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Commentary

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Information specialist collaboration in Europe: collaborative methods, processes, and infrastructure through EUnetHTA

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The history of European health technology assessment (HTA) goes back more than 30 years. Almost as old as HTA agencies themselves is the desire to achieve European collaboration. This gained further impetus with the establishment of the European Network of Health Technology Assessment (EUnetHTA) in 2006. In this context, the field of information management faced specific challenges. Although these services are an integral part of HTA and information specialists play a key role here, this field is often not adequately represented in the HTA agencies within EUnetHTA. Furthermore, the organization of HTA production, including the types of HTAs produced, as well as funding, varies considerably. In order to meet these different conditions, information specialists have created various products and defined processes. With the EUnetHTA guideline, a common methodological understanding for the production of rapid Relative Effectiveness Assessments now exists. Furthermore, the Standard Operating Procedures map the complex information retrieval processes within EUnetHTA in a hands-on manner. The newly established Information Specialist Network (ISN) will in future ensure that information specialists are involved in all EUnetHTA assessments and that the methods are applied consistently in all assessments. In addition, the steering committee of the ISN manages enquiries and can be contacted to discuss methodological issues. Major barriers such as heterogeneity in the daily work of the EUnetHTA members can only be overcome through more collaboration and training.

Introduction

The history of European health technology assessment (HTA) goes back more than 30 years. In 1987, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) was established as the first European HTA agency (1). Since then, nearly all European countries have established at least one HTA agency (2). These agencies differ considerably, not only in the way they are organized and funded, but also in the tasks they perform and in their legal framework. For example, the British National Institute for Health and Care Excellence (NICE) produces HTAs and other evidence syntheses for all health care services, including clinical practice guidelines, and issues decisions on the reimbursement of services provided by the National Health Service (NHS). Moreover, NICE cooperates with external HTA producers. The German Institute for Quality and Efficiency in Health Care (IQWiG) mainly produces HTAs and other evidence syntheses on drugs and nondrug interventions. IQWiG produces only the assessment reports, whereas the supreme decision maker in the German health care system, the Federal Joint Committee (G-BA) decides on the reimbursement of services provided by the Statutory Health Insurance (SHI). IQWiG currently does not produce clinical practice guidelines but assesses them.

Almost as old as the HTA agencies themselves is the desire to achieve European collaboration. This gained further impetus with the establishment of the European Network of Health Technology Assessment (EUnetHTA) in 2006 (https://eunethta.eu/). Over the past 14 years, this EU- and member-state-funded network has aimed to establish scientific and technical standards for HTA collaboration across the EU.

On the basis of EUnetHTA's work, European member states are currently negotiating regulations to establish a legal foundation for long-term, EU-wide HTA collaboration (3). To prepare for this, EUnetHTA has invested substantial resources in the Joint Action 3 program (4).

In this context, the field of information management faced specific challenges. In our understanding, information management includes systematic searching ("information retrieval", e.g. developing search strategies and conducting searches) as well as supportive tasks ("library tasks", e.g. ordering full-texts, organizing subscriptions, and editing reference lists). Additional aspects are repository management, information dissemination, etc.

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Although these services are an integral part of HTA in which information specialists play a key role, this field is often not adequately represented in the HTA agencies of the EUnetHTA member states. Furthermore, the organization of HTA production, including the types of HTAs produced, as well as funding, varies considerably (Table 1). Consequently, the number of information specialists employed, their involvement in HTA production, and daily tasks differ. In some agencies, information specialists are responsible for developing information retrieval methods and conducting literature searches; in others, they also perform library tasks, such as ordering full texts. Furthermore, the different languages and cultural differences in Europe pose a challenge.

In order to meet these different conditions, information specialists involved in EUnetHTA have created various products and defined processes. These include the development of a guideline (5), as well as several process descriptions for rapid Relative Effectiveness Assessments (REAs), which are described below. Furthermore, we discuss a future long-term collaboration model within the EU based on sophisticated information management services.

The development of the EUnetHTA guideline on information retrieval

Some of the authors of this article are also the authors of the EUnetHTA guideline. When we started working on the EUnetHTA guideline in 2014 "Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness" (referred to below as the [EUnetHTA] guideline), most of us had never worked on EUnetHTA assessments before and were not familiar with the EUnetHTA structures. Initially, the guideline mostly summarized recommendations from existing manuals. Since then, we have added information from evidencebased methodological papers identified by systematic literature scanning in each update. The guideline fulfils two main purposes: (a) to increase collaboration between EUnetHTA members; and (b) to allow EUnetHTA members to reflect on which methods and key points they consider important. In addition, we are not aware of any information retrieval manuals that update their content as regularly as we do with the EUnetHTA guideline.

The EUnetHTA guideline was developed as part of Joint Action 2 (6). The aim was to provide an up-to-date and transparent overview of information retrieval methods for EUnetHTA assessments. The guideline is based both on manuals of other organizations, such as the Agency for Healthcare Research and Quality (7;8) and the Cochrane Collaboration (9), as well as literature searches by EUnetHTA members. The guideline provides orientation for systematic searches on clinical effectiveness conducted within the framework of EUnetHTA, and was developed in collaboration with the EUnetHTA members IQWiG, the Norwegian Institute of Public Health (NIPH) and the Andalusian Agency for Health Technology Assessment Area (AETSA), Version 2.0 has recently been published (5).

Guideline structure

The guideline comprises three parts. Part 1 consists of evidence-based recommendations for different aspects of the information retrieval process such as searching in bibliographic databases, study registries, and further information sources. Part 2 provides a practical example with screenshots and further explanations, while Part 3 summarizes the EUnetHTA standards for the work on EUnetHTA assessments.

Special features

The most notable feature of the EUnetHTA guideline is that many members are involved in its development and updating. With IQWiG as the main HTA agency responsible, and NIPH and AETSA as co-authors, a well-established authoring team exists that has been working on the guideline since 2014. Since then, two minor updates and one major update (Version 2.0) have been published, with public consultation on the latter in which nine stakeholders provided 196 comments.

New content in Version 2.0

Most of the work on the guideline was invested in the original Version 1.0 in 2014/2015, but each update involves a substantial additional amount of work. For instance, including new literature means checking whether the corresponding text in the guideline changes and the previous citations still apply or should be deleted. In the case of completely new sections, duplication of previous sections should be avoided and whether the guideline structure is still consistent needs to be checked. In the current Version 2.0, we revised and added the following content:

(a) Further information on Clinical Study Reports (CSRs)

The search for and handling of CSRs is a dynamic field. Due to recent legal changes, access to CSRs and thus their relevance have increased considerably. In this section, we now also provide a clearer distinction between the different types of documents that can be identified via the regulatory agency Web sites, that is, complete CSRs as well as documents provided by the agencies (e.g. Food and Drug Administration [FDA], Medical and Statistical Review documents)

(b) Automation

Automation plays an increasingly important role in information retrieval. This concerns search strategy development as well as study selection. The guideline presents the latest developments and refers, for example, to the Systematic Review Toolbox Web site (10), which offers various tools for the production of HTAs and systematic reviews (summarized as "systematic reviews" below).

(c) Layered searching approach based on systematic reviews

The main methodological change is described in Chapter 4. In recent years, the use of existing systematic reviews has gained considerable importance. In this approach, the relevant systematic reviews are used as the main source for the primary studies considered in the assessment and whether they are of high quality and up-to-date must be checked in advance. In addition, an update search for primary studies is conducted. In our experience, this procedure is used by many HTA agencies. However, standardized methods are still lacking. To the best of our knowledge, this is the first time that the process is described outside the context of rapid reports.

(d) Definition of EUnetHTA standards

As the literature does not always provide clear information retrieval standards, we defined such standards within the context

 Table 1. Information Specialist Involvement per Product within the Six European Agencies Employing Information Specialist Teams

| Product | NICE, UK ¹ | G-BA, Germany ¹ | HAS, France ² | IQWiG, Germany ¹ | NIPH, Norway ¹ | SBU, Sweden ¹ |
|--|--------------------------|-------------------------------|-----------------------------|-----------------------------|------------------------------|-----------------------------|
| Full HTAs | х | | х | Х | х | х |
| Drug assessments (based on the agency's own information retrieval) | х | | | x | Х | |
| Assessments based on industry dossiers (e.g. on drugs) | х | х | | x | Х | |
| Other technology assessments (e.g. medical devices, diagnostics, nondrug topics, etc.) | х | х | | x | Х | |
| Guidelines | Х | | Х | | | |
| Scoping | | Х | | | | |
| Horizon scanning | | | | | | |
| Number of information specialists | 30 | 8 | 7 | 6 (+4 library technicians) | 6 | 4 |

NICE, National Institute for Health and Care Excellence; UK, United Kingdom; G-BA, Federal Joint Committee; HAS, Haute Autorité de santé; IQWiG, Institute for Quality and Efficiency in Health Care; NIPHNO, Norwegian Institute of Public Health; NOR, Norway; SBU, Swedish Agency for Health Technology Assessment and Assessment of Social Services (1) confirmed information, (2) estimation but not officially confirmed.

of EUnetHTA (see new table in the appendix of the EUnetHTA guideline) where necessary.

For example, the literature recommends that information specialists should form an integral part of the assessment team of a systematic review (8;11;12). We have made this recommendation a mandatory component of EUnetHTA assessments, where both the authoring team and the dedicated reviewer group have to include an information specialist. Another example is the question regarding when the last search should be conducted before the planned publication of the assessment report. The available evidence suggests that the last search in a review should be conducted less than 12 months before publication. However, within EUnetHTA, we have agreed that the last search in an assessment is conducted less than 6 months before the planned publication of the assessment report.

Next steps

The future form of collaboration between EUnetHTA members is still being discussed. We assume that the EUnetHTA guideline—in whatever form—will continue to exist. This will also include regular updating. Feedback from the public consultation states that it would be desirable if a guideline update contained a description of information retrieval for further domains of HTAs (economic, ethical, and legal aspects) as well as a specific focus on searching for nonrandomized studies.

Standard Operating Procedures (SOPs)

The systematic development and establishment of quality management for EUnetHTA processes and products were initiated in Joint Action 3 (2016–2021) in order to improve the efficiency and quality of joint work. Thus, in addition to the methodological standards, EUnetHTA processes for information retrieval are also described in a step-by-step manner in SOPs.

So far, six information retrieval SOPs have been completed for rapid REAs on the assessment branches "pharmaceutical technologies" and "other technologies" (Table 2).

Different SOPs for the two branches are required, as the assessments are based on different approaches to information retrieval. The rapid REAs on "other technologies" (https://eunethta.eu/assessments/) are systematic reviews based on literature searches performed by the EUnetHTA authoring team's information specialist. In this team, the information specialist supports the development of the project plan and conducts the literature search. In the dedicated reviewer group, she or he checks the quality of reporting on information retrieval in the project plan and assessment report.

In rapid REAs on "pharmaceutical technologies," information retrieval is performed and a dossier is submitted by the market authorization holder. The information specialist in the EUnetHTA authoring team checks the information retrieval presented in the dossier. The results are documented in an assessment report. The information specialist in the dedicated reviewer group checks the assessment of information retrieval and the supplementary search performed by the authoring team, as well as additional formal aspects. Examples of assessment reports of pharmaceutical technologies can be found on the EUnetHTA Web site (13).

As stated, the SOPs prescribe the involvement of an information specialist. In order to meet this requirement, the EUnetHTA project manager selects an information specialist from a list of project team members using specific selection criteria at the beginning of a rapid REA. If information retrieval expertise is insufficient in the project team, EUnetHTA's newly established Information Specialist Network (ISN) can be asked to support the assessment.

Information Specialist Network

The plan of establishing support groups of specialists (e.g. information specialists, statisticians) from different HTA members to support the HTA production teams was already part of the first proposal for EUnetHTA Joint Action 3. Due to a lack of resources, this initially had to be abandoned. Besides enhancing the quality of joint assessments, the idea was that an ISN would allow a scientific dialogue among information specialists from

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Table 2. Distribution of Information Specialist Tasks in EUnetHTA Assessments

| | Pharmaceutical te | chnologies | Other technologies | | |
|---------------------|---|---|--|--|--|
| | Authoring team | Dedicated reviewer | Authoring team | Dedicated reviewer | |
| Project plan | Writes/checks methods on information retrieval | Review of • PICOS • Information retrieval methods | Writes/checks methods on information retrieval | Review of PICOS Preliminary search Information sources Study selection Citation management | |
| Rapid REA report | Assessment of information retrieval in the submission file Performance of supplementary searches Reporting in assessment report | Review of Information retrieval assessment Supplementary searches Additional formal aspects | Performs information retrieval (databases, study registries) Peer review of search strategies Reporting in draft assessment report | Review of Reporting of information retrieval Consistency of the draft assessment report | |

Shaded box, SOP available 2020.

PICOS, Patient or Population, Intervention, Comparison, Outcome, Study design. REA, Relative Effectiveness Assessment.

different European HTA agencies and promote improved joint understanding of qualitative and methodological issues in HTA.

The idea of an ISN was revived after publication of the SOPs on information retrieval. As not all HTA agencies were able to fulfil the mandatory requirement of the involvement of an information specialist, there was a need for support from agencies able to provide one. The ISN was established by information specialists already involved in EUnetHTA.

The network can be contacted whenever information specialists are needed in an authoring team or dedicated reviewer group. A steering committee—including information specialists from the Austrian Institute for Health Technology Assessment (AIHTA), NIPH, and IQWiG—has been established to manage enquiries and can be contacted to discuss methodological issues.

The EUnetHTA ISN currently consists of seventy-one information specialists, located in twenty-six EUnetHTA member agencies in fourteen countries (Italy, Sweden, Spain, the Netherlands, France, Ireland, Norway, the UK, Estonia, Belgium, Germany, Austria, Finland, and Poland). There are six HTA agencies with information specialist teams (number of information specialists: NICE: 30, G-BA: 8, Haute Autorité de santé [HAS]: 7, IQWiG: 6 (+4 library technicians), NIPH: 6, SBU: 4); thirteen agencies employ one or two information specialists, and seven none.

Implementation issues with the ISN

So far, the ISN has been involved in finding information specialists for individual assessments (mostly as a dedicated reviewer), and in providing advice via e-mail to other information specialists on how to apply the SOPs. A further goal is to provide targeted training on SOP/guideline content, for example, as webinars, and to continue working on structures and processes. Considerable efforts will be needed before EUnetHTA requirements for information retrieval become a standard component in all EUnetHTA assessments.

• Not all agencies involve an information specialist when dealing with information retrieval in EUnetHTA assessments, even if an information specialist is employed in the agency.

- The majority of EUnetHTA members employ only 1–2 information specialists or none at all. For these information specialists, it is difficult to incorporate additional tasks for EUnetHTA assessments.
- The information specialists have varying levels of expertise in the different product types (e.g. dossier-based assessments, guidelines, etc.).
- Although the methodological framework and SOPs for information retrieval are available, their standard use needs to be reinforced.

What future priorities were identified?

The EUnetHTA project will be extended until May 2021 and the negotiations on the proposal for the regulation of HTA (3) will presumably be concluded in 2020. Considerable progress has been made in EUnetHTA over the past 10 years. However, if EUnetHTA assessments are to be jointly prepared in the future, many questions need to be resolved.

Currently, EUnetHTA is preparing the transition from project-based to long-term collaboration. In the following, we discuss the information management tasks required (Table 3) and how they could be implemented (Figure 1).

As stated, information management can be roughly divided into information retrieval as well as library tasks (14;15). This also includes provision of infrastructure and training.

The services could be organized into three different tiers: a central service unit, a supervising steering group committee (part of the ISN), and the individual information specialists in the assessment teams (Figure 1).

A central service unit could provide library tasks, training, and support for general methodological tasks in information retrieval (Table 3) and support the information specialists in the authoring teams and dedicated reviewer groups. It would also be responsible for providing and maintaining information management infrastructure and support, administration issues (e.g. dissemination of reports, copyright issues, etc.), and training. The central service unit and the individual information specialists could be supported by the ISN steering committee, which could supervise the development of methodological information retrieval standards and adherence thereto. For the establishment of a central service

Table 3. Different Information Management Tasks and Infrastructure

Library tasks

- Dissemination of reports (e.g. internal repository)
- Managing subscriptions for journals and databases
- · Providing infrastructure for researchers to order, obtain, and manage full texts
- · Checking adherence to copyright law
- · Selection, management, software support, and administration of tools such as reference management tool and screening tool
- · Provision of software training

Information management infrastructure

- · Screening tool
- Reference management tool
- · Journal access
- · Database access
- · Library repository

Information retrieval - tasks in individual assessments:

- · Selection of information sources
- · Development, conduct, and peer review of systematic searches (e.g. bibliographic databases and study registries)
- · Reporting of information retrieval
- · Involvement in quality assurance

Information retrieval - methodological tasks

- · Responding to methodological questions and provision of targeted training on SOPs/guidelines
- · Routine collection of data (accession numbers of relevant references) from each completed project for future purposes
- · Conduct of information retrieval projects (e.g. development of search filters)
- · Regular assessment of new publications on information retrieval; attendance of main national and international meetings
- Updating of methodological documents (guidelines, SOPs, etc.)
- · Further work on information retrieval methods, structures, processes, and compliance

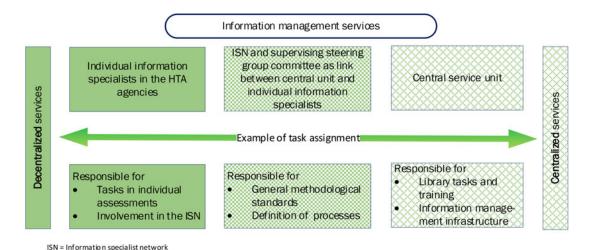


Figure 1. Centralized and decentralized information management services.

unit, general issues on infrastructure, sharing and management of literature, and copyright issues requiring legal clarification and amendment need to be discussed and solved.

Conclusion

Information management in EUnetHTA has made considerable progress over the past 10 years. With the EUnetHTA guideline, a common methodological understanding for the production of rapid REAs now exists. In addition, the guideline can serve as a

general guide for the worldwide HTA information retrieval community. Furthermore, the SOPs map the complex information retrieval processes within EUnetHTA in a hands-on manner. The newly established ISN will in the future ensure that information specialists are involved in all EUnetHTA assessments and that the methods are applied consistently. In addition, the steering committee of the ISN manages enquiries and can be contacted to discuss methodological issues. For future long-term HTA collaboration, we propose a division of work between three different tiers: a central service unit, a steering group, and the individual

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information specialist. However, more collaboration and training are needed to overcome major barriers such as heterogeneity in the daily work of EUnetHTA members.

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