A toolkit for the identification and assessment of new and emerging health technologies

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This report presents the collaborative views of members of the EuroScan International Network on methods used in early awareness and alert systems.


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EuroScan International Network

http://www.euroscan.org

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Foreword

Dear Colleagues

I am pleased, on behalf of the EuroScan International Network, to present you with the second edition of “A toolkit for the identification and assessment of new and emerging health technologies”. This work has been contributed to by all members of EuroScan. Whilst this document has been updated to assist members, it is also publicly available to any organisation that wishes to undertake early assessment and alert activities. These activities apply to the early life cycle of a technology; providing timely information when technologies are emerging, that is prior to adoption, or they are new, that is in the early phase of adoption. This relates to the sequence of developing technologies from basic biomedical research through to clinical use.

Health systems have a need for this type of activity and the information generated, as many technologies are introduced into the healthcare system before a formal health technology assessment is available. EuroScan aims to support the development of methods that result in an output that meets the needs of a variety of organisations including healthcare commissioners, decision makers, research funders and organisations planning the evaluation of emerging technologies.

I commend this updated second edition of the toolkit to you and thank all members of Euroscan and Euroscan Secretariat in the University of Birmingham for their contribution.

Yours sincerely

[Signature]

Professor Brendon Kearney
Chair, Euroscan International Network
Executive summary

The first toolkit for the identification and assessment of new and emerging health technologies was developed by members of the EuroScan International Network and published in 2009. Five years later this revised toolkit continues to focus on methods that are integral to an early awareness and alert (EAA) system. It is once again a collaborative piece of work to which all members have contributed with new information based on their experiences being added.

The main stages involved in EAA systems continue to be: identification of information on new and emerging technologies (horizon scanning); filtration and prioritisation of the identified information; and assessment of the technology or group of technologies. The toolkit provides guidance on these stages and highlights the various approaches that can be taken at each of these stages depending on the context of the EAA system and resources available.
Introduction

EuroScan – the International Information Network on New and Emerging Health Technologies is a collaborative network of member agencies for the exchange of information on important new and emerging health technologies (including drugs, devices, diagnostics, procedures, programmes and settings).

EuroScan International Network is the leading global 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. The network is also 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.

EuroScan International Network is committed to work with a high level of transparency and professionalism, and in partnership with researchers, research centres, governments and international organisations to produce high quality information and effective early awareness and alert (EAA) systems for our respective constituencies. EuroScan is also committed to support the development of existing and new not-for-profit public agencies working in the EAA field.

The goals of the EuroScan International Network are:

- To establish a system to share skills and experience in EAA activities.
- To strengthen activities for the development of methodological approaches for the identification, description and assessment of new or emerging health technologies.
- To improve the exchange of information about new and emerging health technologies and their potential impact on health services and existing health technologies.
- To increase the impact of EuroScan International Network’s output.
- To identify relevant not-for-profit public partners in order to share the results of work with partners/members of the EuroScan International Network collaboration.
- To advise not-for-profit organisations within public administrations who wish to consider the establishment of EAA activities.

One of the ways EuroScan members are contributing to achieving these goals is by sharing their experiences of managing and conducting EAA activities in
this Methods Toolkit. The toolkit was originally published in 2009 but has been reviewed and revised by EuroScan members to incorporate the latest approaches, and findings of research, to inform methods development.

Each member agency is unique in the way it approaches its work but all have a common goal of informing their customers about new and emerging health technologies that may have a significant impact on their health system. Appendix 1 lists EuroScan member agencies.

This document outlines the methods that members of EuroScan employ to identify, select and evaluate relevant new and emerging health technologies. It is aimed at those interested in establishing or improving an EAA system. All members of EuroScan have contributed to the content to ensure different healthcare systems, contexts and methods are represented.

The remainder of this document introduces the reader to EAA systems; gives guidance on the different stages involved in EAA activities; and provides questions that anyone establishing or improving an EAA system should ask themselves or pose to others. There is also a checklist that takes you through each stage involved in early warning and alert activities (Appendix 8) and a list of additional reading materials (Appendix 7).
Early awareness and alert systems

EAA systems are also known as early warning systems or horizon scanning systems (Appendix 2 – Glossary). They aim to identify, filter and prioritise new and emerging health technologies; to assess or predict their impact on health, costs, society and the healthcare system; and to inform decision makers and research planners.

EAA systems can be located in individual agencies providing information to a defined customer or a range of customers. They can also be networks of agencies (within a country e.g. regions collaborating in a network, or internationally) working towards the same goal. The benefits of networks are well documented and form the basis for the development of the EuroScan International Network (www.euroscan.org.uk). Examples of EAA networks include the Canadian Network for Environmental Scanning in Health (CNESH) and the Grupo de Evaluacion de nuevas Tecnologia Sanitarias (GEnTECS) (Appendix 3).

EAA activities are part of a continuum of HTA activities that ranging from primary basic scientific research, evidence of safety and efficacy (e.g. drug licensing), evidence reviews & early assessments, full HTAs and pragmatic trials of a technology in widespread use (Figure 1). From the beginning to the end of this continuum there is a shift from industry to publicly funded research.

![Figure 1 The Continuum of HTA Activities](image-url)
Main stages involved in EAA systems

EAA systems incorporate all or the majority of the stages outlined in Figure 2.

Figure 2 Stages involved in an early awareness and alert system
Benefits of implementing an EAA System

An EAA system ensures that there is a systematic approach to identifying important new and emerging health technologies. They also ensure that technologies are considered for evaluation at the right time, before widespread diffusion, thus protecting patients from ineffective and potentially unsafe health technologies and supporting the uptake of innovative, cost effective health technologies. EAA systems alert policy makers and health service organisations to health technologies that could change current options or decisions; require revision of current guidelines; and/or require further planning or commissioning of activities, e.g. research. Advance notice of an emerging technology can ensure processes are put in place to support and monitor clinical development. For ‘lower-profile’ technologies, for example those aimed at treating less prevalent conditions, EAA systems can raise awareness thus facilitating the development and adoption process.
Stage 1: Identify your customers

The first step in developing an EAA system is to clearly define who the target audience will be and what the objective is for the activity. Even though this may sound obvious, this is decisive in developing the methods appropriate to the system. A system may have several customers or users with differing needs.

Questions to answer

- **What is the purpose of your EAA system?**
  EAA systems can be used to identify a wide range of new and emerging health technologies that may need to be considered for further evaluation or a full health technology assessment (HTA). The information on emerging health technologies can also be used to inform gaps in research activities and requirements for primary research. Information from EAA systems can assist HTA agencies, academic institutions, government departments and others to plan their work and their resource requirements.

- **Who do you intend to inform?**
  - This will be health system dependent. You should always keep in mind the characteristics of the system you are informing (e.g. the population it serves, availability of resources, knowledge and skills of professionals, disease areas covered).
  - Types of stakeholders that might be informed by the system include policy makers, commissioners, purchasers, healthcare professionals, healthcare providers, reimbursement agencies, HTA agencies, commissioners of research, patients and patient organisations.
  - The information could be used by, or targeted at, different levels within your country i.e. national, regional, local users.

EAA activities in a hospital setting are discussed briefly in Appendix 4.

- **What does your customer expect from you (and what not)?**
  It is important to agree on expectations, for example:
  - Volume and format of output.
  - Frequency and timing of reports e.g. in relation to fixed dates for decision making.
• Availability: confidential, limited availability or publicly available.
• Different products may be required depending on different customers’ needs.

• What type of output and information is needed?
  • Content – a brief overview of a technology or a full assessment.
  • Size of documents - a 1-2 page summary, or a lengthier review.
  • Style of documents - written, for example, as a formal report or a newsletter.
  • Format – paper, electronic.
  • Data - confidential information retrieved from manufacturers or only publicly available information sources.

• What is the scope of your EAA system? Methods will vary depending on whether there is interest in one or more of the following:
  • Pharmaceuticals
  • Devices
  • Diagnostics
  • Surgical interventions
  • Medical procedures
  • Hospital care
  • Community care/ programmes
  • Public health interventions
Stage 2: Determine your time horizon

Questions to answer:

- **When does your customer want information?**
  
The timing of an output will depend on the purpose of the EAA system and the customer you are informing but may also depend on the technology type. Information may be required at various points in a technology’s life-cycle:
  
  - several years before the technology enters the healthcare system,
  - when it is about to be launched,
  - at the time when the technology is introduced into the healthcare system or has recently launched,
  - has been launched but is diffusing slowly, or
  - when there is a change in indication or use of the technology.

- **What is the expected time-frame for a technology to enter the healthcare system?**
  
  This will vary depending on technology type and its characteristics:
  
  - The development and regulation pathways for pharmaceuticals are well defined so it is often easier to determine the expected time-frame than it is for other technologies.
  
  - It can be difficult to determine the stage of development of diagnostics and medical devices. These technologies may have a conformity mark (e.g. CE mark) but can still be in varying stages of development. In addition, developments in these technologies may be continual so it is not always obvious which version of the technology you are considering.
  
  - For some new areas of technology development, e.g. cellular therapies, the development and regulatory pathway is more complex and may impact on time to enter the healthcare system.
  
  - Public health interventions and programmes are often developed on a small scale without a regulatory pathway, and may enter the healthcare system initially in one area before being adopted on a wider scale, if at all.
Stage 3: Horizon scanning (Identification)

Horizon scanning is the systematic identification of new and emerging health technologies that have the potential to impact on health, health services, and/or society; and which might be considered for an HTA.

Identification can be:

- **Proactive**: where a range of sources are searched for information on new and emerging health technologies.

- **Reactive**: where systems are in place that allow stakeholders, health professionals, developers and/or consumers to inform the EAA system on new and emerging health technologies.

The former is more resource intensive; the latter may not be as inclusive. A combination of both can be used.

A system needs to be in place to collect and allow management of the information gathered during identification. Constructing a database of identified technologies with additional information fields, such as where the technologies were sourced, is recommended.

Identification sources

The EAA system needs to determine which sources will be scanned. This will depend on the answers to the questions in stages 1 and 2, and resources available. Appendix 5 provides examples of identification sources used by EuroScan member agencies. It is worth noting that the list is not exhaustive or static; new identification sources are regularly being discovered.

- Identification sources should be reviewed periodically to assess their usefulness i.e. yielding topics, or providing sufficient yield for cost of subscription or if different sources are required.

- Existing specialized horizon scanning databases, e.g. EuroScan, can be consulted if your EAA system does not have the resources to scan proactively.

- Many sources can be scanned online and regular email alerts can be subscribed to, often free of charge.
• Frequency of scanning will depend on the source. Email alerts can be sent at regular intervals usually daily or weekly, paper publications are generally less frequent (weekly or monthly) and some sources may only need scanning annually, for example, conference proceedings.

Types of identification sources

• Primary sources – information is obtained directly from sources closest to the technology.

• Secondary sources - information is obtained from sources that have used primary sources but may have edited or filtered the information.

• Tertiary sources – information is obtained from sources that have prioritised the information themselves and perhaps carried out an assessment.

Figure 3 – Examples of potential identification sources
Primary Sources

Commercial developers – pipeline information

Pipeline information may come from:

- Direct contact with commercial developers.
- Indirect information from commercial developers – websites, annual reports, press releases, conference presentations.
- Market analysts, consultants, and other commercial research organisations.
- Commercial pharmaceutical and other specialist health technology media.
- Commercial pharmaceutical and other health technology databases.

Potential issues for identification

- Incomplete, partial, inaccurate or uncertain information (especially indications & time to licensing, market authorization or launch).
- Lack of communication, some companies will not exchange information.
- Industry confidence in the EAA system, particularly dealing with commercial in-confidence information.
- Clarity about role and processes of EAA system.
- Conflict of interest and/or vested interests.

Clinical trial registers

There are a number of official platforms available for registering a clinical trial e.g. ClinicalTrials.gov and WHO International Clinical Trials Registry (WHO ICTRP). Some countries require clinical trials conducted in their country to be registered whereas others do not. For identification purposes trial registers can be searched by disease area or condition, and technology type, to provide information on related research activity. Search engines often allow the user to specify phase of research to ensure search results fit within the EAA timeframe of interest. Searches can produce large numbers of results, and the results may need further investigation to work out if they are relevant. Trial registers may also hold information that is out of date.
Patent applications
A patent protects new inventions and describes features of the invention such as how it works. You can search published applications at Espacenet (http://www.epo.org/searching/free/espacenet.html). However, the amount of information available in an application is often limited and it can be difficult to determine exactly what the technology is and who it will be aimed at.

Secondary Sources
Commercial and medical media
These sources summarise news and developments in health care, health research and the health technology industry. There are numerous products available electronically, some require a subscription and others are free of charge.

These sources:
- Provide early information.
- Vary in the depth of information provided.
- Often have daily or weekly email alerts.

Potential issues for identification
- There is overlap between sources.
- Items can be difficult to follow-up.
- There are plenty of announcements but not all technologies will eventually reach the market.
- There is a trade-off between completeness and efficiency.
Conference proceedings and scientific journals

Most learned societies hold regular conferences and sponsor academic journals for the presentation and discussion of research findings. Searching through relevant conference proceedings and abstracts, and/or a selection of journals can provide EAA systems with information on new and emerging health technologies and research activities. There are many conferences and journals, and an EAA system will need to be selective about those that yield the most relevant results.

Medical societies, for example, American Cancer Society, American Society of Haematology, European Society for Medical Oncology, can be a useful source for:

- Information on ongoing clinical trials.
- Early and preliminary study results.
- Conference highlights.

Medical journals, for example, British Medical Journal, JAMA, The Lancet, NEJM, and Blood, can be a useful source for:

- Published trials – although these are often too late for EAA systems.
- News stories or editorials on emerging health technologies and trends.

Regulatory authorities

Regulatory bodies such as the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA) can be used as an identification source. However, accessible information on technologies may be too near to launch for some EAA systems.

These sources may provide:

- An overview of evidence for licensing.
- Scientific discussions of expert panels, e.g.
  - FDA ODAC – Oncological Drugs Advisory Committee
  - EMA CHMP – Committee for Medicinal Products for Human Use
  - EMA COMP – Committee for Orphan Medicinal Products
  - EMA CAT – Committee for Advanced Therapies.
• Alerts on pending decisions.

• Withdrawals and rejections
  • This information can allow EAA systems to remove technologies from their monitoring lists.

Experts and identification
Engaging with relevant experts to identify new or emerging technologies can be very productive.

• Experts will have relevant experience and knowledge of:
  • Clinical practice,
  • Research – ongoing and past,
  • Conferences and journals.
  • Patients’ characteristics,
  • Infrastructural requirements.

Tertiary Sources
Other EAA systems
Many EAA systems have a website where they publish their non-confidential outputs. In addition, EuroScan members enter information on new and emerging technologies they have identified and/or prioritised into the EuroScan database of new and emerging health technologies. Full access to this database requires membership of EuroScan but many of the fields are available to general users via the EuroScan website (www.euroscan.org.uk) providing basic information on these technologies.

A list of sources used for identification of new and emerging technologies can be found in Appendix 5. This list is not exhaustive and new identification sources frequently emerge.
Stage 4: Filtration

At the filtration stage, technologies found at the identification stage are considered and by applying pre-set criteria, technologies that are relevant to your EAA system and stakeholder are selected. Filtration facilitates the best use of available resources.

**General**

- It is necessary to obtain some information about the technology to inform the filtration process.
- A filtration form can be developed to ensure consistency of information collected and application of filtration criteria.
- The filtration step should take into account the interests of stakeholders and the time horizon, and will thus be health system dependent.
- Organisational, ethical, legal and social aspects should be considered at this stage.

**Questions to be asked at filtration**

Is the technology in the system’s remit?

- **Is the technology relevant to the healthcare system?**
  - Most healthcare systems have disease and healthcare priorities where funding and research will be targeted at. This may influence which technologies are filtered in for further investigation.

- **Is the technology new, equivalent to existing technologies or is an established technology intended for a new indication?**
  - Some EAA systems may only focus on new technologies whereas others may be required to capture information on generic drugs.
  - Innovation may be used as a filtration criteria but it can be difficult to decide if a technology is innovative early in the development cycle or when there is a paucity of information.

- **Is the technology within the timeframe of interest?**
  - This may vary depending on technology type.

- **Does the technology have potential to impact on the healthcare system?**
Even with limited information it may be possible to determine if a technology has the potential to have an impact e.g. clinical benefit, safety, impact on patients (convenience), costs or on infrastructure (staffing, equipment etc.).

Figure 4: Possible framework for filtration
Stage 5: Prioritisation

Once technologies relevant to the EAA system have been filtered, the remaining technologies can be prioritised according to the system’s capacity for assessment or evaluation of the technologies and customer requirements. It is recommended that consideration be given to the construction of a set of pre-defined prioritisation criteria based on stakeholder and customer requirements. Technologies must satisfy one or more of these threshold criteria before being accepted for further consideration.

Some agencies are commissioned to assess all new or emerging health technologies proposed as the prioritisation has been or will be undertaken by stakeholders. As with filtration, further information about a technology may be required to enable its prioritisation. This is particularly important if prioritisation involves external individuals or a committee.

Methods

Prioritisation can be carried out in a number of ways depending on resources and time available, transparency of process and who is involved:

- **Prioritisation without use of criteria** – often staff working in an EAA are able to prioritise the more significant technologies based on prior knowledge of other technologies (organisational memory) and awareness of policy related priorities. This method is the least resource intensive but also the least transparent. However, it may be appropriate for some systems.

- **Pre-defined prioritisation criteria** that a technology must meet. These may include:
  - **Burden of disease**:
    - Number of patients or size of group – prevalence, incidence.
    - Disease characteristics - severity, duration i.e. acute or chronic, mortality, morbidity and service use.
    - Current therapeutic or management options for the patients.
  - **Potential impact on**:
    - Patients - impact on morbidity, mortality, quality of life, diagnosis, safety, compliance vs. current treatment(s).
    - Costs – increased costs or savings, large capital outlay, direct and indirect costs for patients and society.
- Services and organisations - increased or decreased use, service reorganisation, structural changes, staff training requirements, learning curves, quality assurance procedures, safety concerns e.g. radiation compliance.
- Societal and legal issues - ethical issues, controversial method or highly invasive.
- Research and development - impact on improving current or development of alternative approaches for a given health problem.
- Potential for inappropriate diffusion given available evidence:
  - Too fast, too slow or misuse.
- Other:
  - Possible launch date.
  - Is the technology in development for other indications?
  - Are there other technologies in development for the same indication?
- **Scoring tools** – prioritisation criteria can be values allocated to technologies where only those progress to the assessment and evaluation stage if they score above or below a certain threshold.
- **Statistical methods** - a method called Best Worst Scaling (BWS) has recently been applied to EAA activities to prioritise new or emerging technologies that have been identified.

See Appendix 6 for examples of prioritisation methods, criteria and scoring tools.

**Who prioritises?**

Prioritisation can be carried out by:
- **Experts** – these may be clinical, scientific and/or those involved in HTA:
  - in-house using internal expertise;
  - individual external experts;
  - permanent or ad hoc committees of external experts.
- **Health service decision makers or other users of EAA information.**
- **Patients and patient groups.**

Due to a potential conflict of interest, prioritisation does not usually involve industry or commercial developers or clinicians and researchers who work closely with a technology.
Stage 6: Assessment

Assessment of a technology or prediction of potential for impact will depend on stakeholders’ interests and needs.

Types of Assessment

Assessment may be:

- **Rapid**: Taking 24-36 hours to complete, producing a 1-2 page brief overview. Rapid assessments are usually conducted in response to a specific request from a stakeholder about an emerging technology.

- **Brief**: A more detailed but still brief overview taking approximately 0.5-2 weeks to complete and around 4 - 6 pages in length. Includes background information on the technology, how it works, clinical burden of disease, current comparator(s), safety and effectiveness data, costs and social, ethical and legal concerns.

- **In-Depth**: Taking approximately 4-6 months to complete, can be longer than 40 pages. Not a systematic review but a focused assessment using a structured search strategy.

Methods

It is recommended that an assessment template is developed which will remain unchanged for all assessments. The fields (or a selection of the fields) in the EuroScan database form the basis of a template for many EAA systems:

- **Technology related information**: name, description, mode of administration, dose range, company or developer, stage of development, type (i.e. drug, device etc.), use (i.e. therapeutic, diagnostic etc.), licensing/reimbursement plans.

- **Patient and setting related information**: indications, specialty, patient numbers, setting for technology use, current management, alternative or complementary treatment options.

- **Evidence and policy**: clinical evidence and safety; ongoing research; ongoing or planned HTA.

- **Impact predictions**: health; predicted diffusion; cost, infrastructure and economic consequences; ethical, social, legal, political and cultural impact.
A search strategy should be developed to ensure consistency of retrieving relevant information – the comprehensiveness of the search will depend on the product i.e. rapid, brief overview or in-depth report, and the content of the final report. Sources for searching may include:

- Databases on ongoing clinical trials.
- Commercial pharmaceutical databases.
- Registration and licensing sites.
- Relevant scientific conferences.
- Bibliographical databases.

The basic criteria for elaborating evidenced-based information may also be applicable to early assessments. Thus, if possible it is recommended to specify criteria for selecting studies, quality assessment and grading level of evidence.

**Involvement of companies and developers**

Basic information about a technology can usually be found on company websites, in commercial databases and through general internet searches. However to obtain detailed information about a technology such as development status, regulatory or marketing plans, unpublished or ongoing studies and pricing information, it is usually necessary to contact the developer directly.

It can be helpful to have a standard information request document that is sent to companies that sets out the purpose of the information request and the questions the EAA system needs answers to. The document should also ask the company to clearly mark any confidential information they are providing.

EuroScan’s position statement on working with industry can be found on the EuroScan website - [http://euroscan.org.uk/activities/postion-paper-on-industry/](http://euroscan.org.uk/activities/postion-paper-on-industry/).

**Involvement of experts**

Some agencies use scientific and clinical experts to provide information and advice during the assessment process. Experts may be aware of ongoing clinical trials and will have a good overview of the latest ‘noise’ in their area of interest.

It is recommended to involve, if possible, more than one expert in contributing to the output to ensure that a range of views are considered. It is important to establish if an expert has any conflicts of interest at the outset of the process.
Scientific uncertainties

Depending on its format, the assessment may also include a section on scientific uncertainties or knowledge gaps. This section can include a description of what the uncertainty encompasses, and what kind of research is needed to fill the gap in the future.

It is important to raise awareness and to clarify the evidence and its limitations to both decision makers and those allocating resources in healthcare, as well as to carers and patients.
Stage 7: Peer review

Although peer review is placed here at Stage 7, it may also be employed at earlier stages in the process, for example, to confirm prioritisation outcomes or to validate the general work plan. In theory, peer review can be placed even at different stages of assessment including checking methodological accuracy of the process, data accuracy, and answers to the research questions defined. If placed at this stage, peer review is used to check for quality and accuracy of the EAA outputs.

Peer review can be performed both internally and externally.

Internal review

**WHY:** Internal review can be performed, even on the earliest drafts, mainly to check the methodological issues of the assessment (methodological internal audit).

**WHO:** Ideally it should be performed by experts in the organisation or agency that have not been involved in the assessment; they should also be able to give guidance and advice to the authors before the final draft is finalised.

External review

**WHY:** External review can be performed mainly to check the accuracy of data and information as well as to get comments and amendments by stakeholders on the assessment before publication.

**WHO:** It could be performed by:

- Group of experts (collaborating with the EAA system occasionally or on a regular basis) and/or
  - Clinical experts (appointed to collaborate for the specific assessment as having experience with the technology or in the field),
  - Manufacturers of the technology or industry representatives (involved or not, at different stages, according to the EAA system), and/or
  - Patients or patient representatives.

Once the reviewer comments have been collected, these should be considered and discussed internally. Further consultation with the reviewers may be possible if clarification is needed. The decision to include or disregard the changes, as well as the answers to all the comments, may be provided to reviewers.
Stage 8: Dissemination

A dissemination strategy is of vital importance to an EAA system to ensure that the information produced is reaching the correct audience at the right time. Dissemination will depend on the needs of target groups and stakeholders. A structured method of dissemination should be put in place (Figure 5).

**Figure 5: Steps in report dissemination**

**DEFINE TARGET GROUPS**
- Clinicians (individuals, specialty/professional organisations)
- Patients/consumers (individuals, organisations)
- Provider organisations (hospitals, clinics, managed care organisations)
- Government policymakers (international, national, state, local)
- Third party payers (government, private sector)
- Quality assurance and utilization review organisations
- Biomedical researchers
- HTA organisations
- Research funders
- Industry
- News professionals (popular and scientific/professional journalists and editors)
- Academic institutions (schools, continuing professional education programs)
- General public

**DEFINE CIRCULATION**
- RESTRICTED PUBLICATION
- LIMITED RELEASE
- WIDE RELEASE

**IMPLEMENTATION STRATEGIES**
- PATIENT ORIENTED
- CLINICIAN ORIENTED
- INSTITUTION ORIENTED
- PUBLIC ORIENTED

**DEFINE MEDIA**
- PRINTED
  - Newsletter
  - Report
  - Summary sheet
  - Journal article
- ELECTRONIC
  - Established email list (possibly automated list, RSS feeds?)
  - Website – report, newsletter
  - Web-based database
  - Social media
- WORD OF MOUTH
  - Joining and actively participating in EuroScan activities
  - Others?

**ALLOCATE RESOURCES**
- BUDGET
- PERSONAL
- MATERIALS

**EVALUATION OF REPORT DISSEMINATION**
Stage 9: Updating information

Not all EAA systems update information once a report has been completed on a new or emerging health technology. Due to the nature of early assessments the information used can is often incomplete and dynamic and is likely to change or expand before the technology is fully implemented. In some cases information is updated and fed back to customers. On other occasions, it is necessary to consider re-assessments to include new information.

Information can be updated:

- When stakeholders have a specific interest in the technology or are waiting for new studies to see what happens with a promising but not yet approved technology.

- When additional results of studies or data collection from monitoring systems for new and emerging technologies become available.
Stage 10: Evaluation of EAA methods & systems

Evaluation of EAA activities and systems is a logical and necessary step for systems that have been functioning for some time. Besides tailoring the EAA activities more specifically to the needs of the target group, evaluation also allows optimization of resources allocated to the EAA system.

Evaluation should not be thought of as a single event but rather a progressive activity that can take place in several dimensions:

**Structure**

Although structural prerequisites are difficult to change, it may be worthwhile to question the basics of the EAA system to identify and assess issues that may prevent or hinder the system from meeting its objectives. Questions asked may cover:

- Funding – is it sufficient to enable aims to be achieved?
- Governance and mandate – aims, values and codes of practice, steering groups?
- Place in policy making process – is it integral or trying to influence?
- Independence from commercial, political or other influence?
- Staffing – numbers, experience and skills?
- Facilities – information systems, access to information, access to experts?
- Ethos within system to review quality and to measure achievement of aims?

**Process**

Within a given structure, the way available resources are used and handled will determine the outputs and impact of EAA systems. Besides generic management processes such as responsiveness to funder requests, reaction to changes in the wider policy context or financial management, activities specifically related to the EAA system can be evaluated. These include:

- System accuracy
  - Accuracy of identification and reporting e.g. sensitivity and specificity; missing blockbusters and false positives.
• Accuracy of predictions e.g. technologies, timeframes, diffusion and impact.

• Timely identification of topics e.g. the use of high-quality sources, the number of new topics identified.

• Application of explicit and agreed identification criteria.

• Application of explicit and agreed filtration and/or prioritisation criteria.

• Application of agreed investigation and reporting methods e.g. timeliness, quality sources, use of experts, peer review.

• Timely updating of information systems e.g. licensing plans, expert contact details, outputs from system.

**Outputs**

The direct outputs of EAA systems, the assessments or predictions of impact, differ considerably between systems. Several characteristics can be used to describe these assessments, characteristics which can also serve as evaluation criteria. Besides assessments, indirect outputs such as workshops or publications related to EAA activities can be considered for an evaluation.

**Direct – Assessments**

• Number & type

• Relevance to (key) users

• Quality
  • Readability and appropriate style.
  • Based on available evidence.
  • Accuracy.
  • Format and consistency in structure and content.
  • Timeliness.
  • Independence and bias.

• Accessibility
  • ‘Reach’ to other users – professionals, patients, patient groups, other decision makers.

• Coverage across patient groups or priority themes.
Indirect/other

- Workshops, presentations and training delivered.
- Visitors and callers wanting information.
- Student placements.
- Publications.

Impact

The most important question is whether the system achieves what it has set out to do, whether the target audiences’ interests and needs have been met and if the information provided proved useful. Evaluations can be about the:

- Acceptance of agency or products
  - Awareness of agency;
  - Satisfaction with agency or products;
  - Agency’s credibility and respect.
- Utility (use) of information
  - Change in awareness;
  - Change in knowledge;
  - Information considered by decision makers;
  - Information has influenced the decisions taken.

Methods for evaluation

For each dimension and aspect of EAA activities and systems being evaluated, specific standards or measures of success will need to be developed and suitable evaluation tools employed. The diversity of dimensions and aspects of activities and systems that can be evaluated, lead to a range of tools to be considered. Depending on the resources available and the objective(s) of the evaluation, a combination of different methods will often yield the most comprehensive picture. Example tools and methods include:

- Internal audit
  - Presence of agreed procedures and processes for identification, filtration, prioritisation and/or assessment.
  - Adherence to internal procedures and processes.
  - Presence of policies, for example, on handling of confidential information.
Questionnaires, interviews and focus groups

- Depending on the dimension being evaluated the target groups can range from decision makers e.g. clinical, financial, political; experts e.g. researchers, health professionals, technology-specific and patients; employees of the EAA system; to other stakeholders such as manufacturers.
- Questions may be around readability, accuracy, timeliness, accessibility, satisfaction and use of information from EAA system.

Measuring access to EAA system outputs

- Counting requests for EAA system assessments can give an estimate on the acceptance and utility of the EAA.
- There are programmes that can analyse Internet downloads, from simple programmes with only numerical download counts to more sophisticated systems which allow differentiation of user’s nationalities.
- For more refined questions combining download analysis with brief surveys e.g. asking 1 or 2 further questions prior to allow downloads can help in clarifying whether the target audience of the system uses the outputs of an EAA and also which other groups are reached.

Analysis against external information sources

- Audit of responsiveness of EAA system to the publication of new information, on for example licensing plans, on company or other routine websites.
- Sources such as licensing agencies, registries or the EuroScan database are valuable sources to substantiate system accuracy by cross-checking, for example, if all drugs licensed by the European Medicines Agency or if all technologies appraised by a national HTA agency have previously been identified and prioritised by the EAA system.

Content analysis

- Scrutiny of documents used by policy making bodies can show if the information from an EAA system has been considered or used in policy making, or incorporated into policy documents.
- Observation of media coverage may indicate the acceptance and awareness of the agency, the accuracy of the system e.g. public debate on certain block busters, and may also be used for measuring indirect outputs such as workshops or presentations.
Appendices

Appendix 1 - EuroScan member agencies

Agencia de Evaluación de Tecnologías Sanitarias (AETS), Madrid, Spain
Agencia de Evaluación de Tecnologías Sanitarias de Andalucía (AETSA), Seville, Spain
Agenzia Nazionale per I Servizi sanitari Regionali (Age.na.s), Rome, Italy
Assistance Publique-Hôpitaux de Paris, Committee for Evaluation and Diffusion of Innovative Technologies, France (CEDIT)
Australia and New Zealand Horizon Scanning Network (ANZHSN)/Health Policy Advisory Committee on Technology (HPACT)
Basque Office for Health Technology Assessment (Osteba), Spain
Canadian Agency for Drugs and Technologies in Health (CADTH)
Deutsches Institut fur Medizinische Dokumentation und Information (DIMDI)
Division of Medical Technology Policy (DMTP), Ministry of Health, Israel
Health Council of the Netherlands (GR)
Horizon Scanning Center for Innovative Global Health Technology (H-SIGHT), National Evidence-based Healthcare Collaborating Agency, NECA, Korea
HTA Reviews and Dissemination Department, Norwegian Centre for Health Services Research (NOKC)
Institut national d’excellence en santé et en services sociaux (INESSS), Canada
Italian Horizon Scanning Project (IHSP)
Ludwig Boltzmann Institute for HTA (LBI-HTA), Austria
NIHR Horizon Scanning Centre (NIHR HSC), England
Swedish Council on Technology Assessment in Health Care (SBU)
Swiss Federal Office of Public Health (SFOPH)
Appendix 2 - Glossary

Healthcare technology: encompasses all methods used by health professionals to promote health, prevent and treat disease, and improve rehabilitation and long-term care. These methods include pharmaceuticals, devices, diagnostics, procedures (and technologies used as part of a procedure), programmes, settings, and public health activities.

Horizon scanning (health technologies): The systematic identification of new and emerging health technologies that have the potential to impact on health, health services, and/or society. The methods used can also identify health technologies that are becoming obsolete.

Early awareness and alert (EAA) systems (also known as early warning systems or horizon scanning systems): A system that aims to identify, filter and prioritise new and emerging health technologies, or new uses of existing interventions; to assess or predict their impact on health, health services and/or society; and to disseminate information.

An EAA system focuses on health technologies that are:

• new and emerging: A technology that has not yet been adopted in the healthcare system. Emerging pharmaceuticals are at the phase II or III clinical trial, or pre-launch stage. Emerging medical devices are at the pre-marketing stage. New health technologies are generally in the launch, early post-marketing or early diffusion stages,

• represent a change in indication or use of an existing technology, or

• are part of a group of developing technologies that, as a whole, may have an impact.

For further related terms see the HTA glossary
http://htaglossary.net/HomePage
Appendix 3 - Examples of EAA networks and collaborations

International Networks and Collaborations

EuroScan International Network
See www.euroscan.org.uk

Ludwig Boltzmann Institute for HTA (LBI-HTA) and Italian Horizon Scanning Project (IHSP)

LBI-HTA and IHSP have collaborated to produce a number of Horizon Scanning in Oncology reports
See http://hta.lbg.ac.at/page/horizon-scanning-in-der-onkologie-berichte

The agencies both produce reports on oncology drugs and have a similar time horizon for reporting information.

Regional Networks and Collaborations

Canadian Network for Environmental Scanning in Health

In 2011, Canada established a country-specific horizon scanning network: the Canadian Network for Environmental Scanning in Health (CNESH). CNESH is a voluntary network of academics, researchers, clinical experts and decision makers representing national and provincial healthcare perspectives. The primary objectives of CNESH are to identify innovative health technologies, promote horizon scanning methodologies and facilitate information-sharing opportunities across Canada. Such opportunities are currently lacking in this field and this is likely due to the decentralized nature of Canada’s healthcare system; which is characterized by 10 provinces and three territories that deliver healthcare independently of each other. CNESH’s work is intended to inform decision makers (patients, providers and policy makers) and HTA producers at the federal, provincial, regional and local level of Canada’s healthcare system.

Grupo de Evaluación de nuevas Tecnología Sanitarias

GENTecS (Grupo de Evaluación de nuevas Tecnología Sanitarias) was established in 2006 as a collaborative network of agencies and organisations that had established systems for identifying and/or evaluating new and emerging health technologies. The agencies that currently form the network are AETS (Agency for Health Technology Assessment, Instituto de Salud Carlos III),
AETSA (Technology Assessment Agency Health Andalusia), AVALIA-T (Technology Assessment Agency Health Galicia) and Osteba (Technology Assessment Service Health of the Basque Country). All of the agencies are regional agencies, except AETS which is national. The goal of the network is to identify, filter, prioritise and evaluate new and emerging health technologies that may have a significant impact on their health systems. Specific objectives include sharing methodology and improving the identification process. Each agency focuses on specific identification sources to avoid duplication.
Appendix 4 - Hospital-based EAA systems and activities

Hospitals and in particular university hospitals are typically the point of entry and the first adopters of new and innovative technologies. EAA activities in a hospital setting can:

- Take place in close contact with potential users of health technologies and especially the medical profession that often signals new technologies in their fields;

- Benefit from hospital specific information extracted from different IT-systems such as diagnostic resource groups (DRGs), prescription and registries such as cancer registries;

- Interact with teaching and research communities at the hospital: researchers indicating new or emerging technologies and conversely topics of research emerging from EAA activity.

Typically, there is an abundance of technologies to detect and assess with a high level of noise, i.e. a significant quantity of irrelevant and low quality data and technologies.

Horizon scanning (identification) is followed by the filtration and prioritisation stages in which only the technologies with a potential impact are retained for further consideration and assessment. Filtration and prioritisation criteria for the assessment to be performed will reflect the hospitals priorities and interests.

Hospital-based assessment

- Hospital-based HTA addresses context specific issues which are useful in the local decision making process.

- Certain health technologies and in particular some medical devices are not routinely assessed at the national level. Instead the hospital has to perform the assessment by itself prior to the purchase, implementation and use of these technologies.

- When national evaluation exists, the conclusions and recommendations are often too general and do not address hospital selection criteria. Hospitals may not find all the answers needed for the local context and their specific needs.
University hospitals need to assess technologies which may never diffuse in general usage, such as those intended for rare diseases, salvage therapy or last-line therapeutics.

Hospitals have a direct medical, economic or organisational interest in having technologies assessed as soon as possible.

Technologies are assessed at a point where little information is available. However, a possibly provisional decision needs to be taken. Therefore assessment methods have to be adapted specifically to this process.

Hospitals may in some cases collaborate with national or regional HTA agencies.

In conclusion, hospital-based HTA enables local decision makers and healthcare providers to provide access to quality care, use available resources optimally and ensure rapid access to innovations and effective healthcare.

Examples of hospital based EAA systems include CEDIT (Assistance Publique – Hôpitaux de Paris).

Also see the EU funded project AdHopHTA (Adopting Hospital based HTA in the EU) http://www.adhophta.eu/
## Appendix 5 - Identification sources

The table below contains examples of sources used by EuroScan member agencies to identify new and emerging health technologies. It is not a comprehensive list of identification sources nor does inclusion indicate that the source is endorsed by EuroScan member agencies.

<table>
<thead>
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<th>Source</th>
<th>Details and examples</th>
<th>Pharmaceuticals</th>
<th>MedTech</th>
<th>Other</th>
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<td>Commercial Developers</td>
<td>Contact individual companies or trade associations. Company websites often have pipeline information.</td>
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1 Includes drugs, biologics, biotechnology etc.

2 Includes devices, diagnostics etc.
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<td>Medical News Today (daily RSS)</td>
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<td></td>
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<td>Nature Medicine – may be early scientific research</td>
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<td>British Medical Journal</td>
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<td>Regulatory authorities</td>
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<td>EMA – orphan drugs</td>
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**Appendix 6 - Prioritisation: Examples of methods, criteria and scoring systems**

**LBI-HTA Prioritisation Form**

<table>
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<th>Drug XY</th>
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| Are there already other treatment regimen(s) available for this specific indication or is this drug a completely new therapy? | Treatment available  
New therapy |
| Will the drug replace a current drug regimen or is it an add-on therapy? | Add-on  
Replacement  
New therapy |
| Is there potential for a significant health benefit to the patient group (high clinical impact)? | Major  
Minor |
| Is there potential for a significant impact on drug budget if the technology diffuses widely (because of expected moderate to high unit costs and/or because of high patient numbers)? | Major  
Minor |
| Is there potential for inappropriate use (off-label) of the technology? | Major  
Minor |
| Choose Category | Highly relevant – assessment  
Relevant – monitoring  
Not relevant – drop drug |
| Expert’s comment(s) |  |
Best Worst Scaling (BWS)

BWS is “a measurement method based on a theory of how humans choose the two most extreme items in a set of three or more items. BWS assumes that a person examines the options in a set, and chooses the pair of options that exhibits the largest differences on the underlying subjective scale of interest.”

Gallego et al. explored the value of BWS in horizon scanning by investigating clinicians’ views on emerging technologies that will impact outcomes in hepatocellular carcinoma (HCC) in the next 5 to 10 years. The study concluded that BWS could be an important research tool to facilitate horizon scanning.

---


Appendix 7 - Selected member publications

General


EAA systems


**Identification**


Filtration and Prioritisation


## Appendix 8 - EAA checklist

### Stage 1. Identify your market

1. **What is the purpose of your early awareness and alert (EAA) system?**

2. **Who do you intend to inform?**

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<th>Reimbursement agencies</th>
<th>Commissioners</th>
<th>Health Technology Assessment (HTA) agencies</th>
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<th>Healthcare professionals</th>
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<tr>
<td>Local</td>
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</tr>
</tbody>
</table>

3. **What does your customer expect from you?**

4. **What type of output and information is needed?**

5. **What is the scope of your EAAS?**

<table>
<thead>
<tr>
<th></th>
<th>Pharmaceuticals</th>
<th>Surgical interventions</th>
<th>Community care/programmes</th>
<th>Devices</th>
<th>Medical procedures</th>
<th>Public health interventions</th>
<th>Diagnostics</th>
<th>Hospital care</th>
<th>Military medicine</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td></td>
<td></td>
<td></td>
<td>Devices</td>
<td>Medical procedures</td>
<td>Public health interventions</td>
<td>Diagnostics</td>
<td>Hospital care</td>
<td>Military medicine</td>
<td>Other</td>
</tr>
</tbody>
</table>

### Stage 2: Determine your time horizon

6. **When does your customer want information?**

<table>
<thead>
<tr>
<th></th>
<th>Development of innovation</th>
<th>Introduction into the health system</th>
<th>Pre-marketing</th>
<th>Broad diffusion</th>
<th>Marketing</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introduction into the health system</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-marketing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broad diffusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marketing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Stage 3: Identification

7. Identification sources (indicate which sources to be used & list main sources)

<table>
<thead>
<tr>
<th>Source</th>
<th>Use</th>
<th>Main sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial developers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial registers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patent applications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial &amp; medical media</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conference proceedings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scientific journals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory authorities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EAA systems and horizon scanning databases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Stage 4: Filtration

8. Define your filtration criteria (choose and add others to suit EAA system)

<table>
<thead>
<tr>
<th>Possible filtration criteria</th>
<th>Tick if using</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the technology relevant to the health system?</td>
<td></td>
</tr>
<tr>
<td>Is the technology new, equivalent to existing technologies or is it intended for a new indication?</td>
<td></td>
</tr>
<tr>
<td>Is the technology within the timeframe of interest?</td>
<td></td>
</tr>
<tr>
<td>Other (state)</td>
<td></td>
</tr>
<tr>
<td>Other (state)</td>
<td></td>
</tr>
<tr>
<td>Other (state)</td>
<td></td>
</tr>
</tbody>
</table>
### Stage 5: Prioritisation

#### 9. Prioritisation method

<table>
<thead>
<tr>
<th>Method</th>
<th>Tick if using</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prioritisation without use of criteria</td>
<td></td>
</tr>
<tr>
<td>Use pre-defined prioritisation criteria</td>
<td></td>
</tr>
<tr>
<td>Use a scoring tool (state which one)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

#### 10. Who is involved in prioritisation

| In-house using internal expertise                                     |               |
| Individual external experts                                          |               |
| Permanent or ad hoc committees of external experts                   |               |
| Health service decision makers or other users of EAA information      |               |
| Patients and patient groups                                          |               |
| Other                                                                 |               |

#### 11. Define your prioritisation criteria (choose and add others to suit EAA system)

<table>
<thead>
<tr>
<th>Possible prioritisation criteria</th>
<th>Tick if using</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient group and associated burden of disease</td>
<td></td>
</tr>
<tr>
<td>Impact on patients</td>
<td></td>
</tr>
<tr>
<td>Impact on costs</td>
<td></td>
</tr>
<tr>
<td>Impact on services and organisation</td>
<td></td>
</tr>
<tr>
<td>Impact on research and development</td>
<td></td>
</tr>
<tr>
<td>Societal and legal issues</td>
<td></td>
</tr>
<tr>
<td>Potential for inappropriate diffusion</td>
<td></td>
</tr>
<tr>
<td>Other (state)</td>
<td></td>
</tr>
<tr>
<td>Other (state)</td>
<td></td>
</tr>
</tbody>
</table>

### Stage 6: Assessment

#### 12. Type of assessment

- Rapid
- Brief
- In-depth

#### 13. Information included in assessment

<table>
<thead>
<tr>
<th>Technology related</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient related</td>
<td>Policy</td>
</tr>
<tr>
<td>Safety</td>
<td>Impact prediction</td>
</tr>
</tbody>
</table>
### Stage 7: Peer Review

14. Who will peer review outputs?

<table>
<thead>
<tr>
<th>In-house</th>
<th>Methodological experts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual experts</td>
<td>Industry/the manufacturers</td>
</tr>
<tr>
<td>Group of experts</td>
<td>Patients/patient representatives</td>
</tr>
<tr>
<td>Other (state)</td>
<td></td>
</tr>
</tbody>
</table>

### Stage 8: Dissemination

15. Define target groups and/or stakeholders

<table>
<thead>
<tr>
<th>Clinicians</th>
<th>Third party payers</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider organisations</td>
<td>Research funders</td>
<td>Journalists</td>
</tr>
<tr>
<td>Policymakers</td>
<td>Researchers</td>
<td>Academic institutions</td>
</tr>
<tr>
<td>Patients</td>
<td>HTA organisations</td>
<td>General public</td>
</tr>
<tr>
<td>Others (state)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. Define circulation

<table>
<thead>
<tr>
<th>Restricted</th>
<th>Limited release</th>
<th>Wide release</th>
</tr>
</thead>
</table>

17. Define implementation strategy

<table>
<thead>
<tr>
<th>Patient oriented</th>
<th>Institution oriented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician oriented</td>
<td>Public oriented</td>
</tr>
</tbody>
</table>

18. Define media

<table>
<thead>
<tr>
<th>Printed - newsletter</th>
<th>Email list</th>
<th>Word-of-mouth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed report</td>
<td>Website</td>
<td>Social media</td>
</tr>
<tr>
<td>Printed – summary</td>
<td>Database</td>
<td>Journal publication</td>
</tr>
</tbody>
</table>

### Stage 9: Updating information

19. Updating strategy

| No updates to be carried out |
| Update reports on technologies that are being monitored |
| Update reports if significant new information becomes available |
| Update reports if requested by customer |