Horizon Scanning in Oncology

Impact evaluation and environmental analysis

Ludwig Boltzmann Institut
Health Technology Assessment

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List of Abbreviations

AHTAPol	Agency for Health Technology Assessment in Poland
AKDAE	Drug Commission of the German Medical Association
ASCO	American Society of Clinical Oncology
ASH	American Society of Hematology
CADTH	Canadian Agency for Drugs and Technologies in Health
CRD	Centre for Reviews and Dissemination
CVZ	Health Care Insurance Board in the Netherlands
DCGMA	Drug Commission of the German Medical Association
DIMDI	German Institute of Medical Documentation and Information
DMTP	Division of Medical Technology Policy
DSD	Decision Support Document
EHA	European Hematology Association
EMA	European Medicines Agency
EPAR	European Public Assessment Report
ESMO	European Society for Medical Oncology
EUnetHTA	European network for Health Technology Assessment
EuroScan	International Information Network on New and Emerging Health Technologies
FDA	U.S. Food and Drug
G-BA	Federal Joint Committee
HAS	French National Authority for Health
HSO	Horizon Scanning in Oncology
HSS	Horizon Scanning System
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
INAHTA	International Network of Agencies for Health Technology Assessment
IQWiG	Institute for Quality and Efficiency in Health Care
KBV	National Association of Statutory Health Insurance Physicians
LBI-HTA	Ludwig Boltzmann Institute for Health Technology Assessment
MeSH	Medical Subject Headings
MoHCZ	Ministry of Health of the Czech Republic
MRC	Medical Research Council
NCCN	National Comprehensive Cancer Network
NCPE	The National Centre for Pharmacoeconomics in Ireland
NETSCC	Coordinating Centre for Health Technology Assessment

NHS	National Health Service
NHSC	National Horizon Scanning Centre
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
SMC	Scottish Medicines Consortium
TGA	Therapeutic Goods Administration

Summary

Background: Horizon Scanning in Oncology (HSO) was implemented by the Austrian Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA) in 2009 due to increasing expenditures for anti-cancer therapies. Aim of HSO is to facilitate the evidence-based use of new anti-cancer drugs and to pre-estimate their financial implications. Thus, new anti-cancer drugs are evaluated before their routine introduction into clinical practice in order to inform decision-makers.

HSO for early identification and assessment of new anti-cancer drugs

Objective: The aim of this paper is to evaluate the impact of the program HSO.

objective: to evaluate the impact of HSO

Methods: 3 methods were used to evaluate the impact of HSO.

3 methods: download analysis, online survey and environmental analysis

1. A download analysis of all HSO reports published on the website of the LBI-HTA.
2. An online survey amongst recipients of email-alerts on the availability of new HSO reports.
3. An environmental analysis to identify HTA institutes also performing (early) assessments of anti-cancer drugs.

Results:

Download analysis: The websites of LBI-HTA's HSO reports were viewed 13,737 times and reports were downloaded in total 6,671 times between October 2009 and February 2012. On average, reports were downloaded 25 times per month.

HSO reports have been downloaded 6,671 times

Online survey: Out of 126 valid invitations sent to HSO email-alert recipients 36 participated in the survey (response rate: 29%). Most of the survey participants were pharmacists. 72% of the responders were involved in decision-making processes; 94% were satisfied with the structure and content of the report; 89% rated the total quality of the reports to be "very good" or "good". 71% of the responders were using HSO reports, but mainly as an information source (rather than as decision support).

71% of the survey participants used HSO reports

Environmental analysis: A databases search (CRD HTA database, EUnetHTA, EuroScan and INAHTA) for the 24 drugs assessed by the LBI-HTA within its program HSO identified the following organisations as also being involved in (early) assessment of anti-cancer drugs: IQWiG, NETSCC, NICE, NHSC and SMC. The screening of the websites of HTA institutes identified further 5 agencies having published (early) assessment reports: AKDAE, CADTH, CVZ, HAS and NCPE. 2 times the LBI-HTA was the only institute having published an early assessment report And besides the NHSC, the LBI-HTA was amongst the first HTA institutes publishing reports on anti-cancer drugs - on average within 4 months after approval by the European Medicines Agency.

LBI-HTA publishes its reports early – on average 4 months after EMA approval

Conclusion: In general there are indications for an impact of HSO: the reports are increasingly downloaded and are considered (by those who responded to the survey) as a relevant, timely and high-quality information source. The environmental analysis showed that the LBI-HTA is with its early assessments of anti-cancer drugs amongst the earliest institutes publishing reports, on average, within 4 months after the European Medicines

Agency approval. Nevertheless several questions remain unanswered, as, for example, do the HSO documents actually have an influence on decisions or why do clinicians use this source less often?

Zusammenfassung

Einleitung: Aufgrund steigender Ausgaben für Krebstherapien implementierte das österreichische Ludwig Boltzmann Institut für Health Technology Assessment (LBI-HTA) 2009 das Programm „Horizon Scanning in Oncology“ (HSO). Ziel dieses Projekts ist, den evidenz-basierten Einsatz von neuen onkologischen Medikamenten zu ermöglichen und die finanziellen Auswirkungen abzuschätzen. Um EntscheidungsträgerInnen zu informieren, werden deshalb neue onkologische Medikamente vor ihrer routinemäßigen Einführung in den klinischen Alltag im Rahmen dieses Programms evaluiert.

HSO zur Früherkennung und -evaluierung von Onkologika

Zielsetzung: Das Ziel dieser wissenschaftlichen Arbeit ist, die Auswirkungen (= Impact) des Programms HSO zu erheben.

Zielsetzung: Auswirkungen von HSO zu erheben

Methoden: 3 Methoden wurden angewandt, um die Auswirkungen von HSO zu erheben:

1. Eine Download-Analyse der HSO Berichte, die auf der Webseite des LBI-HTA publiziert wurden.
2. Eine Online-Umfrage unter EmpfängerInnen von E-Mail Benachrichtigungen über die Verfügbarkeit neuer HSO Berichte.
3. Eine Umfeldanalyse, um andere HTA Institute, die (Früh-) Bewertungen von onkologischen Medikamenten durchführen, zu ermitteln.

3 Methoden: Download-Analyse, Online-Umfrage und Umfeldanalyse

Ergebnisse:

Download-Analyse: Die Webseite HSO wurde zwischen Oktober 2009 und Februar 2012 insgesamt 13.737 Mal betrachtet und die Berichte wurden insgesamt 6.671 Mal - im Durchschnitt 25 Mal pro Monat heruntergeladen.

HSO Berichte wurden 6,671 Mal heruntergeladen

Online-Umfrage: Von 126 Einladungen, die an EmpfängerInnen der E-Mail Benachrichtigungen über neue HSO Berichte versandt wurden, nahmen 36 an der Umfrage teil (Rücklaufquote: 29%). Die meisten Umfrage-TeilnehmerInnen waren PharmazeutInnen. 72% der TeilnehmerInnen waren in Entscheidungsprozessen involviert; 94% waren zufrieden mit der Struktur und dem Inhalt der Berichte; 89% stuften die Gesamtqualität der Berichte als „sehr gut“ bis „gut“ ein. 71% der Befragten, also die Mehrzahl, verwendeten HSO Berichte als Informationsquelle (statt als Entscheidungshilfe).

71% der Befragten verwenden HSO Berichte

Umfeldanalyse: Eine Datenbanksuche (CRD HTA Datenbank, EUnetHTA, EuroScan und INAHTA) nach den 24 Medikamenten, die vom LBI-HTA innerhalb des HSO Programms bewertet wurden, ermittelte folgende Organisationen, die auch Bewertungen von onkologischen Medikamenten durchführen: IQWiG, NETSCC, NICE, NHSC und SMC. Das Screening der Webseiten von HTA Instituten ergab weitere 5 Institute, die Bewertungen veröffentlichen: AKDAE, CADTH, CVZ, HAS und NCPE. Zwei Mal war das LBI-HTA das einzige Institut, welches Frühbewertungen publiziert hatte und, außer dem NHSC, sind die Berichte unter den am frühesten verfügbaren einzureihen - im Durchschnitt innerhalb von 4 Monaten nach der Zulassung durch die European Medicines Agency.

LBI-HTA LBI-HTA publiziert HSO Berichte früh – im Schnitt 4 Monate nach EMA Zulassung

Schlussfolgerung: Generell gibt es Hinweise für einen Impact des HSO Programms: die Berichte werden zunehmend heruntergeladen und werden als relevante, zeitgemäße und qualitative Informationsquelle betrachtet. Die

Umfeldanalyse zeigte auch, dass das LBI-HTA mit seinen Bewertungen von onkologischen Medikamenten eines der ersten Institute ist - im Durchschnitt innerhalb von 4 Monaten nach der Zulassung durch die European Medicines Agency. Dennoch bleiben einige Fragen unbeantwortet: beeinflussen HSO Berichte Entscheidungen; warum verwenden nur wenige KlinikerInnen diese Berichte?

1 Introduction

1.1 Background Horizon Scanning Systems

HSS to support decision-making processes about new and emerging technologies

Several countries (e.g. UK, Norway, Sweden, Belgium, Canada and Australia) have established so called 'Horizon Scanning Systems' (HSS), 'Early Warning Systems' or 'Early Awareness and Alert Systems' (EAAS) to support decision-makers with information about new or emerging health technologies which might have an important impact (i.e. financial or clinical) for the health care system prior to their wide-spread adoption and introduction into national health care systems [1].

most HSS units are part of an HTA agency

New health technologies raise a lot of questions concerning managed introduction, financial burdens, organisational requirements and clinical practice changes. Consequently, HSS units are often part of an HTA agency since HSS can be seen as the first stage of a comprehensive HTA process [2]. The main difference to regular HTA reports is that HSSs focus on technologies early in their life-cycle, whereas HTA concentrates on the assessment of already established health technologies.

The difference between *new* technologies and *emerging* technologies is that the former ones are in the phase of adoption, they have been available for clinical use only for a short time and are at launch or at early post marketing stages. In contrast, an emerging technology is defined as not yet adopted. In the case of pharmaceuticals, this would correspond to phase II or phase III of clinical development or to pre-launch.

EAASs aim to identify, filter and prioritise new and emerging health technologies, to assess or predict their impact on health, costs, society and the health care system and to inform decision makers [3].

Six main stages are involved in early awareness and alert systems [3]:

6 steps of EAAS:

scanning/ identification,

filtration,

prioritisation,

assessment,

dissemination and updating the information

1. Horizon Scanning/Identification
2. Filtration (identifying new and emerging technologies that are relevant for the individual EAAS)
3. Prioritisation (deciding on technologies in which further resources for investigation are to be invested)
4. Assessment (presenting information on anticipated impact on health care and health services)
5. Dissemination (ensure that the information produced is reaching the correct audience in a timely fashion)
6. Updating information.

1.2 Background Horizon Scanning in Oncology

38,000 are diagnosed with cancer in Austria each year

Around 38,000 people are diagnosed with cancer in Austria each year, with men being affected slightly more frequently than women [4]. After cardiovascular diseases, cancer is the second most common cause of death in both sexes. In view of the fact that these diseases occur primarily in older people, the importance of cancer incidences will continue to grow due to the increasing age of the population [4].

HSO was implemented as standard practice in October 2009

Due to rising expenditures for cancer therapies, an instrument was needed in Austria to facilitate the evidence-based use of new anticancer drugs and to pre-estimate their financial implications [5]. Especially the so-called 'targeted therapies' such as monoclonal antibodies or tyrosine kinase-inhibitors ('small molecules') have stressed hospital budgets. Therefore, the LBI-HTA implemented 'Horizon Scanning in Oncology' (HSO), a HSS specifically targeted on oncology drugs. After a first concept was developed and piloted from July 2007 until May 2008, the HSO program was implemented as standard practice at the LBI-HTA in October 2009.

LBI-HTA published 27 reports on new anticancer drugs since late 2009

The objective of HSO is to provide information about new and emerging anti-cancer drugs with a likely therapeutic and/or financial impact on Austrian hospitals (i.e.hospital management, drug commissions, pharmacists) and funding agencies in order to support budget planning and rational decision making. By scanning information sources on a regular basis, by identifying new and emerging drugs and by prioritising these new drugs through an expert panel, relevant drugs are selected for assessments. Since late 2009 (until 1st March 2012; cut-off date for this analysis), the LBI-HTA has published 24 reports and 3 updates. Besides entries to LBI-HTA's homepage, these reports are disseminated by three different means:

- email-alerts on newly published reports which are sent to relevant decision-makers in Austrian hospitals,
- notifications in the LBI-HTA's monthly newsletter,
- entries to the EuroScan database, the database of a collaborative network of HSS agencies.

2 Objectives and research question

Since considerable resources are dedicated to the HSO project and since anti-cancer drugs are on the agenda of many scientific institutes worldwide, two main questions arose:

impact in Austria?

overlap and room for collaboration?

1. What is the impact of the HSO in Austria?
2. Is there overlap/room for international collaboration with other institutes involved in assessing anti-cancer drugs?

These research questions were operationalized by further breaking them down as follows:

Ad 1.)

usage of the reports?

who are the readers?

applicability of reports?

- What is the usage of the HSO reports (download and access rates)?
- Which HSO reports have been downloaded frequently and which ones rarely?
- Who are the readers of HSO decision support documents?
- Which professional groups use HSO reports?
- Are HSO reports used for decision-making?
- What types of decisions are based on HSO reports?
- Are there any improvements to be made with the reports itself, dissemination and/or marketing strategies?

Ad 2.)

who else assesses anti-cancer drugs?

- Which and how many other institutes assess anti-cancer therapies?
- At what point in time are these assessments published in comparison to the publication date of the HSO?
- What is the scope of these reports?
- Is there any need to adjust ways of identification/prioritization or the compilation of assessment reports in order to reduce redundancies with other HTA institutes?

3 Methods

3.1 Impact evaluation

no generally accepted model of impact evaluation

Although the importance of HTA research has increased over the last few years and its scientific methods are implemented in many countries, there is hardly any evaluation of HTA-based results. Despite existing impact evaluation research, no model has been generally accepted. Furthermore, it is still unclear how to define impact. For example, do people have to be aware of the content of an HTA report only or need recommendations resting on HTA reports be actually implemented [6]?

a framework was developed by LBI-HTA to evaluate impact of HTA reports

This impact evaluation of the HSO program is based on a framework suggested by *Schumacher and Zechmeister* [7]. This framework contains instruments and potential evaluation designs for measuring the impact of HTA products in Austria. According to this report and based on *Gerhardus et al.* [8] seven hierarchically structured dimensions of impact can be differentiated:

7 levels of impact

1. **Awareness:** Affected people know that HTA is available as support for decision-making.
2. **Acceptance:** HTA recommendation is considered as a valid and acceptable decision-support.
3. **Policy process:** HTA is explicitly used within decision-making/development processes.
4. **Policy decision:** A decision is clearly influenced by an HTA result or recommendation.
5. **Practice:** The decision has been put into practice.
6. **Final outcomes:** Changes in practice become visible through benefits in health or budget cutbacks (real objective of HTA).
7. **Enlightenment:** HTA results are not put into clinical practice directly, but decision-making processes as well as communication between researchers and the public are facilitated with available HTA reports.

impact of HTA is multidimensional

impact evaluation gives orientation

The report by *Schumacher and Zechmeister* [7] also highlights that impact of HTA is multidimensional, and can also be direct (i.e. HTA reports are considered and/or recommendations are accepted) or indirect (=unintended effects, i.e. opinion can induce opposing views). Furthermore, several levels where impact can arise can be distinguished: the macro-, meso- or micro-level. The micro-level includes individuals, such as scientists, patients, doctors or citizens. The meso-level comprises institutions and other groups of people such as hospitals, insurance companies, expert panels or professional organizations. The macro-level, on the other hand, consists of players such as political institutions (federations and states), the therein located governing bodies (i.e. federal commission of health, federal health care funds, and committees) and other players (media and industry) [7]. However, even though impact is not a measure for the success of a work program of an HTA-institute *per-se*, evaluation of impact is an important aspect for the future orientation of HTA research [7].

The applications of at least two evaluation methods – a combination of qualitative and quantitative methods – are recommended to validate the results [7]. For the evaluation of the HSO program, the following methods were chosen:

1. a download analysis
2. an online survey.

Table 3.1-1 shows the 7 levels according to which impact can be measured as well as corresponding methods for evaluation. Also, the levels used for measuring the impact of HSO and the methods chosen for this evaluation are displayed.

Table 3.1-1: Adapted framework for measuring impact of HSO in Austria

Impact/ objectives	Indicators	Pool of methods for measuring impact	Methods used for HSO evaluation
awareness	downloads of project reports	data analysis, document analysis, questionnaire, interviews, focus group interviews, cost analysis, discourse analysis	Download analysis Online survey
acceptance	consulted as decision support		Online survey
policy process	HTA research is considered		Online survey
policy decision	HTA is cited as reason for decisions		Online survey
practice	amount (newer/other) devices/technologies		-
final outcomes	health benefits, budget cutbacks		-
enlightenment	transportation of topics in media, changes in journalism, establishment of new research activities, participation of HTA researchers in governing bodies		-

3.1.1 Download analysis

HSO reports are available online

Like most other HTA-institutes the LBI-HTA provides free long-term access to all its publications (all documents are accessible via the website: http://eprints.hta.lbg.ac.at). In total, 27 HSO-reports were published between August 2009 and March 2012: 24 decision support documents and 3 updates. In the first year (2009), 7 HSO reports were published and uploaded to the website. In 2010, further 7 decision support documents were added to the website, another 7 reports and 3 Updates in 2011. In the first 3 months of 2012, 3 further reports were uploaded to the website.

24 decision support documents and 3 updated reports

Access to the HSO reports

general access of scientific reports

The homepage of the LBI-HTA offers a search function in its repository allowing to search by type of publication, subject, author/editor, institution and/or year. By clicking on a publication title a publication window displaying abstract, key words and subject pops up. A PDF file of the publication can be downloaded by following the provided link.

comparison of site-views rate and download rate

The site-views (i.e. how often the websites were viewed) and the download rates (i.e. how often the PDF files were downloaded from the website) were generated for all decision support documents published since the implementation of HSO in late 2009 until 1st of March 2012. To check the plausibility of the download rates, the amount of total downloads were compared with the number of the site-views which is expected to be higher or equivalent because, usually, the websites have to be accessed before the reports can be downloaded.

accessing HSO reports by email-alerts and notices in the HTA-newsletter

However, reports can also be accessed directly, if, for example, the PDF link is sent by email, as is the case with e-mail notifications. These email-alerts on newly available HSO documents are sent to decision-makers in Austrian hospitals and include a direct link to the publication. Another possibility to access reports is via the monthly HTA-newsletter of the LBI-HTA which is sent to approx. 900 subscribers, mostly from Austria and Germany. LBI-HTA's newsletters were downloaded 13,907 times in 2009, increasing to 13,937 downloads in 2010 and to 14,110 in 2011. This newsletter briefly reports on several health technologies assessed either by LBI-HTA or by other HTA-institutes. Newly published decision support documents about anticancer drugs are also reported in these HTA-newsletters but irregularly.

active search on LBI-HTAs website, in Google, other databases or printed/online publications

HSO reports can also be found by searching in the repository of the institute's website, or by a free hand search on the internet or other HTA or public health-related databases. There are several link exchangers or listings within HTA networks (i.e. EuroScan [9], EUnetHTA [10], INAHTA [11]). Additionally, there are hyperlinks to the reports on the Austrian Ministry of Health website. Finally, the HSO program is referenced in various printed and online publications. For example, AKDAE [12] cited LBI-HTA's HSO reports in its advisory opinion on Cabazitaxel and Eribulin.

Therefore, site-views/download rates of the reports are not only the result of email-alerts or the distribution of LBI-HTA's newsletters but are also linked to various other websites and external databases (i.e. CRD database [13], EUnetHTA database [10], EuroScan database [9]).

Aim of the download analysis

how often are decision support documents downloaded?

The aim of the download analysis is to evaluate the impact of the LBI-HTA HSO reports with regards to the amount of website views and publication download rates. The site-views and download rate which are extracted from the institutes website show how often these reports have been viewed and downloaded by the general public.

Questions

questions addressed within the download analysis

The download analysis should answer the following questions:

- How often are decision support documents viewed and downloaded from the website in total and on average?
- Did the amount/rate of downloads change over time?
- Which documents have been downloaded frequently and which ones rarely?
- Are there any links between active notifications (HTA-newsletters, e-mails to HSO mailing list) and download rates?
- Are there any explanations for the frequently/rarely demanded downloads of certain reports?

Methods

statistical evaluation of website-views and download rate

By using AWStats (Advanced Web Statistics 6.9), the amount of site-views (how often the websites were viewed) and the amount of downloads (how often the PDF files were downloaded) were generated. Only the site-views/downloads performed by the public are counted, whereas the clicks performed by staff members are excluded. However, it was not possible to eliminate external multiple downloads (i.e. one person downloading an HSO report more than once) and therefore all external clicks were counted. The total number of downloads, PDF average monthly download rate and the total monthly average were calculated.

total number of downloads and monthly average downloads

The total number of downloads is the number of all downloads from the first month of the publications' upload to the website. However, a proper comparison between reports might be confounded, since some documents have been online longer than others.

calculation of the average monthly download

To ensure comparability between the documents the variable 'PDF average monthly download rate' of all publications was calculated. This variable is calculated by the total number of downloads within a year divided by the months the publications were effectively online.

For example, the report 'Bendamustin' (DSD HSO Nr 10) which was published online in July 2010 was downloaded 261 times in 2010. The monthly average was calculated as follows:

7/2010 until 12/2010 = 6 months online in total in 2010

261/6 = 43.5

calculation of the total average monthly download

The average monthly download rate of 'Bendamustin' was therefore 43.5.

In addition to this average monthly download rate, the total monthly average was calculated. This was performed by calculating of all downloads divided by the total number of months being published online. For example the

same report 'Bendamustin' (DSD HSO Nr 10) with total downloads of 914 the calculation is performed by:

07/2010 until 02/2012 = 20 months online in total

914/20 = 45.7.

The document was downloaded 45.7 times in total in a month.

additional influences: closeness to reimbursement decisions

Download rates of individual HSO-reports might have been influenced by an increasing publicity of the HSO program over the years, by the time/month of publication (e.g. closeness to the annual prospective drug-budgeting in hospitals or reimbursement decisions) etc. However, one can only speculate upon those potential influences, since a more thorough analysis seems to be impossible.

3.1.2 Online survey

about attitude and knowledge

A questionnaire is the most commonly used tool to evaluate the impact of HTA results [7]. Information about attitude and knowledge about HTA reports are assessed. As an indicator for knowledge the item 'Knowing, that HSO reports exist' were used (see Appendix for the questionnaire). In an open section, respondents had the possibility to express their personal opinion and to make suggestions for improvements [7].

Aim of the online survey

aim of the online survey was to question target audience

By asking recipients of the HSO email-alerts, this survey is conducted to assess awareness about the reports, overall satisfaction with the quality and content. Applicability and usefulness of the reports were of particular interest.

Questions

…the underlying questions of the survey

The online survey should answer the following questions:

- How many email-alert recipients are aware of the HSO reports?
- Which professional groups are reading the HSO decision support documents?
- For which type of decisions are the reports used?
- Are the reports used to support decisions about implementing new drugs/reimbursing medical expenses for new drugs?
- What other information on new anti-cancer drugs are read to support in decision making?
- How are readers of HSO reports informed about newly published reports?
- How well are HSO reports perceived in performing in terms of quality (relevance, balanced information etc.)?
- How satisfied are HSO report readers with the content of the DSD documents?
- What are the suggestions for changes and improvements?

Methods

an online survey was created to question the target audience

When new HSO reports are published on the LBI-HTA's website, email-alerts are sent to relevant Austrian decision makers. The recipients of these alerts were invited to participate in the survey. The online survey was created and implemented with the software provided by Enuvo on www.umfrageonline.com. Due to the fact that all survey recipients were either from Austria or from Germany, the survey was in German. Participation in the survey was anonymous and voluntary.

Structure of the online survey

questions about

overall satisfaction with the quality and content of the reports,

applicability and usability of the reports

In general, the survey consisted of questions about overall satisfaction with the quality and content of the reports, applicability and usability of the reports. The first part of the survey asked the participants about their profession and job location. In the second part questions posed intended to assess if participants were involved in decision-making processes (applying new anti-cancer drugs and/or refunding expenses for new anti-cancer drugs). The participants were asked to rate the quality and their satisfaction with the content of the reports. Further, it was of interest to assess which sources were used for decisions on administering/refunding new oncology drugs and if the drugs assessed by LBI-HTA were relevant for the readers. The participants were also asked about the way they received information about new HSO reports. Finally, the participants were invited to give feedback and to make suggestions for improvements on future reports. The questions of the online survey can be found in Table 8.1-1 (see Appendix).

3.2 Environmental analysis

point in the life-cycle

Since anti-cancer drugs are subject of evaluations in many institutes, there might be a considerable overlap in topics assessed. The point of time in the life-cycle when these anti-cancer drugs are assessed (i.e. in relation to the licensing decisions of the European Medicines Agency) as well as the content of the reports are therefore of interest to identify redundancies as well as potential ways for collaboration.

Aim of the environmental analysis

scanning the environment for future collaborations

positioning own assessments

The aim of the environmental analysis is to identify other HTA agencies performing (early) assessments of anti-cancer drugs. An analysis of the immediate environment helps to identify relevant HTA institutions or any other relevant organization for possible future collaborations. In addition to that, the environmental analysis might help to sharpen the specific profile of the HSO program.

Questions

The environment analysis should answer the following questions:

- Who else/ which other HTA-agencies conduct (early) assessments on anti-cancer drugs?
- At what point in time of a life-cycle do other HTA-agencies conduct their assessments?

- Which type of content is provided within other drug assessment reports?
- What is the timing of publication of the LBI-HTA in comparison to other HTA organisations?
- In comparison to licensing decisions by the European Medicines Agency, when are HSO reports published?
- Do LBI-HTA HSO reports have a unique standing concerning closeness to time of approval?

Methods

To identify and thus to get a comprehensive overview about other HTA institutions performing (early) assessments of new and emerging anti-cancer drugs, two research methods were used.

method 1: search in databases

1. The first strategy was to search in scientific databases for the 24 anti-cancer drugs which had been assessed by LBI-HTA since late 2009. In March 2012, the following databases were searched for these anti-cancer drugs: CRD HTA database, INAHTA database, EuroScan database and EUnetHTA POP database (only accessible for members). This strategy identifies other HTA institutes having published assessments on the specified drugs and gives an overview on their products. A brief description of the databases used is provided in the Appendix.

method 2: screening websites of HTA institutes for early assessment reports

2. To identify other HTA institutions possibly performing assessments of anti-cancer drugs, which might not be listed in one of the databases, the second method was to screen the websites from overarching HTA network organizations (INAHTA; EuroScan, EUnetHTA and HTAi). The member lists of these organizsations were pulled together and each institute's website was screened for publications about anti-cancer drugs. The method consisted of searching (1) for relevant material in the publications section of websites if applicable, (2) for the term 'cancer' and (3) for drugs (e.g. Everolimus, Bendamustin, Nilotinib) already assessed by the LBI-HTA.

general inclusion criteria

Inclusion criteria were reports published in English and/or German and publicly available documents.

Method 1: Search in databases

EUnetHTA POP database

in total there were 11 reports relating to anti-cancer drugs

The search in the EUnetHTA POP database was performed by typing in the 24 anti-cancer drugs of LBI-HTA in addition to the MeSH-Term 'neoplasms'. The results showed that there were 214 projects in the database: 3 of them were abandoned, 133 projects were ongoing, 58 were planned and 20 project reports were finalised and published. After reviewing the finished projects 11 reports were related to anti-cancer drugs. The reports were published by IQWiG (Cabazitaxel, Eribulin), NICE (Imatinib, Nilotinib, Cetuximab, Rituximab, Panitumumab) and AHTAPol (Gefinitib).

INAHTA database

The search for publications in the INAHTA publication section was performed by searching for the disease category 'neoplasms'. There were 208 publications listed but no assessment reports about new anti-cancer drugs were detected, because INAHTA is linked to the CRD database.

EuroScan

123 reports which were anti-cancer drugs related

The EuroScan database was searched for the 24 anti-cancer drugs assessed by the LBI-HTA in addition to the MeSH term 'Technology-type: drugs' and 'Specialty: Oncology & radiotherapy'.

Searching for the MeSH terms 'drugs', 'hematology & blood products' and 'oncology & radiotherapy' showed that there were 123 anti-cancer drugs related entries (the 24 LBI-HTA reports excluded). The NHSC had the most entries with 121 reports, IHSP had 20 and DMTP one. Searching for the 24 drugs showed that there were entries by NHSC about nearly all 24 drugs assessed by LBI-HTA except for Bendamustin, S-1 and Vemurafenib. CADTH had a report published on Gefitinib. Entries from DMTP were found for Azacitidine, Gefitinib, Lapatinib, Ipilimumab and Erlotinib but no reports were available online or were found after further search on the agencies' website respectively.

CRD HTA database

…major database with HTA research

Again, this database was searched for the 24 drugs assessed by LBI-HTA. Most of the HSO assessment reports about anti-cancer drugs were found in the CRD database.

Method 2: Screening of HTA institutes websites

106 organizations were screened for listings of reports about anti-cancer drugs

The members list extracted from the overarching HTA networking organisations (INAHTA; EuroScan, EUnetHTA and HTAi) consisted of 106 organisations in total. The screening of these HTA institutes' websites showed that there were in total only 10 institutes/websites with publications about anti-cancer drugs. Out of 10 institutes 8 publish their reports in English and 2 institutes published the reports in German. There were several organisations listed which were not an HTA institute. Also governmental organisations, drug commissions, health services, medicines agencies, ministry of health departments and universities are listed members of these overarching HTA networks. Nevertheless, all websites were screened for available assessment reports on anti-cancer drugs. The inclusion criteria were: assessments of anti-cancer drugs, publicly available and publications written in English and/or German.

4 Results

4.1 Impact evaluation

4.1.1 Download analysis

Overview on downloads

13,737 website-views and 6,671 downloads since October 2009

In general, HSO decision support documents of new or emerging anti-cancer drugs have been viewed in total 13,737 times and downloaded 6,671 times between October 2009 and February 2012. The reports were downloaded between 7 and 51 times on average per month. An overview about the download and site-views rate of all reports is provided in Table 4.1-1.

total downloads on average per month is 25

This table also shows the monthly average download rate of all reports per year. In the first year of publication, reports were downloaded on average 11 times per month. After an increase to 23 downloads on average per month in 2010, downloads remained constant in 2011. In the first 2 months of 2012, the rate increased to 42 downloads on average per month. The total downloads on average per month is 25. As Table 4.1-1 shows there is a trend towards increased downloads of newly published reports over time.

Table 4.1-1: Downloads of all reports on average per month

Year	Number of reports online	Average of monthly downloads of all reports
2009	7	11.1
2010	14	22.5
2011	21	22.8
2012	24	42.3

reports are downloaded at minimum 7 and at maximum 51 times on average in a month

Bendamustin: 914 times
Plerixafor: 419 times

Reports were downloaded at minimum 7 times on average in a month (Ibritumomab: 12/2009) at the beginning of the HSO-program and at maximum 51 times on average in a month (Everolimus – pancreatic cancer: 12/2011, but it had been available only for 2 months) (see Table 4.1-2). The report most often downloaded was Bendamustin (7/2010), which had been published 4 months after the refusal of the EMA (average per month 46, absolute downloads: 914). Plerixafor (3/2010) was downloaded 2nd most often in absolute numbers (419 times), but on average only 18 times per month.

more than 20 times average p.m. and at least 200 times:
4 reports

Other reports which had been downloaded more than 20 times on average per month and at least 200 times (absolute) were: Ipilimumab (12/2010) – 25/ 349 (per month/ absolute), Cabazitaxel (2/2011) – 24/ 516, Dasatinib (2/2011) – 22/241 and Eribulin (6/2011) 31/ 252.

at least 200 times downloads:

11 reports

Other reports which had been downloaded quite often (more than 200 times) in absolute terms, but more rarely on average were: Azacitidine (8/2009) – on average 12/ absolute 342, Cetuximab (9/2009) – 11/ 320, Everolimus (9/2009) – 13/381, Rituximab (10/2009) – 10/ 258, Gefitinib (12/2009) – 12/ 305, Trabectedin (11/2009) 13/334, Lapatinib (5/2010) – 14/272, Panitu-

mumab (6/2010) – 18/353, Trastuzumab (5/2010) – 18/ 357, Pazopanib (10/2010) – 17/272 and Nilotinib (1/2011) – 19/286.

Table 4.1-2: Download analysis of HSO reports

Report No./ Generic name of the drug/ indication	Date of publication	Link	Total web-site views	PDF total downloads	PDF average downloads per month	Download in 2009	Download in 2010	Download in 2011	Download in 2012
1/ Azacitidine/ Myelodys-plastic syndrome	08/2009	http://eprints.hta.lbg.ac.at/852/	744	342	11.79	116	77	129	20
2/ Cetuximab/ EGFR-expressing NSCLC	09/2009	http://eprints.hta.lbg.ac.at/856/	915	320	11.03	108	48	141	23
3/ Everolimus/ 2nd –line therapy for ad-vanced/metastatic kidney cancer	09/2009	http://eprints.hta.lbg.ac.at/857/	1752	381	13.14	114	89	146	32
4/ Rituximab/ 1st- and 2nd-line chronic lymphocytic leukemia	10/2009	http://eprints.hta.lbg.ac.at/860	1016	258	9.56	64	50	120	24
5/ Ibritumomab tiuxetan/ Consolidation therapy for follicular lymphoma	12/2009	http://eprints.hta.lbg.ac.at/861	345	185	6.85	45	33	90	17
6/ Gefitinib/ 1st-line NSCLC	12/2009	http://eprints.hta.lbg.ac.at/868	852	305	12.2	-	99	175	31
7/ Trabectedin/ 2nd-line re-current platinum-sensitive ovarian cancer	11/2009	http://eprints.hta.lbg.ac.at/869	1226	334	13.36	-	135	175	24
8/ Plerixafor/ Autologous stem cell transplantation in patients with lymphoma and multiple myeloma	03/2010	http://eprints.hta.lbg.ac.at/878	590	419	18.22	-	204	182	33
9/ Lapatinib/ 1st-line ad-vanced/metastatic breast cancer	05/2010	http://eprints.hta.lbg.ac.at/882/	381	272	13.6	-	123	137	12
10/ Bendamustin/ Indolent non-Hodgkin's lymphoma (NHL), chronic lympho-cytic leukaemia (CLL) and multiple myeloma (MM)	07/2010	http://eprints.hta.lbg.ac.at/884/	1732	914	45.7	-	261	543	110
11/ Panitumumab/ 1st-line treatment of metastatic co-lorectal cancer	06/2010	http://eprints.hta.lbg.ac.at/880/	470	353	17.65	-	107	215	31

12/ Trastuzumab/ 1st-line advanced gastric cancer	05/2010	http://eprints.hta.lbg.ac.at/881/	456	357	17.85	-	125	206	26
13/ Pazopanib/ 1st line therapy of locally advanced and/or metastatic renal cell carcinoma	10/2010	http://eprints.hta.lbg.ac.at/902	398	272	16.82	-	64	241	31
14/ Ipilimumab/ Pre-treated patients with advanced/metastatic melanoma	12/2010	http://eprints.hta.lbg.ac.at/905	448	349	24.93	-	-	292	57
15/ Nilotinib/ 1st-line treatment of Philadelphia chromosome positive chronic myeloid leukaemia in the chronic phase	01/2011	http://eprints.hta.lbg.ac.at/906	336	286	19.43	-	-	197	25
16/ Cabazitaxel/ 2nd line chemotherapy for castration-resistant metastatic prostate cancer	02/2011	http://eprints.hta.lbg.ac.at/911/	516	262	23.82	-	-	231	31
17/ Dasatinib/ 1st-line treatment of Philadelphia-chromosome positive chronic myeloid leukaemia in the chronic phase	02/2011	http://eprints.hta.lbg.ac.at/910/	398	241	21.91	-	-	194	47
18/ Eribulin/ 3rd- or late-line mono-therapy for advanced/metastatic breast cancer	06/2011	http://eprints.hta.lbg.ac.at/927	304	252	31.5	-	-	204	48
19/ S-1/ 1st-line therapy for patients with advanced NSCLC	07/2011	http://eprints.hta.lbg.ac.at/931	121	95	15.83	-	-	62	33
20/ Abiraterone acetate/ 2nd-line therapy for the treatment of metastatic castration-resistant prostate cancer after docetaxel therapy	11/2011	http://eprints.hta.lbg.ac.at/938	217	139	46.33	-	-	16	123

21/ Axitinib/ 2nd- line treatment of metastatic renal cell carcinoma	01/2012	http://eprints.hta.lbg.ac.at/945	37	37	37	-	-	-	37
22/ Erlotinib/ 1st- line treatment of patients with locally advanced or metastatic NSCLC with EGFR activating mutations	01/2012	http://eprints.hta.lbg.ac.at/941	40	47	47	-	-	-	47
23/ Vemurafenib/ for patients with BRAF V600E mutation positive advanced/metastatic melanoma	01/2012	http://eprints.hta.lbg.ac.at/940	84	71	36	-	-	-	71
24/ Everolimus/ unresectable or metastatic neuroendocrine tumours of pancreatic origin	12/2011	http://eprints.hta.lbg.ac.at/942	54	51	51	-	-	-	51
HSO UPDATES									
25/ Rituximab update	10/2011	http://eprints.hta.lbg.ac.at/937	135	52	26	-	-	19	33
26/ Gefitinib update	08/2011	http://eprints.hta.lbg.ac.at/935/	67	39	9.75	-	-	24	15
27/ Panitumumab update	10/2011	http://eprints.hta.lbg.ac.at/936/	73	38	9.5	-	-	27	11

Timeline of report downloads

most downloads in the first month published

The evaluation of the download rates over time showed that downloads were, in general, highest in the first after publication and were slowly decreasing (see Figure 4.1-1) as time progressed.

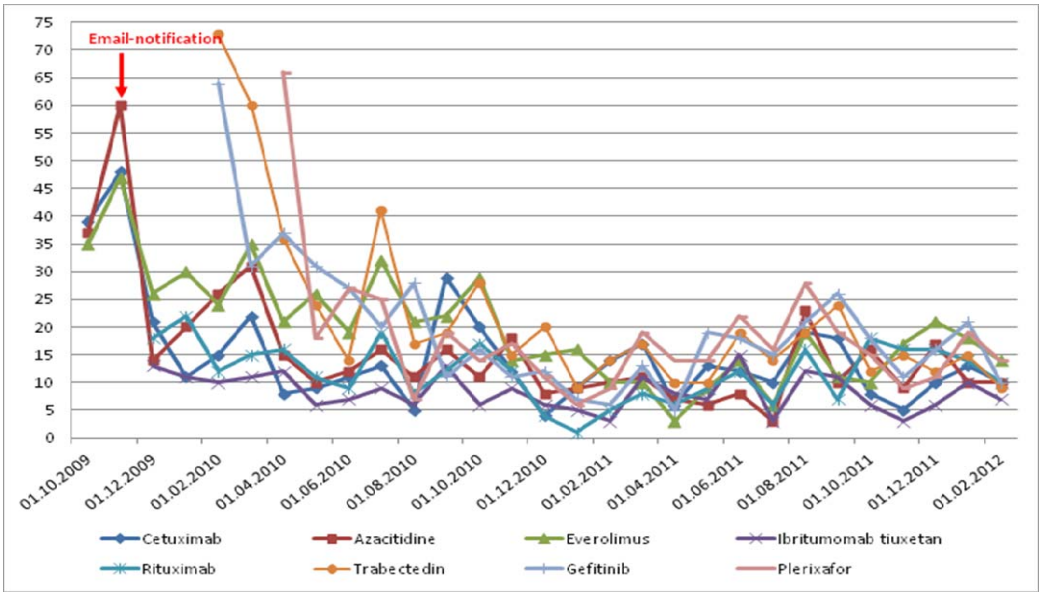

Figure 4.1-1: Timeline of report downloads of HSO-DSD 1-8

Influence of email notifications and HTA newsletters articles on download rates

broad dissemination of HSO-reports

As mentioned above, besides notifications on the LBI-HTA's homepage, two active methods for disseminating the findings of HSO reports are used. These are articles in the LBI-HTA's newsletter and active email-notifications to hospital directors, hospital pharmacists as well as to members of drug commissions. It is of interest, if there is any timely association between these dissemination methods and download rates. The timeline of these different notification methods is also displayed in Figure 4.1-1, Figure 4.1-2 and Figure 4.1-3.

Table 4.1-3: Overview on publication dates and temporal relationship to active dissemination methods for HSO reports

Drug	Publication date on LBI homepage	Email notification date	HTA newsletter date
Axitinib	February 2012	February 2012	-
Everolimus	February 2012	February 2012	-
Erlotinib	February 2012	February 2012	-
Vemurafenib	January 2012	-	-
Abiraterone acetate	December 2011	December 2011	-
Rituximab	December 2011	December 2011	-
Panitumumab	November 2011	December 2011	-
Gefitinib	November 2011	November 2011	November 2011
S-1	September 2011	November 2011	September 2011
Eribulin	July 2011	July 2011	-
Cabazitaxel	April 2011	April 2011	-
Dasatinib	April 2011	April 2011	-
Ipilimumab	January 2011	January 2011	February 2011
Nilotinib	January 2011	January 2011	February 2011
Pazopanib	October 2010	October 2010	-
Lapatinib ditosylate	July 2010	July 2010	September 2010
Bendamustin	July 2010	July 2010	September 2010
Panitumumab	July 2010	July 2010	September 2010
Trastuzumab	July 2010	July 2010	September 2010
Plerixafor	April 2010	-	-
Gefitinib	January 2010	February 2010	-
Trabectedin	January 2010	February 2010	-
Azacitidine	October 2009	November 2011	-
Cetuximab	October 2009	November 2011	-
Everolimus	October 2009	November 2011	-
Rituximab	October 2009	November 2011	-
Ibritumomab tiuxetan	October 2009	November 2011	-

HTA-newsletter or email-notifications increase downloads

Figure 4.1-2 shows an increase in downloads of the anti-cancer drugs Bendamustin, Lapatinib, Panitumumab, and Trastuzumab in September 2010. In this month, the HTA newsletter no. 90 of LBI-HTA was published, introducing these 4 new anti-cancer therapies.

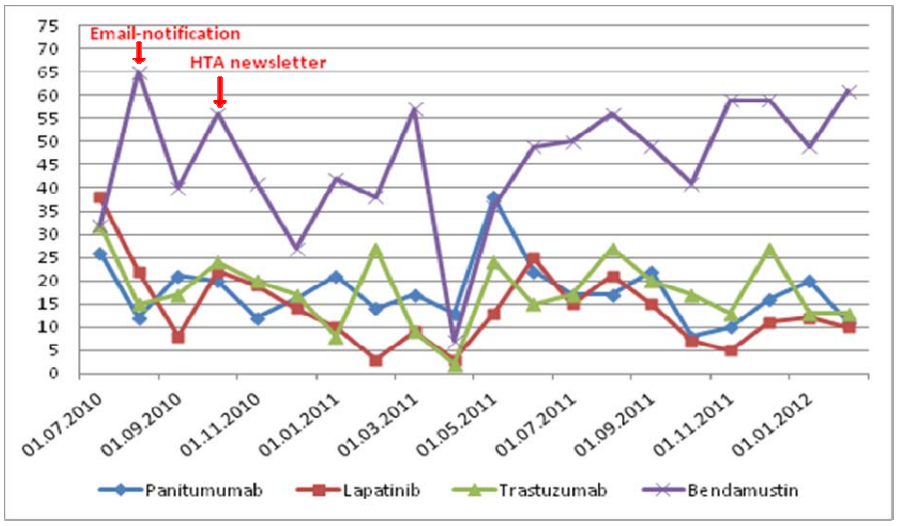

Figure 4.1-2: Timeline of report downloads of HSO-DSD 9-12

increasing download rate of reports

Figure 4.1-3 shows that there was also an increase in the download rate of the reports about Ipilimumab and Nilotinib in early 2011. During this time, the LBI-HTA published its 94th newsletter including articles on these anti-cancer drugs. An email-alert about the newly published report of Pazopanib was sent in October 2010 and another about Nilotinib and Ipilimumab in January 2011. Dasatanib and Cabazitaxel were announced in an email-alert in April 2011.

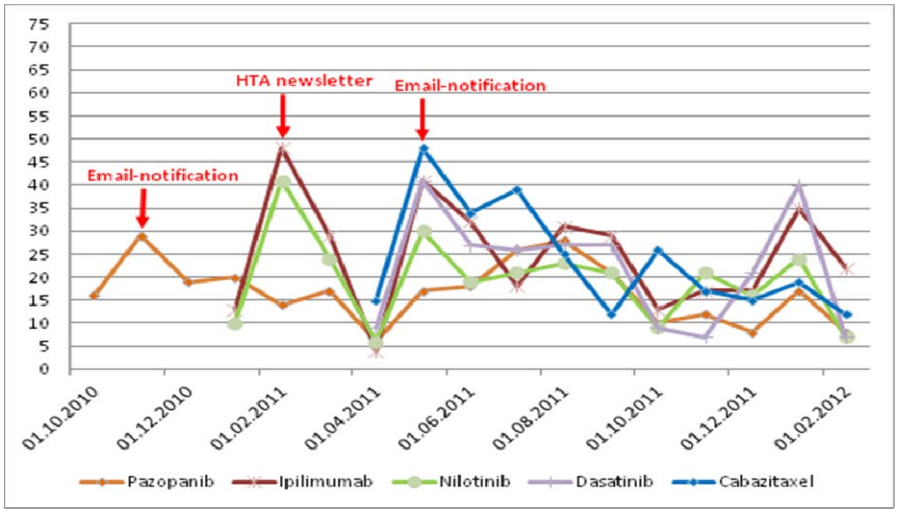

Figure 4.1-3: Timeline of report downloads of HSO-DSD 13-17

4.1.2 Online survey

After a pre-test, the online survey was finally sent out in late March 2012. Overall, the survey was accessible for 3 weeks. On 28th of March 2012 an invitation to participate in the online survey was sent to all email-alert recipients on new HSO reports (n=130). From 130 invitations sent, 4 failure notices returned. These invitees were excluded from the survey. Due to the fact that the participation in the survey was anonymous, reminders were sent to all recipients despite participants having already completed the survey. 17.46% (n=22) of the invitees completed the online survey within the first two days. Two reminders were sent, the last on 16th of April 2012, resulting in a final response rate of 29 % (n=36).

130 invitations to participate in the online survey were sent in March 2012

the response rate increased after 3 weeks to 28.57%.

Socio-demographic data

Questions on socio-demographic data comprised profession and job location. All participants answered these questions. Figure 4.1-4 shows the distributions of the professions. Out of 36 participants 3 interviewees stated to have 2 of the listed job functions. These were 3 pharmacists being also a member of the drug commission.

49% of the participants were pharmacists

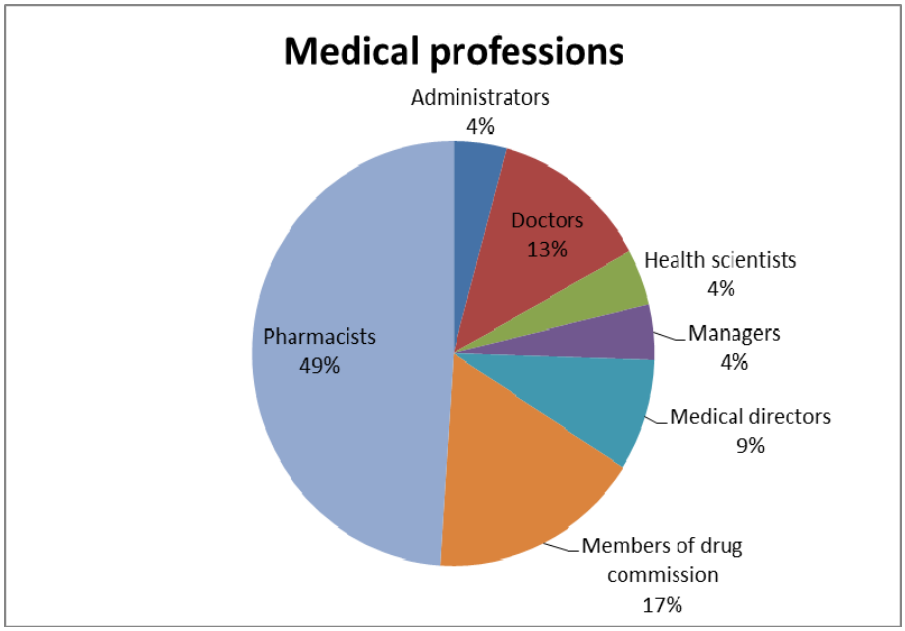

Figure 4.1-4: Professions of the interviewees

94% of the survey participants stated to work in Austria (Vienna (17%), Lower Austria (17%), Upper Austria (17%), Styria (11%), Tyrol (11%), Carinthia (9%), Salzburg (6%), Burgenland (3%) and Vorarlberg (3%)). The remaining 6% were from Germany.

Involvement in decision-making

The question 'Are you involved in decision making on the usage and/or reimbursement of oncology drugs?' was answered also by all 36 participants. 72% of the interviewees (n=36) said that they were either involved in decision making on the usage and/or reimbursement of oncology drugs.

72% are involved in decision making processes

Other information sources used

authorisation papers, primary studies of drugs and documents from the pharmaceutical industry are used most

As Figure 4.1-5 shows, authorisation papers (28%), primary studies of drugs (25%), documents from the pharmaceutical industry (25%), decision support documents provided by LBI-HTA (21%) and others (6%) were used by the interviewees to make decisions about the usage and/or reimbursements of oncology drugs. Other sources specified were reports from organisations such as HAS, CVZ, IQWIG or from NICE. Also listings of organisations relating to haematology/cancer such as American Society of Hematology, National Comprehensive Cancer Network or European Hematology Association were mentioned as information sources.

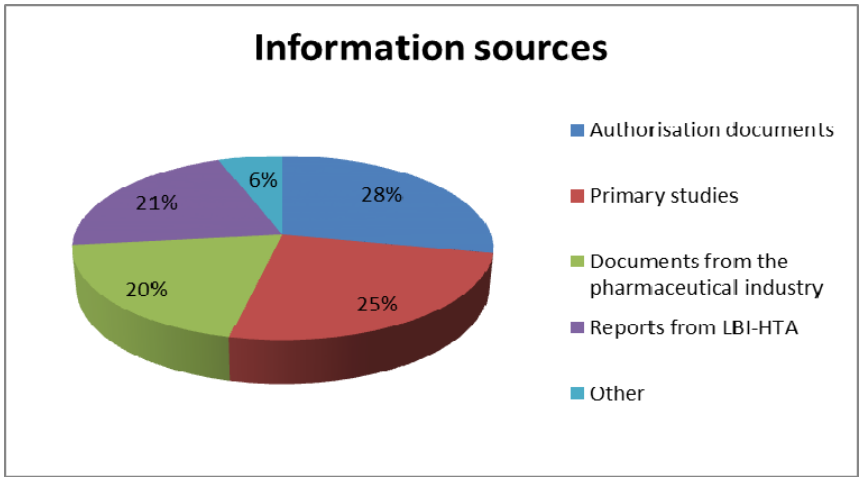

Figure 4.1-5: Information sources used for decision-making processes

Awareness about Horizon Scanning in Oncology

58% of the interviewees were aware of HSO

The mandatory question 'Do you know the work program 'Early assessment of anti-cancer drugs' of the LBI-HTA?' was completed by 33 survey participants, but only 58% answered that they knew HSO.

Participants stating that they did not know HSO were then asked in a subsequent question if they would read HSO reports – 82% responded that they would do so.

Satisfaction with HSO reports

94% are satisfied with the structure and the size of the reports

44% of the participants declared to be 'completely satisfied' and 50% to be 'satisfied' with the structure of the reports. Only 6% stated to be 'somewhat dissatisfied'. The breadth of the reports was 'completely satisfying' for 59% of the participants and 'satisfying' for 35%. Only 6% of the readers stated to be 'fairly satisfied'. 50% of the readers were 'completely satisfied' and another 50% were 'satisfied' with content and quality of the reports.

82% are satisfied with the timing of the publication of the reports

With the timing of the publication, 47% stated to be 'completely satisfied', 35% to be 'satisfied' and 18% to be 'fairly satisfied'. The notification type about new reports (by email-alerts) was 'completely satisfying' for 56% of the readers, 'satisfying' for 39% whereas 6% were not able to answer this question.

Table 4.1-4: Satisfaction with the reports

	completely satisfied	satisfied	fairly satisfied	somewhat dissatisfied	very dissatisfied	not able to judge
structure of the reports	44%	50%	-	6%	-	-
breadth of the reports	59%	35%	6%	-	-	-
quality of the reports	50%	50%	-	-	-	-
timing of the publication	47%	35%	18%	-	-	-
type of notification	56%	39%	-	-	-	6%

Quality of the reports

89% rated the total quality of the reports to be very good or good

The survey participants were asked to rate the quality of the reports. The items were total quality, clarity, comprehensibility and scientific quality 89% evaluated the overall quality of the reports to be 'very good' or 'good'. The scientific quality and comprehensibility of the reports was 'very good' for 61% and 'good' for 39%. For 89% the reports were in terms of clarity 'very good' and for 11% 'good'.

Application of HSO reports

71% of the interviewees are using the reports

71% of the participants said that they were using the reports of LBI-HTA to make informed decisions about applying new anti-cancer drugs and/or refunding expenses of new drugs. 60% of the participants responding with 'yes' to this question were pharmacists, 20% were medical directors, 10% were scientists and 10% were managers. No physician answered this question.

Why are HSO reports not used?

recommendations are lacking

English language as hindrance

too much information

6 interviewees stated that they were not using the reports provided by LBI-HTA. Reasons were: lack of clear recommendations (27%), publication language (English) (18%), not or few relevant for their current job position (18%), publication date (18%), too much information (9%), no clear distinction within the reports (9%) or other reasons e.g. lack of brief description of recommendations or not relevant for work (36%).

Benefit of HSO

The interviewees were asked for which categories HSO has proofed most helpful.

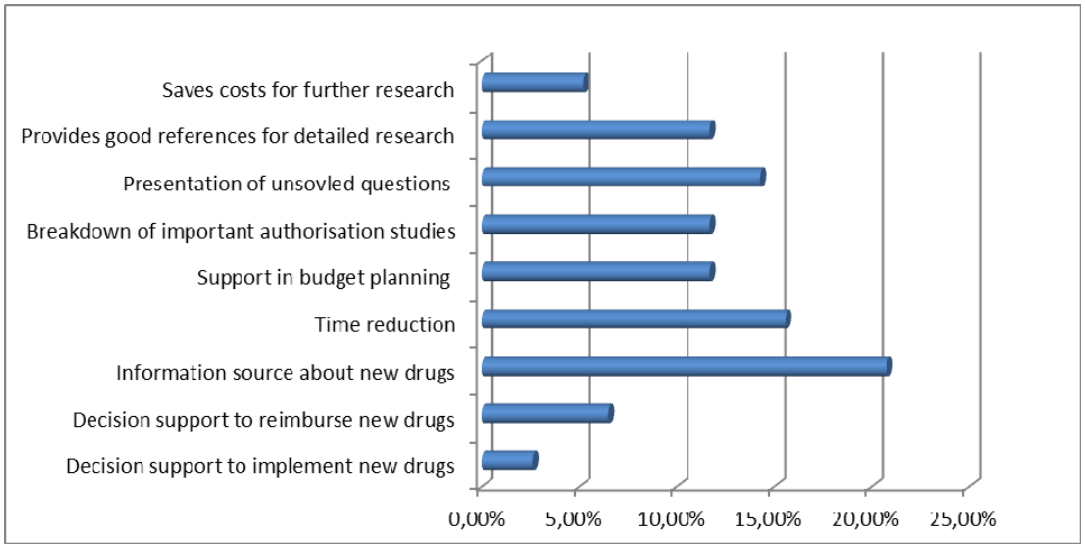

Figure 4.1-6: Type of support provided to readership of HSO reports

HSO reports are mostly used as an information source about new anti-cancer drugs

21% of the interviewees stated that HSO reports were an information source for new anti-cancer drugs, 16% said that they reduced time because they give an overview about important results, 14% said that the reports presented unsolved questions related to new anti-cancer therapies, for 12% the reports aided in budget planning or helped to get an overview about the most important authorisation studies. 12% said that HSO reports provided good references for a more detailed research, 6% stated that HSO reports were a decision support to reimburse new drugs, 5% said they saved costs because no further money is needed for research and 3% said the reports provided support prior to the application of new drugs.

Which professional groups use HSO reports?

Mainly pharmacists (53%) used HSO reports, followed by medical directors (20%), managers (13%), health scientists (7%) and doctors (7%).

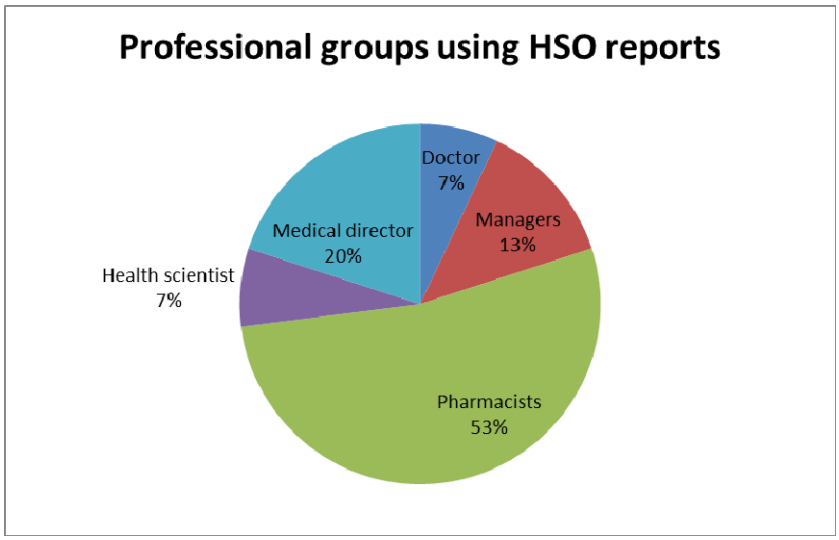

Figure 4.1-7: Professional groups using HSO reports

Which professional group uses HSO reports for which purposes?

information source for pharmacists, medical directors and managers

Pharmacists stated that HSO reports were mostly used as an information source for new drugs (see Table 4.1-5). Furthermore they stated that HSO reports also reduced time and explicitly raised still unresolved questions. Medical directors said that the reports were used as information source, reduce time and support budget planning. Doctors said that the reports offered an overview of important authorisation studies, provided good references for detailed research, reduced time and served as an information source. Scientists stated that the reports saved costs for further research, provided good references for detailed research and were used as decision support to implement new drugs. Administrators used the reports mainly as information source and as decision support document but they also valued to learn about open questions.

Table 4.1-5: Categories that support readers of HSO reports

	totally agree	agree	partly agree	less agree	totally disagree	not able to judge
supportive in applying of new drugs	29%	47%	12%	6%	-	6%
supportive in refunding of new drugs	19%	38%	13%	7%	-	19%
supportive in budget planning	21%	36%	29%	7%	-	7%
information source about innovative anti-cancer therapies	39%	56%	-	6%	-	-
enables elaboration through listing of important research	38%	50%	6%	6%	-	-
information about authorisation status of drugs	31%	44%	13%	13%	-	-
gives an overview about other treatment options	33%	39%	22%	6%	-	-
informs about benefits and risks of new drugs	35%	53%	12%	-	-	-

Relevance of drugs assessed

94% of the responders said that the drugs were of relevance. There was no response to the question which additional drugs would have been of particular relevance.

Type of notifcation about new HSO reports

most readers are notified by email-alerts

44% of HSO report readers stated to be notified by email-alerts of the LBI-HTA. 22% said being informed about new reports by the institute's newsletter, 19% were searching on the website of LBI-HTA and only 6% were searching the internet or databases. In 3%, email-alerts were forwarded by colleagues (see Figure 4.1-8).

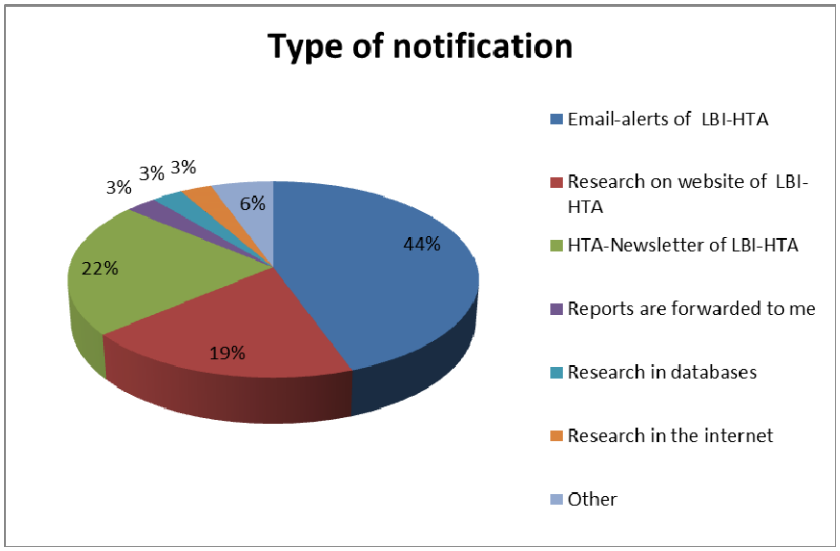

Figure 4.1-8: Distribution - type of notification

Feedback

feedback was provided by 39% of the interviewees

At the end of the survey all interviewees were asked to give feedback on HSO in general and to make suggestions for changes and improvements for future HSO reports. 39% (n=14) of the survey participants gave feedback. In general there were 64% positive feedbacks, 27% suggestions for improvements and 9% negative feedbacks. The 14 positive statements were: reports are important (29%), informative (21%), offered impartial information (21%), gave a good overview about anti-cancer drugs (14%) and 7% were very satisfied with the reports. The two negative comments made were that the reports were not important and that physicians would be able to assess new drugs based on the licensing documents provided by the EMA alone. Last but not least, the 6 suggestions for improvements were: short summary of the report in German, faster assessment, inclusion of a cost-benefit analysis, display of side-effects and quality-of-life aspects and assessments of long established anti-cancer drugs.

4.2 Environmental analysis

Searching the databases and by screening the websites of HTA institutions, 10 institutes performing assessment on anti-cancer drugs were identified. These were:

- Drug Commission of the German Medical Association (AKDAE),
- Canadian Agency for Drugs and Technologies in Health (CADTH),
- Dutch Health Care Insurance Board (CVZ),
- French National Authority for Health (HAS),
- German Institute for Quality and Efficiency in Health Care (IQWIG),
- The National Centre for Pharmacoeconomics in Ireland (NCPE),
- UK's Coordinating Centre for Health Technology Assessment (NETSCC),
- UK's National Horizon Scanning Centre (NHSC),
- National UK's Institute for Health and Clinical Excellence (NICE) and the
- Scottish Medicines Consortium (SMC).

Overall results of searches in the databases and screening of websites

Table 4.2-1 shows the overall search result of method 1 (research performed in the following databases: EuroScan, EUnetHTA, INAHTA and CRD HTA database) and method 2 (screening of the websites of identified HTA institutes for assessment reports which were not listed in the databases).

LBI-HTA was 2 times the single institute having published an early assessment report

Out of 24 reports (updates were not considered), the LBI-HTA was 2 times the only institute having published an early assessment report (S-1 and Vemurafenib). 5 reports (Panitumumab, Ipilimumab, Cabazitaxel, Axitinib, Vemurafenib) had been published prior to approval by the EMA, 18 reports within 6 months after EMA approval and 4 reports 7-20 months after EMA approval. Of note though, after the first 5 drugs (Azacitidine, Cetuximab, Everolimus, Rituximab and Ibritumomab tiuxetan) had been assessed by the LBI-HTA, the filtration and identification criteria were re-defined in order to identify drugs earlier in their life cycle (nearer to approval by EMA). The drug Plerixafor was commissioned by the government (MoH/ Ministry of Health) and was therefore not identified within HSO.

The following list represents a ranking of institutes based on the thematic overlap with the topics assessed by the LBI:

- NHSC: 19 reports (all reports prior to EMA marketing approval)
- SMC: 10 reports (3 reports were published within 6 months, 1 report prior to EMA marketing approval and 6 between 7-32 months)
- AKDAE: 9 reports (7 reports within 6 months and 2 reports were published 7 months after EMA marketing approval)
- NICE: 8 reports (1 report within 6 months after EMA marketing approval and 7 between 7-27 months)
- HAS: 5 reports (3 reports were published within 6 months after EMA marketing approval and 2 reports between 7-12 months)
- NETSCC: 3 reports (within 6 months after EMA marketing approval)

- NCPE: 3 reports (1 report within 6 months and 2 reports 7-17 months after EMA marketing approval)
- IQWiG: 3 reports (1 report within 6 months and 2 reports 7-12 months after EMA marketing approval)

HSO reports were on average published within 4 months after approval by the EMA

On average, the reports provided by LBI-HTA were published within 4 months after approval by the EMA. NHSC published all its 19 reports prior to EMA approval. The 10 reports by SMC were published within 10 months after EMA approval. AKDAE's reports were published within 5 months and reports provided by NICE within 14 months after EMA approval. The 5 drug assessment reports of HAS were published on average within 5 months of EMA approval. NETSCC published its 3 reports within 3 months and IQWiG followed with 8 months. NCPE's reports published the 3 reports on average within 11 months.

Table 4.2-1: Overview of other assessment reports on drugs assessed by LBI-HTA; including drug approval dates of FDA, EMA and TGA

Drug	Indication	FDA approval date	EMA approval date	TGA approval date	Early assessment reports of other HTA institutes
Azacitidine	Myelodysplastic syndrome	05/2004	12/2008	NA	NHSC 09/2007 (prior to EMA approval) HAS 04/2009 (4 months after EMA approval) **LBI-HTA 08/2009 (8 months after EMA approval)** NICE 03/2011 (27 months after EMA approval) SMC 08/2011 (32 months after EMA approval)
Cetuximab	EGFR-expressing NSCLC	02/2004	07/2009 refusal of market authorisation	Under evaluation	NHSC 08/2006 (prior to EMA refusal) **LBI-HTA 09/2009 (2 months after EMA refusal)**
Everolimus	2nd –line therapy for advanced/metastatic kidney cancer	03/2009	08/2009	NA	NHSC 04/2008 (prior to EMA approval) **LBI-HTA 09/2009 (1 month after EMA approval)** NETSCC 11/2009 (3 months after EMA approval) AKDAE 11/2009 (3 months after EMA approval) [1] HAS 01/2010 (5 months after EMA approval) NICE 04/2011 (20 months after EMA approval)
Rituximab	1st- and 2nd- line chronic lymphocytic leukemia	02/2010	01/2009	05/2010	NHSC 09/2007 (prior to EMA approval) NETSCC 01/2009 (around EMA approval) NICE 07/2009 (1st line; 6 months after EMA approval) AKDAE 05/2009 (1st line; 4 months after EMA approval) [1] **LBI-HTA 10/2009 (9 months after EMA approval)** HAS 01/2010 (12 months after EMA approval)
Ibritumomab tiuxetan	consolidation therapy for follicular lymphoma	02/2002	04/2008	NA	SMC 07/2007 (prior to EMA approval) **LBI-HTA 12/2009 (20 months after EMA approval)**
Gefitinib	1st-line NSCLC	05/2003	06/2009	06/2010	NETSCC 11/2009 (5 months after EMA approval) HAS 11/2009 (5 months after EMA approval) **LBI-HTA 12/2009 (6 months after EMA approval)** NICE 07/2010 (1st line; 13 months after EMA approval) NCPE 11/2010 (17 months after EMA approval)
Trabectedin	2nd-line recurrent platinum-sensitive ovarian cancer	NA	09/2009	Withdrawn by the sponsor	NHSC 12/2007 (prior to EMA approval) **LBI-HTA 11/2009 (2 months after EMA approval)** AKDAE 03/2010 (6 months after EMA approval) [1] SMC 08/2010 (11 months after EMA approval) NICE 04/2011 (19 months after EMA approval)

[1] Publication language is German

Plerixafor	autologous stem cell transplantation in patients with lymphoma and multiple myeloma	12/2008	07/2009	05/2010	NHSC 12/2007 (for multiple myeloma; for lymphoma prior to EMA approval) HAS 12/2009 (5 months after EMA approval) SMC 12/2009 (5 months after EMA approval) **LBI-HTA 03/2010 (8 months after EMA approval)**
Lapatinib	1st-line advanced/metastatic breast cancer	01/2010	05/2010	06/2010	NHSC 01/2010 (prior to approval) **LBI-HTA 05/2010 (around EMA approval)** AKDAE 12/2010 (7 months after EMA approval) [1]
Bendamustin	Indolent non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), multiple myeloma (MM)	03/2008	03/2010 - Approval not granted for all European countries	NA	**LBI-HTA 07/2010 (4 months after refusal by EMA)** NICE 10/2010 (7 months after refusal by EMA)
Panitumumab	1st-line treatment of metastatic colo-rectal cancer	09/2006	11/2011 conditional marketing authorisation	12/2011	NHSC 06/2008 (prior to EMA conditional marketing authorisation) **LBI-HTA 06/2010 (prior to EMA conditional marketing authorisation)**
Trastuzumab	1st-line advanced gastric cancer	10/2010	01/2010	09/2010	NHSC 09/2007 (prior to EMA approval) **LBI-HTA 05/2010 (4 months after EMA approval)** SMC 07/2010 and resubmission in 01/2011 (6 months after EMA approval) NICE 11/2010 (10 months after EMA approval) SMC 01/2011 (12 months after EMA approval) and 07/2010
Pazopanib	1st line therapy of locally advanced and/or metastatic renal cell carcinoma	10/2009	06/2010	06/2010	NHSC 04/2008 (prior to EMA approval) **LBI-HTA 10/2010 (4 months after EMA approval)** AKDAE 12/2010 (6 months after EMA approval) [1] NICE 02/2011 (8 months after EMA approval) SMC 03/2011 (9 months after EMA approval) HAS 02/2011 (8 months after EMA approval)
Ipilimumab	Pre-treated patients with ad-vanced/metastatic melanoma	03/2011	07/2011	07/2011	NHSC 04/2008 (prior to EMA approval) **LBI-HTA 12/2010 (8 months prior to EMA approval)** NCPE 09/2011 (2 months after EMA approval) AKDAE 11/2011 (4 months after EMA approval)
Nilotinib	1st-line treatment of Philadelphia chromosome positive chronic myeloid leukemia in the chronic phase	06/2010	12/2010	08/2011	NHSC 06/2008 (prior to EMA approval) **LBI-HTA 01/2011 (1 month after EMA approval)** SMC 07/2011 (7 months after EMA approval)

Cabazitaxel	2nd line chemotherapy for castration-resistant metastatic prostate cancer	06/2010	03/2011	02/2012	NHSC 04/2009 (prior to EMA approval) **LBI-HTA 02/2011 (1 month prior to EMA approval)** AKDAE 08/2011 (5 months after EMA approval) SMC 10/2011 (7 months after EMA approval) IQWiG 01/2012 (12 months after EMA approval) [1] NCPE 03/2012 (14 months after EMA approval)
Dasatinib	1st-line treatment of Philadelphia-chromosome positive chronic myeloid leukemia in the chronic phase	11/2010	12/2010	07/2011	NHSC 09/2009 (prior to EMA approval) **LBI-HTA 02/2011 (2 months after EMA approval)**
Eribulin	3rd- or late- line mono-therapy for advanced/metastatic breast cancer	11/2010	03/2011	NA	NHSC 04/2009 (prior to EMA approval) **LBI-HTA 06/2011 (3 months after EMA approval)** AKDAE 10/2011 (7 months after EMA approval) [1] SMC 10/2011 (7 months after EMA approval) IQWiG 01/2012 (10 months after EMA approval) [1]
S-1	1st-line therapy for patients with advanced non-small cell lung cancer	NA	03/2011	NA	**LBI-HTA 07/2011 (4 months after EMA approval)**
Abiraterone acetate	2nd-line therapy for the treatment of metastatic castration-resistant prostate cancer after docetaxel therapy	04/2011	09/2011	NA	NHSC 05/2010 (prior to EMA approval) **LBI-HTA 11/2011 (2 months after EMA approval)** AKDAE 11/2011 (2 months after EMA approval) [1] IQWiG 12/2011 (3 months after EMA approval) [1] SMC 02/2012 (5 months after EMA approval)
Axitinib	2nd- line treatment of metastatic renal cell carcinoma (mRCC)	01/2012	NA	NA	NHSC 08/2010 (prior to EMA approval) **LBI-HTA 01/2012 (prior to EMA approval)**
Erlotinib	1st- line treatment of patients with locally advanced or metastatic non-small cell lung cancer with EGFR activating mutations	NA	09/2011	11/2010	AHRQ 11/2005 (prior EMA approval) NHSC 08/2010 (prior to EMA approval) NETSCC 11/2011 (2 months after EMA approval) **LBI-HTA 01/2012 (4 months after EMA approval)**
Vemurafenib	BRAF V600E mutation positive advanced/metastatic melanoma	08/2011	02/2012	NA	**LBI-HTA 01/2012 (1 month prior to EMA approval)**
Everolimus	unresectable or metastatic neuroendocrine tumours of pancreatic origin	05/2011	08/2011	NA	NHSC 05/2008 (prior to EMA approval) **LBI-HTA 12/2011 (4 months after EMA approval)**

Overview on organisations with anti-cancer drug assessment reports

NHSC

NHSC is funded by NIHR and aims to provide advance notice of selected new technologies

The NIHR UK's National Horizon Scanning Centre (NHSC) is funded by the National Institute for Health Research (NIHR) and aims to provide key policy makers with advance notice of selected new and emerging health technologies that might require evaluation, consideration of clinical and cost impacts, or modification of clinical guidance up to 2-3 years prior to launch on the National Health Service (NHS) in England. The scope of the horizon scanning activity includes pharmaceuticals, medical devices and equipment, diagnostic tests and procedures, therapeutic interventions, rehabilitation and therapy, and public health activities [14].

The reports published by NHSC contain information about target group, technology description, innovation and/or advantages, availability, launch or marketing and licensing plans, relevant guidance, clinical need and burden of disease, existing comparators and treatments, efficacy and safety, estimated cost and cost impact.

SMC

..analyses newly licensed drugs as quickly as possible

The purpose of the Scottish Medicines Consortium (SMC) is to accept for use those newly licensed drugs that clearly represent good value for money to NHS Scotland. SMC analyses information supplied by the drug manufacturer on the health benefits of the drug and justification of its price. As the NHS has limited resources, SMC works to make sure that those drugs which represent good value for money are accepted for routine use as quickly as possible so that they can benefit patients. The Consortium is made up of lead clinicians, pharmacists and health economists together with representatives of health boards, the pharmaceutical industry and the public [15]. The horizon scanning function, introduced in 2005, is now an established element of SMC's remit. The aim is to improve financial planning at Health Board level through the provision of early intelligence on new medicines in development. The horizon scanning team, comprising pharmacists and management accountants, gathers intelligence on these medicines through engagement with clinical specialists across Scotland as well as the pharmaceutical industry [15].

The reports contain information about indication, dosing information, product availability date, summary of evidence on comparative efficacy, summary of evidence on comparative safety, summary of clinical effectiveness issues, summary of comparative health economic evidence, summary of patient and public involvement, additional information: guidelines and protocols, comparators, cost of relevant comparators, budget impact.

AKDAE

members work voluntarily for AKDAE

AKDAE provides information on rational drug therapy and drug safety

The Drug Commission of the German Medical Association (DCGMA; AKDAE) is the scientific expert committee for drug-related matters of the German Medical Association. It consists of 40 full members and approximately 100 associate members from all areas of medicine and pharmacy. The AKDAE is financed by the German Medical Association (BÄK) and the National Association of Statutory Health Insurance Physicians (KBV). All members work voluntarily for the AKDAE. The main tasks of the commission are providing the medical profession with various and up-to-date information on rational drug therapy and drug safety, advising the BÄK in fundamental questions of pharmaceutical policy and special requests of phy-

sicians and official institutions of health care, reporting, documentation and assessment of adverse drug reactions [12].

The reports provided by AKDAE contain information about indication, assessment, clinical studies, side-effects, contraindications, warning notices, target audience, dosage and costs.

NICE

…publishes guidance to reduce variation in the availability and quality of treatments and care

The National Institute for Health and Clinical Excellence (NICE) was set up in 1999 to reduce variation in the availability and quality of NHS treatments and care. The evidence-based guidance and other products help resolve uncertainty about which medicines, treatments, procedures and devices represent the best quality care and which offer the best value for money for the NHS. All NICE guidance and every NICE quality standard is developed by an independent committee of experts including clinicians, patients, carers and health economists. The guidance is considered and approved by the NICE Guidance Executive, a committee made up of NICE executive directors, guidance center directors and the communications director, prior to publication. The Citizens Council, comprising 30 members of the public, provides NICE with advice that reflects the public perspective on what are often challenging social and moral issues raised by NICE guidance [16].

NICE reports contain information about the technology, manufacturer's submission, consideration of the evidence, implementation, related NICE guidance and review of guidance.

HAS

…implemented by the French government HAS assess drugs, medical devices, publishes guidelines, accreditation of health care organisations and certifications of doctors

The Haute Autorité de Santé (HAS) - or French National Authority for Health - was set up by the French government in August 2004 in order to bring together a number of activities designed to improve the quality of patient care under a single roof and to guarantee equity within the health care system. HAS activities are diverse. They range from assessment of drugs, medical devices, and procedures to publication of guidelines to accreditation of health care organisations and certification of doctors. All are based on rigorously acquired scientific expertise. Training in quality issues and information provision are also key components of its work program. HAS is not a government body. It is an independent public body with financial autonomy. It is mandated by law to carry out specific missions on which it reports to Government and Parliament. It liaises closely with government health agencies, national health insurance funds, research organisms, unions of health care professionals, and patients' representatives. HAS has been built on 3 founding principles: a very broad field of action, which means that it can compare a range of health care initiatives; a high degree of scientific rigor; and independence [17].

The reports contain information about indication, dosage, similar medicinal products, analysis of available data and transparency committee conclusions.

NETSCC

…is funded by NIHR and manages 5 evaluation research programs

NETSCC is another institute being funded by the NIHR and was established at the University of Southampton in 2008. UK government support for medical research is channeled primarily through the NIHR and the Medical Research Council (MRC). Broadly speaking, the NIHR funds later-phase health research, which has the potential to influence the delivery of

health care to patients, while the MRC supports basic and early clinical research. The two bodies work closely together, overseen by the Office for Strategic Coordination of Health Research to ensure that there is a continuum of research opportunities along the translational pathway and to ensure activities are coordinated. NETSCC manages five distinct but interconnected evaluation research programs:- Efficacy and Mechanism Evaluation (EME) program- NIHR Health Services and Delivery Research (HS&DR) program- NIHR Health Technology Assessment (HTA) program- NIHR Public Health Research (PHR) program- NIHR Systematic Reviews (SR) program.

NETSCC's reports contain information about: summary, background, critique of manufacturer's definition of decision problem, clinical effectiveness, economic evaluation, additional analysis undertaken by the ERG, end of life treatment criteria and discussion [18].

NCPE

NCPE assess pharmaceutical products in Ireland

The National Centre for Pharmacoeconomics conducts the HTA of pharmaceutical products for the Health Service Executive (HSE) in Ireland in collaboration with the HSE Corporate Pharmaceutical Unit (HSE-CPU). The aim of the center is to promote expertise in Ireland for the advancement of the discipline of pharmacoeconomics through practice, research and education [19].

The cost-effectiveness reports contain information about indication, cost effectiveness, comparative medicines, sensitivity analysis and budget impact analysis.

IQWiG

the German institute investigates the benefits and harms of medical interventions

IQWiG is an independent scientific institute in Germany that investigates the benefits and harms of medical interventions for patients. IQWiG regularly provides information about the potential advantages and disadvantages of different diagnostic and therapeutic interventions.

The reports contain information about added benefit, results of other reports, probability and extent of added benefit, study design and population, medical benefit and added medical benefit [20].

5 Limitations

There are some major limitations of this impact analysis:

survey:

only among Austrian/ German speaking recipients of HSO-reports

low response rate

The survey: By reasons that the survey was sent to HSO email-alert recipients only, a highly selected group of people was targeted. Those who responded – because of the low response rate only a minority – were rather positive about the HSO reports. A responder bias is thus very likely. Additionally, although the HSO reports are written in English, the primary target group of the email-alerts are German speaking (Austrian) recipients. It is therefore not possible to draw any generalizing conclusions on the impact of HSO reports on both national as well as international readers.

other ways to disseminate HSO-reports: download analysis represents only minimum number

The download-analysis: The download rates must not necessarily represent the number of total downloads, since the reports can be downloaded only once but may be disseminated further, in printed or electronic form. The calculated download rates therefore represent the minimum number of downloads.

Furthermore, calculating the average monthly downloads is very dependent on the time published. Clearly, recently published HSO reports have higher average rates per month, since most downloads happen in the first months. On the other hand, newer reports will inevitably have fewer absolute downloads.

environmental analysis: early assessments in other languages or those not publicly available not included

The environmental analysis: It was not possible to identify all HTA institutions publishing (early) assessment reports since screening websites is a never-ending process. Additionally, not all publications are entered in the HTA databases and many institutions might not publish their reports online and/or in English or German. Therefore, several reports will be missing since they are written in other languages or are not publicly available. Additionally, the scope and methods as well as objectives of reports differ (information for rational decision-making only or basis for reimbursement or for price-negotiations). Therefore a comparison of those reports proves difficult.

Finally, an internal evaluation is always more prone to bias than an external evaluation, because findings are - to a certain extent - interpreted in favour of the HSO program.

6 Discussion and outlook

HSO-program is not too well known

The objectives of the HSO are to identify and assess anti-cancer drugs early and to support hospitals in rational decision making and prospective budget planning. More than one third of the survey participants said that they did not know HSO although they receive email-alerts about newly published HSO reports regularly. Whether they did not receive the email-alerts, were recently added to the email-list, were not reading the email-alerts or were not downloading the reports remains unknown. One explanation could be that the survey participants did not recognise HSO at all or were not aware that the decision support documents are part of HSO.

recipients are mostly pharmacists or

members of drug commissions

The general result of the survey is that there were hardly any decision-makers of hospitals - the intended target audience of HSO - participating/answering. Most survey participants were pharmacists or members of drug commissions. The few medical directors participating in the survey stated that they used HSO reports for rational decision making on costly drugs. Nevertheless the awareness about HSO and usage of HSO reports by hospitals could be higher than evaluated with the online survey.

250 to 350 times downloaded each:

average for Austrian HTA

The download analysis showed nearly 14,000 website-views and nearly 7,000 downloads, with 25 downloads on average per month and 250 to 350 times (with exceptions in both directions) in absolute terms. This is – compared to other (comprehensive) LBI-HTA reports – the average [7]. Even though the feedback on the HSO reports in the survey was generally positive, suggestions for improvements are reaching from a short summary in German to provision of a cost-benefit analysis.

To increase the awareness of the HSO program marketing activities and the email-list could be reviewed and further populated with additional (international) recipients. Also, a button on the website to subscribe to the email-notifications might prove useful.

distinctive LBI-HTA profile:

horizon scanning program with onco-drugs only

within 6 months after EMA approval, ahead of time

critical commentary

One intention for this impact analysis was to find out who the recipients of HSO-reports were and how often or for what reasons the reports were used (downloaded). The second objective was to clarify the market position (=profile) of the LBI-HTA's HSO program and to identify further potential for international collaborations. The general finding of this report is that HSO in its form is the only horizon scanning system concentrating solely on anti-cancer drugs. The HSO reports are published close to EMA-approval and in contrast to other horizon-scanning programs the reports are more elaborated in terms of a critical commentary. Finally, the environmental analysis showed that LBI-HTA is ahead with its early assessments of anti-cancer drugs. The reports were on average published within 4 months after EMA approval and, besides the NHSC, the LBI-HTA was amongst the first HTA institutes having published early assessment reports. 2 times it was the only HTA institute having published a report.

10-12% overlap in drug assessments in EU

collaborations

Based on the POP database, developed in EUnetHTA Joint Action 1 (2010-2012), we know that 10-12% of all European HTA-products are identical. Most of those identical HTAs are drug-evaluations. Based on this knowledge, the LBI-HTA has started actively to search for collaboration partners in order to reduce this enormous redundancy. 8 of such collaborations have taken place among 5 HTA-agencies in the last 2 years. More will come with

EUnetHTA Joint Action 2 (2012-2015) which will apply a standard methodology within a standard format, as piloted on Pazopanib in EUnetHTA Joint Action 1.

Table 6-1: Collaborations on anti-cancer drugs in Europe

LBI-HTA + AHTAPol: Dasatinib (Sprycel®) for the 1st-line treatment of Philadelphia-chromosome positive chronic myeloid leukaemia in the chronic phase; April 2011
LBI-HTA + HTA Centre Bremen: Second-line chemotherapy with Cabazitaxel (Jevtana®) for the treatment of castration-resistant metastatic prostate cancer; May 2011
LBI-HTA + AHTAPol + UVEF (Reg. Veneto): Eribulin (Halaven®) as third- or late-line monotherapy for advanced/metastatic breast cancer, July 2011
LBI-HTA + HTA Centre Bremen: Abiraterone acetate (Zytiga™) as 2nd-line therapy for the treatment of metastatic castration-resistant prostate cancer after docetaxel therapy; December 2011
LBI-HTA + ULSS20: Vemurafenib for patients with BRAF V600E mutation positive advanced/metastatic melanoma; January 2012
LBI-HTA + ULSS20: Axitinib (AG 013736, Inlyta®) for the 2nd-line treatment of metastatic renal cell carcinoma; February 2012
LBI-HTA + UVEF (Reg. Veneto) + AHTAPol: Lenalidomide (Revlimid®) for the treatment of low /intermediate-1 risk myelodysplastic syndrome with chromosome 5q deletion; May 2012
LBI-HTA + ULSS20: Ipilimumab for the first line therapy of advanced/metastatic melanoma (ongoing)

and building on each other's HTAs

Since the need of different health care systems as well as stakeholders will always differ, building on each other's assessment (from assessments of emerging (pre-approval) over the assessment of new drugs (around approval) to assessments for reimbursement or cost-negotiation decisions) might be the way forward.

7 References

1. Geiger-Gritsch, S., *Horizon Scanning in Oncology - Concept Development for the Preparation of a Horizon Scanning System in Austria*. 2008, LBI-HTA: Vienna.
2. Wild, C. and T. Langer, *Horizon Scanning System (HSS). Ein Überblick*. 2006, Ludwig Boltzmann Institute for Health Technology Assessment: Vienna.
3. Simpson, S., et al., *A toolkit for the identification and assessment of new and emerging health technologies*. 2009.
4. Statistik Austria. *Cancer Incidence*. 2012 [cited 01. June 2012]; Available from: http://www.statistik.at.
5. Nachtnebel, A., et al., *Scanning the horizon: development and implementation of an early awareness system for anticancer drugs in Austria.* Health Policy, 2012. 104(1): p. 1-11.
6. Deutsches Institut für Medizinische Dokumentation und Information, *11. Symposium Health Technology Assessment: Theoretische Praxis - praktische Theorie?* 2012: Köln.
7. Schumacher, I. and I. Zechmeister, *Impact of HTA-research in Austria for the health care system. Part 1: Overview - Update*. 2010, LBI-HTA.
8. Gerhardus, A., et al., *What are the effects of HTA reports on the health system? Evidence from the research literature*. 2008, European Observatory on Health Systems and Policies. p. 109-136.
9. Euroscan. [cited 10 June 2012]; Available from: euroscan.org.uk.
10. European network for Health Technology Assessment - EUnetHTA. [cited 28 May 2012]; Available from: www.eunethta.eu.
11. International Network of Agencies for Health Technology Assessment. [cited 28 May 2012]; Available from: http://www.inahta.net/.
12. Arzneimittelkommission der deutschen Ärzteschaft. [cited 12 June 2012]; Available from: http://www.akdae.de/.
13. Centre for Review and Dissemination. [cited 16 June 2012]; Available from: www.crd.york.ac.uk.
14. Horizon Scanning Centre. 2012 [cited 09 June 2012]; Available from: http://www.nhsc-healthhorizons.org.uk/.
15. Scottish Medicines Consortium. [cited 10 June 2012]; Available from: http://www.scottishmedicines.org.uk.
16. National Institute for Health and Clinical Excellence. [cited 12 June 2012]; Available from: http://www.nice.org.uk.
17. Haute Autorite de Sante. [cited 06 June 2012]; Available from: http://www.has-sante.fr.
18. National Institute for Health Research Evaluation, T.a.S.C.C. [cited 06 June 2012]; Available from: http://www.netscc.ac.uk.
19. National Centre for Pharmacoeconomics. [cited 09 June 2012]; Available from: http://www.ncpe.ie/.
20. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. [cited 07 June 2012]; Available from: www.iqwig.de.
21. Health Technology Assessment International. [cited 28 May 2012]; Available from: www.htai.org.

8 Appendix

8.1 Online survey

Table 8.1-1: Questionnaire of the online survey

Welche Funktion üben Sie aus?
In welchem Bundesland arbeiten Sie?
Sind Sie in Entscheidungen über Einsatz und/oder Kostenerstattung von onkologischen Medikamenten involviert?
Welche Quellen verwenden Sie, um Entscheidungen zum Einsatz und/oder zur Kostenerstattung von neuen Onkologika treffen zu können?
Kennen Sie das Arbeitsprogramm „Frühbewertung neuer Onkologika" (auch Horizon Scanning in der Onkologie genannt) vom LBI-HTA?
Wie zufrieden sind Sie allgemein mit den vom LBI-HTA kostenlos zur Verfügung gestellten Berichten neuer onkologischer Medikamente?
Verwenden Sie die Berichte des LBI-HTA um eine Entscheidung zum Einsatz und/oder zur Erstattung von neuen Onkologika zu treffen?
Bitte kreuzen Sie in untenstehender Tabelle an, wie sehr Sie den angeführten Aussagen zustimmen/nicht zustimmen: Die Berichte zur Frühbewertung von neuen Onkologika…
Bitte bewerten Sie die Qualität der Berichte auf der untenstehenden Skala:
Bewerten Sie bitte die einzelnen Kapitel der Berichte. Wie ist der Informationsgehalt der einzelnen Kapitel?
Sind die ausgewählten Arzneimittel in den Berichten für Sie relevant?
In welcher Hinsicht helfen Ihnen die Berichte bei Ihrer Arbeit?
Welche Informationen würden Sie sich zusätzlich in den Berichten wünschen?
Wie erfahren Sie von den Berichten?
Welche anderen Informationsquellen bzw. Publikationen von Frühbewertungen von neuen onkologischen Medikamenten kennen oder verwenden Sie?
Abschließend möchten wir Sie um ein kurzes Feedback (Anregungen, Kommentare und/oder Verbesserungsvorschläge) zum Arbeitsprogramm „Frühbewertung neuer Onkologika" bitten:

8.2 Databases used for the environmental analysis

CRD HTA database

database focuses on completed and ongoing HTA from around the world

Centre for Reviews and Dissemination (CRD) is part of the National Institute for Health Research (NIHR) and is a department of the University of York in Great Britain. NIHR provides research-based information about the effects of health and social care interventions via their databases and undertakes systematic reviews evaluating the research evidence on health and public health questions of national and international importance. The findings of the research outputs are widely disseminated and have impacted health care policy and practice, both in the UK and internationally. The CRD databases provide decision-makers with access to over 9,000 quality assessed systematic reviews, over 11,000 economic evaluations, over 10,000

summaries of completed and ongoing health technology assessments, summaries of all Cochrane reviews and summaries of Campbell reviews. The CRD HTA Database focuses on completed and ongoing health technology assessments from around the world. Database content is supplied by the 52 members of the International Network of Agencies for Health Technology Assessment (INAHTA) and 20 other HTA organisations around the world. Details of other on-going systematic reviews are also registered on the HTA database. All new content is checked, proof read and published on the database by CRD [13].

International Network of Agencies for Health Technology Assessments (INAHTA)

INAHTA links to the CRD database

INAHTA was established in 1993 and has grown to 53 member agencies from 29 countries. The Network stretches from North and Latin America to Europe, Asia, and Australia. INAHTA has several publications online: The Brief series is intended as a forum for member agencies to present overviews of recently published reports. INAHTA briefs are published regularly and placed on the INAHTA website as soon as they become available. HTA Checklists are an aid to furthering a consistent and transparent approach to HTA. They also provide information on the purpose, methods, and contents of an HTA report. Joint projects involve the member agencies in collaborative efforts to evaluate medical technologies of mutual interest [11]. INAHTA offers research in its own database and links to the CRD HTA database.

EuroScan International Network (EuroScan)

developed a database to facilitate access to reports published

The International Information Network on New and Emerging Health Technologies (EuroScan International Network) is a collaborative network of member agencies for the exchange of information on important emerging new drugs, devices, procedures, programs, and settings in health care. EuroScan International Network is a collaborative network that collects and shares information on innovative technologies in health care in order to support decision-making and the adoption and use of effective, useful and safe health-related technologies. It is the principal global forum for the sharing and development of methods for the early identification and early assessment of new and emerging health-related technologies and predicting their potential impact on health services and existing technologies [9]. Since its inception in 1998, EuroScan has established a common terminology and prioritisation criteria; undertaken a comparative analysis of systems; developed a publicly-accessible search of the EuroScan database to facilitate access to reports published by member agencies on their own websites.

EUnetHTA

POP database aims to reduce duplication and facilitate collaboration among HTA agencies

The EUnetHTA collaboration was launched in November 2008 and is implementing the proposal for a sustainable, permanent collaboration for HTA in Europe. Uniting government-appointed organisations from EU Member States, EEA and EFTA countries and a large number of relevant regional agencies and non-for-profit organisations that produce or contribute to HTA, the EUnetHTA collaboration focuses on HTA in Europe to facilitate efficient use of resources available for HTA, to create a sustainable system of

HTA knowledge sharing, and to promote good practice in HTA methods and processes [10]. The POP (Planned and Ongoing Projects) database allows HTA agencies to share with each other information on planned and ongoing projects conducted at each agency. The aim of the database is to reduce duplication and facilitate collaboration among HTA agencies.

Health Technology Assessment International (HTAi)

is a neutral forum for collaboration internationally

HTAi is the global scientific and professional society for all those who produce, use, or encounter HTA. HTAi embraces all stakeholders, including researchers, agencies, policymakers, industry, academia, health service providers, and patients/consumers, and acts as a neutral forum for collaboration and the sharing of information and expertise. HTAi is a global network and has members from 59 countries and six continents. HTAi is actively committed to international collaboration, and has signed formal Memoranda of Understanding with the World Health Organization and the International Network of Agencies for HTA (INAHTA) [21].