Medicine	http://www.nature.com/nm/
	Science Magazine	http://www.sciencemag.org/
Newswires related to Healthcare	Reuters Health	http://www.reutershealth.com
	Ivanhoe Medical Breakthrough	http://www.ivanhoe.com/
	CNN.com Health	http://www.cnn.com/health
	New York Times online, health section	http://www.nytimes.com/pages/health/index.htm
Health portals	Doctor's Guide	http://www.docguide.com
	Medscape	http://www.Medscape.com
	EurekAlert	http://www.eurekalert.org
	National Electronic Library for Health	http://www.nelh.nhs.uk
	Informa Healthcare	http://www.pjbpubs.com/
	NetDoktor	http://www.netdoktor.com

List of several important web sites to identify new and emerging health technologies (accessible: 28.08.06)