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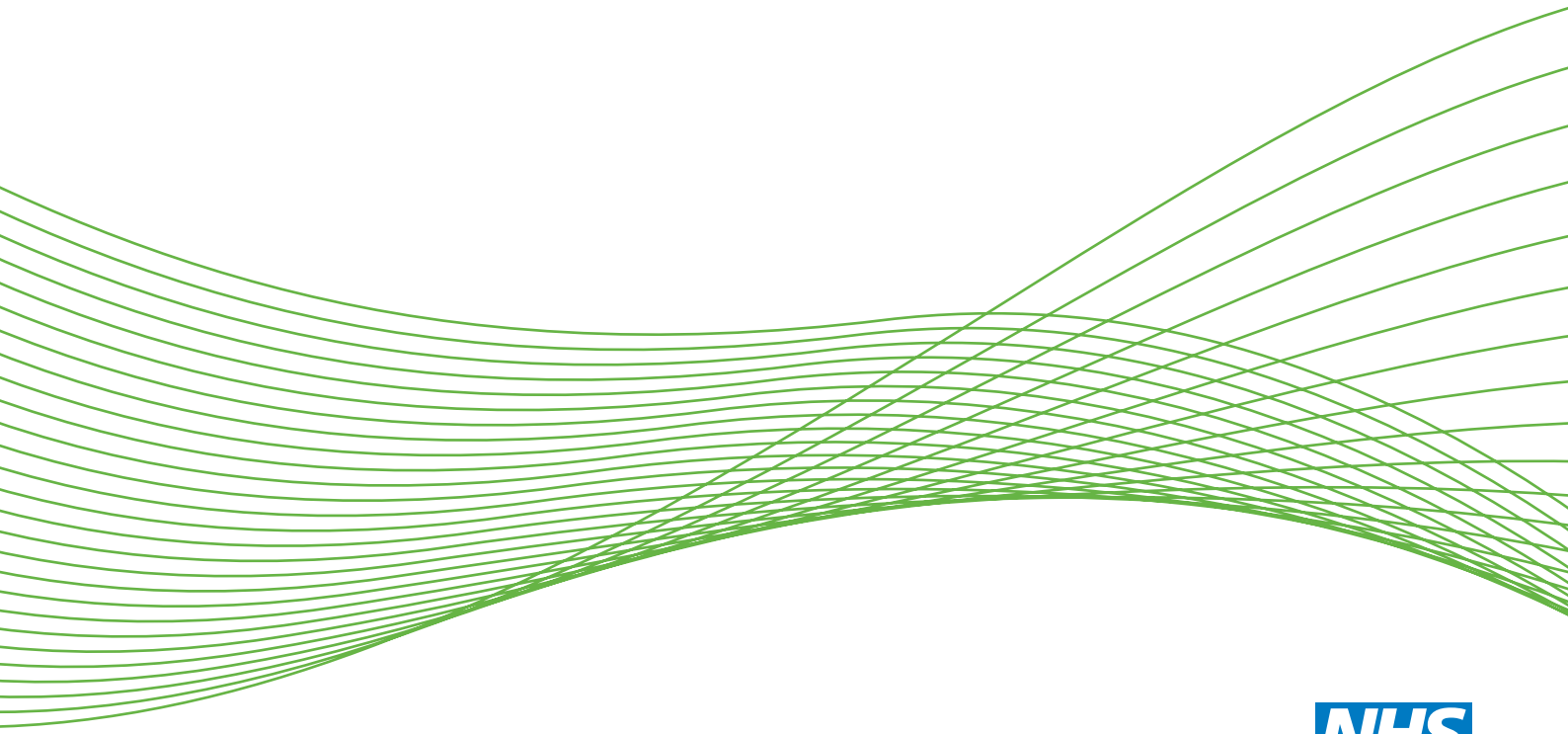

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European network for Health Technology Assessment Joint Action (EUnetHTA JA): a process evaluation performed by questionnaires and documentary analysis

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Abstract

European network for Health Technology Assessment Joint Action (EUnetHTA JA): a process evaluation performed by questionnaires and documentary analysis

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Background: The European network for Health Technology Assessment Joint Action (EUnetHTA JA) project's overarching objective was to 'establish an effective and sustainable HTA [Health technology assessment] collaboration in Europe that brings added value at the regional, national and European level'. Specific objectives were to develop a strategy and business model for sustainable European collaboration on HTA, develop HTA tools and methods and promote good practice in HTA methods and processes. We describe activities performed on behalf of the National Institute for Health Research HTA programme; evaluating the project processes and developing a data set for a registry of planned clinical studies of relevance to public funders.

Methods: Annual self-completion online questionnaires were sent to project participants and external stakeholders to identify their views about the project processes. Documentary review was undertaken at the project end on the final technical reports from the work packages to examine whether or not their deliverables had been achieved. The project's impact was assessed by whether or not the deliverables were produced, the objectives met and additional 'added value' generated. The project's effectiveness was evaluated by its processes, communication, administration, workings of individual work packages and involvement of external stakeholders. A two-stage Delphi exercise was undertaken to identify the data elements that should be included in a registry of planned clinical studies of relevance to public funders. The data set was validated by an efficacy testing exercise.

Results and discussion: High response rates were achieved for the questionnaires sent to project participants and this was attributed to the evidence-based strategy implemented. Response rates to questionnaires sent to external stakeholders were disappointingly lower. Most of the high-level objectives were achieved, although applying the developed tools in practice will be implemented in the European network for Health Technology Assessment Joint Action 2 (EUnetHTA JA2). Most work packages produced their planned deliverables. Networking emerged as one of the main benefits of the project and face-to-face meetings were important. However, the overarching objective did not appear to have been met because there will be a follow-up EUnetHTA JA2 project (reliant on project funding) before the establishment of any permanent network. Twelve organisations from three continents participated in the Delphi exercise to develop the data set. It was demonstrated that a registry for matching pragmatic clinical studies under consideration by funders could be built on a very small data set. This would include 10 unique items, of which five are required to describe a study and the rest are metadata. In the test sample the data set with an appropriate matching rule was able to deliver a sensitivity of between 50% and 100% and a specificity of between 43% and 86% for matching different elements.

Conclusions: A number of recommendations have been made for the next EUnetHTA JA2 project and its evaluation. This included that the evaluation of the EUnetHTA JA2 project should extend beyond the end of the project to allow assessment of its impact; that the quality, usability and cost-effectiveness of tools in 'real-world HTA practice' should be assessed and tangible benefits of international networking should be evaluated. It is worth proceeding to develop a database registry aimed at identifying trials in development based on the data set developed.

Funding: The study was funded by the National Institute for Health Research Health Technology Assessment programme (50%) and the European Union Commission (50%).

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Glossary

HTA Core Model® A methodological framework for shared production and sharing of HTA information. It consists of three components: (1) an ontology containing a set of generic questions that define the contents of a HTA; (2) a methodological guidance that assists in answering questions; and (3) a common reporting structure that enables standardised reporting of HTAs. Information is created and presented as assessment elements. Some elements are prioritised over others to support European collaboration through defining them as 'core elements'.

Stakeholders Those who have an interest in the project or its deliverables. For the EUnetHTA JA project the external stakeholders were in four categories: industry, patients/consumers, providers and payers.

List of abbreviations

AMD	age-related macular degeneration
ATC	Anatomical and Therapeutic Chemical Classification System
COCIR	European Co-ordination Committee of the Radiological Electromedical and Healthcare IT Industry
DG SANCO	Directorate-General of the European Commission for Health and Consumers
ECPC	European Cancer Patient Coalition
EFNA	European Federation of Neurological Associations
EGA	European Generic Medicines Association
EIFFEL	EUnetHTA Interface to Facilitate Furthering of Evidence Level
EPF	European Patients' Forum
EU	European Union
EUnetHTA JA	European network for Health Technology Assessment Joint Action
EUnetHTA JA2	European network for Health Technology Assessment Joint Action 2
EURODIS	The European Rare Diseases Organisation
EVIDENT	the EVIdence DatabasE on New Technologies
HAS	Haute Autorité de Santé (French National Authority for Health)
HTA	Health Technology Assessment
INAHTA	International Network of Agencies for Health Technology Assessment
IT	information technology
MeSH	medical subject heading
NETSCC	NIHR Evaluation, Trials and Studies Co-ordinating Centre
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PICO	population, intervention, comparison and outcome
POP	planned and ongoing projects
RCT	randomised control trial
SAG	stakeholder advisory group
TAVI	transcatheter aortic valve implantation
URL	uniform resource locator
WP	work package

Plain English summary

The National Institute for Health Research Health Technology Assessment programme produces research about health interventions for those who make health-care decisions. The European network for Health Technology Assessment Joint Action project aimed to help collaboration in HTA around Europe. We performed two activities in the project.

We evaluated the project to see whether or not it successfully completed its aims and examined the internal workings of the project. We did this by sending questionnaires each year to people working on the project and those with a relevant interest in it. We also reviewed reports that the individual work activities submitted at the end of the project. The project's main objective did not appear to have been met because there needs to be a follow-up project. Most of the deliverables were produced according to the project plans. One of the main benefits of the project was networking – bringing together European colleagues to discuss HTA.

Those who fund research about health interventions from public money have a duty to ensure this money is used wisely. It is important to know if similar trials are being planned in different countries. This prevents duplication and ensures that trials are designed so their results can be compared. We asked people from different countries which items of data would be useful to know about. We then tested to check that we had identified all the relevant data. It is planned that a database will be developed to store these data about planned trials funded by public money.

Scientific summary

Background

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme [represented by the NIHR Evaluation, Trials and Studies Co-ordinating Centre, (NETSCC)] was invited to join the European network for Health Technology Assessment Joint Action (EUnetHTA JA) project 2010–12. Participation in this project was part-funded by the European Union (EU) Commission and the NIHR HTA programme.

The authors took on formal roles in three work packages under two broad activities.

Evaluation of the processes of the European network for Health Technology Assessment Joint Action project

Health technology assessment produces high-quality research about health interventions for those who make decisions about health care. There have been various initiatives aiming to increase communication and collaboration in HTA across Europe. The EUnetHTA JA project was established in 2010, with the overarching objective being to 'establish an effective and sustainable HTA collaboration in Europe that brings added value at the regional, national and European level.' At its formation the EUnetHTA JA comprised 35 government-appointed organisations from 24 EU member states, Switzerland, Norway and Croatia. The project was co-ordinated by a secretariat and structured into eight work packages. Evaluation is an important facet of project management, and evaluation of the EUnetHTA JA was a prerequisite of the European Union. As recommended in conducting evaluations of European projects, the evaluation plan was a key component and integrated within the EUnetHTA JA project from the beginning. A work package was included in the project to consider this and the authors were invited to lead it. This was their primary role within the EUnetHTA JA. Project evaluation allows monitoring of the processes of the project and achievements against specified criteria for success. This enables assessment of the effectiveness and achievements of the project and the formation of 'lessons learned' recommendations to inform future projects. It also ensures accountability against project plans.

Informing clinical decision-makers about clinical research studies under development: development of a data set to inform a registry

There is progressive growth and interest in pragmatic trials (and other study designs) which deliver clinical effectiveness and cost-effectiveness information to directly inform policy, commissioning and clinical decision-makers. For established, funded clinical trials the scenario is simple. All such studies should be entered into one of a number of international clinical trials registries, such as ClinicalTrials at the National Institutes of Health and Current Controlled Trials. Pragmatic studies reflect the actual clinical environment and create robust evidence. However, there is no widely used registry that tracks such trials in development. Therefore, funders run the risk of duplicating or developing trials in parallel, which may have been avoided or improved if they had been aware of planned parallel activity. There is, therefore, a need for a system to facilitate the identification of pending similar pragmatic studies by international trial funders. This would enable optimisation of scarce public resources, both financial and in terms of patients and researchers. It was, therefore, considered that a registry of 'trials which funders are considering' could have potential for filling this gap. It is important that such a registry contains the appropriate data fields and the authors led an activity to compile such a data set. Building an electronic registry based on the developed data set was beyond the scope of the project, but will be performed by a EUnetHTA JA sister organisation.

Objectives

1. The main objective of the internal evaluation was to evaluate the EUnetHTA JA project with respect to its effectiveness and impact. This considered whether or not the project met its overarching and specific objectives.
2. The secondary objective was to establish the data elements required to inform a registry of clinical studies planned by organisations which provide public funding for pragmatic research.

Methods

Evaluation of the processes of the European network for Health Technology Assessment Joint Action project

A prospective internal evaluation of the EUnetHTA JA was performed. This evaluation was a systematic data collection designed to develop generalisable knowledge to contribute to quality improvement of the EUnetHTA JA project and to inform future projects. The impact of the project was assessed by an outcome evaluation to identify the success of delivering the stated project deliverables. The effectiveness of the project was evaluated by the processes employed during the project. The annual policy-setting meetings were also evaluated by participants. Key success criteria were developed for the project and used to evaluate its performance.

Annual self-completion online questionnaires were sent to project participants and external stakeholders. These were designed according to best practice, including performing a pre-send-out pilot phase and issuing targeted reminders. Special consideration was given to the fact that English was not the native language of most respondents, and the questionnaires contained both 'open' and 'closed' questions. A strategy to optimise response rate was employed. Documentary review was undertaken on the final technical reports submitted from the individual work packages at the end of the project.

Informing clinical decision-makers about clinical research studies under development: development of a data set to inform a registry

The methods for developing a data set to inform a registry for planned clinical studies were in two phases: development of a data set on which to base a registry and assessment of the likely accuracy of that data set. The data set was developed by the consensus-building method of a two-stage Delphi process. This involved developing an initial iteration of the data set. Questionnaires were then distributed to participants and the data set revised in order to achieve a consensus about what data elements should be included. Respondents were asked which clinical areas should be used to test the data set. Suggestions were trastuzumab (Herceptin®, Genentech) for breast cancer, transcatheter aortic valve implantation compared with other surgery for aortic stenosis, vertebroplasty and kyphoplasty compared with conservative therapy (e.g. physiotherapy, occupational therapy) for compression fractures in osteoporosis and bevacizumab (Avastin®, Genentech) for macular degeneration compared with bevacizumab for other indications. Therefore, these indication and intervention combinations were used for efficacy testing of the data set. The Delphi participant organisations were asked to complete the data set for studies they were aware of which may be similar to the index studies listed above.

Results

Evaluation of the processes of the European network for Health Technology Assessment Joint Action project

An excellent response rate was received to the annual evaluation questionnaires sent to project participants: 88% (2010), 86% (2011) and 88% (2012). This is a very high response rate to self-completion questionnaires and indicates the effectiveness of the structured response incentive strategy used. Lower response rates of between 60% and 83% were obtained for the questionnaires distributed to external

stakeholders. It may be that lack of response is itself of value (e.g. leading to the conclusion that the stakeholder organisation does not consider EUnetHTA JA of sufficient importance to engage with), but it would be preferred to have this opinion explicitly stated. It was interesting to observe that the number of project participants changed during the project. The largest overall increase in members was seen from 2010 to 2011. Approximately one-quarter of participants left the project after the initial year and one-third of the 2011 population were new.

The overarching objective of the EUnetHTA JA was to establish an 'effective and sustainable HTA collaboration in Europe that brings added value at the regional, national and European level'. This would be met if the EUnetHTA JA succeeded in establishing an ongoing European HTA collaboration that was independent of project funding. However, an additional EUnetHTA Joint Action 2 project (EUnetHTA JA2), part-funded by the European Union, was developed as a link between the EUnetHTA JA and such a network. Therefore, it was considered that this overarching objective had not been achieved.

EUnetHTA JA had three specific objectives:

1. Development of a general strategy and a business model for sustainable European collaboration on HTA. This was a deliverable of work package 1 and it was reported in their final technical report that this had been delivered by the project end. Unfortunately it was beyond the evaluation scope to consider the quality of this deliverable.
2. Development of HTA tools and methods. All tools and methods were developed by the end of the project apart from methodological guidance for relative effectiveness assessment of pharmaceuticals, which was predicted to be delivered the month following the project end. It was interesting to note that further work was planned in EUnetHTA JA2 to further develop the HTA Core Model® (EUnetHTA, Helsinki).
3. Application and field-testing of developed tools and methods. The EUnetHTA JA project appeared to be successful in developing the tools, but not in testing them in actual practice. This facet will be further pursued in the follow-up EUnetHTA JA2 project.

The impact of the project was evaluated by assessing the project deliverables, which are the results or products of the project. Production of deliverables, according to the work plan, are indicators of project management success and allowed assessment of the performance of the project with respect to time (although considerations of quality and cost were beyond the scope of the present evaluation). In this respect, documentary analysis of the final technical reports revealed that the majority of the deliverables had been produced by the end of the project (December 2012). Deliverables that were tools or methods to help production of HTAs were an online tool for HTA information, a HTA Core Model on screening, a web-based toolkit about evidence generation on new technologies and a quarterly communication protocol for information exchange on ongoing or planned assessments of the same technology. Pilots of HTAs prepared by collaboration were a relative effectiveness assessment of pharmaceuticals and a set of two core HTAs. The tool of methodological guidance for the assessment of relative effectiveness of pharmaceuticals was planned to be delivered after the end of the project. The potential use in practice of these tools, and training requirements prior to use, were also evaluated. It was difficult for participants to predict whether or not they were likely to use these tools in their future HTA practice. The HTA Core Model and the planned and ongoing projects database were the tools that were predicted to be the most useful for producing HTAs.

All project-specific deliverables were produced on time. These were an information management system, a communication and dissemination plan, a stakeholder policy, a business model for sustainability and reports for the EUnetHTA JA.

The processes of the project appeared to run fairly smoothly. However, more time could have been factored in for the start-up of the project. Better budgeting and project management techniques should be used in EUnetHTA JA2 to ensure that sufficient resources are allocated to organisations and specific tasks.

It was interesting that there was a large turnover of project participants during the project; one-third of the population in 2011 was new to the project in that year. Therefore, it was of concern that almost two-fifths of organisations had no succession plan within their organisation. This has important implications for the continuity of the project and necessitates that induction materials are prepared. The overall support offered by the secretariat appeared adequate, although some concern was expressed about the reliance on the project lead. Communication in the common language appeared to be adequate and the important role of the project intranet and face-to-face meetings was highlighted. The involvement of stakeholders seemed to have improved since the EUnetHTA 2006–8 project, but it was noted that this should further evolve in the follow-up EUnetHTA JA2 project.

Recommendations were made from the EUnetHTA 2006–8 project to be followed in the EUnetHTA JA. These were met with respect to securing funding and maintaining a dedicated co-ordinating secretariat, continuing the tool development process, involving people in the work, encouraging collaboration, arranging face-to-face meetings and communicating in English. However, some concerns were noted about the commitment of some members and this will be addressed in EUnetHTA JA2 by grading organisations for their activity. The tools had not been evaluated in routine practice in the EUnetHTA JA. This will be pursued in EUnetHTA JA2.

Informing clinical decision-makers about clinical research studies under development: development of a data set to inform a registry

Twelve of the 13 invited organisations participated in the first Delphi round to develop the data set for pragmatic studies under consideration. This gave a response rate of 92%. Responses were collected in the topic areas of language, coding systems, PICO (population, intervention, comparison and outcome), contact, study title and research question, unit of registration, source of research idea, outcomes and other types of information. Following the responses received the data set was developed into another iteration. A second-round Delphi questionnaire was designed and sent to the same 12 organisations that had responded to the first-round Delphi questionnaire. Ten organisations participated, giving a response rate of 83%. More specific responses were collected in the topic areas of language, coding system, unique identifier, outcomes, unit of registration and other information, building on the responses from the first round. Research studies were submitted by participants in the four topic areas for the validation exercise. In the test sample, the data set with an appropriate matching rule was able to deliver a sensitivity of between 50% and 100%, and a specificity of between 43% and 86% for matching different elements.

Conclusions

A number of recommendations have been made for the next EUnetHTA JA2 project and its evaluation. This included that the evaluation of the EUnetHTA JA2 project should extend beyond the end of the project to allow assessment of its impact; that the quality, usability and cost-effectiveness of tools in 'real-world HTA practice' should be assessed and tangible benefits of international networking should be evaluated. The involvement of stakeholders should evolve from the EUnetHTA JA. Face-to-face meetings are beneficial and this training method should be used for the HTA methodological tools. Support with project management and budgeting should be offered by the secretariat and consideration given to having a deputy project leader.

Funding

The study was funded by the National Institute for Health Research Health Technology Assessment programme (50%) and the European Union Commission (50%).

Chapter 1 Introduction

General introduction

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme [represented by the NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)] was invited to join the European network for Health Technology Assessment Joint Action (EUnetHTA JA) project 2010–12. Participation in this project was part-funded by the European Union (EU) Commission and the NIHR HTA programme.

The authors from NETSCC took on formal roles in three work packages under two broad activities.

Evaluation of the processes of the European network for Health Technology Assessment Joint Action project

It is important that such a project is appropriately evaluated and lessons learnt for future initiatives. A work package was included in the project to consider this and NETSCC was invited to lead it. This was our primary role within the EUnetHTA JA project.

The Directorate-General of the European Commission for Health and Consumers (DG SANCO) requires a process evaluation (rather than an outcome valuation) for all its funded projects. We undertook this role, but extended it slightly by offering some evaluation work to other work packages.

Informing clinical decision-makers about clinical research studies under development: development of a data set to inform a registry

Broadly speaking there are two methods for performing HTA: prospective clinical studies and retrospective systematic reviews. The majority of EU member organisations of the EUnetHTA JA perform only systematic reviews. In addition to these, the UK NIHR HTA programme has a strong history of conducting prospective clinical studies. The Netherlands also commissions such clinical studies and Norway, France, Italy and Portugal have mechanisms to request them. Having a database registry of planned prospective clinical studies would prevent duplication of effort and enable alignment of trial designs to produce more outcome data. It would also be of benefit to those EUnetHTA JA project participants who only perform systematic reviews – they would know when primary research was due to finish and could align the start of their systematic reviews accordingly. It is important that such a registry contains the appropriate data fields and the UK NIHR HTA programme led an activity to compile such a data set. This workstream was within the work package concerned with the production of additional evidence for new technologies [work package 7 (WP7)].

Both activities were performed by the NETSCC using the principles of project management and are described in detail in the following chapters.

Evaluation of the European network for Health Technology Assessment Joint Action project

Health technology assessment in the United Kingdom

Health technology assessment has been described as ‘the provision for health-care decision-makers of high-quality research information on the cost, clinical effectiveness and broader impact of health technologies. Health technologies are . . . all interventions offered to patients’.[1] The findings of applied research studies are vital in supporting an effective and efficient health system.[2]

Early attempts to improve health-care decisions in the UK's NHS were aided by the publication of *Effectiveness and Efficiency: Random Reflections on Health Services* by Cochrane in the early 1970s.[3] This influential book identified the lack of good-quality data to guide health decisions and highlighted the randomised controlled trial (RCT) as the most reliable assessment method. The UK's NIHR Health Technology Assessment programme (formerly the NHS Health Technology Assessment programme) was established in the UK in 1993 with the purpose of producing such information for NHS clinicians.[1] It commissions both evidence syntheses and RCTs.

Previous European Union initiatives in health technology assessment

The EU Commission recognised HTA as a key tool in making health-care decisions.[4] It supported HTA-related studies in the 1980s and this continued throughout the 1990s and 2000s:

- **EUR-ASSESS 1994–7:** This represented the first of a number of initiatives which aimed to form a European network for HTA. It investigated harmonisation of HTA methodology, priority-setting processes, strategies for disseminating results and issues on how to link the results of HTA to coverage.[5]
- **HTA Europe 1997–8:** The main activity of HTA Europe was to describe the HTA processes and health systems of all members of the European Union. These reports were published in the *International Journal of Technology Assessment in Health Care*.[6]
- **ECHTA/ECAHI (the European Collaboration for Assessment of Health Interventions and Technology) 2000–2:** This informal network provided the benefits of working together, sharing information, providing education and training and sharing methodologies.[7]

European network for Health Technology Assessment 2006–8

In 2005 the EU called for proposals for projects to establish a European network for HTA. A group led by the Danish Board of Health was invited to bid for this work, with the goal of developing a set of tools to facilitate co-operation. Following this the EUnetHTA 2006–8 project was formed based on a contract funded by an EU grant. This project aimed to 'create an effective and sustainable network for HTA across Europe that could develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTAs in member states'.[8]

Project structure

The project was divided into eight work packages co-ordinated by a secretariat:

- co-ordination
- communications
- evaluation
- common core HTA
- adapting existing HTAs from one country into other settings
- transferability of HTA to health policy
- monitoring development for emerging new technologies and prioritisation of HTA
- system to support HTA in member states with limited institutionalisation of HTA.

Thirty-four associated partners (contributing to the budget and receiving a share of the grant) and 30 collaborating partners (participating at their own expense) contributed to the project. A 3-year work plan was devised and followed.[8] Governance was through a steering committee (consisting of all associated partners) and an executive committee (consisting of all work package lead partners).

Project deliverables

The main project deliverables were practical tools for conducting HTA. The two tools of potentially immediate use to most HTA agencies were:

1. **The core model:** This is intended to serve as a platform to aid co-operation in developing a new HTA report.[9] It describes a number of domains (e.g. clinical, economic, etc.). The underlying idea is that different HTA organisations can prepare each domain then enter their findings into a central library. Each individual national organisation can then prepare its own local report for its own health economy by drawing mainly on material contained within the central library (with minor modifications to fit local idiosyncrasies).
2. **The adaptation toolkit:** This toolkit helps HTA practitioners convert a report between different health-care settings by working through a number of domains.[10,11]

Evaluation of the European network for Health Technology Assessment 2006–8 project

Internal evaluation of the EUnetHTA project was an essential requirement of the EU and was the subject of work package 3. This had three objectives:

1. to provide an audit function during the project with regular feedback to the European Commission and the project organisation
2. to evaluate changes over time during the project period to show development towards the establishment of an effective and sustainable network
3. to summarise lessons learned to support the effectiveness and sustainability of the network in its next phase, from 2009 and onward.

The prospective evaluation consisted of three approaches: annual surveys of project participants, twice-yearly interviews with work package leads and documentary analysis of work packages.[12] It concluded that the project had been successful in developing tools that describe a standard for conducting and reporting HTAs and this should facilitate greater international collaboration. Support was evident for a future network.[12]

The evaluation report included nine recommendations for a future sustainable network:

1. Secure funding, and maintain a dedicated co-ordinating secretariat.
2. Improve efficiency through an organisational structure made up of work packages managed by a core of dedicated partners, with less committed partners taking part as a wider review group.
3. Continue developing and evaluating the tools as necessary.
4. Involve people in the work to ensure commitment, a high level of knowledge and a broad basis for decision-making processes.
5. Encourage collaboration and communication among all parties to ensure coherence within groups and EUnetHTA.
6. Continue developing the communication platform and functionality of the clearinghouse to make EUnetHTA a central reference point for HTA in Europe.
7. Arrange face-to-face meetings, particularly at the start of group or committee work to strengthen social coherence and reach a common understanding of the work.
8. Evaluate the tools used in real setting and the technical communication platform.
9. English should continue to be the main language.

Evaluation of the European network for Health Technology Assessment collaboration

After the completion of the project at the end of 2008, a number of the partners decided to maintain the network and relationships which had been established over the previous 3 years. This collaboration was established by 25 founding partner organisations from 13 EU member states, Norway and Switzerland.

The main output from this year was an application for funding to DG SANCO's call for a joint action in the field of public health, which became the first EUnetHTA JA.

European network for Health Technology Assessment Joint Action: description of the project

The EUnetHTA JA was a further project funded by DG SANCO, with an overall aim of producing a self-sustaining ongoing European collaboration in HTA. It aimed to 'ensure the completion and development of HTA in the EU, including work on relative effectiveness of drugs'. Collaboration between the EU Commission and member state-appointed HTA agencies resulted in the establishment of a 3-year joint action project (2010–12), which EUnetHTA was asked to perform. At its investure it was foreseen that sustainability following the project would be ensured through an EU directive.[8]

The EUnetHTA JA project was based on a contract of a funding grant with the EU Commission DG SANCO (2009 23 02 – EUnetHTA Joint Action) which specified what it must achieve. The technical annex of the grant agreement described the action as 'exchanging knowledge and best practice' with the subaction, 'Building on the expertise already developed in the field of health technology assessment, ensure the continuation and development of HTA in the EU, including work on relative effectiveness (RE) of drugs'. It is important to make explicit the context of EUnetHTA within local political procedures. The strategic position of the EUnetHTA JA is that 'its outputs will be used to inform, but not mandate the content of national/regional/institutional HTA reports'.[13]

Aims and objectives of the European network for Health Technology Assessment Joint Action project

The project had three aims:[13]

1. to facilitate the efficient use of resources available for HTA
2. to create a sustainable system of HTA knowledge sharing
3. to promote good practice in HTA methods and processes.

The overarching objective of the EUnetHTA JA was to 'establish an effective and sustainable HTA collaboration in Europe that brings added value at the regional, national and European level'.

This was separated into three specific objectives:[13]

1. **Development of a general strategy and a business model for sustainable European collaboration on HTA.** Specifically, this involves constructing a business model for collaboration addressing the sustainability of the HTA collaboration within the EU.
2. **Development of HTA tools and methods.** Specifically, developing principles, methodological guidance and functional online tools and policies.
3. **Application and field-testing of developed tools and methods.** Specifically, testing and implementation of tools and methods.

Project participant health technology assessment agencies

At its commencement in autumn of 2012 the EUnetHTA JA comprised 38 government-appointed organisations from 26 EU member states, Norway and Croatia. Organisations who were members of the EUnetHTA JA were either associate partners (which received 50% funding from the EU grant and 50% from national resources) or collaborating partners (who participated in the project at their own expense). The main partner was the Danish Health and Medicines Authority, which also led the secretariat.

European network for Health Technology Assessment Joint Action: project structure

The work of the EUnetHTA JA was divided into eight work packages: three cross-cutting and five stand-alone (*Table 1*).

TABLE 1 The structure of the EUnetHTA JA

Work package	Title	Aim
1	Co-ordination	To facilitate the achievement of the EUnetHTA JA general objective of putting into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level
2	Communication	To facilitate coherent, effective and sustainable external communication of the EUnetHTA JA, where its aims, objectives, work in progress, results and final products are known to all partners, identified stakeholders and target groups in the EU and at a national regional level
3	Evaluation	To identify to what extent the individual work packages enable the EUnetHTA JA to meet its objective
4	Core model	Further development and testing of the core model developed in the project 2006–8
5	Relative effectiveness assessment of pharmaceuticals	To apply the concepts developed in the core model to provide methods to test the relative effectiveness of pharmaceuticals
6	Information platform	Developing the tools and internal communication platform to support the other work packages
7	New technologies	To support collaboration on new technologies and to contribute to reducing duplication of work by: • exchanging information on and developing tools to facilitate evidence generation (strand A) • exchanging information on current assessments of new health technologies (strand B)
8	Business plan	Construction of a detailed business model for collaboration addressing the sustainability of the HTA collaboration within the EU

All work packages had a lead partner agency that was responsible for submitting the 3-year work plan for the work package, delivering its deliverables and reporting via the annual technical reports. WP2, WP4, WP5 and WP7 also had a co-lead partner agency.

The governance structure is outlined in *Figure 1*.

Executive committee

The executive committee was composed of the lead partners of the eight work packages, the chairperson of the plenary assembly (a non-voting member) and three elected members (from the EUnetHTA JA member agencies). This committee was the main executive body involved in strategic leadership of the project. Regular face-to-face meetings were held and e-meetings were held every 2 months.

Plenary assembly

The plenary assembly was the main governance and policy-setting body of the EUnetHTA JA. It was composed of the head of each partner organisation (or their representative). The chairperson was elected by plenary assembly members and ensured liaison between the executive committee and the plenary assembly. This annual meeting was of crucial importance because it represented the only meeting of all project organisations and its function was to agree policy.

The stakeholder forum

In formation of the EUnetHTA JA the EU Commission emphasised the importance of giving a greater focus to stakeholders than had been given during the EUnetHTA 2006–8 project. The stakeholder forum was

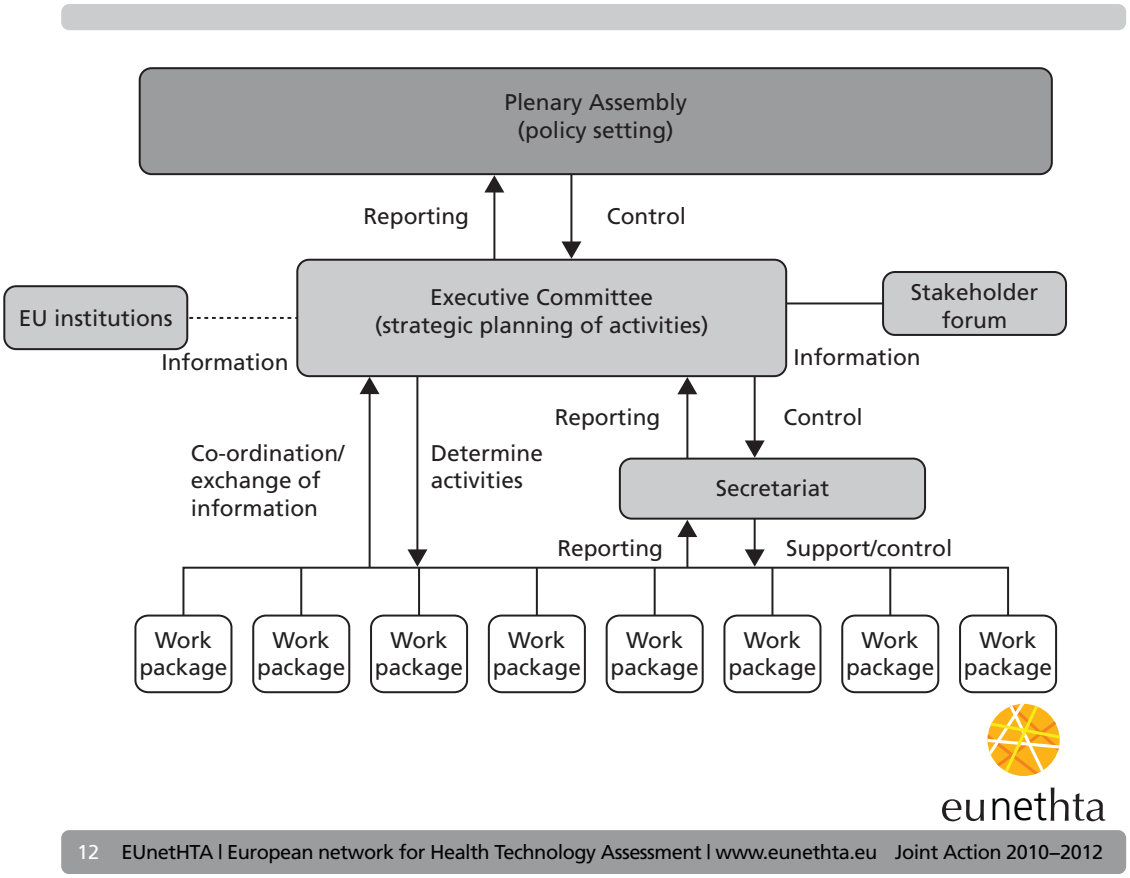

FIGURE 1 The governance structure of the EUnetHTA JA. (Reproduced from www.eunethta.eu with permission from EUnetHTA secretariat).

established in 2010 to facilitate information exchange with the stakeholders and was part of the governance structure for the EUnetHTA JA.

European umbrella organisations, with four types of expertise, were invited to apply to join the stakeholder forum: industry, patients/consumers, providers and payers. Despite several attempts it was not possible to recruit experts to the health media category. Some eligible organisation that were approved for participation in the EUnetHTA JA stakeholder forum were not selected for the final list of the EUnetHTA JA stakeholder forum members because of the limitation of the number of seats per stakeholder group. These organisations received all the information that was circulated to members of the stakeholder forum. They were able to provide written comments on such documents through representative organisations on the forum or via the secretariat. Expertise was represented as follows.

Industry

- The European Co-ordination Committee of the Radiological Electromedical and Healthcare IT Industry (COCIR).
- The European Federation of Pharmaceutical Industries and Associations (EFPIA).
- The European Generic Medicines Association (EGA).
- Eucomed.

Four organisations applied to be members of the stakeholder forum, but were unsuccessful in gaining a place:

- Association of the European Self-Medication Industry (AESGP)
- European Diagnostic Manufacturers Association (EDMA)
- EuropaBio
- The European Association of Pharmaceutical Full-line Wholesalers (GIRP).

Patients/consumers

- The European Consumers' Organisation (BEUC).
- The European Cancer Patient Coalition (ECPC).
- The European Patients' Forum (EPF).
- The European Rare Diseases Organisation (EURORDIS).

An additional organisation applied to join the EUnetHTA JA stakeholder forum, but was unsuccessful in gaining a place:

- The European Federation of Neurological Associations (EFNA).

Providers

- The Standing Committee of European Doctors (CPME).
- European Hospital and Healthcare Federation (HOPE).

Payers

- Association Internationale de la Mutualité (AIM).
- European Social Insurance Platform (ESIP).

European network for Health Technology Assessment Joint Action: project deliverables

There were eleven project deliverables, which are shown in *Table 2*.

TABLE 2 The project deliverables of the EUnetHTA JA[13]

Number	Title	Description	Work package responsible	Month of delivery
1	An online tool and service for producing, publishing, storing and retrieving HTA information	It facilitates the use of the paper-based HTA Core Model developed previously, allowing to produce, publish, store and retrieve core HTAs and other HTA information not included in core HTAs. It supports production of local reports using core HTAs	WP4	December 2012
	HTA Core Model on screening	A new application of the HTA Core Model	WP4	March 2011
2	A set of two core HTAs	Two completely new core HTAs on topics that are pertinent to several HTA agencies and that can be utilised when producing local HTA reports on the same topics	WP4	December 2012

continued

TABLE 2 The project deliverables of the EUnetHTA JA[13] (*continued*)

Number	Title	Description	Work package responsible	Month of delivery
3	A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals	A common methodology for REA of pharmaceuticals consisting of a tutorial that describes the fundamental principles of REA and a toolbox that can be used in daily practice for REA in standardised fashion	WP5	December 2012
4	Operational web-based toolkit including database-containing information on evidence generation on new technologies	Database including information on: • questions that deserve AEG • technologies with (conditional approval) requirements for AEG • planned, ongoing or completed collection of data, e.g. (pragmatic) clinical trials	WP7	September 2012
5	Quarterly communication protocol for information flow on ongoing/ planned national assessments of same technologies	Protocols containing information on ongoing/planned national assessments of identical and therefore alerted topics, to facilitate the analysis of hindrances and chances of collaboration on specific topics	WP7	December 2012
6	IMS and the related documentation, processes and policies	The IMS provides a single point of access ensuring compatibility to resources that help to conduct HTA, with emphasis on automation of the content update processes	WP6	September 2012
7	Communication and dissemination plan	Building on the communication strategy developed during EUnetHTA 2006–8 project, an elaborated communication and dissemination plan will be written and implemented as part of the EUnetHTA JA	WP2	June 2011
8	Stakeholder policy	Development of a stakeholder involvement policy	WP1/WP8	October 2010
9	Collaboratively developed business model for sustainability	Development of a collaborative business model for sustainability	WP8	December 2011
10	A relative effectiveness assessment of a (group of) pharmaceutical(s)	As a part of methodological guidance development and in line with the core-HTA development	WP5	March 2012
11	Final report from the EUnetHTA JA	Final report including evaluation results	WP3	December 2012

AEG, additional evidence generation; IMS, information management system; REA, relative effectiveness assessment; WP, work package.

Tools

Tools were developed during the EUnetHTA JA to help the production of HTA reports and collaboration in HTA:

- **EUnetHTA Planned and Ongoing Projects Database (POP; Ludwig Boltzmann Institute, Vienna, Austria):** This database was developed during the new technologies work package (WP7). It aims to reduce duplication in HTA production and to facilitate collaboration between HTA agencies. During 2010 it was available as an Microsoft Excel datasheet (Microsoft Corporation, Redmond, WA, USA) and was converted into a database in 2011. Access to the POP database was restricted to those EUnetHTA Partners who contributed data.
- **HTA Core Model:** This online tool aims to help with the production, storage and utilisation of structured HTA information. It was developed during the EUnetHTA 2006–8 project and work continued in EUnetHTA JA in the HTA Core Model work package (WP4).
- **EVIdence DatabasE on New Technologies (EVIDENT):** The EVIDENT was developed from the EUnetHTA Interafe to Facilitate Furthering of Evidence Level (EIFFEL) database which was developed during the EUnetHTA 2006–8 project. It allows the sharing of information about promising new health technologies, remaining evidence gaps, recommendations or requests for further information and additional data being collected.

Informing clinical decision-makers about clinical research studies under development: development of a data set to inform a registry

The number of clinical trials is increasing yearly and many are undertaken for regulatory purposes. These are explanatory in nature, thereby identifying whether or not an intervention can produce the desired effect under ideal conditions.[14] Such trials tend to be small in scale or involve investigational interventions which are not in wide clinical use. By their nature they take place within small communities of investigators. They are often funded by manufacturers or research charities – organisations with no wider responsibility beyond their shareholders or donors.[15]

However, there is progressive growth and interest in pragmatic trials (and other prospective study designs) which are designed to deliver clinical effectiveness and cost-effectiveness information to directly inform policy, commissioning and clinical decision-makers. Pragmatic studies reflect the actual environment in which clinical practice occurs and create robust evidence to inform these decision-makers,[16,17] including organisations such as the National Institute for Health and Care Excellence (NICE) in the UK. These studies are often large and expensive – as they often involve active comparators and 'soft' concepts such as 'usual care' and 'best current treatment'.[18] They are often commissioned through publicly funded research management organisations, such as the NIHR in the UK and, hence, these funders must consider taxpayer value for money in their decision-making processes. This is money which if not spent on medical research would, in all likelihood, have been spent on direct clinical care. It behoves such funders to be aware of the activities of their counterparts in other international funding agencies so as not to commission work when the answers would be available elsewhere.

For established, funded clinical trials the scenario is simple. All such studies should be entered into one of a number of international clinical trials registries, such as ClinicalTrials at the National Institute of Health and Current Controlled Trials. Among other benefits, this enables:

- triallists to see what work is under way in their field
- clinicians to identify trials in which they might like to take part or enrol their patients
- reviewers and policy-makers to assess publication bias, by using registered trials as a denominator.

Some funders make this a condition of funding and many journals will only publish studies which have been prospectively registered.[19,20] A funder, therefore, only has to check a limited number of registries for overlapping studies to become aware of what is already under way in a field and decide if it is sufficiently similar to what is planned.

The scenario is much more complex for pragmatic trials when earlier in their gestation. A trial is effectively invisible outside the organisation which may fund it when it is anywhere in its life from a funder having an idea or receiving an application through to a short period of time after a funding decision. Importantly, this runs the risk of multiple funders accidentally spending their limited resource on similar studies – which, perversely, may not be similar enough to allow subsequent meta-analysis of outcomes. Existing registries go part way to addressing this need by allowing funders to identify trials that are under way. However, there remains a gap because there is no widely used registry that tracks trials in development. Therefore, funders run the risk of developing trials in parallel, which may have been avoided or ameliorated if they had been aware of parallel activity.

An example of limited alignment of outcome measures is illustrated by the SOLD (Synergism or Long Duration), PERSEPHONE (Phase III Randomized Study of Neoadjuvant or Adjuvant Trastuzumab (Herceptin®) in Women With HER2-Positive Early Breast Cancer) and PHARE (Protocol of Herceptin Adjuvant With Reduced Exposure, a Randomised Comparison of 6 Months vs 12 Months in All Women Receiving Adjuvant Herceptin) trials, which were all funded around 2006.[21,22] These studies all compared the use of various durations of trastuzumab (Herceptin®, Genentech), using patient relevant outcomes and were, in essence, pragmatic in design. The commissioned trials are comparatively 'stand alone'. None of their primary outcomes were directly comparable – they used different measures, and those with similar measures assessed them at different end points. It is likely that had the agencies been aware of these trials in parallel development, they could have included appropriate outcome measures to facilitate meta-analysis or other comparison between them.

An example of what should be possible is the interaction between the CATT (Comparison of Age-Related Macular Degeneration Treatments Trials) and IVAN [A randomised controlled trial (RCT) of alternative treatments to Inhibit VEGF in patients with Age-related choroidal Neovascularisation (IVAN)] trials.[23–25] These trials investigated the use of ranibizumab and bevacizumab (Avastin®, Genentech) in the management of wet age-related macular degeneration (AMD). Briefly, both agents are manufactured by the same drug company. Ranibizumab is licensed for the management of wet AMD and bevacizumab is not. Ranibizumab is approximately two orders of magnitude more expensive. There were good biological reasons to believe that both drugs would have similar clinical effectiveness in the management of wet AMD. Discussion between the trial teams during the design and set up of these trials led to an agreed set of primary and secondary outcome measures and a subsequent demonstration that neither drug is superior to the other. Given the hostility of the pharmaceutical industry towards these trials (and the implication of their findings for industry profit margins), the similar results demonstrated against the same outcome measures will give commissioners added confidence should they decide to commission a service based on the cheaper (and, hence, more cost-effective) agent.

There is, therefore, a need for a system to facilitate the identification of pending similar pragmatic studies by international trial funders. This would enable optimisation of scarce public resources – both financial, and in terms of patients and researchers. Desbiens suggested that a 'Registry of Hypothesis' should be developed and shared by the medical community.[26] It seems to us that such a registry is too far divorced from the reality of actual funding of a trial – there are many ideas but not all are worth committing resources to. In addition, to a funder, what is important is not who had an idea, but who else might be funding a relevant trial.

It was therefore considered that a registry of 'trials which funders are considering' could have potential for filling this gap, and led to several opportunities:

- Funders could commit to one multinational study, rather than multiple smaller studies.
- Funders could ensure that at least some outcome data in multiple studies would be directly comparable – thus facilitating meta-analysis.
- On a global basis, this would facilitate an optimum distribution of trial funding, e.g. knowledge of what each funder had planned could facilitate interfunder discussion to obtain maximum value from the resources each had to contribute.
- With an indicative map of possible trials, systematic reviewers may be able to better plan when to conduct updates of existing reviews.
- Similarly, policy-makers may be able to plan when to consider updates of their guidance.

Such a registry could (indeed, should) include the hypothesis to be tested, therefore addressing Desbiens' call for hypotheses to clearly be developed a priori.[26]

We considered who such a registry should be aimed at and, specifically, who should register potential studies and who should have read access. The two options are funders and researchers. The incentives and disincentives are different for the two groups.

Funders are motivated to avoid unconscious duplication of funding and maximise the value of the overall research resource they control. They are, therefore, more likely to register studies they are considering with a registry and keep that information up to date.

A researcher might feel this, but is also driven to obtain funding for their own ideas and, hence, avoid the risk of having their research ideas copied by others. We considered that an individual researcher is less likely to submit their ideas to a public registry.

Therefore, we consider that a registry for pragmatic trials in development is more likely to work if the main adopting groups are trial funders.

Should a registry go ahead, consideration should be given to its performance characteristics, but also whether or not it contributes to the originally identified issues of reducing unconscious duplications and promoting discussion and potentially collaboration between funders.

Chapter 2 Methods

Evaluation of the processes of the European network for Health Technology Assessment Joint Action project

Evaluation approach

Internal evaluation process

Evaluation is an important facet of project management and evaluation of the EUnetHTA JA was a requirement of the EU. There are two types of evaluation: internal evaluation (performed by staff directly involved in the project work) and external evaluation (performed by an expert who is not involved in the project). The EU Commission had specified that the former approach should be used, as it had been used in the previous EUnetHTA 2006–8 project. As recommended in conducting evaluations of European projects, the evaluation plan was a key component and integrated within the EUnetHTA JA project from the beginning.[27]

These activities were the subject of a specific work package [WP3 (Evaluation)], led by the NETSCC represented by Dr Eleanor Guegan and Dr Andrew Cook.

Strategic evaluation outcome

Rationale

Evaluation has been defined as, the 'systematic assessment of the operation and/or the outcomes of a program or policy, compared with a set of explicit or implicit standards, as a means of contributing to the improvement of the program or policy'.[28] Such critical reflection can be performed retrospectively (after the programme has ended) or prospectively (designed at the start of the programme). A prospective methodology is the gold standard for evaluation research and was used to evaluate the EUnetHTA JA.

Project evaluation allows monitoring of the processes of the project and achievements against specified criteria for success. This enables assessment of the effectiveness and achievements of the project and the formation of 'lessons learned' recommendations to inform future projects. It also ensures accountability against project plans.[29] There are three main types of evaluation for projects:[29]

1. **Formative evaluation:** This ongoing evaluation starts early in the project and assesses the nature of the project, the needs that the project addresses and monitors the progress of the project. It identifies gaps in the content and operational aspects.
2. **Process evaluation:** This monitors the project to ensure it is being completed as designed and to the time schedule.
3. **Summative evaluation:** This is an overall assessment of the project's achievements and the effectiveness of its processes. It is completed at the end of the project and provides evidence to support the performance of future projects.

The first stage in the evaluation process was creating a project evaluation plan. The main purpose of the evaluation was to identify to what extent the individual work packages enabled the EUnetHTA JA to meet its objectives. This included project participants' and external stakeholders' perception of the project processes and deliverables. Documentary review enabled identification about whether or not the deliverables had been produced by the work streams according to the work plan.

This evaluation was a systematic data collection designed to develop generalisable knowledge and to contribute to quality improvement of the EUnetHTA JA project:

i. The impact of the project was assessed by an outcome evaluation (identifying the success of delivering the stated project deliverables). However, it should be noted that, although it was possible to measure whether or not the outputs had been delivered in accordance with the work plan, assessment of their quality and cost–utility was beyond the scope of the evaluation agreed by the EU Commission.
ii. The effectiveness of the project was evaluated by its processes (identifying the effectiveness of the processes employed during the project).

Evaluation questions

There were two primary evaluation questions:

1. Will the EUnetHTA JA achieve its overarching objective, and ultimately did it?
   The overall objective was defined in the technical annex for the EUnetHTA JA as, 'The overarching objective of the JA, including work on relative effectiveness of pharmaceuticals, is to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level.'
   This was assessed by whether or not an effective and sustainable HTA collaboration, not reliant on project funding, had been set up at the end of the EUnetHTA JA project.

2. Will the EUnetHTA JA achieve its specific objectives, and ultimately did it?
   Three subobjectives were defined in the technical annex of the grant agreement for the EUnetHTA JA[13] as:

   – Development of a general strategy and a business model for sustainable European collaboration on HTA.
   – Development of HTA tools and methods.
   – Application and field-testing of developed tools and methods.

   - Documentary analysis was used to determine whether or not the work packages had produced their deliverables by the end of the EUnetHTA JA project.
   - A prospective evaluation strategy mapped out and evaluated how the activities and deliverables of the individual work packages supported the EUnetHTA JA objectives. The individual work packages within the EUnetHTA JA can themselves be seen as individual projects (with their own objectives, milestones and deliverables) contributing to the overall programme of work of the EUnetHTA JA. This means it was necessary to aggregate evaluation outcomes from the individual projects.

Questions were included in the questionnaires sent to participants to examine:

- demographic information about the nature of participants, their organisations and the HTA information they produce
- the setting-up process for the project
- progress of the project in the interim year
- administrative support and communication from the co-ordinating secretariat
- the role of information technology in supporting the project
- involvement of external stakeholders
- the workings of the eight internal work packages
- the planned follow-up project – European network for Health Technology Assessment Joint action 2 (EUnetHTA JA2).

Questions were included in the questionnaires sent to external stakeholders to examine:

- the mechanisms of the stakeholder forum
- the EUnetHTA JA project
- the workings of the eight internal work packages
- the planned follow-up project – EUnetHTA JA2.

Various terms were used in the evaluation and these are summarised in *Box 1*.

Evaluation methodology

Possible evaluation methods

Several research instruments could have been used to perform the evaluation, such as interviews, focus groups, observations, case studies, questionnaires and document review, which are described below:

- **Interviews:** This research methodology enables the probing of a topic with one interviewee to explore meanings and uncover new areas not anticipated at the outset of the research.[30] These can adhere strictly to a formalised interview schedule (structured) or allow divergence from a schedule to pursue an idea in more detail (semistructured).[30] They have the advantage of probing a subject in detail to obtain rich qualitative data, but are expensive and can be difficult to arrange. It would have been useful to have used this methodology in the evaluation to probe the questionnaire data in greater depth, but unfortunately this was beyond the resource agreed by the EU.
- **Focus groups:** This is a form of group interview that generates data from the interaction of the group participants.[31] This has particular advantages in exploring the way people think and perceive things, with findings being generated as a result of group discussions. Like individual interviews, they allow the probing of qualitative data. However, they are expensive and it can be difficult to arrange all participants together in one location at a specified time to conduct the focus group.[31] It would have been useful to have employed this methodology in the evaluation, for instance with a group of stakeholders, but unfortunately this was beyond the resource agreed by the EU.

BOX 1 Terminology used in the evaluation

Overarching objective: This was the main objective of the EUnetHTA JA and was assessed by whether or not an effective and sustainable HTA collaboration, not reliant on project funding, had been set up at the end of the EUnetHTA JA project.
Specific objectives: These were the secondary project objectives of the EUnetHTA JA and were assessed by documentary analysis of whether or not the specified deliverables had been produced.
Deliverables: These were the 11 specific deliverables (see *Table 2*) that the project committed to produce. Whether or not these had been delivered according to plan was assessed by documentary analysis of final technical reports submitted by work packages at the project end.
Performance indicators: These are criteria developed for evaluation of the overall success of the project.
Project impact: This was measured by evaluating whether or not the project's overarching objective and specific objectives had been met and the deliverables produced. These were the specific performance indicators to enable judgement about the project's impact.
Project effectiveness: This was measured by evaluating how well the project's processes had worked. The specific performance indicators for this were assessment of communication within the project, administration by the co-ordinating secretariat, involvement of external stakeholders and management of the eight constituent work packages. Whether or not lessons had been learnt and progress made from the preceding EUnetHTA 2006–8 project was also evaluated.

- **Observations:** This methodology involves the researcher systematically watching people and events to discover behaviours and interactions in a setting, then describing and analysing what has been observed.[32] This allows identification of any discrepancies between what people say they do and what they actually do. This method was not considered appropriate for the current evaluation.
- **Case studies:** This research methodology is used when broad questions need to be addressed in complex circumstances and it typically involves mixed methods of quantitative and qualitative methods.[33] The selection of sites is of key importance to this methodology. This method was not considered appropriate for the current evaluation.
- **Self-completion questionnaires:** These confer several advantages for collection of data from project participants and external stakeholders: standardisation of question wording eliminates the possibility of interviewer bias, respondents are allowed to complete the questionnaire at their own convenience and a greater degree of confidentiality is provided than in interviews.[34] However, they also pose several disadvantages; they are difficult to design, are impersonal and inflexible and are dependent on having a valid sampling frame of the correct details of recipients.[27] They are often the only viable survey format when trying to obtain information from a large cohort of respondents that are within a geographically dispersed population.[35]
- **Documentary review:** This allows review of a project using documents routinely produced without artificially interfering with the project. This enables retrieval of contextual and historical information about a project. However, by definition this means that the data collection is limited and inflexible, and incomplete data might be encountered.

It was necessary to select which evaluation methods would be most appropriate and feasible within the economic, geographic and time restraints of the project. The methods chosen were self-completion questionnaires (owing to the international location and large number of evaluation participants) and documentary review. It would have been ideal to have also used key informant interviews to obtain richer, qualitative data about what was going well in the project, what could be improved and suggestions for improvement, etc. However, unfortunately, this was not possible owing to time and cost restraints (according to the scope of the evaluation agreed by the EU), and this is a major limitation of the methodology. This meant that it was unfortunately not possible to follow up non-respondents to questions with qualitative enquiry to interpret their views. This has meant that the reasons for non-response have been speculated but it was impossible to substantiate this.

Self-completion questionnaires

The evaluation participants were in two survey populations:

- project participants – members of EUnetHTA JA partner organisations
- external stakeholders.

This allowed triangulation of information between the project participants and external stakeholders for common topics. Participants at the annual policy-setting plenary assembly meeting were asked to evaluate the meeting.

- Annual electronic surveys were sent to project participants and external stakeholders. In some cases the same questions were repeated in questionnaires of different years to allow some assessment of longitudinal data. However, evaluation of such longitudinal elements was severely limited because the large turnover of staff meant it was difficult to assess whether an element had changed over time or this change was due to the responses of different respondents.
- Paper questionnaires were disseminated at each of the annual plenary assembly meetings which asked respondents to evaluate the meeting.

The process for each questionnaire followed the same schedule (*Figure 2*).

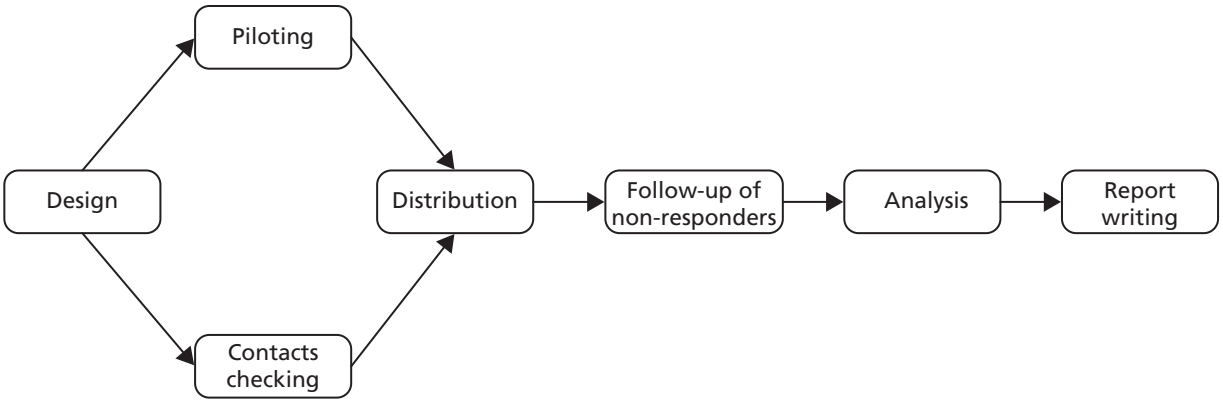

FIGURE 2 The processes followed for the questionnaires.

Compilation of questionnaire themes

The first stage in the design of a questionnaire is the preparation of a 'questionnaire specification' – a comprehensive list of every variable that must be measured.[36] In the current research these were the important aspects, or 'dimensions of performance', of the EUnetHTA JA project that needed to be measured.[27] In any evaluation it is impossible to assess all component parts of a project and, therefore, a conscious selection process was performed to consider what needed to be evaluated. Questions were then grouped into a series of 'question modules' each concerned with a particular variable, as recommended for survey design.[36] Attention was paid to the order of the individual questions within the question modules to ensure a logical sequence throughout the questionnaire.

Evaluation of the processes of the European network for Health Technology Assessment Joint Action project

A mapping exercise was undertaken to identify which aspects of the project should be assessed at the different time points. One of the objectives of the evaluation was to 'generate maximum support for the work packages whilst actively seeking evaluation and monitoring solutions that minimise the burden'. This objective was met by decreasing the burden of answering extra questionnaires issued by different work packages. This was achieved by combining questions from other work packages into the questionnaires. The evaluation had been specifically contracted to include questions from the information management work package (WP6). As a courtesy it also included questions from the training strand of the WP8 work package in all three questionnaires and from the dissemination work package (WP2) in 2010. Extensive collaboration was undertaken with the leaders of these other EUnetHTA JA work packages to incorporate their questions. In addition, a questionnaire design workshop was held with participants of the WP6.

Evaluation was performed at three checkpoints within the project, i.e. baseline, interim and towards the end:

- The formative evaluation started at the baseline of the project (month 6, June 2010). This incorporated the key processes of measuring and monitoring to enable identification of emerging issues, and feedback to the executive committee by evaluation reports. These reports were an appendix to the annual reporting mechanism. The baseline questionnaire captured expectations for the project, experiences during the set-up and identified early concerns about the project.
- The interim evaluation (mid-term evaluation) of progress against the project plan was performed in month 18 of the project (June 2011). This identified progress against the plan and identified problems requiring corrective action, which were fed back to the executive committee.
- The final annual questionnaire survey was performed in month 30 (June 2012). This was a towards-the-end evaluation to identify whether or not the objectives of the EUnetHTA JA had been met and flagged-up problems effectively resolved. A limitation of the evaluation was that the EU had requested this be completed before the end of the project.

Evaluation of the plenary assembly meetings

Following the process described above, a standard paper evaluation form was designed to measure participants' attitudes about attributes of this policy-setting meeting. This was designed to consider:

- whether or not the meeting met its objectives
- satisfaction with the conference venue and facilities
- what the best thing about the meeting was
- what the worst thing about the meeting was
- how the next year's meeting could be improved.

Analysis of the 'open' questions from the 2010 survey allowed identification of themes. Therefore, the 2011 and 2012 surveys also included a grid of meeting attributes and Likert answer options to address these themes:

- receiving meeting documents in advance
- leadership of the meeting
- relevance of items discussed
- meeting and networking with colleagues
- venue and meeting facilities
- social event.

At the request of the secretariat, additional questions were included in the 2011 and 2012 surveys. These addressed:

- when meeting documents were received
- when meeting documents were read
- input into developing the meeting agenda.

Question design

Broadly speaking, there are two types of questions that can be used in questionnaires: 'closed' questions and 'open' questions. Both types of questions were used in the questionnaires.

Closed questions have possible answers predefined by the survey designer and are analysed by frequency measures. They are several different formats: multiple choice, only one choice, Likert scale and matrix. They have the advantage of being easier to analyse than open questions.[37] Multiple-choice questions allowed various choices to be chosen as applicable or may only allow one answer. Likert questions requested respondents to indicate their response according to a predefined scale. However using closed questions means that respondents do not have the ability to provide their own response and, therefore, the richness of potential responses can be limited.[38] There is also the possibility that the answer options are biased and it is important to test this during the piloting phase. A limitation of closed questions is that respondents do not have the ability to explain their answers.[39] This aspect was considered in the design of the questionnaires in the evaluation. To counterbalance this potential problem, most closed questions also included a free-text box to allow respondents to explain their answer, if they wished. This type of question is classified as an 'expansion' open question. Such questions act as safety nets, explaining the results of closed questions and identifying new issues not covered by closed questions.[24]

Open or free response questions allow respondents to provide their own answers and allow respondents to express their thoughts in their own language.[36] These enable respondents to explain their responses and provide qualitative data. Although these types of questions provide rich data they require more effort to analyse and this was factored into the analysis period.[39] The Cochrane systematic review about methods to increase response to postal and electronic questionnaires identified that the odds of response were reduced by more than half when open questions are used.[40] It was important to be aware of this and to design the questionnaire to contain both open and closed questions. The majority of questions combined

a closed question with an open question asking the participant to provide further detail about their response.

The questions included in the participant questionnaires are summarised below in *Table 3*.

The questions included in the external stakeholder questionnaires are summarised in *Table 4*.

Attention was paid to the design and wording of the individual questions, according to recognised guidance:[36,41]

- avoid long questions
- avoid double-barrelled questions
- avoid double negatives
- ensure inclusion of 'Don't Know' and 'Not Applicable' answer options where applicable
- use simple words, avoid jargon, and avoid abbreviations
- avoid ambiguous words
- make questions specific
- ensure all reasonable response alternatives are included.

TABLE 3 Questions included in questionnaires for the project participants

Question topic	Question type	Baseline questionnaire (2010)	Interim questionnaire (2011)	Final questionnaire (2012)	Tracker question
Demographics					
Professional expertise	Closed	✓	✓	✓	✓
Gender	Closed	✓	✗	✗	✗
Age	Closed	✓	✓	✓	✓
Length in HTA	Open	✓	✗	✓	✓
Membership of international HTA organisations	Closed	✓	✗	✗	✗
HTA practitioner	Closed	✗	✓	✓	✓
Lead person	Closed	✗	✓	✓	✓
Organisational expertise	Closed	✗	✗	✓	✗
Organisational and HTA information					
Difficulties applying	Combined	✓	✗	✗	✗
Sufficient funding	Combined	✓	✓	✓	✓
Sufficient staff	Combined	✓	✓	✓	✓
Succession planning	Combined	✓	✗	✗	✗
HTA information	Closed	✓	✗	✓	✓
Setting-up process					
Achievement of objectives	Combined	✓	✗	✗	✗
Set-up with EU	Combined	✓	✗	✗	✗
Organisation into work packages	Combined	✓	✗	✗	✗
Understand the aims of work packages	Closed	✓	✗	✗	✗

continued

TABLE 3 Questions included in questionnaires for the project participants (*continued*)

Question topic	Question type	Baseline questionnaire (2010)	Interim questionnaire (2011)	Final questionnaire (2012)	Tracker question
Foundation as a sustainable collaboration	Combined	✓	✗	✗	✗
Progress					
Achievement of objectives	Combined	✗	✓	✓	✓
Foundation of a sustainable European collaboration	Combined	✗	✓	✓	✓
Value added	Combined	✗	✓	✗	✗
Concerns about work packages	Combined	✗	✓	✓	✓
Evaluation					
Achievements	Combined	✗	✗	✓	✗
Personal gain	Combined	✗	✗	✓	✗
External promotion	Open	✗	✗	✓	✗
Administration and communication					
Secretariat leadership	Combined	✓	✓	✓	✓
Secretariat administration	Combined	✓	✓	✓	✓
Secretariat other activities	Combined	✓	✗	✗	✗
Understood information needed	Combined	✓	✗	✗	✗
Secretariat e-mails	Combined	✓	✗	✗	✗
Project intranet	Combined	✓	✗	✓	✓
E-meetings	Combined	✓	✗	✗	✗
Communication issues	Combined	✓	✓	✓	✓
Communication methods	Combined	✗	✓	✓	✓
Project conference	Combined	✗	✗	✓	✗
Renewal of project identification	Combined	✗	✗	✓	✗
Improvement of communication	Open	✗	✓	✗	✗
Project challenges	Open	✓	✓	✓	✓
Project benefits	Open	✓	✓	✓	✓
Negative effects of participation	Combined	✗	✓	✓	✓
Positive effects of participation	Combined	✗	✓	✓	✓
Information technology					
Operating system	Closed	✓	✗	✗	✗
Browser	Closed	✓	✗	✗	✗
Software packages	Closed	✓	✗	✗	✗
Communication systems	Closed	✓	✗	✓	✓
Social media	Closed	✓	✗	✓	✓
Smart phone/tablet	Closed	✗	✗	✓	✗

TABLE 3 Questions included in questionnaires for the project participants (*continued*)

Question topic	Question type	Baseline questionnaire (2010)	Interim questionnaire (2011)	Final questionnaire (2012)	Tracker question
Tools					
Use/awareness	Closed	✓	✓	✓	✓
Priority for training	Closed	✓	✓	✓	✓
Preferred training method	Closed	✓	✗	✓	✓
Anticipated mobile use	Closed	✗	✗	✓	✗
Barriers to tools	Closed	✓	✓	✓	✓
Improvements to tools	Open	✓	✓	✓	✓
Stopped using tools	Open	✗	✗	✓	✗
Stakeholders					
Concerns	Open	✗	✓	✓	✓
Benefits	Open	✗	✓	✗	✗
EUnetHTA JA2					
Concerns	Combined	✗	✓	✓	✓
Process	Combined	✗	✓	✗	✗
Impact of planning	Combined	✗	✓	✗	✗
Improvement	Open	✗	✓	✗	✗
Use as a follow-up	Combined	✗	✗	✓	✗
Main learning point	Open	✗	✗	✓	✗
Involvement of stakeholders	Open	✗	✗	✓	✗
Improvement of communication	Open	✗	✗	✓	✗
Work packages					
WP1	Combined	✓	✓	✓	✓
WP2	Combined	✓	✓	✓	✓
WP3	Combined	✓	✓	✓	✓
WP4	Combined	✓	✓	✓	✓
WP5	Combined	✓	✓	✓	✓
WP6	Combined	✓	✓	✓	✓
WP7	Combined	✓	✓	✓	✓
WP8	Combined	✓	✓	✓	✓

TABLE 4 Questions included in the questionnaires for the external stakeholders

Question topic	Question type	Baseline questionnaire (2010)	Interim questionnaire (2011)	Final questionnaire (2012)	Tracker question
Stakeholder forum					
Purpose of stakeholder forum	Open	✓	✓	✗	✓
Fulfilment of purpose	Combined	✗	✓	✓	✓
Awareness of stakeholder forum	Open	✓	✗	✗	✗
Why applied for membership	Open	✓	✗	✗	✗
Membership role as expected	Combined	✗	✓	✗	✗
Role as a member of the forum	Open	✓	✗	✗	✗
Role represents a good use of organisation's time	Combined	✗	✓	✓	✓
Benefits of membership	Open	✓	✗	✓	✓
Challenges of membership	Open	✗	✗	✓	✗
Effectiveness of the stakeholder advisory groups	Open	✗	✓	✓	✓
Contributions to the project	Open	✗	✓	✓	✓
Offer by membership	Open	✓	✗	✗	✗
Setting up of the forum	Combined	✓	✗	✗	✗
Comments about relevant documents	Open	✓	✗	✗	✗
Comments about the meetings	Open	✓	✓	✓	✓
Consideration of stakeholders' views	Combined	✓	✓	✓	✓
Feedback to stakeholders	Open	✓	✓	✓	✓
Correct organisations included	Combined	✗	✗	✓	✗
Concerns about involvement of stakeholders	Combined	✗	✗	✓	✗
EUnetHTA JA project					
Achieving objectives	Combined	✓	✓	✓	✓
Organisational structure	Combined	✓	✗	✗	✗
A foundation for a European collaboration	Combined	✓	✓	✗	✓
Functions of a European collaboration	Open	✓	✓	✓	✓
Added value of a European collaboration	Combined	✗	✗	✓	✗
Achievement of a European collaboration	Open	✗	✓	✗	✗
Interactions of a European collaboration with stakeholders	Open	✗	✓	✗	✗
Attendance at plenary assembly meeting	Combined	✗	✓	✗	✗
External project promotion	Combined	✗	✗	✓	✗

TABLE 4 Questions included in the questionnaires for the external stakeholders (*continued*)

Question topic	Question type	Baseline questionnaire (2010)	Interim questionnaire (2011)	Final questionnaire (2012)	Tracker question
Use of tools for HTA producers	Combined	✗	✗	✓	✗
Would appreciate training in tools	Combined	✗	✗	✓	✗
Holding a regular conference	Combined	✗	✗	✓	✗
EUnetHTA JA2					
Consultation about planning	Combined	✗	✓	✗	✗
Concerns about EUnetHTA JA2	Combined	✗	✓	✓	✓
Usefulness as a project follow-up	Combined	✗	✗	✓	✗
Learning from EUnetHTA JA to inform EUnetHTA JA2	Open	✗	✗	✓	✗
Improvement of communication	Open	✗	✗	✓	✗
Work packages					
WP4	Combined	✓	✓	✓	✓
WP5	Combined	✓	✓	✓	✗
WP7	Combined	✓	✓	✓	✗

Formatting

It is important that questionnaires are designed to be visually attractive as this has been shown to encourage high response rates.[39] In this respect, the layout and flow of the questionnaires was important and the ordering of questions needed to be logical.

Checking of recipient details

It was vital to have an accurate sampling frame for the questionnaires. This ensures that all relevant recipients have been surveyed and ensures integrity of the response rate calculation. It is difficult, but necessary, to differentiate between genuine non-responders and those recipients for whom an incorrect name or e-mail address has been used; therefore, the use of an accurate mailing is essential.[42]

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It was feasible to survey the entire population and, therefore, no selected sampling was required. An Excel database was obtained from the EUnetHTA JA secretariat which contained details of the EUnetHTA JA project participants in the individual project work packages. This was restructured into a comprehensive database of all the project participants using the following data fields:

- first name
- surname
- e-mail address
- organisation
- membership of individual work packages.

The heads of each organisation were asked to confirm the validity of the information of their staff working for EUnetHTA JA. This feedback resulted in a fairly substantial refinement of the contact database.

A pre-notification e-mail was sent to all project participants in advance of sending them a questionnaire. This enabled the correction of any incorrect information and querying of e-mails for which 'bounce backs' were obtained. Pre-notification of survey recipients prior to the questionnaire send-out is a strategy that has been shown to increase response rate by 50%.[40] It emphasises the legitimacy of the questionnaire and communicates the value of response.[43] For the current study each recipient of a questionnaire was sent an e-mail 1 week before the send-out notifying them when the questionnaire would be sent to them, the importance of their completing it and the deadline for completion. This also served the purpose of checking e-mail addresses and correcting any errors about work package membership (in the case of project participants) or sending the survey to a nominated colleague instead (in the case of stakeholders).

Details of the representatives of the stakeholder organisations were also obtained from the EUnetHTA JA secretariat.

Evaluation of the plenary assembly meetings

All participants who attended a meeting were surveyed. Therefore, it was unnecessary to perform this stage because the recipients were physically in the room.

Piloting

One disadvantage of the use of self-completion questionnaires is that questions may remain non-completed, without the possibility of explanation. Therefore, time and effort must be spent on designing useful, unambiguous questions. It is important that both the *reliability* and *validity* of the questionnaire instrument is assured:

- Reliability concerns how different people will interpret a question. For a question to be classified as 'reliable' respondents must interpret it in the same way and it must therefore be repeatable.[36]
- Validity concerns whether or not the questionnaire actually measures the data it intends to.[27]

Before sending out the questionnaire to the recipients it is essential to pilot it on a representative sample first. This is a 'quality assurance' method to ensure that the questionnaire contains the correct spelling, is grammatically correct and has a good layout. It also aims to prevent any problems with comprehension and to ensure that the format of the overall survey instrument and individual questions are appropriate.[39] It was important to consider that this was a European project with participants communicating in the common language of English. This was therefore not the native language of the vast majority of participants. Special considerations must be given to the interpretation of question wording and answer options by respondents who are not native English speakers, ensuring the concept is properly understood. This meant that it was necessary to pilot the questionnaires with people who were non-native speakers of English, including those whose primary language was French, German or Spanish.

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Questionnaires were piloted with members of the lead partner organisation who were non-native English speakers. Comments were also sought from members of the EUnetHTA JA executive committee and the European Commission. A design workshop was held with members of WP6 in 2010 and the lead partners of WP6 (French) and WP8 (Spanish) also piloted the questionnaires prior to the send-out.

Evaluation of the plenary assembly meetings

The form was piloted by members of the lead partner organisation.

Distribution

When disseminating a questionnaire it is necessary to choose between the possible distribution methods of postal, telephone or internet. Until the 2000s, the primary means of distribution of questionnaires was by face-to-face interviews or postal questionnaires and the advantages and disadvantages of these approaches have been discussed.[36,40,41] However, the 2000s saw the advent of new distribution methods such as e-mail and the internet. The earliest electronic questionnaires involved the distribution of a document [designed in Microsoft Word® (Microsoft Corporation, Redmond, WA, USA) or similar] by e-mail. The EUnetHTA 2006–8 project was also evaluated by questionnaire. However, these were sent by e-mail and the respondent required to record their responses on a Microsoft Word document and e-mail this back to the questionnaire administrator. The effort required in e-mailing the survey back may have contributed to the low response rates received for that questionnaire (23–26% over the years 2006, 2007 and 2008).

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The choice of mode of transmission of the questionnaires in the current research was between postal mail, telephone, e-mail and web based. For this study the participants were geographically dispersed over Europe and, therefore, postal distribution was not a practical possibility owing to financial and logistical limitations. Telephone questionnaires were also impractical. A web-based questionnaire that could be completed at the convenience of the respondent was preferable and the recipients were familiar to e-mail communications and using the internet.

Web-based surveys offered several advantages compared with post for the current research: there was a significant cost reduction when considering the international survey population and a quicker turnaround time.[44] In addition to electronic transmission of surveys by e-mail, web-based applications enable automatic data collection. The design of web surveys may be more important than for print surveys. This is primarily because a web-based survey can be displayed differently to a respondent as a result of computer-related glitches and the coding system offers more design capabilities than print.[44] However, the increased ability for design capabilities must be used with some caution because too many design features may lead to overcomplication and a decreased response rate.

Different possible online survey platforms were investigated for the distribution of the questionnaires and SurveyMonkey.com® (Palo Alto, CA, USA) was selected for ease of use and function capability. A paid, professional account was selected from SurveyMonkey.com.[45] This enabled:

- an unlimited number of questions and responses
- a custom uniform resource locator (URL)
- a branded survey with a logo – use of the EUnetHTA logo and colours
- a survey completion progress bar
- a custom redirect on survey completion – to the eunethta.net project page
- a printable PDF version for sharing during design collaboration
- importing e-mails into the 'survey manager' send-out function
- easy tracking of non-respondents and distribution of follow-up e-mails.

Care was taken that the questionnaire invitations were not sent during the weekends and that the public holidays in the different European countries were avoided. As far as possible these invitations were not sent during the summer holiday season (particularly avoiding the month of August).

Evaluation of the plenary assembly meetings

The analysis of the annual EUnetHTA JA plenary assembly meetings was performed by anonymous self-completion paper questionnaires. These were included as part of the agenda pack given to the meeting participants. They were reminded to complete the questionnaire and hand it in at the end of the meeting.

Follow-up of non-respondents

It is important that as many recipients as possible submit their replies because the non-respondents might differ significantly to the respondents, thereby introducing bias into the results.[36] There seems to be no generalisable recommendation for an acceptable survey response rate. However, this should aim for the highest rate possible and above 50% has been deemed adequate.[34,46]

It should be noted that the questionnaire recipients were all associated with the EUnetHTA JA project – either project participants or external stakeholders. Therefore, they had an implicit duty to respond to the questionnaires. However, it was still necessary to employ appropriate strategies to obtain a high response rate to limit bias. A review of methods to increase the response to postal and electronic questionnaires revealed that the odds of response were increased by more than one-quarter when non-respondents were adequately followed up.[40]

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The recipients had been given a guarantee of confidentiality but not anonymity. This meant that through using the SurveyMonkey.com online platform it was possible to send targeted reminder e-mails to non-respondents. These were personalised e-mails that contained a personal weblink to the questionnaire. E-mails were designed to include two strategies that have been shown to be effective in increasing response rate: each e-mail included a statement that indicated others had responded and provided a deadline for response.[40] Reminders were generally sent 1 week after the date requested for the questionnaire completion and non-respondents were requested to complete the questionnaire within 3 weeks. Two follow-up reminders were sent at 3-weekly intervals.

Evaluation of the plenary assembly meetings

Survey response was anonymous and there was no possibility of tracking non-respondents. Therefore, it was not possible to follow up non-respondents.

Analysis

The overall percentage response rate to questionnaires was calculated as:

$$(\text{Number of questionnaires completed} \div \text{Number of questionnaires distributed}) \times 100 \quad (1)$$

It is important that the response rate to individual questions was also defined. The National Center for Education Statistics has stated that key items should achieve a response rate of at least 90%.[47] Accordingly, actual completion rates were shown for each individual question. Data from the two types of question were analysed:

- The computer software program Statistical Product and Service Solutions (SPSS®, version 19; IBM, New York, NY, USA) was used for the analysis of the quantitative questions. Descriptive statistics were included for categorical data, showing frequency and percentages.
- Thematic analysis was performed on the qualitative data responses provided to the open questions. Such inductive reasoning involves analysing the data to generate ideas.[48] The grounded theory methodology was used to compare pieces of data to develop conceptualisations to create descriptive knowledge.[48] Topics were identified and clustered into themes. This qualitative analysis was performed by only one researcher owing to the resource limitation of the evaluation agreed with the EU. This has a limitation because it might have biased the results as only one person's opinion was used. The software program NVivo® (Version 10; QSR International, Victoria, Australia) was used to help analyse the qualitative comments. When analysing open-ended questions it is important to outline the main themes and illustrate them as necessary with quotes[36] and this was done in the individual survey reports that were submitted to the secretariat annually.

Report writing

Individual reports were written for each questionnaire. These individual questionnaire reports formed appendices to the technical report submitted to the EUnetHTA JA secretariat each year.

- 2010:
  - plenary assembly evaluation survey
  - EUnetHTA JA participants' 2010 baseline survey
  - EUnetHTA JA stakeholder forum 2010 baseline survey
  - EUnetHTA JA for those that applied to join the stakeholder forum but were not successful 2010 baseline survey.
- 2011:
  - plenary assembly 2011 evaluation survey
  - EUnetHTA JA participants' 2011 interim survey
  - EUnetHTA JA stakeholder forum 2011 interim survey.
- 2012:
  - plenary assembly 2012 evaluation survey
  - EUnetHTA JA participants' 2012 final survey
  - EUnetHTA JA stakeholders' 2012 final survey.

These reports were uploaded to the EUnetHTA JA members only intranet website. Reports were written as appropriate for work package leaders and tool developers. Articles were submitted to the EUnetHTA JA project e-newsletters to encourage response rates and to report questionnaire results.

Documentary analysis

Each of the eight individual work packages was responsible for writing a final technical report about its performance in the EUnetHTA JA and these were submitted to the secretariat in mid-January 2013. The secretariat was requested to send a copy of each report for analysis in this evaluation. The documentary analysis involved one of the researchers reading the report submitted by each work package and identifying whether or not the work package stated it had produced its deliverable (in accordance with the EUnetHTA JA Grant agreement).[13] This analysis was limited because budgetary restraints of the evaluation meant that it was performed by only one researcher. In addition, it consisted solely of whether or not a work package had self-reported that it had produced the deliverable, rather than an actual observation of the existence of a deliverable.

Informing clinical decision-makers about clinical research studies under development: development of a data set to inform a registry

The project was divided into three phases:

1. development of a data set on which to base a registry
2. assessment of the potential accuracy of that data set
3. building an electronic registry based on the developed data set.

These first two phases are reported below; these are the stages of most relevance to the NIHR Health Technology Assessment programme. The final phase was performed by the French organisation, and fellow member of EUnetHTA, Haute Autorité de Santé (HAS; French National Authority for Health).

Developing the data set

The data set was developed through using the Delphi survey technique.[49–52] This is a method designed to facilitate a decision-making process by groups. It is a technique that aims to reach a consensus of a group by distributing several rounds of anonymous structured questionnaires.[50] The responses from each round are fed back to participants and the responses obtained from a round are used to formulate the next round.[50] Opinions are collected and systematically analysed to obtain consensus.[52]

Identifying participants

It was important that the data set should be of a minimum practical size, and limited to contact details and a high-level project description. It appeared evident that for a registry to be both widely accepted and useful the elements in it would need to be widely supported. Therefore, participants to our Delphi process were recruited as widely as possible.

Recruited participants fell into four groups:

1. personal contacts
2. organisations identified through the International Network of Agencies for Health Technology Assessment (INAHTA)[53]
3. organisations identified through EUnetHTA[54]
4. organisations identified through contacting groups 1–3.

We built our sampling frame by initially contacting organisations in groups 1–3. We asked each organisation which responded if it was aware of other organisations which may be interested in participating in this project. We then contacted all newly identified organisations (group 4), and repeated this process until we had exhausted all suggestions.

We initially contacted organisations that were known to relevant individuals and organisations that relevant individuals were aware had reputation as a funder or requester of pragmatic studies. A 'funder of pragmatic studies' was defined as an organisation which has a remit to allocate funds (either by grant or through a contract) for the research costs associated with pragmatic primary research. The 'study requester' is more interesting. Some organisations have a statutory power to request studies to be delivered from certain private sector entities, for example HAS can request drug studies from the pharmaceutical industry.

Organisations within two international membership organisations for HTA [INAHTA (global) and EUnetHTA (European)] were also approached. They were asked for contact details of organisations within members' countries which may fund clinical studies of this type. Each organisation that responded was also asked about other groups that they were aware of which may have been interested in this project. These groups were then contacted and, where they responded, the process was repeated (i.e. a snowball technique).

At the end of this process 17 organisations from eight countries on three continents had agreed to participate. Some countries handled their responses centrally, pooling responses from several organisations. In other countries organisations participated individually. This meant that 12 separate entities responded to the Delphi rounds *(Table 5*).

Delphi rounds

All participants were asked to take part in up to three Delphi rounds: two were initially planned, with a third held in reserve in case any issues were unresolved at the end of the second.

For each round, a background paper was prepared by the authors at NETSCC, outlining the issues to be addressed in the round and the group's thoughts so far. For the first round the authors prepared an initial draft of the data set in order to give the group something to start critiquing and changing. A questionnaire was prepared using SurveyMonkey.com for participants to complete. The principles of

TABLE 5 Respondents to the Delphi rounds

Country	Organisation
UK	Programme Grants for Applied Research
	Research for Patient Benefit
	NETSCC
France	Haute Autorite de Santé
	Institut du Cancer
The Netherlands	College voor Zorgverzekeringen
	ZonMW
Norway	Combined Norwegian response, co-ordinated by the Norwegian Knowledge Centre for the Health Services
Israel	The Israeli Centre for Technology Assessment in Health Care
Australia	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
USA	Blue Cross Blue Shield Association Technology Evaluation Centre (also responding on behalf of the Veterans' Administration, Agency for Healthcare Research and Quality, and the Veterans' Administration)
Canada	Institute of Health Economics
	Canadian Institutes of Health Research

questionnaire design and the use of SurveyMonkey.com has been described in detail in *Chapter 2* (*Identifying participants*). Copies of the background documents and questionnaires are included in *Appendices 12–15*.

Validating the data set

After agreeing the elements of the data set, the next step was to validate the data set. This was done by assessing the data set's potential accuracy, its ability to match similar studies and identify dissimilar studies as dissimilar. If the data set could not do this, then it would not be fit for purpose. The number of trials we had to consider was small – the aim of this phase was to look for a signal that the data set could be fit for purpose, not to definitively demonstrate so.

As a first part of this phase we identified a set of three potential matching rules, based on matching one or more of the elements of the PICO [population, intervention, comparison and outcome; definition of a research question (e.g. did two elements in the database match on one, two or three elements of population, intervention, and a union of the intervention and comparator conditions]. The intervention and comparator fields were amalgamated for this matching process because a match should not depend on which role a technology is fulfilling, just that it is present in the study.

For this phase Delphi participants were firstly asked to identify clinical and technological topics where they thought that multiple agencies may have undertaken work. The four work areas that were most commonly suggested were selected. For each clinical area we selected an exemplar study from the NIHR HTA programme portfolio. Participants were then asked to submit descriptions of projects that they had undertaken or considered which were similar to the exemplar studies, structured according to the proposed data set. They were also asked to provide studies in similar areas which should not generate a match with the index study when tested. Next, the previously identified matching rules were applied to determine which had the best performance, as defined by Delphi participants.

Chapter 3 Summary results and discussion

This chapter presents a summary of the results and accompanying discussion. For each section the results are presented followed by interpretation and recommendations.

Evaluation of the processes of the European network for Health Technology Assessment Joint Action project

Evaluation of international projects

A project has been defined as 'directed work that is aimed at achieving specific goals within a defined budget and schedule'. An international project 'involves multiple locations, entities, organizations and business units' across different countries.[55] Therefore, the EUnetHTA JA was classified as an international project. Such projects are complicated, owing to the large number of organisations, wide purpose and scope and high cost.[55] At its inception the EUnetHTA JA project had 35 government-appointed organisations. Each of these organisations could have several employees working in a number of work package projects. This meant that communication provided by the co-ordinating secretariat and the specific work packages was important. The EUnetHTA JA had a wide purpose, which necessitated the work to be divided into eight separate work packages. International projects operate in a unique context, where different countries have different economic and political systems,[46] all of which have an impact on the management and success of the project.

The evaluation of a large project should include the traditional measures of whether or not the work was completed according to time, cost and quality standards. This should also be expanded to include delivery of new capabilities and business objectives, and assessment of the project's long-term impact.[56] Project performance can be measured during the lifetime of a project. However, the success or failure of a project can usually only be evaluated months or years after its finish, when the resultant impact can be measured.[57] Consideration of whether or not the deliverables were produced on time was within the scope of the evaluation of the EUnetHTA JA. Unfortunately, the scope of the evaluation was limited by the resources committed by the EU – this meant that evaluation of the project's delivery according to cost and quality standards and its long-term impact were outside the evaluation's scope. Owing to limitations mandated by the major funder (the EU), it was only possible to prepare the evaluation 6 months before the end of the project. This is a major limitation of this evaluation process.

Different individuals can have varying measures of project success, depending on their relationship to the project. Project team member's perspective often includes whether or not they had a satisfactory experience with the project and if it met their needs, while the sponsor considers if the project has provided the desired performance improvement.[56] Therefore, evaluation of participants' perceptions of the challenges and benefits of the project was included in the evaluation. Project success can also be indicated by high team satisfaction, good morale, increased skill, retention and growth of team members and avoidance of burnout. Therefore, staff members were asked about their perceptions of the project. It was interesting that there was a pattern of approximately one-third of project participants changing between each year of the project. However, consideration about whether or not this might have been related to poor experience on the project or natural movement of the employees was out of the scope of the evaluation. Consideration of the views of external stakeholders were also included in the evaluation.

To achieve project success there must be a clear purpose, specific plans, commitment, open communication, respect and trust, collaboration, political support, clear roles and responsibility and an effective leadership style.[56]

Factors leading to the success of a complex project include:[58]

- clarity of the goals and commitment to them by the project team
- establishing smooth communications with supporting infrastructure
- recruiting project team members with sufficient technical capabilities
- context of the project considered
- a supportive project culture.

Key point 1

The EUnetHTA JA is an example of an international project composed of virtual work teams. Such projects are complex and have specific implications. Project performance can be evaluated during a project. However, evaluation can only be performed months or years after its completion. Therefore, the necessity of performing the final evaluation 6 months before the end of the project was a limitation.

Response rate to questionnaires

It is important that high response rates are received to evaluation questionnaires. It is impossible to conjecture about the opinions of non-respondents and how they might differ from those of respondents. Therefore, it is essential to decrease the proportion of non-respondents to ensure the true validity of the results.

The first stage in achieving a high response rate is ensuring that the population survey list is complete and valid. For the stakeholders' surveys this was relatively straightforward because the secretariat maintains a contact list for these organisations, which are few in number. However, this was more problematic for the project participants' surveys, perhaps because of the large number of project participants and the complexity of the eight different work packages. This meant that a large degree of 'data cleaning' was necessary, for example by contacting the leads of organisations and work packages to receive information about their colleagues.

Key point 2

There is a need for the secretariat to maintain complete and up-to-date details about the staff working on this large international project.

Disappointingly low proportions of questionnaires were completed during the internal evaluation of the previous EUnetHTA 2006–8 project. The response rates for the three annual questionnaires were 23% (2006), 23% (2007) and 26% (2008).[12] Some possible factors that might have contributed towards this low response rate could have included:

- The questionnaire needed to be completed as a Microsoft Word® document and then e-mailed back. This required some effort from the respondents and there might have been concerns about the confidentiality of results.
- The questionnaire asked for insertion of the name of the respondent. This again might have caused worries about the confidentiality of data provided.
- The authors had intended individual participants to complete the questionnaires, but in some instances organisational responses were provided.

It is important that lessons were learnt from the previous evaluation of the EUnetHTA 2006–8 project and resultant mitigating interventions taken for the evaluation of the EUnetHTA JA. Therefore, a structured strategy was implemented to encourage a high response rate, which included targeted follow-up of non-respondents as well as inclusion of both inducing and punitive factors (*Box 2*).

Project participants' surveys

The following survey codes have been used throughout this report for ease of reporting:

- project participants' 2010 survey; p2010
- project participants' 2011 survey; p2011
- project participants' 2012 survey; p2012.

The response rates to the project participants' questionnaires ranged from 86% to 88% (*Table 6*). The number of project participants who answered the questionnaires is shown in *Figure 3*.

For the project participants' surveys it was interesting to note that there was a small increase in response rate by using a third send-out in 2010 and 2011 (a 5% and 2% increase respectively). Although the increase was larger in 2012 (9%), a satisfactory response rate of 79% had already been achieved after the second send-out.

If the same strategies are used to maximise response rate, consider in EUnetHTA JA2 that a third send-out may not be required for participants.

BOX 2 The strategy used to encourage a high response to project participant questionnaires

Structured strategy to encourage high response rates to project participant questionnaires

Inducement factors

Certificates were awarded at the annual plenary assembly meeting.
A prize was awarded to the organisation with the highest response rates over the annual surveys.

Punitive factors

Non-respondents were reported to the secretariat and at the plenary assembly.
Non-respondents were reported to organisational leads.

TABLE 6 Response rates to the project participants' questionnaires

Questionnaire	Number of questionnaires distributed	First mailing	Second mailing	Third mailing	Total received (*n*)
P2010	175	67%	83%	88%	154
P2011	201	78%	84%	86%	172
P2012	204	72%	79%	88%	179

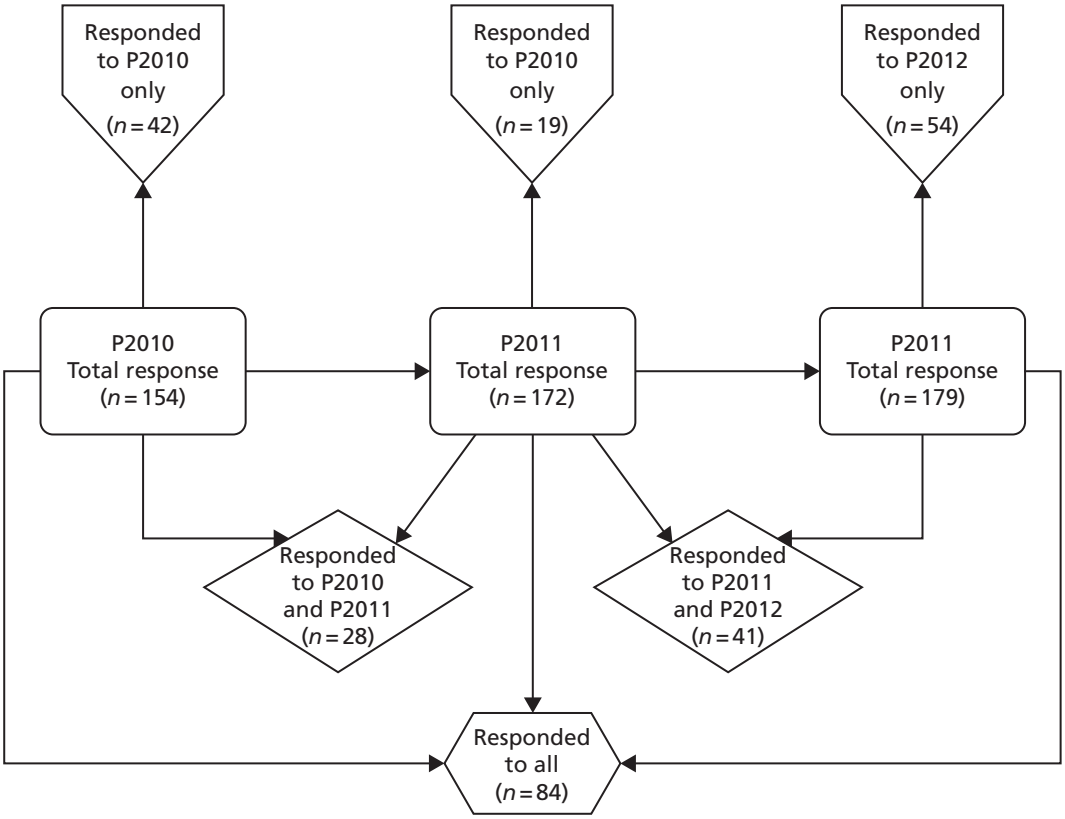

FIGURE 3 Breakdown of responses to the project participants' questionnaires.

Stakeholders' questionnaires

For ease of reporting reference to the following survey codes have been used throughout this report:

- stakeholder forum 2010 survey; s2010
- stakeholder forum 2011 survey; s2011
- stakeholders' 2012 survey (for members of the stakeholder forum); s2012a
- stakeholders' 2012 survey (for those not successful in gaining a place on the forum); S2012b
- 'other' stakeholders' survey 2010; O2010.

The response rates to the stakeholders' questionnaire range from 60% to 83% (*Table 7*). The number of project participants per year of the project is shown in *Figure 4*.

TABLE 7 Response rates to the external stakeholders' surveys

Questionnaire	Number of questionnaires distributed	First mailing	Second mailing	Third mailing	Total received (*n*)	Non-respondents
S2010	12	58%	58%	83%	10	ECPC, EGA
O2010	5	80%	100%	–	5	–
S2011	12	25%	50%	67%	8	COCIR, EURODIS, EPF, Eucomed
S2012a	12	42%	58%	75%	8	ECPC, EPF, EGA, Eucomed
S2012b	5	40%	40%	60%	3	EFNA, Europabio

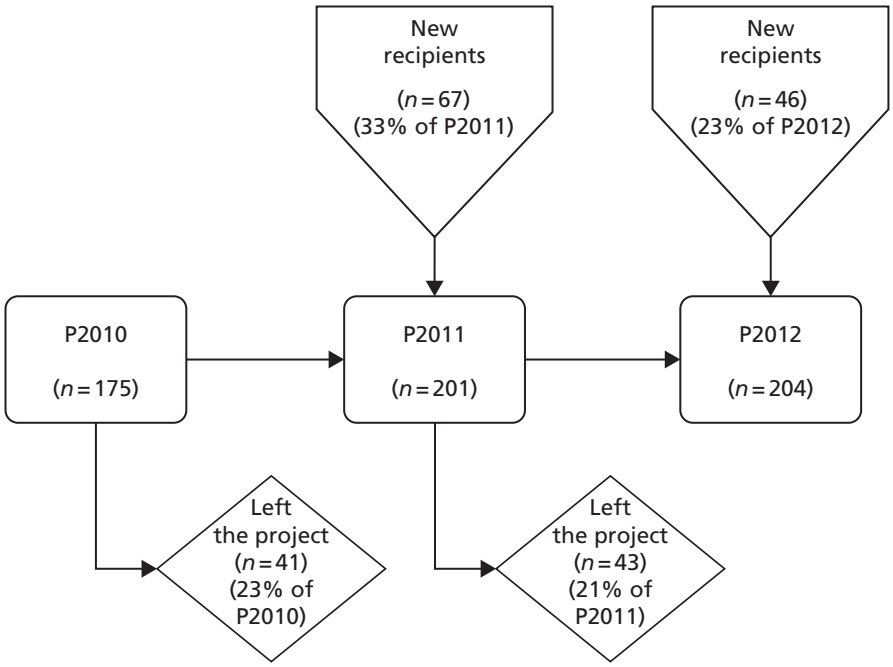

FIGURE 4 Project participants in the different years of the project.

Project participant turnover

The stakeholder organisations were appointed to the stakeholder forum, or were not appointed but were kept informed by their representative, for the lifetime of the EUnetHTA JA project. This meant that, although the individual contact person sometimes changed, the number and type of organisations did not change.

However, it was interesting to observe that the number of project participants changed during the project. The largest overall increase in members was seen from 2010 to 2011. Approximately one-quarter of participants left the project after the initial year and one-third of the 2011 population was new. A similar pattern was observed for the 2012 questionnaire when one-quarter of recipients were new and one-fifth had left after the 2011 questionnaire.

This has important implications for project management and induction of new members. This suggests that organisational knowledge about the project might be lost and extra time required to initiate new members. It should also be considered that the new members might differ in some facet compared with the ones who have left, for example in outlook and knowledge and this might be reflected in the differences in responses to the longitudinal questions.

Key point 3

It is recommended that concise induction material about the project is provided to facilitate the induction progress of new project members.

Project participant demographics

These results were mostly obtained from closed questions. A range of demographic questions were included in all three annual questionnaires.

As well as evaluating the EUnetHTA JA, the questionnaire also served a dual function of enabling data capture of further information about the nature of member organisations and the project participants. Knowledge of such information about network members could be important in fostering increasing collaboration in the future.

There were a large number of medical doctors working in the HTA organisations, along with other health-care professionals, economists, researchers and project managers. There was an apparent clustering of participants having worked within HTA for between only 0 and 4 years. Approximately two-thirds of agencies had organisational expertise available in health economics, clinical effectiveness research and clinical expertise. These could be considered key expertise needed for preparation of HTA reports. Less frequent, and possibly more specialist, skills that are not intrinsic to HTA were also available in some agencies. This included skills in information technology (IT), communication, legal services, organisational science and development of surveys. It could be important for members of the network to identify fellow members who have a specialist skill and could help them with a particular task.

A list of ongoing HTA projects, and a final published report, was produced by the majority of organisations: 88% and 81% respectively. An English summary was commonly produced. This would help collaboration to a certain degree. However, a final report completely available in English was always available in only one-fifth of organisations. This could hamper collaboration because the details of the findings and methods sections would be inaccessible to persons not speaking the same native language. A list of planned HTA projects was only publicly available in less than half of cases, but in addition approximately one-third of organisations would share it within the EUnetHTA JA project. This demonstrates the importance of the EUnetHTA JA project and would, hopefully, facilitate collaboration in future projects.

Key point 4

This evaluation has contributed to awareness within the network of types of expertise available and the nature of HTA information produced by individual organisations.

Key performance indicators

Success criteria are measures by which the success or failure of a project can be judged. This extends beyond the traditional measure of whether or not deliverables have been produced according to the project plan.[57]

Key performance indicators were developed for the EUnetHTA JA project and these are shown in *Box 3*.

Project impact

The impact of the project was evaluated by assessing the deliverables of the project. These are the results, or products, of the project. Some of these deliverables were tools and methods for conducting HTA. For these cases the potential use in practice of these tools, and training requirements prior to use, were also evaluated. Production of deliverables, according to the 3-year work plan and grant agreement,[13] are indicators of project management success. They allow assessment of the performance of the project with respect to time (although considerations of quality and cost were beyond the scope of the present evaluation).

Production of deliverables

These results were obtained documentary analysis of work packages' final technical reports about whether or not the deliverable actually had been produced.

BOX 3 Key performance indicators for the EUnetHTA JA project

Project impact

- Production of deliverables according to the 3-year work plan and grant agreement.
- Objectives (as defined in the Grant agreement) met.
- Additional added value generated.

Project effectiveness

- Effective communication within the project.
- Effective project administration by the secretariat.
- Optimal involvement of external stakeholders.
- Good management of the constituent work packages.

Lessons learned

- Progress from the predecessor EUnetHTA 2006–8 project.

1a. An online tool and service for producing, publishing, storing and retrieving HTA information; December 2012 (WP4 strand A)
The HTA Core Model was developed as part of the EUnetHTA 2006–8 project. The development of an online format of the tool aimed to make it easier to use and to enable easier access to information (Ms Julia Chamova, EUnetHTA, Copenhagen, 2010, personal communication).

i. The final technical report submitted by WP4 in January 2013 indicated that this had been delivered.

1b. HTA Core Model on screening; March 2011 (WP4 strand A)
Applications of the HTA Core Model tool already existed for medical and surgical interventions and diagnostic technologies, developed during the EUnetHTA 2006–8 project (Ms Julia Chamova, EUnetHTA, Copenhagen, personal communication). An additional application of screening was planned for the EUnetHTA JA project.

i. The final technical report submitted by WP4 in January 2013 indicated that this had been delivered. The report specified that this had been validated during autumn 2012.

2. A set of two core HTAs; December 2012 (WP4 strand B)

i. It was planned that two core HTAs would be produced by HTA agencies using the online tool. This enabled application and field-testing of the core model. The final technical report submitted by WP4 in January 2013 indicated that these had been delivered.

3. A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals; December 2012 (WP5)
This was a new activity of the EUnetHTA JA project, stemming from the wish of DG SANCO and DG Enterprise to assimilate interest in joint assessments of relative effectiveness of pharmaceuticals into existing networks, like EUnetHTA (Ms Julia Chamova, EUnetHTA, Copenhagen, personal communication).

i. The final technical report from WP5 indicated that methodological guidelines would be finalised and published at the end of February 2013 (therefore missing the December 2012 target). There was a plan that this would be published in the planned special joint action edition of the *International Journal of Technology Assessment in Health Care* in 2013. It was noted that this was a model for rapid assessment. Owing to the high workload in WP5 it had been decided to not pursue the model for full relative effectiveness of pharmaceuticals.

4. Operational web-based toolkit including database-containing information on evidence generation on new technologies; September 2012 (WP7a)
   This activity continued from the previous project when the EIFFEL platform was developed to share evidence on new technologies. This was refined in the current project to create the EVIDENT database (Ms Julia Chamova, personal communication).

   i. The final technical report submitted by WP7 in January 2013 indicated that this had been delivered. It was not possible to identify in what month this had been delivered and if this had met the target of September 2012.

5. Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies; December 2012 (WP7b)
   This was a new activity – of developing a database for information on ongoing and planned assessment, with the aim of providing alerts about topics with the potential for collaboration.

   i. The final technical report submitted by WP7 in January 2013 indicated that this had been delivered.

6. Information management system (IMS) and the related documentation, processes and policies; September 2012 (WP6)
   Following on from the project, WP6 aimed to further develop the project intranet site to provide a single point of access to resources that help with conducting HTA, with emphasis on automating content update processes (Ms Julia Chamova, EUnetHTA, Copenhagen, personal communication).

   i. The final technical report submitted by WP6 in January 2013 indicated that this had been delivered. However, it was not possible to identify in which month this was produced.

7. Communication and dissemination plan; June 2011 (WP2)
   Building on the communication strategy developed during the previous project it was planned to write and implement a further elaborated plan.

   i. According to the final technical report of WP2 this was delivered according to the work plan in month 18 (June 2011).

8. Stakeholder policy; October 2010 (WP8)
   Stakeholder involvement was considered during the 2006–8 project and formed part of the internal evaluation during the final year of the project. However, the EU Commission emphasised that there must be greater involvement in the EUnetHTA JA project. This policy was required, for implementation through a formal stakeholder forum (Ms Julia Chamova, EUnetHTA, Copenhagen, personal communication).

   i. The final technical report of WP8 indicated that this had been delivered (although it was not possible to identify whether or not this had been in the target month).

9. Collaboratively developed business model for sustainability; December 2011 (WP8)

    i. This detailed business model would address sustainable European collaboration on HTA. The final technical report of WP8 indicated that this had been delivered (although it was not possible to identify whether or not this had been in the target month).

10. A relative effectiveness assessment of a (group of) pharmaceutical(s); March 2012

    i. The final technical report from WP5 indicated that the 'pilot of rapid assessment of a pharmaceutical' had been published on the EUnetHTA website in January 2013.

11. Interim and final technical and financial reports from the EUnetHTA JA project; various (WP1)

    i. This evaluation report is part of the final technical report of the EUnetHTA JA compiled by the secretariat. Therefore, it was not possible to evaluate whether or not this report would be submitted to the EU Commission by the deadline.

Anticipated use of deliverables

These results were obtained from a combination of closed and open questions.

It was important to consider whether or not project participants and stakeholders thought that these tools would actually be helpful in day-to-day HTA work. In the final year of the project, both participants and stakeholders were asked how useful they thought they would find deliverables, and activities, developed as part of the project in their professional life. One of the limitations of performing the evaluation 6 months before the end of the project was that respondents were asked to make predictions – a notoriously difficult concept for questionnaire respondents and one that should be avoided as much as possible.

The facet with the highest proportion rating as 'very useful' for both participants and stakeholders was 'networking with contacts made from participating in the EUnetHTA JA', with three-fifths of participants rating this very highly and over two-thirds of stakeholders reporting it to be very useful. The vast majority of respondents found the networking they had experienced had been of at least some use.

Key point 5

It is recommended that evaluation of the EUnetHTA JA2 includes consideration about the tangible benefits of networking. This could include a case-study approach to demonstrate the practical benefits of networking.

One-third of respondents did not think they would find the HTA Core Model on screening useful or did not know if they would or not. Over one-quarter of respondents did not think they would find the following tools useful, or did not know if they would or not; 'A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals', 'Operational web based toolkit including database-containing information on evidence generation on new technologies (EVIDENT)' and 'Accessing the EUnetHTA tools by a single sign on through the MO (members-only) site'.

Almost half of respondents thought that the HTA Core Model and the POP database would be 'very useful'. A slightly lower proportion of two-fifths of respondents thought the EVIDENT database would be 'very useful'.

It should be considered that participant respondents have different types of professional activity, for example in respect to whether or not they prepare HTA reports. Analysis of qualitative comments also identified that the access to tools could vary for different organisations and be dependent on the access policy for specific tools.

Key point 6

It is still too early to assess the benefit of the tools in practice, although prediction of use is encouraging. This suggests that the EUnetHTA JA's third objective of 'application and field-testing of tools' has not been met. However, results at this stage are positive and suggest that they will be of future benefit. The EUnetHTA JA2 project will follow on with further real-life application and testing of the tools.

Tools

The main deliverables of the EUnetHTA JA were a series of structures to help in the production process of HTA reports – the tools. There were also tools to help communication within the project;

- tools for production of HTA reports: adaptation glossary, adaptation toolkit, core HTA model, EVIDENT (formerly known as EIFFEL), POP workroom/database
- tools for communication: contact database, e-meetings, EUnetHTA toolbar, mailing list, MO website, MO workrooms, news aggregator, workroom bulletin board.

Use of tools

These results were obtained from a closed question included in all three of the questionnaires.

Unsurprisingly, the most often used tools were those for project communication – the MO intranet website, workrooms and e-meetings. Not all members used the project intranet site (the MO website), although the proportion of respondents using it increased from 2010 to 2012. However, the missing proportion said they were aware of it and are likely to use it in the future.

Workrooms were areas assigned within the project intranet for the individual work packages. Although approximately three-fifths of respondents used them, they rated them poorly. It is, therefore, suggested that their use is helpful, because they were used by a large proportion of participants. However, there is obviously an important need for them to be improved in EUnetHTA JA2. Workroom bulletin boards were less often used, with only approximately 15% of project participants reporting use. It seems that respondents used the website, but not the subsplit workroom provisions. Further evaluation needs to be performed in EUnetHTA JA2 to identify whether these workroom bulletin boards could be useful if they were improved or if participants considered them superfluous and they communicate by other means, such as e-mail.

There was increasing use of the following other communication tools from 2010 to 2012 (although they were still only used by less than half of participants): contact database (a database of details of all the project participants), EUnetHTA toolbar (used on the internet) and mailing list (a list of all project participants).

Unsurprisingly, the results for use of the HTA tools were significantly lower. This can be explained because most of the tools were still in a development stage, even in summer 2012 (which again illustrates the limitations of performing evaluation before the end of the project). The HTA Core Model was the tool that the most participants had used, and the proportion that had used it doubled during the lifetime of the project to three-fifths. In each year, approximately 90% indicated they had used it or might use it in the future. The adaptation glossary and adaptation toolkit were under development, and this is reflected

in the results of limited use. Although being developed as part of the project, the EVIDENT database had been used in the previous project (as EIFFEL) and, therefore, a number said they had used it. This database was seen as being relatively less popular because approximately 60% saw a future use for it. The POP tool was converted from a static datasheet to an interactive site during the project and this was reflected in the results; the proportion of participants using it doubled to 50%. Roughly 80% had either used it or saw future use for it.

Key point 7

The tools had not been delivered by the final evaluation and, therefore, it was too early to assess their use in practice. The majority of respondents saw future use for the tools, particularly in the HTA Core Model and the POP database. The actual use of the developed tools is an important topic for evaluation in EUnetHTA JA2.

Priority for training

These results were obtained from a closed question included in all three of the questionnaires.

The HTA tools were consistently seen as being a higher priority for training throughout the lifetime of the project than the project communication tools (which were mostly cited as low priority or of no importance). Therefore, the 'content' tools were seen as of greater importance than the 'process' tools of the project. Possible reasons for this include that there was greater need within the project for more methodological tools, that such type of tools are more complex to use or that communication tools were easy to navigate. In each year the tool most often cited as 'top priority' for training by project participants was the core HTA model. The importance of training both partners and stakeholders in EUnetHTA tools and methods was emphasised in the plans for the EUnetHTA JA2 project. One of the deliverables of the JA2 project is 'Report on yearly training courses on EUnetHTA tools and methodology'. It is planned that three face-to-face training workshops will be held on EUnetHTA tools and methodology. It is also planned that three additional training courses will be held for the core HTA model. These plans were proposed as a result of evaluation questionnaire findings of EUnetHTA JA.

Training method

These results were obtained from a closed question included in the 2010 and 2012 questionnaires.

In general, the most preferred training method for tools was self-directed with a manual. However, a 'face-to-face workshop' was the preferred training method for the HTA Core Model, with over half of respondents preferring this option. As a consequence of the 2010 survey results, a face-to-face workshop about the HTA Core Model was organised as part of the project. It was interesting that the proportion of respondents requesting a face-to-face workshop about the EVIDENT and the POP databases noticeably increased from 2010 to 2012. It is difficult to conjecture the reason for this, but this could have been in part due to satisfaction of respondents with the workshop they had attended about the HTA Core Model. One advantage of using a manual is that learning is self-directed and can be undertaken at a time and place to suit the convenience of the learner. Self-directed manual use is also a cheaper method and negates the need to travel to attend a face-to-face workshop; however, it has the disadvantage that queries and difficulties using a tool cannot be as easily resolved as they could be at a training workshop.

Key point 8

Self-directed manuals are considered a suitable training method for the project-focused tools. Face-to-face workshops are preferred for the HTA methodology tools and this should be considered and developed in the EUnetHTA JA2.

Barriers to using the tools

These results were obtained from a closed question included in all three of the questionnaires.

Respondents were asked whether or not any barriers had prevented them using the tools from 'organisational', 'training', 'the tool itself' and 'IT'. Encouragingly there was an overall general trend that the frequencies of all barriers decreased during the lifetime of the project. This may have been because problems were resolved during the project – informally or formally. There was a general trend that the effect of training being a barrier to tool use decreased during the project throughout the lifetime of the project from 2010 to 2012. It is possible that as the project progressed, participants picked up knowledge about using the tools either informally or formally (i.e. by the training course for the HTA Core Model). IT was seen as a significant barrier to the performance of e-meetings and training was a noticeable barrier to the HTA Core Model (and is reflected in the decision to hold face-to-face workshops in EUnetHTA JA and EUnetHTA JA2). When asked in 2012 why they had stopped using a tool, few responses were obtained. Reported problems included tools not yet being active, problems with passwords and IT problems with e-meetings.

Perceived ability of the European network for Health Technology Assessment Joint Action project achieving its objectives

These results were obtained from a combined closed and open question included in the 2011 and 2012 questionnaires.

The difficulty of managing the diversity of project members, and formulating a goal that all members remain committed to, over the long duration of an international project has been recognised.[58] One factor that can mitigate this is developing objectives at the start of the project. Achievement of defined objectives can also be used to measure the success of the project.[57] Definition of the project objectives is also important for managing the commitment of external stakeholders.

According to the grant agreement[13] the overarching objective of the EUnetHTA JA was to 'establish an effective and sustainable HTA collaboration in Europe that brings added value at the regional, national and European level'.

Project participants and stakeholders were asked in year 2 of the project what would indicate that this had been achieved. They thought that this would have been achieved when a formal EU HTA agency/network not dependent on project funding had been formed, collaboration was achieved, EUnetHTA tools were adopted at a regional or national level, a library of HTA reports and topics was available, HTA was included in decision-making and impact was evaluated. Stakeholders also cited reduction in duplication of effort, evaluation of measurable objectives, consistent exchange of information and collaboration outputs using national and regional levels. The majority of participants and stakeholders thought that such a sustainable EU collaboration would bring added value to both the national and European level. However, there was less confidence about whether or not this would bring added value to the regional level, with about one-third not knowing whether or not this would be achieved. Comments included that such added value would be seen when there is a reduction in redundant work at the regional and national level and better European leverage.

Key point 9

The fact that such a sustainable European collaboration (as defined by the project participants and stakeholders) had not been established following the EUnetHTA JA (necessitating a second joint action) indicates that the project had not been successful at meeting its overarching objective.

Almost three-quarters of the project participants and external stakeholders thought that the planned EUnetHTA JA2 project was a useful follow-up to the EUnetHTA JA project. This suggests that there was an apparent gap between the JA project and the permanent collaboration on HTA. Comments included that the EUnetHTA JA2 was required to build on the EUnetHTA JA, the tools required further development, there was a need to test the efficacy/effectiveness of join report production, that the EUnetHTA JA2 would act as a bridge to a permanent network for HTA, that it will have a different focus of operational work which will identify feasible co-operation between HTA agencies and allow the testing of models of iterative stakeholder involvement, it is a necessary follow-up to EUnetHTA JA and will provide the occasion to examine in practice the methods developed.

The anticipated timeline of achieving a permanent European HTA network is shown in *Figure 5*.

The EUnetHTA JA had three defined objectives, and participants and stakeholders were asked annually whether or not they thought these would be achieved. These objectives were tangible, i.e. production of a strategy business model document, delivery of tools and field-testing of the tools. Documentary analysis was also undertaken to assess whether or not these objectives had indeed been met.

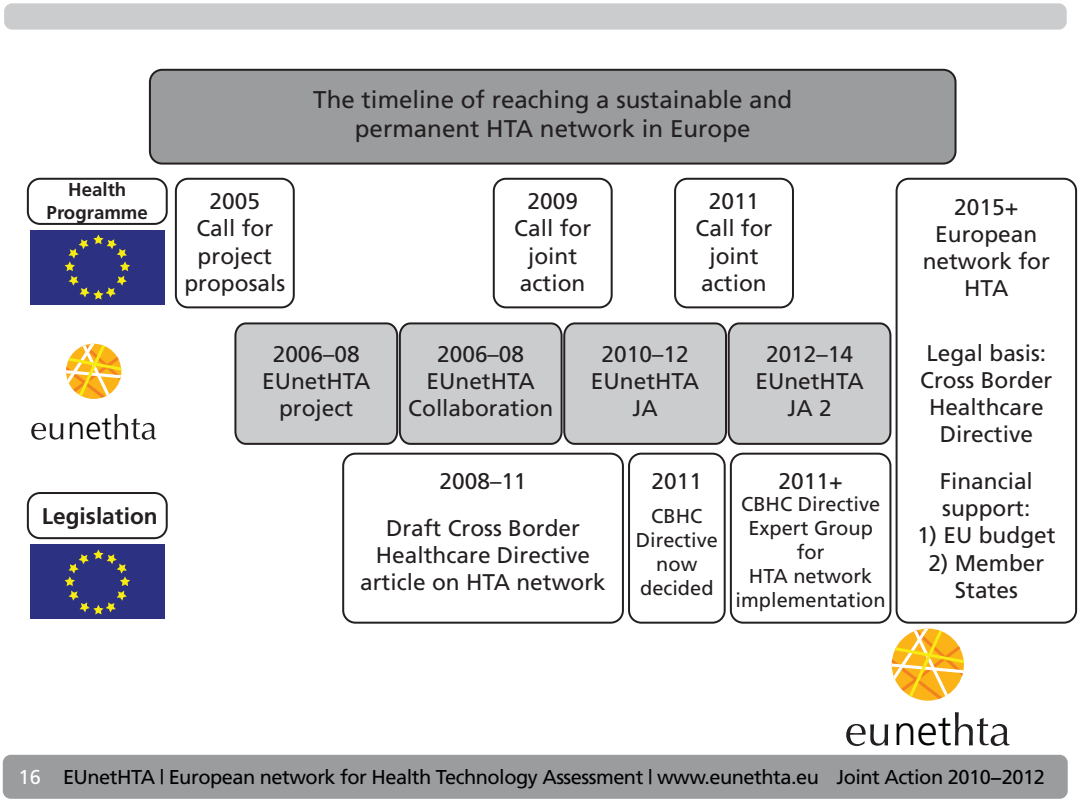

FIGURE 5 The anticipated timeline of achieving a permanent HTA network in Europe. (Reproduced from www.eunethta.eu with permission from EUnetHTA secretariat.)

Development of a general strategy and business model for sustainable European collaboration on health technology assessment

The majority of participants and stakeholders had confidence that this objective would be achieved. Indeed, this was the objective that participants and stakeholders had the highest confidence would be met. However, it was interesting that approximately one-tenth of stakeholder forum members in 2011 and 2012 did not think this would be achieved. According to the final technical report, of WP8 this general strategy and business model had been delivered by the end of the project.

This strand of activity is planned to continue in the EUnetHTA JA2 project, 'Thus, an overarching objective is to develop the background for a general strategy, the principles and the proposal for implementation of a sustainable European Collaboration on HTA in the light of the Directive on CBHC . . .'.[13]

Key point 10

The general strategy and business model were developed according to the work plan during the EUnetHTA JA. However, further work is planned during the EUnetHTA JA2 project to further develop this towards a sustainable European HTA Collaboration.

Development of health technology assessment tools and methods

The majority of project participants thought this objective would be met. However, it is interesting to note that participants' confidence in this being achieved apparently dropped from 2010 to 2012 by approximately 10% and there was a corresponding rise in the number of respondents who indicated they did not know if this would be achieved. There was a similar pattern of apparent doubt by stakeholders because two-fifths were unsure whether or not this would be achieved when asked in 2012.

The proposed HTA tools and methods were all developed according to the grant agreement and the work plan (see *Chapter 1, Project deliverables* for further details): HTA Core Model, EVIDENT and POP database. The methodological guidelines for relative effectiveness assessment of pharmaceuticals were predicted to be delivered by the end of February 2013. It is notable that further work is planned in the EUnetHTA JA2 project to develop the HTA Core Model. Deliverable 10 will be an 'Upgraded and updated package of HTA Core Model'. This is to include 'updated applications on medical/surgical interventions, diagnostic and screening technologies and pharmaceuticals'.[13]

Key point 11

All HTA tools and methods were delivered according to the work plan and hence it appears that this objective was achieved. However, further work is planned in EUnetHTA JA2 to further develop the HTA Core Model.

Application and field-testing of developed tools and methods

The majority of participants and stakeholders again showed some apparent confidence that this objective would be achieved. However, a large number of respondents indicated 'don't know'. This might have been because they thought that an objective would not be met but were reluctant to choose the negative option choice, but it is difficult to conjecture in the absence of probing respondents to explain their response in greater depth. The apparent confidence of the participants decreased over the years and the proportion who did not know increased. In contrast the number of stakeholders who thought this would

be achieved increased over time whilst the number who did not know decreased. However, the number of stakeholders in the forum who did not know whether or not tools would be applied and field-tested was large: three–fifths in 2010 and a half in 2012.

The general objective of the EUnetHTA JA2 is stated in the grant agreement as being 'to strengthen the practical application of tools and approaches to cross-border HTA collaboration . . .' (page 35). The first part of this aim indicates that application and field-testing of tools had not been fully completed in the EUnetHTA JA as a follow-up project was necessary. This was specified in the grant agreement as 'The JA2 will complement the current JA1 by testing the implementation of structures and tools developed previously by way of conducting a set of pilot assessments on technologies to be selected according to common information needs'.[13]

Key point 12

It appears that this objective of application and field-testing of tools had not been completely fulfilled by the EUnetHTA JA project and a follow-up EUnetHTA JA2 project was necessary.

Perceived achievements of European network for Health Technology Assessment Joint Action

These results were obtained from a combined closed and open question in the 2012 questionnaire.

Consideration of benefits provided to team members by participation in a project has often been overlooked, or combined into consideration of meeting the project's objectives.[48] However, it is an important measure of the success of a project. It was a positive finding that the majority of participants thought that the project had achieved what their organisation had hoped for. However, it was concerning that less than half of project participants said that the EUnetHTA JA had achieved what they *personally* had hoped it would. There was also a large proportion of participants who did not know whether or not it had achieved what they wanted. This, therefore, poses the suggestion that they went into the project not knowing what they wanted it to achieve.

Those who felt achievements had been made cited collaborations and connections developed, successful project progress, network development, the tools and methods developed by the project, information exchange between project members and the effect of greater awareness of policy-makers about HTA in general. In addition to delivering according to the project objectives, this indicates added value of the project. Those who felt that achievements had not been made cited slow progress, lack of change at their local agency, lack of collaborative HTAs produced, difficulties inherent in an international project, lack of cohesion and participation, tools not fit for purpose and that a self-sustaining collaboration had not yet been established. A noticeably larger proportion of participants indicated that they had personally got what they hoped from the project. Reasons included networking, HTA knowledge, information sharing, collaboration, involvement in HTA report production, usefulness of the POP database, ability to act as an ambassador for EUnetHTA and support for establishment of HTA in their own country. One-tenth had not personally got what they hoped from the EUnetHTA JA and reasons included unclear localisation of work, lack of interaction with academia, they had been instructed to take part, tools not being used and difficulties in collaboration.

Key point 13

The main success criteria of a project are meeting its objectives and producing its deliverables according to plan. However, added-value gains are also important. These included networking and information exchange. Such tangible benefits should be measured by the evaluation of the EUnetHTA JA2.

Benefits

These results were obtained from an open question asked in all three of the questionnaires.

Benefits of the EUnetHTA JA from participants' perspectives included information sharing, collaboration, forming a network, development of methods and tools for doing HTA, networking and greater awareness of recent developments. After analysis of the emergent themes from the P2010 questionnaire results the prevalent project benefits were categorised into a quantitative question using a three-point Likert scale. 'Networking with colleagues' and 'sharing information' were the two most common project benefits classified as 'very useful'. When combined into frequencies for all benefits of some use, the vast majority (nine-tenths) of participants found networking, information sharing and awareness of HTA developments of greatest benefit.

The ultimate aim of the European HTA projects is to lead to the formation of a sustainable network. It is encouraging that participants found benefit from networking with others. This might mean that they have built connections with counterparts in different organisations and are able to learn from them and share their own experiences, and it would be useful to investigate this further in EUnetHTA JA2. As well as sharing local information, participants were also able to increase their knowledge about specific HTA-related developments. Other benefits were cited as capacity building, training and face-to-face meetings.

Key point 14

Networking was an added benefit of the project process of the EUnetHTA JA project. It is important that this is further evaluated in the EUnetHTA JA2 project to identify what tangible benefits this has led to, e.g. in terms of topic identification, collaboration on HTA reports, etc.

Project effectiveness

The effectiveness was evaluated by the processes of the project. These are the inputs into the project that may lead directly or indirectly to the success of the project.[57] These project processes can be used to subjectively evaluate the performance of a project.

Set-up of the project

Project start-up

These results were obtained from a combined closed and open question included in the 2010 questionnaire.

Approximately three-fifths of participants were satisfied with the set-up of the project, but one-fifth thought it could have been better. Suggestions included better transparency, decreased bureaucracy, better communication from the JA secretariat and the EU Commission, greater preparation time and maintenance of constant personnel dealing with the project.

The initiation stage of a project is crucial. The most important factor is gaining consensus from project participants about what is to be achieved, and how this should be done, at the outset.[55] A well-planned project will avoid scope creep further down the line by defining the purpose, scope, roles, costs and schedule.

Key point 15

More time should be factored in for this crucial design stage for complex projects than was allowed for the EUnetHTA JA. It is important that individual participants feel included in this formative stage and communication is clear at the outset. This stage is important in ensuring all participants are clear at the outset and it should not be rushed.

Organisation into work packages

These results were obtained from a combined closed and open question included in the 2010 questionnaire.

In common with other such international projects, the EUnetHTA JA project was structured by division into eight distinct work packages. The majority of participants and stakeholders who expressed an opinion thought this structuring was positive, but approximately one-quarter of participants thought there would also be negative aspects associated with this division of work. Concerns centred around possible overlap between the aims and work of individual work packages and the importance of effective communication between them. Most projects funded by the EU are formed in this structure of individual work packages that can be viewed as discrete projects. As one participant responded, 'it is difficult to see how else the project could have been arranged'. However, this structure means that communication was required between the individual work packages to avoid duplication of work and, wherever possible, enable collaboration. This was done by bimonthly meetings of the executive committee, which included the leaders of all work packages along with the secretariat and the representative of the European Commission. Such a steering committee is recommended for complex, international projects. These committees prevent tension between the individual projects and allow for greater flexibility at the operational level.[58] In their consideration of international project management Lientz and Rea considered having two committees: an overseeing committee and one composed of more senior work package leaders.[55]

Key point 16

Consideration could be given to establish a second committee in the EUnetHTA JA2. This could be made up of an individual worker of each work package and could meet virtually by e-meetings to strengthen links between the subproject teams.

Sufficient resources

These results were obtained from a combined closed and open question included in all of the three questionnaires.

Participants provided broadly similar results between 2010 and 2012, with only about a half indicating that their organisation had sufficient funding and three-fifths indicating that there was sufficient staff. The proportion that thought they did not have enough resources was fairly constant at approximately one-fifth

over the 3 years. A large number of participants indicated that they did not know whether or not their organisation had sufficient funding or staff to fulfil their obligations to the EUnetHTA JA project. This may be because not all respondents were senior enough to know details about financing, but a lack of staff might be more apparent to them. In hindsight, it might have been better to have asked this question to the organisational lead to obtain views from only senior staff (although this might be biased).

It is obviously important that organisations had sufficient staff and resources to be able to fulfil their commitment to the EUnetHTA JA. From the data collected it is unclear whether it was actually the case that organisations did not have sufficient resources or this was the perception of their staff. Implications of insufficient funding cited by project participants were that the work required extra time for completion than had been estimated or organisations were subsidising the work themselves by working at weekends, devoting more staff to EUnetHTA than were paid by project funding. Lack of staff meant increased workload within the team, and this could have a negative effect on staff morale. For an international project it is important to realise the importance of the self-interest and resources of each of the individual organisations at the start.[55] It is important that the individual participant organisations feel that they will benefit from the project. It cannot be assumed that organisations will contribute their best resources or effort to the project, to make up any shortfall. This can mean that the work was conducted to a basic standard, with the project work being viewed as a non-priority task. Conflict with normal work of a project participant is also an important factor. Most international team members are not solely dedicated to the project, but must fulfil requirements of their regular job in addition.[55] This could also lead to decreased enthusiasm within an organisation for participation in future international projects. This seemed to be particularly important in this project because the funding was obtained in a 50 : 50 ratio from the EU and the member state.

Cultural factors and different styles of work in an international project should also not be overlooked. Business needs are diverse in each country involved in the project. The project should address such local issues otherwise it will be seen as negative – requiring resources but not delivering benefits.[55] Also, in the EUnetHTA JA the individual work packages can be seen as inter-related individual projects. It is important to realise that these projects can share the same resources and together can exact too high a stress level from workers.[55]

Key point 17

There should be greater use of project management and budgeting techniques in the EUnetHTA JA2 to ensure sufficient resources are allocated to organisations and specific tasks.

Difficulty joining the project

These results were obtained from a combined closed and open question included in the 2010 questionnaire.

Hearteningly, less than one-tenth of respondents reported a problem with their organisation joining the project. Problems reported included lack of a plan, lack of transparency and lack of distinction in work between performed in the preceding collaboration year and the start of the EUnetHTA JA project. It is important that the process for organisations joining a project is straightforward and easily manageable. Almost one-quarter of project participants in 2010 had a suboptimal or mixed understanding about the information that was required from the secretariat before the project started. The proportion who understood requirements increased from before the project began (two-fifths) to after the project started (three-fifths). Concerns included that the information was not always clear and recognition about the complexity of the project. The relative scarcity of problems can be seen as a good indicator of success.

It should also be borne in mind that the number and types of organisations within the EUnetHTA was a fluid situation, with organisations able to leave and join during the project. It would be useful to have a type of induction process for organisations that joined part-way through the project. It could also be useful to produce a map of the characteristics and expertise of the different organisations joining the project, to enhance collaboration opportunities within the network.

Key point 18

Organisations had mostly had a good experience of joining the project, although communication from the secretariat during this period could have been improved somewhat. However, other organisations subsequently joined the EUnetHTA JA project when it was already established. It would be useful to produce an induction pack for such organisations for the EUnetHTA JA2.

Succession planning

These results were obtained from a combined closed and open question included in the 2010 questionnaire.

Almost two-fifths of organisations had no succession plan in place in case a member of staff became ill or left the organisation, with a further one-fifth not knowing whether or not they had one. It is vital that there is a plan in place in case members of staff leave, to ensure that this does not affect the work of the project. Loss of team members can mean that experience and knowledge is lost and activity in an organisation can grind to a halt.[55] In combination with the fluid nature of high turnover of project staff, there was an apparent lack of succession planning. This again reinforces the need for communication and induction of new staff. Examples of this included the secretariat administrator going on maternity leave and the individual leading the contribution of the lead partner of WP2 leaving mid-way through the project. For an international project, there needs to be a local commitment that the project team is stable and committed, and members are not pulled off the project by local management to perform other work.[55] However, in practice little can be done to mitigate the effect of individuals leaving to take up other jobs, going on maternity or sick leave or dying.

Key point 19

In future international HTA projects all participant organisations should be responsible for outlining who will be locally responsible for an organisation's commitment to the project if key staff become unavailable.

Challenges

These results were obtained from an open question included in all of the three questionnaires.

Qualitative comments from participants about the challenges inherent in the project included the large scope of the project, its international nature, high workload, limited time and resources, the work itself, communication, administration, national/organisational conflict, requirements of individual work packages, imbalance between contributions of participants and problems with collaborative working. A specific problem in 2010 and 2011 was orientation within the project.

After analysis of the emergent themes from the P2010 results, the prevalent project challenges were categorised into a quantitative question using a three-point Likert scale. A large effect was assigned to conflict with other work activities and insufficient organisational funding and staff. Combining the

frequencies for the effects showed that approximately three-quarters were affected to some degree by conflict with other work and insufficient staff and funding. The effects of insufficient organisational funding and staff, and conflict with other work have been discussed in earlier sections.

The effects of the large project scale and demands of the individual work packages were small. Interestingly, the demands of individual work packages seemed to increase between 2011 and 2012. The large project scale is one of the inherent problems of international projects and this leads to a complex nature of subprojects. A large proportion of project participants were members of more than one work package, which meant they had to juggle various work demands.

Hearteningly, more than half of respondents experienced no effect from difficulty in communicating in English and difficulties in communicating generally. Communication is affected by various types of culture and it can be difficult to manage different styles in an international project.[58] In addition, project participants had various natural and functional languages. In the EUnetHTA JA project it was necessary to use a common language, which was English. However, it must be considered that the use of a language by non-native speakers can result in insufficient project feasibility, loss of speed, loss of creativity, poor decisions, underuse of resources and unexpected misunderstandings. It is possible that such problems were experienced by participants, but were not deemed sufficiently important to affect the project work significantly.

Key point 20

Broadly speaking, communication within the EUnetHTA JA project was successful. However, coping with the large project scale and conflicts from work of the subprojects was more of a challenge. The greatest challenge was from conflict from other work and insufficient staff and funding. This could be helped by greater use of project planning techniques.

Support from the secretariat

Secretariat leadership

These results were obtained from a combined closed and open question included in all of the three questionnaires.

Approximately three-fifths of respondents thought the secretariat had offered effective leadership. The number of respondents who thought the leadership was OK (but could be better) increased from less than one-tenth in 2010 to one-fifth in 2012 suggesting an apparent slight decrease in confidence as the project progressed. The qualitative data revealed that concerns included negative aspects relating to communication from the secretariat, implications of changes in the secretariat staff, recognition of the difficulty of the task, a distant style used, and a lack of direction provided by the secretariat and that this needs to evolve in the future.

Important attributes for leaders of international projects have been defined.[55] These include problem-solving ability, ability to cope in multiple cultures with diverse political problems, tenacity and the capability of pursuing issues, ability to communicate, a sense of humour, familiarity and knowledge of the business and prior experience in projects. It is also important that the project leader is aware of the intra- and inter-organisational links in the project and is aware of the hidden agenda of individual organisations.

Owing to the specific nature of the EUnetHTA JA project, it was also important that the leader had a strong steer for HTA in Europe. It has been recommended that there are two leaders for international

projects.[58] In the EUnetHTA JA project, as in the EUnetHTA 2006–8 project, the leadership was provided by Finn Borlum Kristensen. The secretariat manager was Julia Chamova. From the comments above, it would seem that the leadership was sometimes perceived as somewhat distant and this could be helped by more regular communication about 'leadership issues' with participants throughout the project. There was some concern expressed about the over-reliance on Finn Borlum Kristensen and what would happen if he became ill.

Key point 21

Consideration could be given in future projects to have a deputy leader, possibly based in another country.

Secretariat administration

These results were obtained from a combined closed and open question included in all of the three questionnaires.

Effective project administration is essential for any international project. Such a co-ordination role can organise the project files and project history, oversee the lessons learned and issues log, and support and mentor the project leaders. As such, the secretariat functioned as the project management office and it had an important role in both the internal project processes (e.g. monitoring the performance of individual work package projects) and connection to the external world (e.g. by interacting with external stakeholders). For the EUnetHTA JA project, as for the EUnetHTA 2006–8 project, this function was performed by the secretariat, based at the National Board of Health, Denmark.

Approximately three-fifths of respondents thought the administration had been effective. The proportion who thought secretariat leadership was OK (but could be better) rose from one-tenth in 2010 to one-fifth in 2012. This indicates that there was a slight increase in dissatisfaction with the administration as the project progressed. The qualitative data showed that concerns included, problems with e-mail, general communication problems, too short timelines, quicker feedback required, problems with work packages and the belief that more staff were needed in the secretariat.

The main method by which the project secretariat communicated with work package leaders and individual project participants was by e-mail. Therefore, participants were asked about their opinions about the nature of this communication. Approximately three-quarters of respondents thought the e-mails from the secretariat were acceptable, in terms of frequency and content. Comments related to clarity, frequency and length, that e-mails had improved from the previous EUnetHTA project, the importance of ensuring relevant addressee and suggestions for improvement (e.g. to use a standard template and include the work package number and deadline in the subject line). Although e-mail is a practical mode of communication, it is low down the hierarchy of communication methods because of its inherent problems. Suggestions have been made to improve e-mail communications in international projects. These include using specific titles, making the important point(s) in the first six to eight lines and avoiding overloading participants with e-mails.[55]

Additional support from the secretariat

These results were obtained from a combined closed and open question included in the 2010 and 2011 questionnaires.

Approximately one-fifth of respondents in 2011 thought there were other activities that the secretariat could do to support the project, and this proportion had risen from 2010. Suggestions included facilitating relationships, providing greater feedback, providing advice about monthly budgeting, being more

customer orientated, facilitating development of effective tools, facilitating information exchange, providing project management and enabling effective communication.

Key point 22

Overall, participants were positive about the assistance offered by the secretariat. Various additional activities were suggested, and it is hoped that in EUnetHTA JA2 with greater funding the activities can be expanded, for example to include support with project budgeting and project management.

Communication

Communicating in English

These results were obtained from a combined closed and open question included in all of the three questionnaires.

In any international project, communication is likely to be difficult because all members do not share a common language. It is important that there is a common language for communication.[58] Encouraging, approximately three-quarters of respondents had not experienced any significant problems when communicating in English during the project. The qualitative data showed that concerns included recognition of the inherent nature of communication problems, difficulty with English text, difficulty with audio, difficulty with speech, the need for greater time when communicating in English, recognition that language barriers exist, differences between nationalities, causes problems during meetings, difficulty in finding staff with good English-language skills and the suggestion of checking of documents by native English speakers. It should also be considered that there can be cultural aspects of communication. For example, Scandinavians and north Europeans tend to use a low-context style, where communication is explicit and unambiguous. In comparison in high-context styles (typical of southern Europeans), meanings of words can be hidden.[58]

Key point 23

Attention must be given to the difficulty of communicating in a common language. This should include consideration of strategies to overcome this, such as factoring in more time for dialogue and considering the possibility of getting documents checked by native English speakers.

Communication methods

These results were obtained from a combined closed and open question included in the 2011 and 2012 questionnaires.

Owing to the large and complex structure of the project, it was essential that communication was optimal. Participants working on tasks in the individual work packages were examples of virtual teams, '. . . teams of workers who are dispersed across geographical, temporal, and organizational boundaries, yet collaborate using information and telecommunications technology'.[55] To help facilitate this, a large number of different types of communication methods were used. Of these, the apparent most useful mechanism was face-to-face meetings. This method was most frequently described as very useful in all years (although this decreased from three-quarters in 2011 to two-thirds in 2012). In the hierarchy of communication

methods, in person communication has been ranked as the gold standard method because it is possible to see a person's body language and catch the tone of voice and any specific nuances.[55] This method is also the best mode for establishing trust[59] and discussing any controversial issues.[58] The observed inclination for face-to-face meetings might indicate that the EUnetHTA JA is a 'relationship-orientated culture' as such cultures prefer face-to-face meetings because of the benefits of physical, social and situation context.[58] A preference for face-to-face meetings goes hand-in-hand with the importance of networking and reinforces the importance of participants meeting in person as opposed to working solely in virtual teams. However, the benefits of this communication method need to be balanced with the inherent implications in terms of financial and logistical costs. Therefore, it is important that face-to-face meetings are conducted in an optimal manner and this demonstrates the importance of evaluating the policy-setting annual plenary assembly meetings.

Other popular methods for communication were by using the project intranet (the MO website) and by secretariat e-mails. These e-mails were a synchronous mode of communication, in that all (relevant) participants received the information at the same time. This is a communication better suited to task-orientated communications.[58] The MO website acted as the project intranet and was a central repository of project information. A large proportion of members did not know about the effectiveness of the plenary assembly. This was to be expected, because only one representative per organisation was permitted to attend this meeting.

Participants considered that communication could be improved in the EUnetHTA JA2 by having a formal communications plan, devoting more resources to it, improving the current systems (e-meetings, secretariat, website), using social networks, online tools, expanding networking opportunities, using project management techniques and improving communication with stakeholders. Stakeholders mostly considered this from the perspective of their receiving more information themselves rather than communication between workers on the project. Social interactions and networking is especially important for geographically dispersed teams.[59] In this respect, use of social networks such as Facebook (San Francisco, USA), Twitter (San Francisco, USA), LinkedIn (San Francisco, USA). may be useful. This point will be further investigated in the EUnetHTA JA2.

Key point 24

The most popular form of interaction was from face-to-face meetings and these should be used wherever appropriate in the EUnetHTA JA2. It is important that lessons are learned about how such meetings should be conducted and evaluation of the plenary assembly meetings is important in this respect. The project intranet site was very important and should be improved in the EUnetHTA JA2, particularly with respect to the workroom areas.

External promotion

These results came from an open question included in the 2012 questionnaire.

For projects generally little attention has been given to project marketing, which is concerned with communicating the long-term consequences of a project. The relationships between internal and external stakeholders are important. Suggestions for improvement included the need for a greater presence at conferences, need for more published information, improvement of the public website, national relevance should be communicated to countries, a need to target relevant stakeholders, social networks should be employed, missing an individual approach, more training needed and that promotion will be demonstrated best by collaborative HTA reports. There should be a distinction between whether the project has been insufficiently promoted externally or if that is a perception. This workstrand was the subject of the

dissemination work package, WP2. Detailed comments about the functioning of this work package are described below.

Key point 25

External promotion of the project should be improved for the EUnetHTA JA2 project. Strategies that have been suggested include better public website, advertisement of timelines and achievements, use of social media, etc.

Operation of work packages

Participants were asked questions in each questionnaire about the work packages they were involved with.

All work packages

All project participants, both members and non-members, were asked general questions about the individual work packages. External stakeholders were also asked for their opinions about the work packages.

Notably concern was expressed from the participants about the tool-generating work packages: WP4 (by almost one-quarter), WP5 (by almost one-fifth) and WP7 (by almost one-fifth). One-fifth of respondents had concerns about WP8. Almost half of respondents did not know if they had concerns about WP2 or WP3, and it is speculated that the fact these respondents did not know if they had concerns or not indicated a general lack of knowledge about these work packages. In contrast, external stakeholders had a higher rate of concerns about work packages which were not associated with developing HTA tools, i.e. WP1, WP2, WP3, WP6 and WP8.

This apparent concern about HTA tool-generating work packages by participants was apparently not reflected in whether or not participants thought their objectives would be met. However, for most work packages over half of the respondents did not know whether or not the objectives would be met. It is possible that respondents who were not part of a specific work package did not know whether or not the objectives of other work packages would be met or it could be that they thought the objectives would not be met but were unwilling to provide a negative response. The proportion of respondents who did not know was also very high for the stakeholders, again over 50%. This could suggest a lack of confidence in work packages being able to meet their objectives. Stakeholders showed lack of knowledge about objective meeting by work packages not associated with developing HTA-tools.

Approximately one-fifth of participants thought they had not received appropriate communications from the majority of work packages. However, a higher proportion thought they had not been adequately informed about WP2 and WP8. Two-fifths of stakeholders thought they had received insufficient communication from WP1. One-quarter of stakeholders thought they had received insufficient communication from WP2, WP6 and WP8.

There were minimal proportion of participants who expressed an opinion that work packages were not worth having. However, approximately half of respondents did not know if WP2 and WP8 were worth having in the project.

There was an indication from stakeholders that they had received insufficient communications from work packages in which they were not members of. They requested greater involvement of stakeholders in other work packages (e.g. by stakeholder advisory groups being set up) and involvement of professionals with specialist expertise in dissemination and business development.

Specific work packages

For the following section, project participants who were members of the individual work packages were asked detailed questions about them.

The individual work packages of the EUnetHTA JA can be viewed as individual projects in a portfolio. A virtual organisation is formed of virtual groups of workers.[59] A virtual work place forms a barrier to the richness of face-to-face interactions and for this reason the usefulness of face-to-face meetings have been used to jump-start an effective team.[59] Three factors are important for the performance of successful virtual teams: shared understanding, integration (working together in a way that creates value) and mutual trust.[59] A list of attributes of team members of international projects has been developed, which includes experience in similar projects, previous experience in international projects, ability to work with other people on tasks, ability to solve problems and work within the organisation, sensitivity to issues and potential problems, availability from their other work to perform tasks on the project, communication skills, ambition and energy, ability to cope with different cultures, ability and willingness to travel, and the ability to work hard at understanding and getting ideas across.[55] All project members have a responsibility for building trust, communicating, using and adhering to common ground rules and managing conflicts.[58]

Duties of a project manager of an international project include defining the project by dealing with ambiguity and politics, organising the project, dealing with the routine work, addressing issues and crises, leading by example, co-ordinating administration (e.g. logistical arrangements of face-to-face meetings.[55] Trust between project members is of vital importance in international projects, alongside the belief that fellow team members are putting their best efforts into the work and everyone is working towards the project goal.[58] Such trust is one of the prerequisites of managing global teams. This is difficult to establish in an international project because of knowledge of collaborating partners being low and reliance on virtual working practices.[58] It is also helpful to have informal interaction opportunities for each team.

Some of the main sources of conflict in international projects include ambiguity of project objective, insufficient authority of the project manager, manpower resources, costs, equipment and facilities, priorities and responsibilities.[58] One factor that can be important in the on-time delivery of a project is 'adequacy of documentation of organisational responsibilities on the project'.[57]

Work package 1: co-ordination

- There appeared to be a slight depreciation over time as the proportion who agreed increased and proportion who strongly disagreed decreased for leadership and communication being effective within the work package and deliverables being clear.
- The proportion who disagreed increased over time about the objectives of the work package being clear and the amount of work being manageable, which was one-tenth in 2012.
- Approximately one-fifth disagreed that the work package had benefited from the inclusion of stakeholders and one-quarter that all partners had contributed to the work adequately (2012 questionnaire).
- Almost one-third did not know how this work package had progressed in 2011, but this decreased in 2012 where approximately half thought it had been OK and half that it had progressed well.
- The proportion of respondents having concerns about the work package increased over time to one-fifth in 2011. The qualitative data showed that concerns included continuity, high dependency on the lead, too many face-to-face meetings, increased workload, overlap with EUnetHTA JA2 and about the business model.

Overall, this work package appeared to perform well over time with respect to effective leadership, clear objectives and manageable workload. However, concerns included the benefit of stakeholder inclusion and equal contribution of partners. There appeared to be a strong dependency on the lead partner. Concerns about the delivery of the business model and overlap with the EUnetHTA JA2 project have been addressed previously.

Work package 2: dissemination

- The proportion of respondents who disagreed about leadership and communication being effective within the work package increased over time to one-quarter and two-fifths respectively.
- The proportion of respondents who did not know was two-fifths or more for the planning timeline being clear, objectives being clear (P2011), progression of the work package over the past year (P2011), frequency of e-meetings, frequency of face-to-face meetings and whether or not the work package had communicated adequately with other work packages.
- Four-fifths did not know about the benefit of involving stakeholders in the work package.
- One-fifth of respondents thought the progression of the work package was poor. The qualitative data showed that concerns included the need for more communication, internally and externally, and more support from the co-lead partner.

Overall, this work package appeared to have performed somewhat poorly, with respect to effective leadership and communication. Particular concern was about the leadership, communication and benefit from the involvement of stakeholders. It was relevant that the representative from the colead organisation had died and the representative from the lead partner organisation had left part way through the project. This emphasises the importance of continuity of a project and the need for induction processes so that the project can continue seamlessly.

Work package 3: evaluation

This work package only contained one organisation (NETSCC) and two members of staff and, therefore, the evaluation questions were not asked for this work package.

Work package 4: core health technology assessment model

This was one of the core work packages of the EUnetHTA JA, with the aim of producing a tool for performing HTA. Therefore, stakeholders were also asked about how they thought it had performed.

- The proportion of respondents who agreed increased, but the proportion who strongly agreed decreased for leadership being effective, objectives being clear, and deliverables being clear.
- The proportion of respondents who disagreed about communication between members being effective increased over time to one-fifth in 2012.
- Approximately one-fifth of respondents disagreed about the amount of work being manageable, collaboration between members to produce core HTAs and benefit from the involvement of stakeholders. About two-fifths disagreed about whether or not all members had contributed to the work adequately.
- The proportion with general concerns about this work package decreased over time from one-quarter to one-fifth. The qualitative data showed that concerns included the applicability of the model, co-ordination issues, communication issues, workload and that stakeholders had been of little use
- By the final year approximately half of respondents thought it had progressed OK and half that it had progressed well. The qualitative data showed that concerns included slow progress, lack of participation in pilots and would form the basis for EUnetHTA JA2.
- Stakeholder concerns included limited applicability of the model in practice.

Overall, this work package appeared to perform well, with respect to effective leadership, and clear objectives and deliverables. However, some concerns were expressed about the amount of work, collaboration on the work, contribution of members and involvement of stakeholders. This was one of the work package that contained a larger amount of participants, which could have magnified intrinsic difficulties in communicating, dividing the work evenly and working together.

Work package 5: relative effectiveness assessment of pharmaceuticals

This was one of the core work packages of the EUnetHTA JA, with the aim of producing a tool for performing HTA. Therefore, stakeholders were also asked about how they thought it had performed.

- There appeared to be some degree of improvement in the leadership being effective and communication between members being effective because one-tenth disagreed in 2010, but this decreased to zero in 2011 (when one-tenth did not know).
- The proportion of respondents who disagreed about the amount of work being manageable increased to approximately one-third and a similar proportion disagreed about the contribution of staff.
- Almost one-fifth disagreed about the division of work and one-fifth disagreed about the number of face-to-face meetings being appropriate.
- Approximately half did not know about the benefits of stakeholder involvement, but half agreed involvement of stakeholders had benefited the work package.
- Concerns about the work package's progress decreased from two-fifths in 2010 to one-fifth in 2011. The qualitative data showed that concerns included that there had been a change in focus from developing a full and rapid model for assessment to only a rapid model, high workload beyond the schedule, applicability concerns, insufficient number of face-to-face meetings, and difficulty in managing stakeholder and political interest.
- The qualitative data showed that stakeholder concerns included lack of involvement, lack of information exchange and inappropriate influence of industry.

Overall, this work package appeared to perform well, with respect to effective leadership and communication. However, there were concerns about the amount of work, division of work, contributions of members and the number of face-to-face meetings (in 2010). This was again one of the work packages with a large number of members, which could cause intrinsic difficulties and the need for face-to-face meetings is highlighted. There was an apparent perception of high workload. It is difficult to conjecture whether there was too much work that had grown from the work plan or if this was members' perceptions. It is important that workers contribute as equally as possible so that the burden can be shared.

Work package 6: information management system

- There appeared to be improvement over the lifetime of the project, with the proportion of respondents who agreed decreasing and the proportion of those who strongly agreed increasing for communication between members being effective, objectives being clear, the planning timeline is clear and number of meetings was appropriate.
- Approximately one-tenth of respondents thought the technical issues were unclear in 2011.
- Three-fifths of respondents did not know about the benefits of involving stakeholders in the work package.
- Approximately one-fifth of members had concerns about the work package, which included that the work was dependent on the other work packages, the inherited IT system from the previous project and they would appreciate e-meetings to discuss the work between the planned face-to-face meetings.
- The proportion of respondents who thought the project had progressed well increased from approximately one-half to two-thirds in 2012.

Overall, this work package appeared to perform very well, with respect to effective communication between partners, clear objectives, clear planning timeline and an appropriate number of e-meetings. Some concern was shown about the equal involvement of members and of stakeholders. The information technology infrastructure is important for a geographically dispersed project and the other work packages were dependent on it.

Work package 7: new technologies

This was one of the core work packages of the EUnetHTA JA, with the aim of producing a tool for performing HTA. Therefore, stakeholders were also asked how they thought it had been performed.

- There was a noticeable level of disagreement in 2010, which improved slightly over the project; communication between members being effective (one-quarter in 2010), objectives being clear (one-fifth in 2010), leadership being effective, deliverables being clear and planning timeline being clear.
- The proportion of respondents who strongly agreed about the leadership being effective increased, while the proportion who disagreed also increased between 2010 and 2012.
- Three-fifths of participants were unsure about the benefit of involving stakeholders.
- Only about one-third of respondents agreed or strongly agreed that all members had contributed to the work adequately.
- The proportion who thought progress had been good increased in 2011 to three-fifths. The qualitative data showed that concerns included that the two strands had developed quite differently: lack of partners populating the POP database and obscure development of EVIDENT.
- The qualitative data showed that stakeholder concerns included delay in deliverables and lack of involvement of stakeholder advisory groups (SAGs) in the process.

One of the objectives of the process evaluation was to 'prospectively be vigilant of emerging issues and support the achievement of objectives'. It was identified in the first survey in 2010 that there were concerns about the leadership of WP7. This matter was raised with the lead organisation of WP7 and the executive committee. The WP7 lead partner explained that they had experienced lack of staff to fulfil some of their leadership activities as a result of a staff member going on maternity leave and they had plans to resolve this matter. This was not an apparent problem in the next annual survey of 2011 and so it seemed that the matter had been effectively resolved.

Overall, this work package seemed to progress quite well. After a somewhat disappointing start, it seemed to improve over the life of the project. However, there were some apparent concerns over unequal contribution of partners to the work.

Work package 8: strategy and business model development

- There was still significant disagreement in 2012 of at least one-fifth for communication being effective and the deliverables and objectives being clear.
- Two-fifths did not know if all members had contributed to the work adequately.
- Almost half did not know about communication with other work packages and the benefit of involvement of stakeholders in the work package work.
- This work package was split into three subsections and by the end of the project about one-tenth of respondents for each section thought it had progressed poorly.
- Approximately one-third of respondents had concerns in 2010 about the work package, but this decreased to one-fifth in 2011. The qualitative data showed that concerns included confusion about constitution and structure of the work package into three different work streams.

This was a complex work package and was subdivided into three separate work streams. This was reflected in the concerns expressed about the work package's structure and may have impacted on concerns about the communication, deliverables and objectives.

Plenary assembly meetings

Paper questionnaires were distributed to participants of the annual plenary assembly meetings and the response rates are shown in *Table 8*.

TABLE 8 Response rates to the plenary assembly questionnaires

Questionnaire	Number of questionnaires distributed	Response rate	Total *n* received
Plenary assembly evaluation 2010	39	74%	29
Plenary assembly evaluation 2011	47	77%	36
Plenary assembly evaluation 2012	50	78%	39

The plenary assembly was an annual meeting to which a representative of all project participant organisations was invited, alongside members of the stakeholder forum. It had an elected chairperson and was a policy-setting forum. These meetings were costly, in respect of financial cost of members travelling to a foreign city and person-hours involved. Therefore, it was essential that these meetings were as productive as possible. The academic literature shows that it is important that meetings are reviewed at their outset and learning used to improve future events.[60] Therefore, the meetings were evaluated and the results fed back to the secretariat in a detailed report to lead to quality improvement initiatives. The findings will be of use in planning the plenary assembly meetings of the EUnetHTA JA2.

A meeting can be considered a project tool.[61] Meetings can fulfil various functions; information sharing, brainstorming, problem solving, and decision-making and socialising.[61] Characteristics of meetings have been studied and classified as temporal (relating to the use of time in a meeting, e.g. use of a break), physical (relating to the meeting environment, e.g. meeting space), procedural (relating to how the meeting is conducted, e.g. following a formal agenda) and attendee (relating to members, e.g. the role of the meeting facilitator).[61]

Objectives

Participants were asked a closed question in each questionnaire about whether or not they thought the meetings' objectives had been achieved.

Overall, approximately one-tenth of meeting participants did not know whether or not the meetings' objectives had been met in 2010 and 2012. About one-fifth were not sure for the 2011 meeting. It is recommended that the meeting objectives are made explicit from the outset. It was concerning that one-tenth of participants thought the meeting's objectives had not been met in 2011. Causes for concern included questions not being answered, lack of useful information and lack of time for debate. When indicating that the meeting objectives had been met, it appeared that participants cited factors that had been important for them personally, such as information gain and endorsement of decisions.

Key point 26

The objectives of the meeting should be made explicit on the agenda before the meeting.

Most preferred aspect

Participants were asked an open question in each questionnaire about what the best aspect of the meeting had been.

Overall, meeting participants seemed to appreciate meeting people face-to-face, discussions, information sharing, social activity and good meeting logistics.

The academic literature has shown that the agenda is crucial in meetings and it has been recommended that meetings begin with a few easy items to settle participants in.[60] Difficult items should be placed around breaks. Frequent breaks should be factored into meetings because concentration typically wanes after about 45 minutes. This also enables participants more opportunities for informal networking. Larger meetings have been correlated with a lower quality and demonstrated the need for a facilitator. Other attributes that have a positive effect include having a break, sufficient lighting and temperature of the room, room space and refreshments.[61]

Least preferred aspect

Participants were asked an open question in each questionnaire about what the worst aspect of the meeting had been.

In 2010 problems seemed to centre around technical problems with microphones during the meeting and difficulties getting to the venue. Good meeting logistics are important for a successful interaction and functioning microphones are an important facet of this. In 2011 there were apparent difficulties posed because of the meeting venue (such as seeing the slides) and chairing of the meeting (such as lack of summing up and apparently treating comments at different levels). It is crucial that tables and chairs are positioned so that the chairperson and all the members may participate appropriately. The academic literature has shown that seating the chairperson separately might help them exert their authority over proceedings[60] and it is important that participants are able to express their opinions and everyone is heard, and that discussions are respectful.[61] How the participants viewed the meeting can have important attitude and behavioural implications and can impact negatively on the ability of a meeting to reach its goal and support of future meetings. Perception of meetings can also have an effect on employee morale. In 2012 there was an apparent lack of people participating in discussions in the plenary assembly meetings. A common theme throughout the three meetings was lack of time for discussions and participants wishing the opportunity to prepare themselves in greater detail before the meeting. Statistically significant benefits have been found in the academic literature with prior access to an agenda and it is believed that this helps in setting expectations in advance of the meeting and allows for pre-meeting preparation.[61] The working environment of meetings is very important and emphasises the finding that this affects mood and influences behaviour.[61] To make meetings more interesting the format of presentations in the plenary assembly meetings can be changed, for example using group breakout sessions and different visual presentations (e.g. flip charts, video clips, etc.). Other important facets of a meeting include a productive, morale-boosting nature and presentations of adequate content and length.[61]

Meeting attributes

In 2011 and 2012 participants were asked to rate attributes of the meeting in a combined closed and open question.

The factor that was rated very good most often was the social event. The second best was meeting or networking with colleagues, with 97% of participants in 2011 and 99% in 2012 rating this as good or very good. An important facet of building trust within an international team is providing informal interaction opportunities.[58] Establishing trust is integral for a successful international project, but is difficult to establish. It cannot be achieved by a one-off meeting but takes time and is a reiterative process in order to cement relationships.[58] The importance of combining a team meeting with a team-building activity, such as having a meal in a restaurant, has been emphasised.[58] Reviews of research have highlighted the importance of initial face-to-face meetings in 'jump starting' effective virtual teams.[59]

It was noticeable that the meeting venue in 2011 was poor – only 8% rated this as very good compared with 64% in 2012. Leadership of the meeting was also better in 2012 than 2011 with 95% rating this as good or very good in 2012. In decision-making meetings the chairperson should use a participatory style rather than an autocratic one. At the end of a meeting the discussions should be summarised and actions denoted.[62]

Involvement of stakeholders

The concept of a project's value can also be reflected in its worth to different stakeholders.[63] Stakeholders can be defined as 'actors who have an interest in the issue under consideration, who are affect by the issue, or who – because of their position – have or could have an active or passive influence on the decision-making and implementation process'.[64] Alongside the individual project participants this also included external stakeholders. Such stakeholders for a project can be from heterogeneous organisations, from different cultures and hold different values.[63] Knowledge about relevant external stakeholders is vital for international projects. It is important that their influence level is assessed and their objectives in relation to project strategies and deliverables identified. Stakeholder position in a project can be defined as ally (agree with the need for the project, support the strategies and can influence other stakeholders), oppose (disagree with the strategies and dissent from the project) and neutral (do not have a special interest, but will not suffer from the project's completion).[65] It is important that an analysis of stakeholders is performed at the start of a project. This allows mapping of an individual stakeholder's relation to the project, as well as the relationship between stakeholders.[64]

Views of project participants about the involvement of stakeholders

Participants were asked open questions in 2011 and 2012 about concerns associated with involvement of stakeholders in the project. They were asked what the benefits of stakeholder involvement had been by an open question included in the 2011 questionnaire.

When participants were asked in 2012, only two-fifths had no concerns about the actual involvement of stakeholders in the EUnetHTA JA. A further two-fifths did not know if they had concerns and one-fifth had concerns. Only one-third of participants had no concerns about the level of commitment of stakeholders, one-fifth had concerns and half did not know. The qualitative data showed that concerns centred around lack of participation and commitment of stakeholders and the heterogeneous nature of stakeholders. Therefore, there was a large proportion of concern or apparent lack of knowledge, which might have indicated a lack of added value.

Response rates to stakeholder questionnaires

For the S2011 survey, only half of the four industry representatives and half of the four patients/consumers responded. The situation was repeated in S2012 (although the individual non-responding organisations were different). It may be that lack of response is itself of value (e.g. leading to the speculated conclusion that the stakeholder organisation does not consider EUnetHTA of sufficient importance to engage with), but it would be preferred to have this opinion explicitly stated. Unfortunately, it was beyond the scope of the evaluation (agreed with the EU Commission) to include follow-up of non-respondents.

Key point 27

Stakeholders must commit to answer evaluation questionnaires in the EUnetHTA JA2, so that their opinions can be considered.

Formation of the stakeholder forum

A combination of closed and open questions were included in the questionnaires about the formation of the forum, its purpose, why stakeholders had applied to join it, what they could contribute and whether or not appropriate organisations had been included.

A prerequisite of the EUnetHTA JA project was an acknowledgement of the importance of communicating with stakeholders.[13] With this aim a formal stakeholder forum was established in 2010. This contained four seats for stakeholder categories of industry, patients/consumers, providers and payers. Stakeholders became aware of this forum from various avenues, including from the EU Commission, the EUnetHTA

secretariat and key project personnel and other stakeholders. Stakeholders had applied to be an external stakeholder for various reasons, including contributing to the JA project, to enable reciprocal working patterns and ensuring a balance of stakeholder expertise. Stakeholders believed they could contribute to the project by providing specialist HTA knowledge, providing access to experts, providing a governance role and disseminating the project results. They saw the purpose of the forum as facilitating the stakeholder involvement process by providing an intermediary link between the stakeholders and the JA project, overseeing work package and SAG activities, developing consensus for decision-making and being 'transparent, responsive, accountable and participative'.

In practice, only two organisations applied for the four seats in both the provider and payer categories. This only represents half-capacity take-up and it is suggested that possibly these were inappropriate types of stakeholder expertise to include in the project or that the call for stakeholders was too limited. There were more participants than spaces for the industry and patients/consumer groups, and this meant that some applicants were excluded. The perceived risk from non-inclusion of these organisations were suggested as missing expertise, decreased scope of JA activities, decreased confidence in the project and inclusion of less experienced representatives. It was notable that only one-fifth thought that the way of setting up the forum was straightforward. The qualitative data showed that concerns included the process itself, that it was organised to fulfil a certain type of stakeholder involvement, restricting stakeholder members prevented equal contributions, lack of clarity about why applicants were rejected and complexity in assigning a representative. However, about three-quarters of stakeholders questioned near the end of the project thought the formation of the forum had been an effective mechanism for involving stakeholders. Over two-thirds of respondents surveyed in 2012 thought the appropriate organisations had been included. Those members who had applied to join the forum but had been excluded from the forum were represented by a representative for their specific group. At the start of the project the majority of these organisations were concerned that they would not be represented adequately. However, these concerns appeared unfounded because by the end of the project all agreed that they had been kept adequately updated by either their forum representative or by the secretariat.

The qualitative data showed that there were apparent initial concerns about the formation of the forum because it was seen as a complicated business and there were concerns about restriction of expertise. However, by the end of the project this was seen as having been an effective mechanism and mostly included the correct stakeholders. Those who had not been successful in gaining a place had been kept informed by their representative.

Key point 28

Overall, the stakeholder forum seemed to be an effective means of involving external stakeholders in the EUnetHTA JA. Non-members appeared to have been adequately informed by their designated representative.

Operation of the stakeholder forum

A combination of closed and open questions were included in the questionnaires to identify stakeholders' views about the operation of the forum, whether or not it was fulfilling its purpose and comments on the meetings held.

In 2011, all respondents agreed that the forum was fulfilling its purpose, recognising an initial start-up period. It was seen as being inclusive, evolving and that there was increasing trust. Its purpose was cited as being a special advisory group to the executive committee, commentating on work package tasks, overseeing SAGs, gaining consensus for decisions. The majority thought membership was involving what they had envisaged and it seemed to be improving over time. However, in 2012 about one-third thought it was not fulfilling its purpose and about one-third did not know if it was or not. Of the third who thought

it was not fulfilling its purpose, half were patient organisations and half were industry. It could be worth probing stakeholders in greater depth to analyse why the functioning of the forum appeared to depreciate between 2011 and 2012 (but unfortunately this was beyond the scope of the evaluation agreed with the EU Commission).

Regular stakeholder meetings were held (both electronically and face-to-face) and almost three-quarters thought these had been useful. In general, these seemed to be appreciated, were well organised and of a suitable frequency. Suggestions for improvement included having pre-preparation materials sent in advance, a stakeholder chairperson, facilitating more contribution from stakeholders and more suitable agenda items following greater dialogue about setting the agenda.

Key point 29

Stakeholder forum meetings were appreciated and should continue in the EUnetHTA JA2. Improvements could be made, for example by having a more participatory nature, greater dialogue about setting the agenda and considering having a stakeholder chairperson.

Half of respondents had concerns about the principles of stakeholder involvement in the EUnetHTA JA (stakeholder policy and standard operating procedures). Of these five organisations all types of stakeholder were included.

Key point 30

There is a need to review the documents and processes for stakeholder involvement in EUnetHTA JA2.

Nature of being a stakeholder of the European Network for Health Technology Assessment Joint Action

A combination of closed and open questions were included in the questionnaires about what it meant to be a stakeholder in the project: how they had been involved, how their opinions and expertise had been used, if adequate feedback had been received and how involvement of stakeholders could be improved in EUnetHTA JA2.

At the start of the project stakeholders thought their involvement and contributions would include general input and specific HTA knowledge/expertise, attending meetings, being involved in work packages, facilitating experts, sharing information, providing a governance role and disseminating project results. In the interim year, almost three-quarters of stakeholders indicated that involvement in the stakeholder forum had involved what they thought it would, although some concerns centred around balance of the forum's representativeness. During the project and at the end, they commented how they had been involved. This broadly included the activities they had anticipated, along with being a member of SAGs, participation in the plenary assembly, organising a joint industry response, regular contact with work package leaders, participating in the EUnetHTA JA conference and in discussions about the future of EUnetHTA JA2. However, it was of concern that almost three-quarters had worries about the actual involvement of stakeholders in the EUnetHTA JA1. Half did not think that their organisation's expertise had been appropriately used. Of these five organisations, two were from industry, two were patient organisations and one was a payer organisation.

Half had concerns about the 'principles of stakeholder involvement in the EUnetHTA JA'. The majority of stakeholders either had concerns about the commitment of stakeholders in the JA or did not know if they had concerns or not. Of the four who had concerns, two were from patient organisations, one was from industry and one was from providers.

About one-third of stakeholders thought that stakeholders' views were not adequately considered and the proportion of those who thought that were considered increased from one-third to one-half by the final year. The two organisations which disagreed were industry and patient organisations. Suggestions for improvement included involving stakeholders at an earlier stage in iterative planning, producing summaries of contributions and making the forum more participatory in nature.

Key point 31

There was a sense that stakeholders thought they had much to offer the work of the EUnetHTA JA project but that they could have been involved to a greater degree.

In the interim year, the majority thought that being a member of the stakeholder forum had been a good use of their organisation's time, but this decreased to two-thirds in 2012. The organisations which thought it had not been a good use of time were both patient organisations. In contrast all organisations who were not participants of the forum had 'got what it hoped by being a Stakeholder of the JA' and that it had been a useful use of their time. Participation was seen to confer benefits to stakeholders; increasing general HTA knowledge, recognition for the umbrella stakeholder organisation and ability to comment on documents before publication.

Stakeholder advisory groups were formed for WP4, WP5 and WP7 with the purpose of organising stakeholder input into the work of the EUnetHTA JA. This way of working was apparently well received, with about two-thirds of respondents appreciating this style of involvement. However, the qualitative data showed that concerns included short timelines for responding to consultations and the diverse nature of the stakeholder forum made it difficult to balance points of view.

Key point 32

Developed during the project, stakeholder advisory groups appeared to function well. Concerns, such as short timelines for responding to consultation and the difficulties of obtaining a balance view should be addressed in EUnetHTA JA2.

The stakeholders did not know at baseline whether or not they would be provided with adequate feedback about the project and they suggested that a stakeholder chairperson be appointed to better link them to the project. However, these fears seemed to be unfounded because the majority thought they had received adequate feedback in the interim and final years. There were still some suggestions for improvement, such as that having earlier information about work packages would enable better participation. The one organisation that disagreed was a patient organisation.

Key point 33

The provision of information to stakeholders had generally been adequate. Improvements could be made, for example by providing information earlier, etc.

There was some apparent concern by some members that the forum was a homogeneous group of experts who could be biased (particularly towards the pharmaceutical industry). In the future, efforts must be made to ensure greater participation and representation of all groups' views.

Key point 34

The different natures, interests and level of influence must be recognised in EUnetHTA JA2. Processes and documents must ensure a participatory nature and inclusion of the views of all relative stakeholders.

Improvement in European network for Health Technology Assessment Joint Action 2

Stakeholders considered that positive involvement had been seen through SAGs, that the diversity of different stakeholder groups on the forum needs to be managed and that earlier involvement of stakeholders, such as in formulating the project objectives and evaluation criteria, would be appreciated. Participants also thought that stakeholders should be involved earlier in the process, that the involvement of stakeholders should prevent bias towards industry, that the forum had been a good mechanism and that communication between project participants and stakeholders should be improved.

Key point 35

There was a sense that stakeholders appreciated involvement in the EUnetHTA JA. However, they felt they had more expertise to offer and this could be facilitated by earlier and more inclusive involvement in work package tasks with longer deadlines for review. Participation could also be helped by an inclusive stakeholder forum that appreciated the heterogeneous nature of stakeholders and valued contributions from all groups equally.

European network for Health Technology Assessment Joint Action 2

The EUnetHTA JA2 project has been formed by a grant agreement with the European Commission. Its general objective is to 'strengthen the practical application of tools and approaches to cross-border HTA collaboration'.[66] It is notable that the main outcome of the EUnetHTA JA2 will be similar to the overarching objective of the EUnetHTA JA, 'the implementation of the permanent network for HTA in Europe'.[66] This project will operate from 2012 to 2015 and it will be composed of the following work packages:

- WP1 – co-ordination
- WP2 – dissemination
- WP3 – evaluation
- WP4 – testing collaborative production of HTA information for national adaptation and reporting
- WP5 – applying the HTA Core Model for rapid assessment for national adaptation and reporting

- WP6 – information management infrastructure and services
- WP7 – methodology development and evidence generation: guidelines and pilots production
- WP8 – maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information.

Purpose

The majority of stakeholders, and almost three-quarters of participants, thought the EUnetHTA JA2 would serve as a useful follow-up to the EUnetHTA JA project, with the rest not knowing whether or not it would be. Comments revolved around the fact that EUnetHTA JA2 would benefit from the experiences of the EUnetHTA JA, that it is a necessary follow-up project, that it has a different focus, that further development of tools for HTA is required, there is a need to test the effectiveness of joint report production, this would identify co-operation between agencies and enable examination of the methods developed in actual practice. It was seen as a bridge between the EUnetHTA JA and the permanent network. This seemed to be an indication that the EUnetHTA JA had not completely fulfilled its objectives and that it needed a further joint action project to be able to actually apply the tools in practice.

Concerns

The proportion of project participants who had concerns about the EUnetHTA JA2 project decreased from 2011, when over half had concerns, to 2012, when approximately one-fifth had concerns. Different concerns were noted in the 2 years. The qualitative data showed that concerns in 2010 included worries about an overlap with the current JA, HTA reports, poor definition of the project and political aspects. The qualitative data showed that concerns in 2011 included integration of deliverables, scope of the project and involvement of the correct expertise. Lack of resources was noted in both years. Almost one-third of stakeholders had concerns, which included stakeholders not being sufficiently involved or representation of different stakeholders. These also included commitment of governments to implement outputs and the need to have clear obligations and a timetable. About one-third of project participants had concerns about the actual planning process, which included lack of time in submitting the plans, and problems with the overlap between the two projects. About three-fifths thought it was having an impact on the time available for work on the EUnetHTA JA project. Suggestions for how it could have been better included having more time for preparatory work, a bigger focus on capacity building, greater stakeholder input and incorporating recognised project management techniques.

Lessons learned from the European network for Health Technology Assessment Joint Action

Project participants and stakeholders had different perspectives on what could be learnt from the EUnetHTA JA to inform the next project. Participants recognised the importance of collaboration and communication and contribution of participants, better project planning and budgeting, more accurate scoping of work at the start, information sharing, development of tools and appropriate involvement of stakeholders and experts. Stakeholders felt less complexity and greater transparency was needed, a formalised lessons learned document was required from the EUnetHTA JA to build on and stakeholder involvement should be strengthened.

Involvement of stakeholders

Suggestions for improving the involvement of stakeholders included earlier involvement, need for more balanced representation to avoid industry bias, recognition that they have an important role in validating the tools, sharing deliverables with them, the positive effect of SAGs and to share timelines earlier. This indicates the impression that stakeholder involvement was a developing process; it was recognised as needed from the EUnetHTA 2006–8 project, developed through the EUnetHTA JA project with the establishment of the stakeholder forum and SAGs and needs further evolvement in the EUnetHTA JA2 project. In this respect, it is hoped that the lessons learned from the evaluation of the JA project will be helpful.

Key point 36

It was not possible to progress from the EUnetHTA JA to the permanent network, but a bridging project seemed necessary: the EUnetHTA JA2 project. It is important that lessons are learned from the EUnetHTA JA. These included utilising better project planning and budgeting and stakeholder involvement. Stakeholder involvement is seen as an evolving process; recognised as needed by the EUnetHTA 2006–8 project, developed during the EUnetHTA JA project and requiring further development in the EUnetHTA JA2 project.

Lessons learned from the European network for Health Technology Assessment 2006–8 project

The objective of the EUnetHTA 2006–8 project was:

> *. . . to establish an effective and sustainable European network of Health Technology Assessment to inform policy decisions. The overall strategic objective is to connect public national health technology assessment (HTA) agencies, research institutions and health ministries, enabling an effective exchange of information and support to policy decisions by member states.*

A key part of effective project management is learning from previous experiences, in a quality improvement process. This should ensure that learning is embedded into continuous improvement of project processes.[57] Therefore, it was important to identify the recommendations made in the evaluation report of the EUnetHTA 2006–8 project and to assess whether or not these had been acted on for the EUnetHTA JA. Similarly to the EUnetHTA JA project, one work package was responsible for the internal evaluation of the EUnetHTA 2006–8 projects and delivering a final report. This included the following recommendations 'for a future sustainable network'[67] shown in *Box 4* below.

It is important to note that the recommendations that were made from the evaluation of the EUnetHTA 2006–8 project were for 'the future sustainable network' which, at the time of writing the report, was thought to be established in 2009. However, this was not achieved as anticipated directly following the

BOX 4 Recommendations from the EUnetHTA 2006–8 project [Haheim LL, Iglesia II, Laubli M, Gasparetto T, Gonzalez-Enriquez J, Trofimovs I, *et al. EUnetHTA Internal Evaluation Report (2006–2008).* 2008. URL: www.eunethta.eu/outputs/eunethta-internal-evaluation-report-2006-2008 (accessed March 2014)][67]

1. Secure funding and maintain a dedicated co-ordinating secretariat.
2. Ensure efficiency through an organisational structure made up of work packages managed by a core of dedicated partners, with less committed partners taking part as a wider review group.;
3. Continue developing and evaluating the tools as necessary and in real settings.
4. Involve people in the work to ensure commitment, a high level of knowledge, and a broad basis for decision-making processes.
5. Encourage collaboration and communication among all parties to ensure coherence within groups and within the EUnetHTA collaboration.
6. Continue developing the communication platform and clearinghouse functionality to make the EUnetHTA collaboration the central reference point for HTA in Europe.
7. Arrange face-to-face meetings at the outset of group or committee work to strengthen social coherence and reach a common understanding of the work.
8. Evaluate the technical communication platform.
9. English has been the main language and should continue to be so.

2006–8 project. Instead, it was necessary to have the EUnetHTA JA project and the EUnetHTA JA2 project to bridge the gap between the initial EUnetHTA 2006–8 project and the sustainable network which is currently expected to be established by 2015.

Secure funding and maintain a dedicated co-ordinating secretariat

The EUnetHTA 2006–8 project was cofunded by an EU grant and the individual participating organisations in a ratio of 1 : 1. For the EUnetHTA JA this was also part funded, in a 1 : 1 ratio from the EU and from Associate partner organisations.[13] As for the EUnetHTA 2006–8 project, the main partner was the Danish Health and Medicines Authority (formerly the National Board of Health). It acted as a dedicated co-ordinating secretariat and led the co-ordination work package (WP1). One aim of this work package was to ensure the submission of technical reports to the EU Commission on time and meeting deadlines of deliverables.

In the EUnetHTA JA project, the co-ordinating secretariat was maintained. Evaluation results showed that approximately three-fifths of project participants thought they had provided effective administration and three-quarters thought their communication by e-mails was adequate. Other activities that could be performed by the secretariat included a greater role in facilitating relationships, providing project management guidance and providing greater feedback about the project. It is suggested that this be considered for EUnetHTA JA2.

Conclusion: Funding was secured for the JA project. The secretariat was maintained as a dedicated co-ordinating support.

Assure efficiency through an organisational structure made up of work packages managed by a core of dedicated partners, with less committed partners taking part as a wider review group

The evaluation of the 2006–8 project concluded that 'work packages have proven to be a good working model', while recognising that clarification was needed about how each partner could contribute. The structure of work packages had been shown to be effective by the previous project and is a common method of organising the structure of international projects.[58] Therefore, this structure was chosen again for organisation of the EUnetHTA JA project.

The majority of participants and stakeholders who expressed an opinion in the evaluation of the EUnetHTA JA thought this method of organising the work was positive. However, approximately one-quarter of participants thought there would also be negative aspects associated with this division. Concerns centred around possible overlap between the aims and work of individual work packages and the importance of effective communication between them.

Each work package was led by a designated lead partner organisation and the executive committee brought these organisations together, along with the plenary assembly chairperson and EU representative, every 2 months.

In the EUnetHTA JA project there were some apparent suggested cases of unequal contributions from partners. Going forward to the EUnetHTA JA2 project there are plans to manage contributions by classifying organisations as either 'active' or 'less active' and managing financial reimbursement accordingly.

Conclusion: The same work package format (common to DG SANCO-funded projects) was used for the EUnetHTA JA. Some concerns about apparent unequal contributions means that organisations will be graded for the level of their activity in the EUnetHTA JA2.

Continue developing and evaluating the tools as necessary

Evaluation of the previous project identified that tools had been produced within the project lifecycle according to the scheduled timeframe. However, it identified that adjustments and further development of

ideas was needed and, therefore, tools had not been piloted in a real-life setting (although two pilots had been performed for the HTA Core Model; 'core HTA on drug-eluting stents' and 'core HTA on multislice computerised tomography angiography'). One of the three specific objectives of the EUnetHTA JA project was 'application and field-testing of developed tools and methods'.

The documentary analysis revealed that most of the 11 project deliverables had been produced by the end of the EUnetHTA JA project. These included the following tools; HTA Core Model on screening, an 'operational web-based toolkit including database-containing information on evidence generation on new technologies' and a 'quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies'. It was predicted that the 'methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals' would be delivered after the project end, in February 2013.

Although the HTA tools had been further tested in the EUnetHTA JA project there seemed little opportunity to evaluate their use in practice. Therefore, one of the main tasks of EUnetHTA JA2 must be to pilot the tools in actual practice of preparing HTAs.

Conclusion: The HTA tools and methods had been further developed in the EUnetHTA JA project. However, there had been little opportunity to evaluate their use in practice and this appears to be the task of the EUnetHTA JA2 project.

Involve people in the work to ensure commitment, a high level of knowledge and a broad basis for decision-making processes

One of the apparent added values of the EUnetHTA JA project was the opportunity for project participants to network and share information with each other. This contributed to achieving a high level of knowledge within the project.

Some considerable turnover in project participants was seen during the lifecycle of the project and it is important to develop a suite of induction materials to involve new staff in the work quickly and efficiently. In view of this turnover it was of concern that only two-fifths of respondents were aware that their organisation had a sufficient plan to mitigate this in succession planning. Commitment to the work might be affected by lack of staff or resources and careful budgeting and project planning would help this in the EUnetHTA JA2.

Conclusion: One of the added values of participation in the project included information sharing. Commitment to the work was demonstrated by the fact that all deliverables were produced according to the work plan. Potential turnover of staff must be managed and processes implemented to manage resources.

Encourage collaboration and communication among all parties to ensure coherence within groups and within European network for Health Technology Assessment

It is slightly ambiguous what the evaluation considered as 'all parties' and 'groups'. Members seemed to collaborate on the work effectively within the separate constituent work packages. It was notable that one of the main benefits of the EUnetHTA JA project was seen by participants as networking. There seemed to be little evidence of tangible collaboration on HTA during the EUnetHTA JA, although some was performed using the HTA Core Model. More collaboration is planned during the EUnetHTA JA2. Communication within the EUnetHTA JA appeared to be effective and the mechanism most preferred by project participants was face-to-face meetings.

Conclusion: Members appeared to collaborate on the tasks within work packages. There was less evidence on collaboration on HTA reports, but this will be progressed in the EUnetHTA JA2 project. Communication seemed to be effective and face-to-face meetings were the preferred mechanism.

Continue developing the communication platform and clearinghouse functionality to make European Network for Health Technology Assessment the central reference point for HTA in Europe

This was not continued during the JA project.

Conclusion This was not continued in the JA project.

Arrange face-to-face meetings at the start of group or committee work to strengthen social coherence and reach a common understanding of the work

Networking was highly valued by project participants and face-to-face meetings were the preferred means of communication. It has been suggested that such meetings are important in fostering trust between virtual teams of an international project.

Conclusion: Face-to-face meetings seemed highly valued by project participants and should be arranged for the start of group work in the EUnetHTA JA2.

Evaluate the tools in real work settings and the technical communication platform

As discussed previously, the focus of the EUnetHTA JA seemed to be on the development of the tools. The focus of the EUnetHTA JA2 will be on evaluating the tools in real work settings. The technical communication platform of the information management system performed well. The intranet site was used by most members. However, some improvements in the workrooms and for the e-meeting system were required.

Conclusion: There appeared little chance to evaluate the tools in real-life work settings, and this will be the focus of EUnetHTA JA2. The information management system supported the communications of the project well.

English has been the main language and should continue to be so

In an international project it is practical if a common language is used. It was encouraging that the majority of participants had not experienced a serious difficulty with either written or spoken English.

Conclusion: Communicating within the project in English has worked well and this should continue for the EUnetHTA JA2 project.

Conclusions

Nature of the project and the evaluation

- The EUnetHTA JA was a complex international project with a 3-year lifecycle.
- This evaluation has contributed to the awareness within the network about types of expertise available in, and HTA information produced by, member organisations.
- There was a high degree of project participant turnover within the lifecycle of the project. This necessitates the provision of high-quality induction materials.
- The evaluation methodology of repeat cross-sectional population surveying by online questionnaires worked well. The strategy for optimising response rates was effective.
- One of the requirements of the EUnetHTA JA project was to have this internal evaluation. However the final evaluation results had to be collated 6 months before the end of the project, which limits the evaluation. To be most effective, final evaluation of a project should be done following its end, to enable assessment of impact.

Project impact

- The impact of the project was measured by assessing whether or not the deliverables and objectives of the project had been met.
- The majority of deliverables were produced by the end of the project, according to the final technical reports submitted. The methodological guidance for the assessment of relative effectiveness of pharmaceuticals was predicted to be delivered in the month following the project close (by the end of February 2013).
- The project's overarching objective was to 'establish an effective and sustainable HTA collaboration in Europe that brings added value at the regional, national and European level'**.** Using the definitions provided by project participants and stakeholders it appeared the JA had not been successful in meeting this objective. The foundations laid by the EUnetHTA 2006–8 and the EUnetHTA JA project will be followed by the EUnetHTA JA2 project before evolving into the permanent network in 2015.
- The business model and strategy was delivered as planned. This strand of activity is being continued in the EUnetHTA JA2.
- The HTA tools and methods were produced as planned. It is notable that further development of the HTA Core Model is planned during EUnetHTA JA2.
- The objective of application and field-testing of HTA tools and methods was apparently not met and this will be further explored in EUnetHTA JA2.
- Only half of respondents thought the EUnetHTA JA had achieved what they wanted, but a larger proportion had personally benefited from the project. Such added value included networking, information sharing and improved awareness of HTA developments.
- The tools had not been delivered by the time that the final evaluation was conducted and, therefore, it was too early to assess their quality and use in practice. Project participants had used the tools for communication, including the project intranet. Future benefit was anticipated from use in practice of the HTA Core Model, the POP database and, to a slightly lesser extent, the EVIDENT database. The highest priority for training was the HTA Core Model. Face-to-face workshops seemed to be the training method of choice for these 'content' tools. Self-directed training with a manual was preferred for the 'process' tools – the project communication tools. There is a need to evaluate the effectiveness of the HTA methodology tools in EUnetHTA JA2.

Project effectiveness

- Effectiveness was measured by evaluating the processes of the project.
- The set-up of the project, including structure into eight work packages, seemed to be effective. The need for communication between the work packages was emphasised to prevent duplication of effort and harmonisation of processes.
- Only about half of respondents thought funding was sufficient and budgeting and project planning processes should be used in EUnetHTA JA2 to help with this. Succession planning within organisations is also essential.
- The main challenges of being involved in the project were insufficient funding or staffing and conflicts with other work. Other problems included the large project scale and demands of individual work packages.
- Overall the leadership and administration from the secretariat had been effective. There was some apparent concern about the over-reliance on the project's leader.
- The majority of participants had not experienced a significant problem in communicating in English, the official language of the project. The most effective method of communicating was by meeting face to face.
- There seemed to be a lack of knowledge from participants about the work packages that they were not involved in and this could be improved for the EUnetHTA JA2.
- The plenary assembly meetings had generally worked well. There seemed to be some problems due to the room lay out in 2011 and lack of involvement of participants in 2012.

- Involvement of stakeholders seemed to be an evolving process that began in the EUnetHTA 2006–8 project, progressed during the EUnetHTA JA project and requires improvement in the EUnetHTA JA2 project. Analysis of stakeholders' views was hampered by the fact that not all organisations had completed their questionnaire. All organisations must commit to answer evaluation questionnaires in the EUnetHTA JA2, so that their opinions can be considered.
- Overall, the stakeholder forum seemed to be an effective means of involving external stakeholders in the EUnetHTA JA. Non-members appeared to have been adequately informed by their designated representative. Stakeholder forum meetings were appreciated and should continue in the EUnetHTA JA2. Improvements could be made, such as by having a more participatory nature, greater dialogue about setting the agenda and considering having a stakeholder chairperson. Participation could also be helped by an inclusive stakeholder forum that appreciated the heterogeneous nature of stakeholders and valued contributions from all types of members equally. There is a need to review the documents and processes for stakeholder involvement in EUnetHTA JA2.
- Developed during the project, SAGs appeared to function well. Concerns, such as short timelines for responding to consultation and the difficulties of obtaining a balanced view should be addressed in EUnetHTA JA2. The different natures, interests and level of influence of different stakeholder categories must be recognised in EUnetHTA JA2. Processes and documents must ensure a participatory nature of inclusion of the views of all relative stakeholders. There was a sense that stakeholders appreciated involvement in the EUnetHTA JA. However, they felt they had more expertise to offer and this could be facilitated by earlier and more inclusive involvement in work package work with longer deadlines for work review.
- EUnetHTA JA2 is the follow-up project to the EUnetHTA JA and there was an overlap between the two. It was not possible to progress from the EUnetHTA JA to the permanent network, but a 'bridging' project seemed necessary – the EUnetHTA JA2 project. It is important that lessons are learned from the EUnetHTA JA. These included utilising better project planning and budgeting and stakeholder involvement.

Lessons learned from European network for Health Technology Assessment 2006–8 project

Overall the EUnetHTA JA project seems to have used the recommendations made by the internal evaluation of the EUnetHTA 2006–8 project with the following being maintained: a co-ordinating secretariat, structure made up of work packages, development of tools, involvement of participants, development of the communication platform, holding face-to-face meetings and using English as a common language. In addition, there seemed to have been some improvement in involving stakeholders in the EUnetHTA JA compared with the EUnetHTA 2006–8 project, aided by the formation of a stakeholder forum. However, there seemed to be limited progress on collaboration between partners and evaluating the tools in real-work settings. The clearinghouse functionality developed during the EUnetHTA 2006–8 project had been apparently abandoned.

Key project success criteria

Success criteria were developed for the project and have been previously defined. These were individually assessed and comments have been provided in *Table 9*.

Recommendations

- The final part of the internal evaluation had to be performed 6 months before the end of the EUnetHTA JA project. For future projects the final evaluation should be performed after the end of the project, thereby allowing assessment of the project's impact.
- Owing to the large turnover of participants in the project, it is recommended that an induction pack be produced to orientate new staff.
- It is important that a valid database of all project participants is maintained by the secretariat and kept up to date. It is also the responsibility of leads or organisations, and work package leads, to provide details of any changes of staff in a timely manner.

TABLE 9 Comments about achievement of project success criteria

Project success criteria	Comments
Production of deliverables according to the 3-year work plan and grant agreement	Most deliverables were produced by the end of the project. One was anticipated to be delivered in the month following the project close (February 2013) and was delivered March 2013
Objectives (as defined in the grant agreement) met	More work in EUnetHTA JA2 will enable meeting the overarching agreement of establishing a permanent network. The three subobjectives were met
Additional added value generated	Additional value included networking, information sharing and increased knowledge of HTA developments
Effective communication within the project	No serious communication problems were reported. Face–to-face meetings were the preferred communication method
Effective project administration by the secretariat	Leadership and administration by the secretariat was effective. Possible additional functions were cited by respondents and these could be considered for EUnetHTA JA2
Optimal involvement of external stakeholders	Stakeholder involvement had evolved from the EUnetHTA 2006–8 project with respect to the formation of the stakeholder forum. This can be continued in the EUnetHTA JA2 project, particularly in managing the interests of the heterogeneous stakeholders
Good management of the constituent work packages	Overall, work packages seemed to perform well. There were some concerns about WP2 and WP8. There were some intrinsic difficulties in managing of the large number of participants in WP4 and WP5
Progress from the predecessor EUnetHTA 2006–8 project	Recommendations from the EUnetHTA 2006–8 project seemed to have been acted on

- The evaluation strategy was effective for project participants. If the same inductive and punitive factors are used, it might not be necessary to deliver a third send-out to participants.
- Half of patient groups and half of industry did not complete their evaluation questionnaires. All stakeholders must commit to answering their evaluation questionnaires in the EUnetHTA JA2 so that their views may be considered.
- During the evaluation it was possible to identify whether or not deliverables had been produced according to the 3-year work plan. However, it was beyond scope to assess the quality of these deliverables.
- There is a need to investigate the quality and usability of the HTA methodology tools in real-world HTA practice. There should be an assessment of the quality, usability and cost-effectiveness of the HTA Core Model compared with other methods of HTA report production within the EU. Similarly, the effectiveness and cost-effectiveness of the POP database should be assessed. In regard to the POP database, it is recommended that it be assessed how many collaborations have been undertaken as a result of its use.
- In future HTA collaborations, the involvement of stakeholders needs to evolve. This process had begun in the EUnetHTA 2006–8 project and developed during the EUnetHTA JA with the establishment of the stakeholder forum. Involvement of stakeholders in the EUnetHTA JA2 needs to expand, particularly in regard to managing heterogeneous stakeholder groups.
- Some progress seems to have been made since the EUnetHTA 2006–8 project in areas such as refining the HTA tools. However, there has been some suggestion that other aspects (including the communication plan and the business model and application of the tools) need further development. This is planned during the EUnetHTA JA2.
- The HTA tools had not been delivered by the final evaluation and, therefore, it was too early to assess their use in practice. The majority of respondents saw future use in the HTA Core Model and the POP database. These tools should be evaluated in real-life practice in the EUnetHTA JA2.

- It is recommended that evaluation of the EUnetHTA JA2 includes consideration about the tangible benefits of networking and information exchange. This could include a case-study approach to demonstrate the practical benefits of networking, such as collaborations initiated and topics identified. Any benefits should be compared with the costs that face-to-face meetings entail.
- Efforts should be made during the EUnetHTA JA2 to improve the project intranet (the MO website), especially with regard to the workrooms and bulletin boards.
- Face-to-face training workshops about the HTA methodological tools (HTA Core Model), POP and EVIDENT should be performed in the EUnetHTA JA2. Self-directed training with a manual is more appropriate for the project-focused tools.
- More time should be factored in for the crucial design stage of large, complicated HTA projects. This enables learning from previous similar projects. It is important that individual participants feel included in this formative stage and communication is clear at the outset. This stage is important in ensuring all participants are clear at the outset and should not be rushed.
- Consideration could be given to establish a second 'operational' committee in the EUnetHTA JA2. This could be made up of an individual worker of each work package and could meet virtually to strengthen links between the subprojects.
- The greater use of project management and budgeting techniques could be used in the EUnetHTA JA2 to ensure sufficient resources are allocated to organisations and specific tasks.
- In future international HTA projects all participant organisations should be responsible for outlining who will be locally responsible for an organisation's commitment to the project if key staff become unavailable.
- Consideration should be given in future projects to have a deputy leader, possibly based in another country.
- Various additional activities that could be performed, and it is hoped that in EUnetHTA JA2 with greater funding the activities can be expanded, such as to include support with project budgeting and project management.
- The most popular form of interaction was face-to-face meetings, and this should be considered in the EUnetHTA JA2. It is important that lessons are learned about how such meetings should be conducted and evaluation of the plenary assembly meetings is important in this respect.
- External promotion of the project should be improved for the EUnetHTA JA2 project. Strategies that have been suggested include a better public website, advertisement of timelines and achievements and greater use of social media.
- Overall, the stakeholder forum seemed to be an effective means of involving external stakeholders in the EUnetHTA JA.
- The objectives of plenary assembly meetings should be made explicit on the agenda before the meeting.

Informing clinical decision-makers about clinical research studies under development: development of a data set to inform a registry

Delphi round 1

Response rate

Thirteen organisations had agreed to participate in the Delphi round. The first-round questionnaire was distributed in October 2010. Following a targeted follow-up strategy, 12 of the organisations responded: a 92% response rate.

Language

All organisations from countries where English is not the common language of everyday use supported English being the main language of the data set.

One-quarter of respondents suggested some kind of native (i.e. non-English) language involvement would be useful. Therefore, this issue was carried forward to the second Delphi Round.

Coding systems
Half of respondents recommended using a coding system/controlled vocabulary in addition to English.

All those who recommended using a coding system supported medical subject headings (MeSH). Overwhelmingly the use of terms was supported over codes. The use of ATC (Anatomical Therapeutic Chemical Classification System) was suggested by one respondent and this issue was carried forward to the second Delphi Round.

Population Intervention Comparison and Outcome
The majority of respondents recommended keeping the intervention and control as separate headings, rather than combining the two. This was seen to confer the advantages of:

- clarity in the designs of trials, and the use of technologies in different countries
- searching within the database for technologies which are being compared
- the absence of comparator indicating that a study may not be comparative.

Contact
All respondents indicated that e-mail is an appropriate default contact method.

Study title and research question
There was a mixed result about whether or not a study's title should be recorded in a country's native language as well as English. This issue was carried forward to the second Delphi round.

Unit of registration
Having a unique identifier for each record was essential. This would be further explored in the second Delphi round.

Source of research idea
Giving a fully referenced source for a research idea was recommended by the majority of respondents.

Outcomes
It was recommended that a menu of outcomes was developed (including a subsequent trial or registry number).

Types of other information
Types of other information were recommended and this will be explored in the second Delphi.

Delphi Round 2

Response Rate
The second Delphi Round was sent to the 12 organisations that had responded to the first Delphi round. The questionnaire was sent in November 2010 and a targeted follow-up strategy resulted in 10 organisations responding, giving an 83% response rate.

Language
There had been indication from the first Delphi round that consideration should be given to including native language.

The majority agreed that adding optional non-English-language fields for the study title and research question was appropriate.

Coding system

A respondent had suggested including ATC codes.

Only a minority of respondents were able to provide ATC codes for their projects. Therefore, it was decided not to add a specific field for this. However, it may be appropriate for the database programmer to consider encouraging inclusion of these codes in a descriptive free-text field.

Unique identifier

It had been identified from the first Delphi Round that not all organisations maintain unique identifiers for their projects.

Respondents indicated that it would be suitable for either an organisation to allocate a unique identifier for a project, or the registry would generate one.

Outcomes

A list of outcome possibilities was derived from the responses to the second Delphi round questions.

Study went ahead:

1. type of study (required)

    i. funded as a trial (include trial reference number from registry, or similar information)
    ii. funded as another type of study (include reference number and registry, if any)
    iii. results likely to be available on <date>
    iv. study going ahead (if no other outcome appropriate)

2. funding arrangements (optional)

    i. cofunded with specified public sector funder(s)
    ii. cofunded with specified private sector funder(s)
    iii. not cofunded
    iv. cofunding arrangements not available.

Study did not go ahead:

1. lack of clinical need for knowledge
2. lack of researcher capacity
3. competing studies already under way leading to a lack of clinical capacity to deliver the research
4. lack of research funding.

Unit of registration

We suggested the unit of registration should be the project, which may contain one or more substudies in parallel or series. The majority of respondents agreed with this suggestion. Therefore, the unit of registration will be the overarching project, with details of substudies recorded in the summary field.

Other information

- Based on the results received from the respondents it was decided that an optional summary field would be included in the data set. A country field would also be included, with the possibility of recording multiple countries against this field.
- All respondents supported the inclusion of the planned country, where a planned study would be undertaken. A country field will be included, with the ability of recording multiple countries against the field.

The process of validating the data set

Respondents were asked what clinical areas should be used to test the data set. Suggestions received from more than one organisation were:

(a) trastuzumab for breast cancer
(b) transcatheter aortic valve implantation (TAVI) compared with other surgery for aortic stenosis
(c) vertebroplasty and kyphoplasty compared with conservative therapy (e.g. physiotherapy, occupational therapy) for compression fractures in osteoporosis
(d) bevacizumab for macular degeneration compared with bevacizumab for other indications.

Therefore, these indication and intervention combinations were used for efficacy testing of the data set.

Potential accuracy testing

The Delphi participant organisations were asked to complete the data set for studies they were aware of from their own organisations which may be similar to the exemplar studies listed above.

Both authors reviewed the submitted data and made decisions on whether or not the elements for any pair of studies were sufficiently similar that a funder would consider them a close match. Disagreements were resolved by discussion. Had discussion not resolved disagreements we would have referred the disagreement to an identified third person within our organisation, but this did not arise.

The results of the comparisons are shown in *Tables 10–13* below.

We then derived the sensitivity, specificity, positive and negative predictive values for each matching rule by constructing a 2 × 2 table of whether or not a project was intended to match the exemplar study on one axis, and whether or not the reviewers considered that it matched the other and then applying a standard technique using the statistical computing package R® (version 2.15.3).[82]

TABLE 10 Consideration of the data set for studies relating to trastuzumab in breast cancer

Study	Intended match	Population	Intervention/ control	Outcomes
Reference Study: UK (PERSEPHONE)[68]		Women with HER-2+ breast cancer	Trastuzumab (different durations)	Quality of life Disease-free survival
Netherlands (real-world efficiency of trastuzumab in early breast cancer) (Benien Vingerhoed Van Aken, ZonMW, 2011, personal communication)	Y	✓	✓	✗
France (protocol of herceptin adjuvant with reduced exposure)[69]	Y	✓	✓	?
UK and others (Synergistic Or Long Duration; SOLD)[70]	Y	✓	✓	?
UK [an international RCT to compare TARGeted Intra-operative radioTherapy (TARGIT) with conventional post-operative radiotherapy for women with early breast cancer][71]	N	✗	✗	✓

N, no; Y, yes.
A tick symbol (✓) indicates that the reviewers thought that this element of the study was sufficiently similar that a funder would consider it a close match.
A cross symbol (✗) indicates that the reviewers thought that the element was sufficiently dissimilar that a funder would not be interested.
A question mark (?) indicates that the reviewers considered there was some non-important overlap.
Many of these projects are internal to the individual agencies and details are not publicly available. Therefore, references have not been included for some studies.

TABLE 11 Consideration of the data set for studies relating to bevacizumab and ranibizumab in wet age-related macular degeneration

Study	Intended match	Population	Intervention/ control	Outcomes
Reference Study: UK (IVAN)[72]		Patients with wet AMD	Bevacizumab Ranibizumab	Visual acuity Quality of life
Netherlands [comparing the effectiveness and costs of bevacizumab to ranibizumab in patients with exudative age-related macular degeneration (COSD)] (Benien Vingerhoed Van Aken, ZonMW, 2011, personal communication)	Y	✓	✓	?
Netherlands (cost-effectiveness and outcome of current treatment strategies in exudative age-related macular degeneration)[73]	Y	✓	✓	✓
UK (a multi-centre RCT comparing the efficacy, safety and cost-effectiveness of intraocular telescopic devices compared with standard intraocular lens implants in visual impairment in age-related macular degeneration) (Internal NETSCC data)	N	✓	✗	✓
UK (assessment of the effectiveness of the Acrysof natural intraocular lens in retarding the progression of age-related macular degeneration) (Internal NETSCC data)	N	?	✗	?
UK (verteprofin photodynamic therapy for neovascular age-related macular degeneration: cohort study for the UK)[74]	N	✓	✗	✓
UK [Macular EpiRetinal brachytherapy versus Lucentis Only Treatment (MERLOT). A randomised controlled trial of epiretinal brachytherapy for previously treated neovascular age-related macular degeneration][75]	Y	✓	✓	✓
UK (regenerative laser therapy in the treatment of early age-related macular degeneration) (Internal NETSCC data)	N	?	✗	✗

N, no; Y, yes.
A tick symbol (✓) indicates that the reviewers thought that this element of the study was sufficiently similar that a funder would consider it a close match.
A cross symbol (✗) indicates that the reviewers thought that the element was sufficiently dissimilar that a funder would not be interested.
A question mark (?) indicates that the reviewers considered there was some non-important overlap.
Many of these projects are internal to the individual agencies and details are not publicly available. Therefore, references have not been included for some studies.

TABLE 12 Consideration of the data set for studies relating to transcatheter aortic valve replacement for aortic stenosis

Study	Intended match	Population	Intervention/ control	Outcomes
Reference Study: UK (UK-TAVI)[76]		Patients with moderate and severe aortic stenosis	Transcatheter aortic valve replacement Open aortic valve replacement	Quality of life Survival
Norway [a randomised clinical trials of transcatheter aortic valve implementation compared with surgery in patients with high risk aortic valve stenosis (tentative title)] (Inger Natvig Noderhaug, Kunnskapssenteret, 2011, personal communication)	Y	✓	✓	✓
France (medical and economic assessment of aortic valves)[77]	Y	✓	✓	✓
USA (the PARTNER trial: Placement of AoRTic TraNscatheter Valve Trial)[78]	Y	✓	✓	✓

N, no; Y, yes.
A tick symbol (✓) indicates that the reviewers thought that this element of the study was sufficiently similar that a funder would consider it a close match.
Many of these projects are internal to the individual agencies and details are not publicly available. Therefore, references have not been included for some studies.

TABLE 13 Consideration of the data set for studies relating to vertebroplasty in osteoporosis

Study	Intended match	Population	Intervention/ control	Outcomes
Reference study: UK (vertebroplasty versus physiotherapy for osteoporotic vertebral collapse) (Internal NETSCC data)		Patients with symptomatic osteoporotic vertebral collapse	Vertebroplasty Kyphoplasty Physiotherapy Usual care	Quality of life Pain
Netherlands (percutaneous vertebroplasty in the treatment of osteoporotic vertebral fractures)[79]	Y	✓	✓	✓
UK [SPinal Osteoporotic Fracture Exercise Trial (SPOFET)] (Internal NETSCC data)	N	✓	✓	✓
UK [Local Anaesthetic with BupivacaineE and Lidocaine for vertebral fracture trial (LABEL)][80]	Y	✓	✓	✗
UK [a pragmatic randomised controlled trial of screening for osteoporosis in older women (SCOOP)][81]	N	✗	✗	✗

N, no; Y, yes.
A tick symbol (✓) indicates that the reviewers thought that this element of the study was sufficiently similar that a funder would consider it a close match.
A cross symbol (✗) indicates that the reviewers thought that the element was sufficiently dissimilar that a funder would not be interested.

Sensitivity and specificity calculations

All figures followed by 95% confidence interval, calculated using the statistical computer package R.[82]

Sensitivity and specificity calculations were computed and these are shown in *Table 14*. The data set is provided in *Table 15*.

TABLE 14 Sensitivity and specificity calculations for the data set

Rule	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
Match at least one element in P(IC)O	1.0 (0.62 to 1.0)	0.43 (0.10 to 0.82)	0.73 (0.54 to 0.92)	1.0 (0.19 to 1.0)
Match at least two elements in P(IC)O	1.0 (0.62 to 1.0)	0.57 (0.18 to 0.9)	0.79 (0.49 to 0.95)	0.79 (0.49 to 0.95)
Match at least three elements in P(IC)O	0.5 (0.19 to 0.81)	0.86 (0.42 to 1.0)	0.83 (0.36 to 1.0)	0.55 (0.23 to 0.83)

CI, confidence interval.

TABLE 15 The data set (version 5)

Number	Item	Definition	Mandatory	Example
1	Funder	The name of the funder considering the study	Y	NIHR Health Technology Assessment programme
2	Contact e-mail of funder	A contact e-mail for the funder	Y	hta@hta.ac.uk
3	Title	The English title for the study	Y	Multi-centre randomised controlled trial of the cost-effectiveness of intra-inguinal percutaneous transluminal angioplasty (PTA) vs. reconstructive surgery for severe limb ischaemia (BASIL)
4	Native language title	The native language title for the study, expressed in the preferred language of the funder	Y	Multi-centre randomised controlled trial of the cost-effectiveness of intra-inguinal percutaneous transluminal angioplasty (PTA) compared with reconstructive surgery for severe limb ischaemia (BASIL)
5	Unique ID	A unique ID for the study. This will be a unique code for the study either provided by the funder or generated by the database. In combination with item 1 it will uniquely identify a study within the database	Y	96/05/01
6	Country	One or more countries where the study is planned to take place	Y	UK
7	Source of question	Where the question came from, e.g. was it specified by a national policy-making or research co-ordinating body	N	URL of NICE guidance specifying the question

TABLE 15 The data set (version 5) (*continued*)

Number	Item	Definition	Mandatory	Example
8	Research question (English language)	The primary research question of the project, expressed in English language	Y	What is the clinical effectiveness and cost-effectiveness of angioplasty compared with surgery in the management of severe limb ischaemia?
9	Native language research question	The primary research question of the project, expressed in the preferred language of the funder	N	What is the clinical effectiveness and cost-effectiveness of angioplasty compared with surgery in the management of severe limb ischaemia?
10	P	English-language description of the population eligible for study inclusion	N	Patients with limb ischaemia
11	P-MESH	MeSH codes or terms for the populations eligible for study inclusion (may need to refer to anatomy and disease process)	Y	Femoral artery (A07.231.114.351)
12	I	English-language description of the new intervention(s) considered in the study	N	Angioplasty
13	I-MeSH	MeSH codes or terms for the new intervention(s) considered in the study	Y	Angioplasty (E02.148.050)
14	C	English-language description of the control intervention(s) considered in the study	N	Surgery
15	C-MeSH	MeSH codes or terms for the control intervention(s) considered in the study	Y	Blood vessel prosthesis implantation (E04.100.814.868.500)
16	O	English-language description of the key outcome of interest	N	Mortality, amputation, quality of life, cost-effectiveness
17	O-MeSH	MeSH codes or terms for the key outcomes of interest	Y	Fatal outcome (E05.318.308.985.550.325) Amputation (E04.555.080) Quality-adjusted life-years (E05.318.740.100.500.700) Cost–benefit analysis (N03.219.151.125)

N, no; Y, yes.

It was demonstrated that a registry for matching pragmatic clinical studies under consideration by funding agencies could be built on a very small data set. This would include 10 unique items, of which only five are required to describe a study and the rest are metadata.

By the end of the first Delphi round the participants had agreed on the overall shape of the data set, honing down to the most important information to be contained.

- demographics/epidemiology – funder, contact details
- trial specific – title, PICO, outcome.

Discussions had been initiated about the most appropriate use of language; whether entering data in English alone was acceptable or if users who usually worked in other languages should have the option to include data in that language too.

The trade-offs between human-readable language and coding systems for the elements of the data set that would describe the key elements of a study were also discussed. A small selection of coding systems were considered.

In round 2, several smaller issues which had arisen in round one were addressed. This included the way organisations group and refer to their studies internally. By the end of the round the coding system, the role of non-English entries and a menu of possible outcomes to record had been agreed. Another important element of round 2 was establishing clinical and technology areas within which to validate the data set. Responders were asked to suggest areas where they might have appropriate studies to carry out some efficacy testing.

By the end of the second round it was clear that participants agreed about the elements of the data set, so the efficacy-testing phase was initiated. Participants were asked what the characteristics of a good matching algorithm would be. There was general agreement that the best algorithm would minimise false negatives, and that false-positive matches were more acceptable than false-negative ones.

The characteristics of the matching rules assessed vary as might have been expected. The more elements a test tries to match before declaring two studies are similar, the higher the specificity and positive predictive value, and the lower the sensitivity and negative predictive value.

It is likely that the most important characteristic of a future database to a funder is the negative predictive value. The funder wants to ensure that they know about all potentially similar studies, and a high negative predictive value (ideally 100%) would provide this reassurance. They also do not want be flooded with false matches – although we know from the Delphi survey that the groups who responded would prefer false-positive matches to missing potential similar studies – although their attitude may change if any data set implemented is unable to minimise false positives. Unfortunately, as the predictive values of a diagnostic test are dependent on population-level frequencies, it is not possible to calculate these without implementing an actual registry. Useful estimates of positive and negative predictive values can only be obtained from a live database containing real-life examples of studies, so this should be done for any subsequent database which may be developed from this data set.

It was envisaged that such a registry could be built progressively as subscribers query the database. Studies entered to search for possible matches would be entered into the database as well as used for searching. Should a match be identified, then the registry would alert both the organisations who entered the matched studies. Those organisations would then discuss between themselves whether the match was true or false, and what (if anything) to do about it. Using this approach would result in minimal extra work for funders searching for similar studies. It would be useful if they could return when a final decision is

made on their proposed study. This would enable entry of information on when the study is no longer under consideration to record what its fate was, and more importantly, so the study is no longer flagged up as a possible match for other organisations. However, there could be a default time to retire a study from matches after a particular time should a data owner not return to update their records. There were insufficient data to decide on efficacy regarding diagnostic studies. Depending on the future use of this data set, it would probably be worth investigating in future in a live database registry.

Overall, it seems that a database based on this data set is plausible. Success will depend on the willingness of the research community to engage with it. It will be necessary to develop matching rules within a live database, but we have suggested some starting points.

Chapter 4 Summary

We describe in detail the activities that the authors led on in the EUnetHTA JA, and that were part-funded by both the NIHR Health Technology Assessment programme and the European Commission.

The impact and effectiveness of the project was evaluated by self-completion questionnaires of project participants and external stakeholders, and documentary analysis. One of the best things was the opportunity for networking with HTA experts from other countries. Many learning points were identified which will be helpful to the follow-up EUnetHTA JA2 project.

A data set was developed to inform the creation of a registry for prospective clinical studies. It is hoped that it will help identification of similar studies that are being planned and enable alignment of outcome measures.

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Contributions of authors

Eleanor Woodford Guegan (Senior Research Fellow) had primary responsibility for performing the evaluation survey; design of the survey, communication with partners, sending the survey, analysis of results and drafting of the chapters. Andrew Cook (Consultant Advisor) contributed to this process.

Andrew Cook had primary responsibility for performing the data set Delphi exercise; design of the survey, analysis of results and drafting of the chapters. Eleanor Woodford Guegan contributed to this process.

Both authors have reviewed the entire contents of the manuscript.

The sole responsibility for the content of this report lies with the authors and the European Commission is not responsible for any use that may be made of the information contained therein www.eunethta.net

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Appendix 1 Participant questionnaire 2010

EUnetHTA JA individuals' baseline survey 2010

Introduction

We ask for your assistance in completing this baseline survey for INDIVIDUALS of organisations involved in EUnetHTA JA work. Please complete this survey PERSONALLY and do not forward it to anyone else; your colleagues will have received separate emails too. However, please email eunethta@soton.ac.uk if you hear about anyone who should have received an invitation but hasn't.

In order to decrease the number of survey requests you will get from EUnetHTA JA work packages (WPs) this survey combines questions from 4 WPs; WP2:Dissemination,WP3:Evaluation,WP6:Information Management System & WP8:Strategy & Business Model Development. Testing has shown that it should take you approximately 45mins to complete.

The EUnetHTA JA Executive Committee requests your early response to this survey and by MAY 17th at the latest.

Instructions

- Please complete this survey PERSONALLY and do not forward it to anyone else.
- The survey has been designed to be easily completed; most questions just require you to tick a box.
- Your answers will be kept confidential outside the evaluation team and you will not be personally linked to your response in reports. In exceptional cases we might contact you to ask you for further clarification about responses.
- It is web-based, so the results will be automatically sent to us when you click the FINISH button.
- Certificates will be awarded to those who have submitted their answers by clicking on the FINISH button.

Please click NEXT when you have answered all questions on a page. You can click PREVIOUS should you wish to go back to the page before. Please click FINISH at the end to submit your answers.

Many thanks for your help completing this survey!

EUnetHTA JA individuals' baseline survey 2010

1. Demographics

This section asks for information about you. However, this will be kept confidential so that you will not be personally identified to your responses in summary reports.

1. Please indicate your MAIN professional expertise within HTA

- ○ Economist
- ○ Information scientist
- ○ Medical doctor (eg physician)
- ○ Other healthcare professional (eg pharmacist)
- ○ Project manager
- ○ Statistician
- ○ Other - please specify;

2. Please indicate your gender

- ○ Female
- ○ Male

3. Please indicate your age group

- ○ 20-29
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70+

4. Please indicate the number of FULL years you have worked in HTA.

If you have worked in HTA for less than 1 year please enter 0.

EUnetHTA JA individuals' baseline survey 2010

5. Are you/your organisation a member of any other international HTA organisations?

Please tick ALL that apply

- ☐ EUROSCAN
- ☐ HTAi
- ☐ INAHTA
- ☐ None
- ☐ Don't Know
- ☐ Other - please specify;

EUnetHTA JA individuals' baseline survey 2010

2. Specific organisational and HTA information

This section asks for information about your organisation and the HTA information it produces.

1. Did your organisation experience any difficulties in applying to join the EUnetHTA JA?

- ○ No
- ○ Don't Know - I was not involved
- ○ Yes

Please explain any difficulties & how these could have been avoided; (250 word limit)

2. Do you think your organisation has sufficient FUNDING to be able to do what it said it will for the entire EUnetHTA JA?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any funding concerns; (250 word limit)

3. Do you think your organisation has sufficient STAFF to be able to do what it said it will for the entire EUnetHTA JA?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any staffing concerns; (250 word limit)

EUnetHTA JA individuals' baseline survey 2010

4. Does your organisation have a plan in case staff members suddenly become ill or leave, to allow its EUnetHTA JA work to continue?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns; (250 word limit)

5. Please use the drop-down menus to indicate HTA information produced by your organisation.

If your organisation does not produce a certain information type (or you don't know) please indicate this in the 1st column and leave the other columns blank.

	Is this produced by your organisation?	Is a summary available in English?	Is the full document available in English?	What is the confidentiality level for this?
Raw data (eg extraction forms)				
Planned projects list				
Ongoing projects list				
Preliminary report (available internally but not published)				
Final published report				
Impact record (eg policy decision)				

EUnetHTA JA individuals' baseline survey 2010

3. Setting up process

This section asks for your opinions about the way the EUnetHTA JA was set up.

1. Do you think that the EUnetHTA JA will be successful in achieving its objectives?

	No	Yes	Don't Know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA JA meeting its objectives; (250 word limit)

2. Are you satisfied with the way the EUnetHTA JA was set up (between the European Union, the EUnetHTA JA partners & the Secretariat)?

- ○ No
- ○ Yes, but could have been better
- ○ Yes
- ○ Don't Know

Please explain how this could have been better; (250 word limit)

3. What effect do you think organising the EUnetHTA JA work in 8 workpackages will have?

- ○ Negative
- ○ Mixed (both negative & positive)
- ○ Positive
- ○ Don't Know

Please explain any concerns & how the EUnetHTA JA could have been better organised; (250 word limit)

EUnetHTA JA individuals' baseline survey 2010

4. Do you think you understand the aims of the EUnetHTA JA workpackages?

	No	Yes
WP1: Coordination	○	○
WP2: Dissemination	○	○
WP3: Evaluation	○	○
WP4: Core HTA	○	○
WP5: Relative Effectiveness Assessment of Pharmaceuticals	○	○
WP6: Information Management System	○	○
WP7: New Technologies	○	○
WP8: Strategy & Business Model Development	○	○

5. Do you have any concerns at this time about the EUnetHTA JA workpackages?

	No	Yes
WP1: Coordination	○	○
WP2: Dissemination	○	○
WP3: Evaluation	○	○
WP4: Core HTA	○	○
WP5: Relative Effectiveness Assessment of Pharmaceuticals	○	○
WP6: Information Management System	○	○
WP7: New Technologies	○	○
WP8: Strategy & Business Model Development	○	○

Please explain any concerns about any of the workpackages; (500 word limit)

6. Do you think that the EUnetHTA JA could serve as a foundation for a sustainable European collaboration at the end of the project?

○ No ○ Don't Know

○ Yes

Please explain your answer; (250 word limit)

EUnetHTA JA individuals' baseline survey 2010

4. Administration & Communication

This section asks for your opinions about administration & communication within the EUnetHTA JA.

1. Do you think the Secretariat has shown effective LEADERSHIP during the setting-up of the EUnetHTA JA?

- ○ No
- ○ Yes, but could have been better
- ○ Yes
- ○ Don't Know

Please explain any concerns & how this could have been better; (250 word limit)

2. Do you think the Secretariat has provided effective ADMINISTRATIVE SUPPORT during the setting-up of the EUnetHTA JA?

- ○ No
- ○ Yes, but could have been better
- ○ Yes
- ○ Don't Know

Please explain any concerns & how this could have been better; (250 word limit)

3. Do you think the Secretariat could be doing anything else to support the success of the project?

- ○ No
- ○ Yes
- ○ Don't Know

Please specify anything else you think the Secretariat could be doing; (250 word limit)

EUnetHTA JA individuals' baseline survey 2010

4. Have you understood what information the Secretariat has wanted from you?

	No	Mixed (No & Yes)	Yes	Don't Know	Not Applicable
Before the EUnetHTA JA started	○	○	○	○	○
Contributing to the EUnetHTA JA	○	○	○	○	○

Please explain any difficulties; (250 word limit)

5. How have you found emails from the SECRETARIAT?

	Too much	About right	Too little	Don't Know
FREQUENCY	○	○	○	○
CONTENT	○	○	○	○

Please provide any comments; (250 word limit)

6. Have you logged into the Members' Only EUnetHTA JA website? click here for the website

- ○ No
- ○ Yes

Please provide any comments about this website; (250 word limit)

7. How have you found participating in a EUnetHTA JA e-meeting using the Saba Centra software?

- ○ Not applicable - I have not participated in an e-meeting
- ○ Difficult
- ○ Some problems
- ○ Easy

Please specify any problems participating in an e-meeting & how this could be improved; (250 word limit)

EUnetHTA JA individuals' baseline survey 2010

8. Have you experienced any language communication problems that could affect the work of the EUnetHTA JA?

- ○ No
- ○ Yes - spoken
- ○ Yes - written
- ○ Yes - both spoken & written

Please specify any communication problems & how these could be improved; (250 word limit)

9. What do you think are the main CHALLENGES of being involved in the EUnetHTA JA? (500 word limit)

10. What do you think are the main BENEFITS of being involved in the EUnetHTA JA? (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Information Technology (IT)

This section asks for information about your IT use & will be used to help develop tools for the EUnetHTA JA.

1. What operating system do you USUALLY use on your computer AT WORK?

- ○ Linux
- ○ Mac OSX
- ○ Windows (all versions)
- ○ Don't Know
- ○ Other - please specify;

2. What browser do you USUALLY use to connect to the internet AT WORK?

- ○ Google Chrome
- ○ Internet Explorer
- ○ Mozilla Firefox
- ○ Safari
- ○ Don't Know
- ○ Other - please specify;

3. On average how often do you use these IT software packages AT WORK?

	Daily	At least once a week	Monthly	Seldom (less than monthly)	Never
Gradepro	○	○	○	○	○
Microsoft Office	○	○	○	○	○
OpenOffice	○	○	○	○	○
RevMan	○	○	○	○	○
Reference Management Software	○	○	○	○	○

EUnetHTA JA individuals' baseline survey 2010

4. On average how often do you use these communication systems AT WORK?

	Daily	At least once a week	Monthly	Seldom (less than monthly)	Never
Document management system (eg Sharepoint)	○	○	○	○	○
Mailing list	○	○	○	○	○
RSS feed reader *	○	○	○	○	○
Video calling (eg Skype)	○	○	○	○	○
Web-based discussion forum	○	○	○	○	○
Wiki #	○	○	○	○	○

*: click here to see a definition of RSS #: click here to see a definition of wiki

5. Do you personally have an account for the following social networking sites?

This will help WP2 know whether it would be useful to promote EUnetHTA JA on networking sites.

	No	Yes - but I wish to keep this private	Yes - I would post a EUnetHTA JA link on this
Del.icio.us	○	○	○
Facebook	○	○	○
LinkedIn	○	○	○
Slideshare	○	○	○
Twitter	○	○	○
YouTube	○	○	○

EUnetHTA JA individuals' baseline survey 2010

6. EUnetHTA tools

This section asks for information about your use of EUnetHTA tools & will be used to help develop them.

1. Please use the drop-down menus below to indicate your use/awareness of the EUnetHTA tools and opinions about training. Please only select ONE tool as top priority for training.

	Use/Awareness	Priority for training	Preferred training method
Adaptation glossary			
Adaptation toolkit			
Contact database			
Core HTA model			
EIFFEL			
E-meetings			
EUnetHTA toolbar			
Mailing list			
Members' Only (MO) internet website			
Members' Only (MO) workrooms			
News aggregator			
Planned & ongoing projects workroom			
Workroom bulletin boards			

*click here to see a definition for webcast

EUnetHTA JA individuals' baseline survey 2010

2. What may affect your personal use of EUnetHTA tools?
Multiple options can be chosen for each tool.

	None	From the tool design	IT issues	Organisational issues	Training	Don't Know
Adaptation glossary	☐	☐	☐	☐	☐	☐
Adaptation toolkit	☐	☐	☐	☐	☐	☐
Contact database	☐	☐	☐	☐	☐	☐
Core HTA model	☐	☐	☐	☐	☐	☐
EIFFEL	☐	☐	☐	☐	☐	☐
E-meetings	☐	☐	☐	☐	☐	☐
EUnetHTA toolbar	☐	☐	☐	☐	☐	☐
Mailing list	☐	☐	☐	☐	☐	☐
Members' Only (MO) internet website	☐	☐	☐	☐	☐	☐
Members' Only (MO) workrooms	☐	☐	☐	☐	☐	☐
News aggregator	☐	☐	☐	☐	☐	☐
Planned & ongoing projects workroom	☐	☐	☐	☐	☐	☐
Workroom bulleting boards	☐	☐	☐	☐	☐	☐

3. Please suggest any ideas to overcome problems using the EUnetHTA tools; (250 word limit)

EUnetHTA JA individuals' baseline survey 2010

7. Specific Workpackages

These sections ask for your opinions about the workpackages (WP) you are PERSONALLY involved in.

WP1: COORDINATION

1. Are you PERSONALLY involved in the work of WP1?

- ○ No --> Please click NEXT at the bottom of the page to go to the next section.
- ○ Yes

2. Please indicate your organisation's membership of WP1

- ○ Associate partner
- ○ Collaborating partner
- ○ Lead partner

3. Please show what you think about these sentences for WP1.
Please only answer if you PERSONALLY are involved in the work of WP1.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○

4. Do you have any concerns about WP1, including from the table above?
Please only answer if you PERSONALLY are involved in the work of WP1.

- ○ No
- ○ Don't Know
- ○ Yes - please specify your concerns & how these can be resolved; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Do you know how Stakeholders will be involved in WP1?

Please only answer if you PERSONALLY are involved in the work of WP1.

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

WP2: Dissemination

WP2: DISSEMINATION

1. Are you PERSONALLY involved in the work of WP2?

- ○ No --> Please click NEXT at the bottom of the page to go to the next section.
- ○ Yes

2. Please indicate your organisation's membership of WP2

- ○ Associate partner
- ○ Collaborating partner
- ○ Co-lead partner
- ○ Lead partner

3. What do you think about these statements for WP2?
Please only answer if you PERSONALLY are involved in the work of WP2.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○

4. Do you have any concerns about WP2, including from the table above?
Please only answer if you PERSONALLY are involved in the work of WP2.

- ○ No
- ○ Don't Know
- ○ Yes - please specify your concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Do you know how Stakeholders will be involved in WP2?

Please only answer if you PERSONALLY are involved in the work of WP2.

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

WP4: Core HTA

WP4: CORE HTA

1. Are you PERSONALLY involved in the work of WP4?

- ○ No --> Please click NEXT at the bottom of the page to go to the next section.
- ○ Yes

2. Please indicate your organisation's membership of WP4

- ○ Associate partner
- ○ Collaborating partner
- ○ Co-lead partner
- ○ Lead partner

3. What do you think about these statements for WP4?
Please only answer if you PERSONALLY are involved in the work of WP4.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○

4. Do you have any concerns about WP4, including from the table above?
Please only answer if you PERSONALLY are involved in the work of WP4.

- ○ No
- ○ Don't Know
- ○ Yes - please specify your concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Do you know how Stakeholders will be involved in WP4?

Please only answer if you PERSONALLY are involved in the work of WP4.

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

WP5: Relative Effectiveness Assessment of Pharmaceuticals

WP5: Relative Effectiveness Assessment of Pharmaceuticals

1. Are you PERSONALLY involved in the work of WP5?

- ○ No --> Please click NEXT at the bottom of the page to go to the next section.
- ○ Yes

2. Please indicate your organisation's membership of WP5

- ○ Associate partner
- ○ Collaborating partner
- ○ Co-lead partner
- ○ Lead partner

3. What do you think about these statements for WP5?
Please only answer if you PERSONALLY are involved in the work of WP5.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○

4. Do you have any concerns about WP5, including from the table above?
Please only answer if you PERSONALLY are involved in the work of WP5.

- ○ No
- ○ Don't Know
- ○ Yes - please specify your concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Do you know how Stakeholders will be involved in WP5?

Please only answer if you PERSONALLY are involved in the work of WP5.

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

WP6: Information Management System

WP6: Information Management System

1. Are you PERSONALLY involved in the work of WP6?

- ○ No --> Please click NEXT at the bottom of the page to go to the next section.
- ○ Yes

2. Please indicate your organisation's membership of WP6

- ○ Associate partner
- ○ Collaborating partner
- ○ Co-lead partner
- ○ Lead partner

3. What do you think about these statements for WP6?
Please only answer if you PERSONALLY are involved in the work of WP6.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○

4. Do you have any concerns about WP6, including from the table above?
Please only answer if you PERSONALLY are involved in the work of WP6.

- ○ No
- ○ Don't Know
- ○ Yes - please specify your concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Do you know how Stakeholders will be involved in WP6?

Please only answer if you PERSONALLY are involved in the work of WP6.

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

WP7: New Technologies

WP7: New Technologies

1. Are you PERSONALLY involved in the work of WP7?

- ○ No --> Please click NEXT at the bottom of the page to go to the next section.
- ○ Yes

2. Please indicate your organisation's membership of WP7

- ○ Associate partner
- ○ Collaborating partner
- ○ Co-lead partner
- ○ Lead partner

3. What do you think about these statements for WP7?
Please only answer if you PERSONALLY are involved in the work of WP7.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○

4. Do you have any concerns about WP7, including from the table above?
Please only answer if you PERSONALLY are involved in the work of WP7.

- ○ No
- ○ Don't Know
- ○ Yes - please specify your concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Do you know how Stakeholders will be involved in WP7?

Please only answer if you PERSONALLY are involved in the work of WP7.

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

WP8: Strategy & Business Model Development

WP8: Strategy & Business Model Development

1. Are you PERSONALLY involved in the work of WP8?

- ○ No --> Please click NEXT at the bottom of the page to go to the next section.
- ○ Yes

2. Please indicate your organisation's membership of WP8

- ○ Associate partner
- ○ Collaborating partner
- ○ Co-lead partner
- ○ Lead partner

3. What do you think about these statements for WP8?
Please only answer if you PERSONALLY are involved in the work of WP8.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○

4. Do you have any concerns about WP8, including from the table above?
Please only answer if you PERSONALLY are involved in the work of WP8.

- ○ No
- ○ Don't Know
- ○ Yes - please specify your concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

5. Do you know how Stakeholders will be involved in WP8?

Please only answer if you PERSONALLY are involved in the work of WP8.

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (500 word limit)

EUnetHTA JA individuals' baseline survey 2010

Survey End

1. Is there anything else you think we should know about the EUnetHTA JA? (500 word limit)

Many thanks for completing this survey!

Please click on the 'Finished' button below to submit your answers. A summary report will be produced which will not identify you to your answers.

Appendix 2 Participant questionnaire 2011

EUnetHTA JA individuals' interim survey 2011

Introduction

Please complete this interim 2011 survey for INDIVIDUALS of organisations in the EUnetHTA Joint Action (JA).

It combines questions from WP3: Evaluation and WP8: Strategy & Business Model Development to decrease the number of surveys you get from the EUnetHTA JA.

Testing has shown it should take you approximately 30-45 minutes to complete (depending on how many workpackages you are in).
The EUnetHTA JA Executive Committee requests your early response to this survey and by MAY 24 at the latest please.

Instructions:
• Please complete this survey PERSONALLY and do not forward it to anyone else.
• It has been designed to be easily completed; most questions just require you to tick a box.
• Your answers will be kept confidential and you will not be personally linked to your response in reports. In exceptional cases we might contact you to ask you for further clarification about responses.
• The survey is web-based, so the results will be automatically sent to us when you click the FINISH button.
• Please email e.guegan@soton.ac.uk if you hear about anyone who should have received an invitation but hasn't.
• Certificates will be awarded at the Plenary Assembly to those who have submitted their answers by clicking on the FINISH button.

Please click NEXT when you have answered all questions on a page. Click PREVIOUS if you want to go back to the page before. Click FINISH at the end to submit your answers.

Many thanks for your help!
Eleanor Guegan (NETSCC, WP3 lead partner), e.guegan@soton.ac.uk

EUnetHTA JA individuals' interim survey 2011

1. Demographics

This section asks for information about you. This will be kept confidential so that you will not be personally identified to your responses in summary reports.

1. Please indicate your MAIN professional expertise within HTA.

- ○ Administrator (eg secretary)
- ○ Economist
- ○ Information scientist
- ○ Medical doctor (eg physician)
- ○ Other - please specify;
- ○ Other healthcare professional (eg pharmacist)
- ○ Project manager
- ○ Researcher
- ○ Statistician

2. Please indicate the approximate number of FULL years you have worked in HTA. If less than 1 year - please enter 0.

3. Please indicate your age group.

○ 20-29 ○ 30-39 ○ 40-49 ○ 50-59 ○ 60-69 ○ 70+

4. Are you an 'HTA doer'? ***ie are you actively involved in preparing HTA assessment reports?***

○ No ○ Yes ○ Don't Know

If you wish, please comment here;

5. Does your organisation have enough resources to be able to do what it said it will for the entire EUnetHTA JA?

	No	Yes	Don't Know
Funding	○	○	○
Staff	○	○	○

If you wish, please comment here;

EUnetHTA JA individuals' interim survey 2011

6. Are you the lead person within your organisation, with overall responsiblity for EUnetHTA JA activities?

- ○ No
- ○ Don't Know
- ○ Yes

If you wish, please comment here;

EUnetHTA JA individuals' interim survey 2011

2. Administration & Communication

This section asks about administration & communication within the EUnetHTA JA.

1. Has the Secretariat shown effective support within the EUnetHTA JA?

	No	Ok (but could be better)	Yes	Don't Know
Leadership	○	○	○	○
Administration	○	○	○	○

Please explain any concerns & how this could be better; (250 word limit)

2. Could the Secretariat be doing anything else to support the success of the project?

○ No ○ Don't Know

○ Yes

Please specify anything else you think the Secretariat could be doing; (250 word limit)

3. Have you experienced any language communication problems that could affect the work of the EUnetHTA JA?

○ No ○ Yes - spoken ○ Yes - written ○ Yes - both spoken & written

Please specify any communication problems & how these could be improved; (250 word limit)

EUnetHTA JA individuals' interim survey 2011

4. How useful do you find communication methods within the EUnetHTA JA?

	Not Useful	Ok (but could be better)	Very useful	Don't Know
Members' Only (MO) Website	○	○	○	○
Members' Only (MO) Workrooms	○	○	○	○
Workroom Bulletin Boards	○	○	○	○
Members' E-newsletters (quarterly)	○	○	○	○
Emails from Secretariat	○	○	○	○
E-meetings	○	○	○	○
Face-to-face Meetings	○	○	○	○
Plenary Assembly	○	○	○	○

Please explain your answers; (250 word limit)

5. How could communication within the EUnetHTA JA be improved? (500 word limit)

EUnetHTA JA individuals' interim survey 2011

3. EUnetHTA tools

This section asks about your use of EUnetHTA tools, to help develop them.

1. Please use the drop-down menus below to indicate your use/awareness of the EUnetHTA tools and opinions about training.

Please only select ONE tool as top priority for training.

	Use/Awareness	Priority for training
Adaptation Glossary		
Adaptation Toolkit		
Contact Database		
EIFFEL		
E-meetings		
EUnetHTA Toolbar		
HTA Core Model		
Mailing List		
Members' Only (MO) internet website		
Members' Only (MO) workrooms		
News Aggregator		
POP* Database		
Workroom Bulletin Boards		

* POP = Planned and Ongoing Projects

EUnetHTA JA individuals' interim survey 2011

2. Have any problems affected your use of the tools?

Multiple options can be chosen for each tool.

	Design of the tool	IT issues	Organisational issues	Training	Other problems	None
Adaptation Glossary	☐	☐	☐	☐	☐	☐
Adaptation Toolkit	☐	☐	☐	☐	☐	☐
Contact Database	☐	☐	☐	☐	☐	☐
EIFFEL	☐	☐	☐	☐	☐	☐
E-meetings	☐	☐	☐	☐	☐	☐
EUnetHTA Toolbar	☐	☐	☐	☐	☐	☐
HTA Core Model	☐	☐	☐	☐	☐	☐
Mailing List	☐	☐	☐	☐	☐	☐
Members' Only (MO) internet website	☐	☐	☐	☐	☐	☐
Members' Only (MO) workrooms	☐	☐	☐	☐	☐	☐
News Aggregator	☐	☐	☐	☐	☐	☐
POP Database	☐	☐	☐	☐	☐	☐
Workroom Bulletin Boards	☐	☐	☐	☐	☐	☐

Please explain any problems you have had with the tools; (250 word limit)

3. Please suggest any ideas to overcome problems using the EUnetHTA tools; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

4. Progress

This section asks about the progress of the EUnetHTA JA.

1. What have been the main CHALLENGES of being involved in the EUnetHTA JA? (500 word limit)

2. What have been the main BENEFITS of being involved in the EUnetHTA JA? (500 word limit)

3. Have the following negatively affected your participation in the EUnetHTA JA?

	Yes-big effect	Yes-small effect	No effect	Don't Know
Difficulty in communication - within the project	○	○	○	○
Difficulty in communication - specifically using English	○	○	○	○
Conflict with other work activities	○	○	○	○
Large project scale	○	○	○	○
Demands of individual workpackages	○	○	○	○
Insufficient organisation funding	○	○	○	○
Insufficient organisation staffing	○	○	○	○

Please explain the effect of these challenges; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

4. How useful have you found the following in the EUnetHTA JA?

	Not useful	Ok (of some use)	Very useful	Don't Know
Networking with colleagues	○	○	○	○
Information sharing	○	○	○	○
Capacity building	○	○	○	○
Training	○	○	○	○
Increased awareness of HTA developments	○	○	○	○
Face-to-face meetings	○	○	○	○

Please explain your answers; (500 word limit)

5. Do you think that the EUnetHTA JA will be successful in achieving its 3 official objectives?

	No	Yes	Don't Know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA JA meeting its objectives; (250 word limit)

6. Do you think the EUnetHTA JA will serve as a foundation for a sustainable European collaboration at the end of the project?

○ No ○ Don't Know

○ Yes

Please explain your answer; (250 word limit)

7. Please explain how you will know that a sustainable European collaboration has been achieved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

8. Would a sustainable European collaboration add value?

	No	Yes	Don't know
National level	○	○	○
Regional level	○	○	○
European level	○	○	○

Please explain what value would be added, or why no value would be added; (250 word limit)

9. Do you have any concerns at this time about the EUnetHTA JA workpackages?

	No	Yes
WP1: Coordination	○	○
WP2: Dissemination	○	○
WP3: Evaluation	○	○
WP4: Core HTA	○	○
WP5: Relative Effectiveness Assessment of Pharmaceuticals	○	○
WP6: Information Management System	○	○
WP7: New Technologies	○	○
WP8: Strategy & Business Model Development	○	○

Please explain any concerns; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

5. Stakeholders

This section asks about the involvement of stakeholders in the EUnetHTA JA.

1. Do you have any concerns about the involvement of experts or stakeholders in the EUnetHTA JA? (500 word limit)

2. Have you experienced any benefits from the involvement of experts or stakeholders within the EUnetHTA JA? (500 word limit)

EUnetHTA JA individuals' interim survey 2011

6. Potential EUnetHTA Joint Action 2

1. Are you directly involved in planning for the EUnetHTA JA2?

- ○ No --> Please click on Next at the bottom of the page
- ○ Yes --> Please continue answering questions on this page

2. Do you have any concerns about the planned EUnetHTA JA2?

- ○ Yes
- ○ Don't Know
- ○ No

Please explain any concerns; (250 word limit)

3. Do you have any concerns about the PROCESS of planning the EUnetHTA JA2?

- ○ Yes
- ○ Don't Know
- ○ No

Please explain any concerns; (250 word limit)

4. How much has planning for the EUnetHTA JA2 impacted on the time you can work on the current EUnetHTA JA?

- ○ A lot
- ○ A little
- ○ Not at all
- ○ Not Applicable

If you wish, please comment here;

EUnetHTA JA individuals' interim survey 2011

5. Please provide any comments about how the planned EUnetHTA JA2 could be better; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

7. Specific Workpackages

These sections ask about the workpackages (WP) you are PERSONALLY involved in.

1. What workpackages are you PERSONALLY a member of?

	No	Yes
WP1: Coordination	○	○
WP2: Dissemination	○	○
WP3: Evaluation	○	○
WP4: Core HTA Model	○	○
WP5: Relative Effectiveness Assessment of Pharmaceuticals	○	○
WP6: Information Management System	○	○
WP7: New Technologies	○	○
WP8: Strategy & business model development	○	○

EUnetHTA JA individuals' interim survey 2011

WP1: Coordination

Please only answer these questions if you **PERSONALLY** are a member of WP1. If you are NOT, then please click NEXT at the bottom of the page to go to the next page.

1. How has WP1 progressed over the past year?
Please only answer if you PERSONALLY are involved in the work of WP1.

○ Poorly ○ Ok (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

2. WP1's workplan states that 'Interim and Final Technical and Financial Reports from the Joint Action' will be delivered in months 12 (December 2010), 24 (December 2011) & 36 (December 2012). Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. Please show what you think about these sentences for WP1.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○
The amount of work is ok	○	○	○	○	○

EUnetHTA JA individuals' interim survey 2011

4. Do you have any concerns about WP1?

- ○ No
- ○ Don't Know
- ○ Yes

Please specify your concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

WP2: Dissemination

Please only answer these questions if you **PERSONALLY** are a member of WP2. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP2 progressed so far?

Please only answer if you PERSONALLY are involved in the work of WP2.

○ Poorly ○ Ok (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

2. The workplan says that WP2 will deliver a 'Communication and Dissemination plan' in month 18 - June 2011.

Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. What do you think about these statements for WP2?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○
The amount of work is ok	○	○	○	○	○

EUnetHTA JA individuals' interim survey 2011

4. Do you have any concerns about WP2, including from the table above?

- ○ No
- ○ Don't Know
- ○ Yes

Please specify any concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

WP4: Core HTA

Please only answer these questions if you **PERSONALLY** are a member of WP4. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP4 progressed so far?

Please only answer if you PERSONALLY are involved in the work of WP4.

○ Poorly ○ Ok (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

2. How have the two workstreams of WP4 collaborated?

○ Poorly

○ Ok (but could be better)

○ Well

○ Don't Know

Please explain any concerns; (250 word limit)

WP4's workplan lists 3 deliverables - we are interested in your views about them.

3. 'An online Tool & Service for producing, publishing, storing and retrieving HTA information' should be delivered in month 36 - December 2012.

Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' interim survey 2011

4. 'Screening application of the HTA core model' should be delivered in month 15 - March 2011. Do you think that has happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

5. 'A set of two core HTAs' should be delivered in month 36 - December 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

6. What do you think about these statements for WP4?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○
The amount of work is ok	○	○	○	○	○

EUnetHTA JA individuals' interim survey 2011

7. Do you have any concerns about WP4, including from the table above?

- ○ No
- ○ Don't Know
- ○ Yes

Please specify any concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

WP5: Relative Effectiveness Assessment of Pharmaceuticals

Please only answer these questions if you **PERSONALLY** are a member of WP5. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP5 progressed so far?

○ Poorly ○ Ok (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

WP5's workplan lists 2 deliverables - we are interested in your views about them.

2. 'A relative effectiveness assessment of a (group) of pharmaceutical(s)' should be delivered in month 27 - March 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. 'A methodological guidance that will be appropiate for the assessment of relative effectiveness of pharmaceuticals' should be delivered in month 36 - December 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' interim survey 2011

4. What do you think about these statements for WP5?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○
The amount of work is ok	○	○	○	○	○
Management of stakeholders' interests is ok	○	○	○	○	○

5. Do you have any concerns about WP5, including from the table above?

○ No ○ Don't Know

○ Yes

Please specify any concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

WP6: Information Management System

Please only answer these questions if you **PERSONALLY** are a member of WP6. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP6 progressed over the past year?
Please only answer if you PERSONALLY are involved in the work of WP6.

○ Poorly ○ Ok (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

2. The workplan says that 'Information Management System (IMS) and the related documentation, processes and policies' will be delivered in month 33-September 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. What do you think about these statements for WP6?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○
Technical issues are clear	○	○	○	○	○
The amount of work is ok	○	○	○	○	○

EUnetHTA JA individuals' interim survey 2011

4. Do you have any concerns about WP6, including from the table above?

- ○ No
- ○ Don't Know
- ○ Yes

Please specify any concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

WP7: New Technologies

Please only answer these questions if you **PERSONALLY** are a member of WP7. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP7 progressed over the past year? Please only answer if you PERSONALLY are involved in the work of WP7.

○ Poorly ○ Ok (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

WP7's workplan lists 2 deliverables - we are interested in your views about them.

2. 'Operational web-based toolkit including database containing information on evidence generation on new technolgies' should be delivered in month 33-September 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. 'Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies' should be delivered in month 36-December 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' interim survey 2011

4. What do you think about these statements for WP7?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
Partners are appropriately involved in the work	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○
The amount of work is ok	○	○	○	○	○

5. Do you have any concerns about WP7, including from the table above?

○ No ○ Don't Know

○ Yes

Please specify any concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

WP8: Strategy & Business Model Development

Please only answer these questions if you **PERSONALLY** are a member of WP8. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

WP8 is split into 3 workstreams - we are interested about the progress of each workstream. If you are not a member of the workstream, please tick 'Not Involved'.

1. How has WP8 progressed?

	Poorly	Ok (but could be better)	Well	Don't Know	Not Involved
Strategy & business model development	○	○	○	○	○
Facilitation of national strategies for continuous development and sustainability of HTA	○	○	○	○	○
HTA training & capacity building	○	○	○	○	○

Please explain any concerns; (250 word limit)

WP8 has 2 deliverables in its workplan - we are interested in your views about them.

2. 'Stakeholder Policy' should be delivered in month 10 - October 2010.

Do you think this has happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. 'Collaboratively developed business model for sustainability' should be delivered in month 24 - December 2011.

Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' interim survey 2011

4. What do you think about these statements for WP8?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Leadership from the Lead partner is effective	○	○	○	○	○
Communication between the members is effective	○	○	○	○	○
The objectives are clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The planning timeline is clear	○	○	○	○	○
The number of e-meetings planned is appropriate	○	○	○	○	○
The number of face-to-face meetings planned is appropriate	○	○	○	○	○
The amount of work is ok	○	○	○	○	○

5. Do you have any concerns about WP8, including from the table above?

○ No ○ Don't Know

○ Yes

Please specify any concerns & how these could be resolved; (500 word limit)

EUnetHTA JA individuals' interim survey 2011

Survey End

1. Is there anything else you think we should know about the EUnetHTA JA? (500 word limit)

2. Please estimate the time it has taken you (in minutes) to complete this survey

Many thanks for completing this survey!

Please click on the 'Finished' button below to submit your answers. A summary report will be produced which will not identify you to your answers.

Appendix 3 Participant questionnaire 2012

EUnetHTA JA individuals' final survey 2012

Introduction

Please complete this 2012 survey for INDIVIDUALS of organisations in the EUnetHTA Joint Action (JA) from WP3.

It combines questions from 4 workpackages to decrease the number of surveys you get from EUnetHTA JA; WP1:Coordination, WP3:Evaluation, WP6: Information Management System and WP8: Training strand.

Testing has shown it should take you approximately 30-45 minutes to complete (depending on how many workpackages you are in).
The EUnetHTA JA Executive Committee requests your early response to this survey and by MAY 21 at the latest please.

Instructions:
• Please complete this survey PERSONALLY and do not forward it to anyone else.
• It has been designed to be easily completed; most questions just require you to tick a box.
• Your answers will be kept confidential and you will not be personally linked to your response in reports. In exceptional cases we might contact you to ask you for further clarification about responses.
• The survey is web-based, so the results will be automatically sent to us when you click the FINISH button.
• Please email e.guegan@soton.ac.uk if you hear about anyone who should have received an invitation but hasn't.
• Certificates will be awarded at the Plenary Assembly to those who have submitted their answers by clicking on the FINISH button.

Please click NEXT when you have answered all questions on a page. Click PREVIOUS if you want to go back to the page before. Click FINISH at the end to submit your answers.

Many thanks for your help!
Eleanor Guegan (NETSCC, WP3 lead partner), e.guegan@soton.ac.uk

EUnetHTA JA individuals' final survey 2012

1. Demographics

This section asks for information about you. This will be kept confidential so that you will not be personally identified to your responses in summary reports.

1. Please indicate your MAIN professional expertise within HTA.

- ○ Administrator (eg secretary)
- ○ Economist
- ○ Information scientist
- ○ Medical doctor (eg physician)
- ○ Other healthcare professional (eg pharmacist)
- ○ Project manager
- ○ Researcher
- ○ Statistician

Other - please specify;

2. Please indicate the approximate number of FULL years you have worked in HTA. If less than 1 year - please enter 0.

3. Please indicate your age group.

○ 20-29 ○ 30-39 ○ 40-49 ○ 50-59 ○ 60-69 ○ 70+

4. Are you an 'HTA doer'? ***ie are you actively involved in preparing HTA assessment reports?***

- ○ No
- ○ Yes
- ○ Don't Know

If you wish, please comment here;

EUnetHTA JA individuals' final survey 2012

5. Does your organisation have enough resources to be able to do what it said it will for the entire EUnetHTA JA? (until Dec 2012)

	No	Yes	Don't Know
Funding	○	○	○
Staff	○	○	○

If you wish, please comment here;

6. Are you the lead person within your organisation, with overall responsiblity for EUnetHTA JA activities?

○ No ○ Don't Know

○ Yes

If you wish, please comment here;

EUnetHTA JA individuals' final survey 2012

1. Please indicate which of the following types of expertise are available in your organisation. Please tick ALL that apply.

- ☐ Clinical effectiveness research
- ☐ Clinical expertise
- ☐ Communication services
- ☐ Development of surveys
- ☐ Health economics
- ☐ IT
- ☐ Legal expertise
- ☐ Organisational science
- ☐ Social science

Other (please specify);

2. Please use the drop-down menus to indicate HTA information produced by your organisation. If your organisation does not produce a certain information type (or you don't know) please indicate this in the 1st column and leave the other columns blank.

	Is this produced by your organisation?	Is a summary available in English?	Is the full document available in English?	What is the confidentiality level for this?
Raw data (eg extraction forms)				
Planned projects list				
Ongoing projects list				
Preliminary report (available internally but not published)				
Final published report				
Impact record (eg policy decision)				

EUnetHTA JA individuals' final survey 2012

2. Administration & Communication

This section asks about administration & communication within the EUnetHTA JA.

1. Has the Secretariat shown effective support within the EUnetHTA JA?

	No	Ok (but could be better)	Yes	Don't Know
Leadership	○	○	○	○
Administration	○	○	○	○

Please explain any concerns & how this could be better for EUnetHTA JA2; (250 word limit)

2. Have you experienced any language communication problems that could affect the work of the EUnetHTA JA?

○ No ○ Yes - spoken ○ Yes - written ○ Yes - both spoken & written

Please specify any communication problems & how these could be improved; (250 word limit)

EUnetHTA JA individuals' final survey 2012

3. How useful do you find communication methods within the EUnetHTA JA?

	Not Useful	Ok (but could be better)	Very useful	Don't Know
Members' Only (MO) Website	○	○	○	○
Members' Only (MO) Workrooms	○	○	○	○
Workroom Bulletin Boards	○	○	○	○
Members' E-newsletters (quarterly)	○	○	○	○
Emails from Secretariat	○	○	○	○
E-meetings	○	○	○	○
Face-to-face Meetings	○	○	○	○
Plenary Assembly	○	○	○	○

Please explain your answers; (250 word limit)

4. Lead partners and Co-lead partners decided not to hold a conference at the end of the EUnetHTA JA. Instead there was one in 2011 in Gdansk. Was this the right decision?

○ No

○ Yes

○ Don't Know

Please explain your answer; (250 word limit)

EUnetHTA JA individuals' final survey 2012

3. Information Technology

This section asks about your use of Information Technology at work.

1. Have you logged on to the Members' Only (MO) EUnetHTA JA website? click here for the website

- ○ No
- ○ Yes

Do you have any suggestions for improvement in EUnetHTA JA2?

EUnetHTA JA individuals' final survey 2012

1. How was the process for renewing your EUnetHTA ID (your unique log in to the MO website and tools)?

	Disagree	Agree	Don't Know
Process was clear	○	○	○
Process was quick	○	○	○

Please add any comments;

2. Have you experienced problems accessing the MO after renewing your EUnetHTA ID?

○ Regularly ○ Occasionally ○ Rarely ○ Never

EUnetHTA JA individuals' final survey 2012

1. Are you aware of the HTA Europe group on LinkedIn?

- ○ Don't use LinkedIn
- ○ Not aware of it
- ○ Aware of it but not a member
- ○ Yes-member but don't actively contribute
- ○ Yes-member who actively contributes

2. Do you have a smart phone and/or tablet for professional use? ***Please tick all that apply.***

☐ Smart phone ☐ Tablet ☐ Neither

3. On average how often do you use these communication systems AT WORK?

	Daily	At least once a week	Monthly	Seldom (less than monthly)	Never
Document management system (eg Sharepoint)	○	○	○	○	○
Mailing list	○	○	○	○	○
RSS feed reader	○	○	○	○	○
Video calling (eg Skype)	○	○	○	○	○
Web-based discussion forum	○	○	○	○	○
Wiki	○	○	○	○	○
Cloud storage (eg Dropbox)	○	○	○	○	○
Blog	○	○	○	○	○
Online chat	○	○	○	○	○
Intranet comments (eg commenting on a blog)	○	○	○	○	○

EUnetHTA JA individuals' final survey 2012

3. EUnetHTA tools

1. Please use the drop-down menus below to indicate your use/awareness of the EUnetHTA tools and opinions about training.

Please only select ONE tool as top priority for training.

	Use/Awareness	Priority for training	Preferred Training Method	Anticipated mobile use
Adaptation Glossary				
Adaptation Toolkit				
Contact Database				
E-meetings				
EUnetHTA Toolbar				
EVIDENT (formerly EIFFEL)				
HTA Core Model				
Mailing List				
Members' Only (MO) internet website				
Members' Only (MO) workrooms				
News Aggregator				
POP Database				
Workroom Bulletin Boards				

2. Does your organisation currently have access to the POP Database?

○ No ○ Yes ○ Don't Know

3. If you have used a tool in the past but have now stopped, please tell us the tool and explain why you stopped using it; (250 word limit)

EUnetHTA JA individuals' final survey 2012

4. Have any problems affected your use of the tools?

Multiple options can be chosen for each tool.

	Design of the tool	IT issues	Organisational issues	Training	Other problems	None
Adaptation Glossary	☐	☐	☐	☐	☐	☐
Adaptation Toolkit	☐	☐	☐	☐	☐	☐
Contact Database	☐	☐	☐	☐	☐	☐
E-meetings	☐	☐	☐	☐	☐	☐
EUnetHTA Toolbar	☐	☐	☐	☐	☐	☐
EVIDENT	☐	☐	☐	☐	☐	☐
HTA Core Model	☐	☐	☐	☐	☐	☐
Mailing List	☐	☐	☐	☐	☐	☐
MO internet website	☐	☐	☐	☐	☐	☐
MO workrooms	☐	☐	☐	☐	☐	☐
News Aggregator	☐	☐	☐	☐	☐	☐
POP Database	☐	☐	☐	☐	☐	☐
Workroom Bulletin Boards	☐	☐	☐	☐	☐	☐

Please explain any problems you have had with the tools; (250 word limit)

5. Please suggest any ideas to overcome problems using the EUnetHTA tools; (500 word limit)

EUnetHTA JA individuals' final survey 2012

4. Evaluation of EUnetHTA JA

This section asks for your evaluation of the EUnetHTA JA.

1. Has the EUnetHTA JA achieved what you hoped it would?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (250 word limit)

2. Have you personally got what you hoped by being a member of the EUnetHTA JA?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (250 word limit)

3. What have been the main CHALLENGES of being involved in the EUnetHTA JA? (500 word limit)

4. What have been the main BENEFITS of being involved in the EUnetHTA JA? (500 word limit)

EUnetHTA JA individuals' final survey 2012

5. How useful do you think the following will be for your day-to-day HTA work?

	Not Useful	Of some use	Very useful	Don't Know
Networking with contacts made from participating in the EUnetHTA JA	○	○	○	○
The HTA Core Model (the online Tool & Service for producing, publishing, storing and retrieving HTA information) (WP4)	○	○	○	○
The HTA Core Model on screening (WP4)	○	○	○	○
A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals (WP5)	○	○	○	○
Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies (WP7)	○	○	○	○
Operational web-based toolkit including database containing information on evidence generation on new technologies (EVIDENT) (WP7)	○	○	○	○
Accessing the EUnetHTA tools by a single sign-on through the MO site (WP6)	○	○	○	○

Please add any comments; (250 word limit)

6. Have the following negatively affected your participation in the EUnetHTA JA?

	Yes-big effect	Yes-small effect	No effect	Don't Know
Difficulty in communication - within the project	○	○	○	○
Difficulty in communication - specifically using English	○	○	○	○
Conflict with other work activities	○	○	○	○
Large project scale	○	○	○	○
High workload of individual workpackages	○	○	○	○
Insufficient organisation funding	○	○	○	○
Insufficient organisation staffing	○	○	○	○

Please explain the effect of these challenges; (500 word limit)

EUnetHTA JA individuals' final survey 2012

7. How useful have you found the following in the EUnetHTA JA?

	Not useful	Ok (of some use)	Very useful	Don't Know
Networking with colleagues	○	○	○	○
Information sharing	○	○	○	○
Capacity building	○	○	○	○
Training	○	○	○	○
Increased awareness of HTA developments	○	○	○	○
Face-to-face meetings	○	○	○	○

Please explain your answers; (500 word limit)

8. Do you think that the EUnetHTA JA will be successful in achieving its 3 official objectives by the end of the project (December 2012)?

	No	Yes	Don't Know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA JA meeting its objectives; (250 word limit)

9. Would a sustainable European collaboration add value?

	No	Yes	Don't Know
National level	○	○	○
Regional level	○	○	○
European level	○	○	○

Please explain what value would be added, or why no value would be added; (250 word limit)

EUnetHTA JA individuals' final survey 2012

10. What would make you know that a sustainable European Collaboration on HTA has been achieved? (500 word limit)

11. Do you have any comments about how EUnetHTA JA has been promoted externally? (500 word limit)

e.g.the promotional leaflet, public website, groups on social networking sites, videos (on Youtube & website) and presence at conferences

12. Do you have any concerns about the involvement of external stakeholders in the EUnetHTA JA?

	No	Yes	Don't Know
The principles of stakeholder involvement in the JA (Stakeholder involvement policy and SOP)	○	○	○
The actual involvement of stakeholders in the JA	○	○	○
The level of commitment of stakeholders in the JA	○	○	○

Please explain your answers, if you wish; (250 word limit)

EUnetHTA JA individuals' final survey 2012

13. Please complete the evaluation table for ALL the EUnetHTA JA workpackages;

	Do you have any concerns about this WP?	Will it achieve its objectives by the end of the EUnetHTA JA?	Have you received appropriate communication from this WP?	Has this WP been worth having in the EUnetHTA JA?
WP1: Coordination				
WP2: Dissemination				
WP3: Evaluation				
WP4: Core HTA				
WP5: Relative Effectiveness Assessment of Pharmaceuticals				
WP6: Information Management System				
WP7: New Technologies				
WP8: Strategy & Business Model Development				

Please explain your answers, if you wish; (500 word limit)

EUnetHTA JA individuals' final survey 2012

5. EUnetHTA Joint Action 2

This section asks for your opinions about the EUnetHTA JA2 and how experiences from the EUnetHTA JA can be used to inform it.

1. Do you think the EUnetHTA JA2 (2012-2014) will serve as a useful follow-up to EUnetHTA JA?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer; (250 word limit)

2. What are the main learning points from the EUnetHTA JA that should inform the EUnetHTA JA2?

3. What can be learnt from EUnetHTA JA about how to best involve external stakeholders and/or experts in EUnetHTA JA2?

4. How can communication (internal or external) be improved in EUnetHTA JA2? (500 word limit)

EUnetHTA JA individuals' final survey 2012

5. Do you have any concerns about the planned EUnetHTA JA2?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns and what could be done about them; (250 word limit)

EUnetHTA JA individuals' final survey 2012

6. Specific Workpackages

These sections ask about the workpackages (WP) you are PERSONALLY involved in.

1. What workpackages are you PERSONALLY a member of?

	No	Yes
WP1: Coordination	○	○
WP2: Dissemination	○	○
WP3: Evaluation	○	○
WP4: HTA Core Model	○	○
WP5: Relative Effectiveness Assessment of Pharmaceuticals	○	○
WP6: Information Management System	○	○
WP7: New Technologies	○	○
WP8: Strategy & business model development	○	○

EUnetHTA JA individuals' final survey 2012

WP1: Coordination

Please only answer these questions if you **PERSONALLY** are a member of WP1. If you are NOT, then please click NEXT at the bottom of the page to go to the next page.

1. How has WP1 progressed over the past year?
Please only answer if you PERSONALLY are involved in the work of WP1.

○ Poorly ○ OK (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

2. WP1's workplan states that 'Final Report from the Joint Action' will be delivered in month 38 (February 2013).
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' final survey 2012

3. Please show what you think about these sentences for WP1.

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
By the end of the EUnetHTA JA (Dec 2012) we will have achieved what we set out to achieve in WP1	○	○	○	○	○
Leadership from the Lead partner has been effective	○	○	○	○	○
Communication between members has been effective	○	○	○	○	○
The objectives were appropriate	○	○	○	○	○
The deliverables were appropriate	○	○	○	○	○
The 3-year workplan has been followed	○	○	○	○	○
The amount of work has been ok	○	○	○	○	○
All members have contributed to the work adequately	○	○	○	○	○
WP1 has communicated effectively with other workpackages	○	○	○	○	○
WP1 has benefitted from the involvement of external stakeholders	○	○	○	○	○

Please explain your answers, if you wish;

4. Is there anything else you want to say about WP1?

EUnetHTA JA individuals' final survey 2012

WP2: Dissemination

Please only answer these questions if you **PERSONALLY** are a member of WP2. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP2 progressed so far?

Please only answer if you PERSONALLY are involved in the work of WP2.

○ Poorly ○ OK (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

2. The workplan for WP2 should have delivered a 'Communication and Dissemination plan' in month 18 - June 2011.

Do you think this happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' final survey 2012

3. What do you think about these statements for WP2?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
By the end of the EUnetHTA JA (Dec 2012) we will have achieved what we set out to achieve in WP2	○	○	○	○	○
Leadership from the Lead partner has been effective	○	○	○	○	○
Communication between the members has been effective	○	○	○	○	○
The objectives were appropriate	○	○	○	○	○
The deliverables were appropriate	○	○	○	○	○
The 3 year work plan has been followed	○	○	○	○	○
The amount of work has been ok	○	○	○	○	○
All members have contributed to the work adequately	○	○	○	○	○
WP2 has communicated effectively with other workpackages	○	○	○	○	○
WP2 has benefitted from the involvement of external stakeholders	○	○	○	○	○

Please explain your answers, if you wish;

4. Is there anything else you want to say about WP2?

EUnetHTA JA individuals' final survey 2012

WP4: Core HTA

Please only answer these questions if you **PERSONALLY** are a member of WP4. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP4 progressed so far?
Please only answer if you PERSONALLY are involved in the work of WP4.

○ Poorly ○ Ok (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

WP4's workplan lists 3 deliverables - we are interested in your views about them.

2. 'An online Tool & Service for producing, publishing, storing and retrieving HTA information' should be delivered in month 36 - December 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. 'Screening application of the HTA core model' should have been delivered in month 15 - March 2011. Do you think this happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' final survey 2012

4. 'A set of two core HTAs' should be delivered in month 36 - December 2012.

Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

5. What do you think about these statements for WP4?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
By the end of the EUnetHTA JA (Dec 2012) we will have achieved what we set out to achieve in WP4	○	○	○	○	○
Leadership from the Lead partner has been effective	○	○	○	○	○
The 2 workstreams have collaborated well	○	○	○	○	○
Communication between the members has been effective	○	○	○	○	○
The objectives were appropriate	○	○	○	○	○
The deliverables were appropriate	○	○	○	○	○
The 3 year work plan has been followed	○	○	○	○	○
The amount of work has been ok	○	○	○	○	○
Members have collaborated effectively to produce Core HTAs	○	○	○	○	○
All members have contributed to the work adequately	○	○	○	○	○
WP4 has communicated effectively with other workpackages	○	○	○	○	○
WP4 has benefitted from the involvement of external stakeholders	○	○	○	○	○

Please explain your answers, if you wish;

6. Is there anything else you want to say about WP4?

EUnetHTA JA individuals' final survey 2012

EUnetHTA JA individuals' final survey 2012

WP5: Relative Effectiveness Assessment of Pharmaceuticals

Please only answer these questions if you **PERSONALLY** are a member of WP5. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP5 progressed so far?

○ Poorly ○ OK (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

WP5's workplan lists 2 deliverables - we are interested in your views about them.

2. 'A relative effectiveness assessment of a (group) of pharmaceutical(s)' should have been delivered in month 27 - March 2012.
Do you think this happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

3. 'A methodological guidance that will be appropiate for the assessment of relative effectiveness of pharmaceuticals' should be delivered in month 36 - December 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' final survey 2012

4. What do you think about these statements for WP5?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
By the end of the EUnetHTA JA (Dec 2012) we will have achieved what we set out to achieve in WP5	○	○	○	○	○
Leadership from the Lead partner has been effective	○	○	○	○	○
Communication between the members has been effective	○	○	○	○	○
The objectives were appropriate	○	○	○	○	○
The deliverables were appropriate	○	○	○	○	○
The 3 year work plan has been followed	○	○	○	○	○
The amount of work has been ok	○	○	○	○	○
All members have contributed to the work adequately	○	○	○	○	○
Members have collaborated effectively in the pilots	○	○	○	○	○
The 'rapid model' for REA of pharmaceuticals is useful	○	○	○	○	○
The 'full model' for REA of pharmaceuticals is useful	○	○	○	○	○
Dividing the work between 5 sub-groups has been effective	○	○	○	○	○
WP5 has communicated effectively with other workpackages	○	○	○	○	○
WP5 has benefitted from the involvement of external stakeholders	○	○	○	○	○

Please explain your answers, if you wish;

5. Is there anything else you want to say about WP5?

EUnetHTA JA individuals' final survey 2012

WP6: Information Management System

Please only answer these questions if you **PERSONALLY** are a member of WP6. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP6 progressed over the past year?

Please only answer if you PERSONALLY are involved in the work of WP6.

○ Poorly ○ OK (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

2. The workplan says that 'Information Management System (IMS) and the related documentation, processes and policies' will be delivered in month 33-September 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' final survey 2012

3. What do you think about these statements for WP6?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
By the end of the EUnetHTA JA (Dec 2012) we will have achieved what we set out to achieve in WP6	○	○	○	○	○
Leadership from the Lead partner has been effective	○	○	○	○	○
Communication between the members has been effective	○	○	○	○	○
The objectives were appropriate	○	○	○	○	○
The deliverables were appropriate	○	○	○	○	○
The 3 year work plan has been followed	○	○	○	○	○
The amount of work has been ok	○	○	○	○	○
Members have contributed to the work equally	○	○	○	○	○
WP6 has communicated effectively with other workpackages	○	○	○	○	○
WP6 has benefitted from the involvement of external stakeholders	○	○	○	○	○

Please explain your answers, if you wish;

4. Is there anything else you want to say about WP6?

EUnetHTA JA individuals' final survey 2012

WP7: New Technologies

Please only answer these questions if you **PERSONALLY** are a member of WP7. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

1. How has WP7 progressed over the past year?

Please only answer if you PERSONALLY are involved in the work of WP7.

○ Poorly ○ OK (but could be better) ○ Well ○ Don't Know

Please explain any concerns; (250 word limit)

WP7's workplan lists 2 deliverables - we are interested in your views about them.

2. 'Operational web-based toolkit including database containing information on evidence generation on new technolgies' should be delivered in month 33-September 2012.

Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' final survey 2012

3. 'Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies' should be delivered in month 36-December 2012.

Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

4. What do you think about these statements for WP7?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
By the end of the EUnetHTA JA (Dec 2012) we will have achieved what we set out to achieve in WP7	○	○	○	○	○
Leadership from the Lead partner has been effective	○	○	○	○	○
The 2 workstreams collaborated well	○	○	○	○	○
Communication between the members has been effective	○	○	○	○	○
The 3-year workplan has been followed	○	○	○	○	○
The objectives were clear	○	○	○	○	○
The deliverables were clear	○	○	○	○	○
The amount of work has been ok	○	○	○	○	○
Members have contributed to the work equally	○	○	○	○	○
WP7 has communicated effectively with other workpackages	○	○	○	○	○
WP7 has benefitted from the involvement of external stakeholders	○	○	○	○	○

Please explain your answers, if you wish;

EUnetHTA JA individuals' final survey 2012

5. Is there anything else you want to say about WP7?

EUnetHTA JA individuals' final survey 2012

WP8: Strategy & Business Model Development

Please only answer these questions if you **PERSONALLY** are a member of WP8. If you are NOT then please click NEXT at the bottom of the page to go to the next page.

WP8 is split into 3 workstreams - we are interested about the progress of each workstream. If you are not a member of the workstream, please tick 'Not Involved'.

1. How has WP8 progressed?

	Poorly	Ok (but could be better)	Well	Don't Know	Not Involved
Strategy & business model development	○	○	○	○	○
Facilitation of national strategies for continuous development and sustainability of HTA	○	○	○	○	○
HTA training & capacity building	○	○	○	○	○

Please explain any concerns; (250 word limit)

WP8 has 2 deliverables in its workplan - we are interested in your views about them.

2. 'Collaboratively developed business model for sustainability' should have been delivered in month 24 - December 2011. Do you think this happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

EUnetHTA JA individuals' final survey 2012

3. 'Stakeholder policy' should have been delivered in month 10 - October 2011. Do you think this happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns; (250 word limit)

4. What do you think about these statements for WP8?

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
By the end of the EUnetHTA JA (Dec 2012) we will have achieved what we set out to achieve in WP8	○	○	○	○	○
Leadership from the Lead partner has been effective	○	○	○	○	○
Communication between the members has been effective	○	○	○	○	○
The objectives were clear	○	○	○	○	○
The deliverables are clear	○	○	○	○	○
The 3 year workplan has been followed	○	○	○	○	○
The amount of work was ok	○	○	○	○	○
Members have contributed to the work equally	○	○	○	○	○
Being a member of EUnetHTA JA has helped your organisation develop its HTA activities	○	○	○	○	○
The training course about the HTA Core Model was useful	○	○	○	○	○
WP8 has communicated effectively with other workpackages	○	○	○	○	○
WP8 has benefitted from the involvement of external stakeholders	○	○	○	○	○

Please explain your answers, if you wish;

5. Is there anything else you want to say about WP8?

EUnetHTA JA individuals' final survey 2012

Survey End

1. Is there anything else you think we should know about the EUnetHTA JA? (500 word limit)

2. Please estimate the time it has taken you (in minutes) to complete this survey

Many thanks for completing this survey!

Please click on the 'Finished' button below to submit your answers. A summary report will be produced which will not identify you to your answers.

Appendix 4 Stakeholder questionnaire 2010

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

1. Introduction

We ask for your help in completing this baseline survey for organisations which are members of the EUnetHTA Joint Action Stakeholder Forum. We are requesting one response from your organisation.

Your response may be attributed to you unless you indicate otherwise (when it would be kept confidential within the EUnetHTA Joint Action Stakeholder Forum, Executive Committee, Secretariat and the WP3 evaluation team). In exceptional cases we might contact you to ask you for further clarification about responses.

There is no word count limit for your answers and the reply boxes expand.

Please click NEXT when you have answered all questions on a page. You can click PREVIOUS should you wish to go back to the page before. Please click FINISHED at the end to submit your answers.

Many thanks for your help completing this survey!

Please complete this survey as soon as possible and by 2nd August.

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

2. EUnetHTA Joint Action Stakeholder Forum

What do you think is the purpose of the EUnetHTA Joint Action Stakeholder Forum?

How did your organisation become aware of the EUnetHTA Joint Action Stakeholder Forum?

Why did your organisation apply to be a member of the EUnetHTA Joint Action Stakeholder Forum?

What do you think your role as a member of the EUnetHTA Joint Action Stakeholder Forum will involve?

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

What do you think you will gain from being a Stakeholder for the EUnetHTA Joint Action?

What do you think you will offer by being a Stakeholder for the EUnetHTA Joint Action?

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

3. EUnetHTA Joint Action Stakeholder Forum

Was the process of setting up the EUnetHTA Joint Action Stakeholder Forum straightforward?

- ○ No
- ○ Yes
- ○ Don't know

Please explain any concerns about the setting up of the EUnetHTA Joint Action Stakeholder Forum;

Do you have any comments about the EUnetHTA Joint Action Stakeholder Involvement Policy & Standard Operating Procedure documents?

Do you have any comments about the EUnetHTA Joint Action Stakeholder Forum meetings?
(These are the planned yearly face-to-face meetings & quarterly e-meetings).

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

Do you feel confident that the views of Stakeholders will be adequately considered in the EUnetHTA Joint Action?

- ○ No
- ○ Yes
- ○ Don't know

Please explain any concerns about how Stakeholders' views will be considered;

Do you feel confident that adequate feedback about the EUnetHTA Joint Action will be provided to Stakeholders?

- ○ No
- ○ Yes
- ○ Don't know

Please explain any concerns you have about the provision of feedback to Stakeholders;

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

4. EUnetHTA Joint Action

Do you think that the EUnetHTA Joint Action will be successful in achieving its objectives?

	No	Yes	Don't know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA Joint Action meeting its objectives;

What effect do you think organising the EUnetHTA Joint Action work in 8 workpackages will have?

- ○ Negative
- ○ Mixed (both negative & positive)
- ○ Positive
- ○ Don't know

Please explain any concerns & how the EUnetHTA Joint Action could have been better organised;

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

Do you think that the EUnetHTA Joint Action could serve as a foundation for a sustainable European collaboration at the end of the project?

- ○ No
- ○ Yes
- ○ Don't know

Please explain your answer;

What do you think an ongoing European HTA collaboration should be doing?

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

5. Work packages of the EUnetHTA Joint Action

WP4: Core HTA Model

What do you think are the aims of WP4?

Do you have any concerns about WP4?

- ○ No
- ○ Yes - please explain any concerns about WP4;

WP5: Relative Effectiveness Assessment of Drugs

What do you think are the aims of WP5?

Do you have any concerns about WP5?

- ○ No
- ○ Yes - please explain any concerns about WP5;

WP7: New Technologies

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

What do you think are the aims of WP7?

Do you have any concerns about WP7?

- ○ No
- ○ Yes - please explain any concerns about WP7;

Do you have any other comments about any of the other EUnetHTA Joint Action workpackages?

Do you have any other comments about the EUnetHTA Joint Action 3-year work plan?

EUnetHTA Joint Action Stakeholder Forum Baseline Survey 2010

6. Submission

Is there anything else you would like to add?

Many thanks for completing this questionnaire!

Please now click the 'Finished' button to submit your answers.

Appendix 5 Stakeholder questionnaire 2011

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

1. Introduction

Please complete this interim 2011 survey for organisations which are members of the EUnetHTA Joint Action Stakeholder Forum. We ask for one response from your umbrella organisation.

The survey has been designed to be easily completed and should take you no longer than 30-45 minutes (depending on how much you write for the free-text questions).

Your response may be attributed to you unless you indicate otherwise (when it would be kept confidential within the EUnetHTA Joint Action Stakeholder Forum, Executive Committee, Secretariat and the WP3 evaluation team). In exceptional cases we might contact you to ask you for further clarification about responses.

There is no word count limit for your answers and the reply boxes expand.

Please click NEXT when you have answered all questions on a page. You can click PREVIOUS should you wish to go back to the page before. Please click FINISHED at the end to submit your answers.

Please complete this survey as soon as possible and by 24 June at the latest.

Many thanks for your help.
Eleanor Guegan (NETSCC, WP3 lead partner); e.guegan@soton.ac.uk

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

2. EUnetHTA Joint Action (JA) Stakeholder Forum

What do you think is the purpose of the EUnetHTA JA Stakeholder Forum?

Do you think the EUnetHTA JA Stakeholder Forum is fulfilling its purpose?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer;

Has your role as a member of the EUnetHTA JA Stakeholder Forum involved what you thought it would?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer;

Is being a member of the EUnetHTA JA Stakeholder Forum a good use of your organisation's time?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

How have you contributed to the EUnetHTA JA?

Please comment on how well the Stakeholder Advisory Groups (SAGs) are operating;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

3. EUnetHTA JA Stakeholder Forum

Do you have any comments about the EUnetHTA Joint Action Stakeholder Forum meetings?
(These are the planned yearly face-to-face meetings & quarterly e-meetings).

Do you think that the views of Stakeholders are being adequately considered in the EUnetHTA JA?

- ○ No
- ○ Yes
- ○ Don't Know

Please explain any concerns;

Do you think that adequate feedback about the EUnetHTA JA is being provided to Stakeholders?

- ○ No
- ○ Yes
- ○ Don't Know

Please explain any concerns;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

4. EUnetHTA JA

Do you think that the EUnetHTA JA will be successful in achieving its 3 official objectives?

	No	Yes	Don't Know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA JA meeting its objectives;

Do you think the EUnetHTA JA will serve as a foundation for a sustainable European collaboration at the end of the project?

○ No ○ Don't Know

○ Yes

Please explain your answer;

Please explain how you will know that a sustainable European collaboration has been achieved.

What do you think an ongoing European HTA collaboration should be doing?

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

How should an ongoing European HTA collaboration successfully interact with stakeholders, such as your organisation?

Did you, or your organisational representative, attend the Plenary Assembly 2011?

- ○ No
- ○ Yes

Please provide any comments from your organisation about the Plenary Assembly;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

5. EUnetHTA JA2

Have you been consulted about planning for the EUnetHTA JA2?

- ○ No
- ○ Yes

Who consulted you about planning for the EUnetHTA JA2?

Do you have any concerns about the planned EUnetHTA JA2?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

6. WP4: Core HTA Model

Is your organisation involved in WP4?

- ○ No
- ○ Yes
- ○ Don't Know

How do you think WP4 has progressed so far?

- ○ Poorly
- ○ Ok (but could be better)
- ○ Well
- ○ Don't Know

Please provide any comments;

WP4's workplan lists 3 deliverables - we are interested in your views about them.

'An online Tool & Service for producing, publishing, storing and retrieving HTA information' should be delivered in M36 - December 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

'Screening application of the HTA core model' - delivery of this is being revised. Do you think this will be delivered in Nov-Dec 2011 as is now planned?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

'A set of two core HTAs' should be delivered in month 36 - December 2012.

Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

Do you have any concerns about WP4?

○ No ○ Don't Know

○ Yes

Please specify any concerns & how these could be resolved;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

7. WP5: Relative Effectiveness Assessment of Pharmaceuticals

Is your organisation involved in WP5?

- ○ No
- ○ Yes
- ○ Don't Know

How has WP5 progressed so far?

- ○ Poorly
- ○ Ok (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP5's workplan lists 2 deliverables - we are interested in your views about them.

'A relative effectiveness assessment of a (group) of pharmaceutical (s)' should be delivered in month 27 - March 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

'A methodological guidance that will be appropiate for the assessment of relative effectiveness of pharmaceuticals' should be delivered in month 36 - December 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

Do you have any concerns about WP5?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns & how these could be resolved;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

8. WP7: New Technologies

Is your organisation involved in WP7?

- ○ No
- ○ Yes
- ○ Don't Know

How has WP7 progressed so far?

- ○ Poorly
- ○ Ok (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP7's workplan lists 2 deliverables - we are interested in your views about them.

'Operational web-based toolkit including database containing information on evidence generation on new technolgies' should be delivered in month 33-September 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

'Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies' should be delivered in month 36-December 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

Do you have any concerns about WP7?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns & how these could be resolved;

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

9. Work packages of the EUnetHTA JA

Do you have any concerns about any of the other EUnetHTA JA Work packages?

	No	Yes	Don;t Know
WP1; Coordination	○	○	○
WP2; Dissemination	○	○	○
WP3; Evaluation	○	○	○
WP8; Strategy & Business Model Development	○	○	○

Please explain any concerns & how these could be resolved;

How are Work packages interacting with you to involve you in their work? Please explain any problems & how these could be improved.

Do you have any other concerns about the EUnetHTA Joint Action 3-year work plan?

EUnetHTA Joint Action Stakeholder Forum Interim Survey 2011

10. Submission

Is there anything else you think we should know about the EUnetHTA JA?

Please estimate the time (in minutes) that it has taken you to complete this survey.

Many thanks for completing this questionnaire!

Please now click the 'Finished' button to submit your answers.

Appendix 6 Stakeholder questionnaire 2012

EUnetHTA JA Stakeholder Forum Final Survey 2012

Introduction

Please complete this 2012 survey for organisations which are members of the EUnetHTA Joint Action Stakeholder Forum. We ask for one response from your umbrella organisation.

The survey has been designed to be easily completed and should take you no longer than 30-45 minutes (depending on how much you write for the free-text questions).

Your response may be attributed to you unless you indicate otherwise (when it would be kept confidential within the EUnetHTA Joint Action Stakeholder Forum, Executive Committee, Secretariat and the WP3 evaluation team). In exceptional cases we might contact you to ask you for further clarification about responses.

There is no word count limit for your answers and the reply boxes expand.

The EUnetHTA JA Executive Committee requests your early response to this survey and by JUNE 19 at the latest please.

Please click NEXT when you have answered all questions on a page. Click PREVIOUS if you want to go back to the page before. Click FINISH at the end to submit your answers.

Many thanks for your help,
Eleanor Guegan (NETSCC, WP3 lead partner), e.guegan@soton.ac.uk

EUnetHTA JA Stakeholder Forum Final Survey 2012

2. EUnetHTA Joint Action (JA) Stakeholder Forum

This section asks for your evaluation of the EUnetHTA JA Stakeholder Forum.

1. Please indicate your agreement with the following statements;

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Being a member of the Stakeholder Forum has been a good use of my organisation's time	○	○	○	○	○
My organisation has got what it hoped by being a member of the Stakeholder Forum	○	○	○	○	○
The EUnetHTA JA Stakeholder Forum has fulfilled its purpose	○	○	○	○	○
The appropriate organisations were included in the Stakeholder Forum	○	○	○	○	○
The formation of a Stakeholder Forum was an effective way of organising Stakeholder input into the EUnetHTA JA	○	○	○	○	○
The Stakeholder Advisory Groups (SAGs) have been a good way of being involved in the EUnetHTA JA	○	○	○	○	○
The Stakeholder Forum meetings have been useful	○	○	○	○	○

Please add any comments;

EUnetHTA JA Stakeholder Forum Final Survey 2012

EUnetHTA JA

This section asks for your evaluation of the EUnetHTA JA.

1. Please indicate your agreement with the following statements;

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
The EUnetHTA JA has achieved what my organisation hoped	○	○	○	○	○
Stakeholders' views have been adequately considered in the EUnetHTA JA	○	○	○	○	○
Adequate feedback from the EUnetHTA JA has been provided to Stakeholders	○	○	○	○	○
My organisation's expertise has been appropriately used in the EUnetHTA JA	○	○	○	○	○
It would be useful to have a EUnetHTA conference on a regular basis	○	○	○	○	○

Please add any comments;

2. Do you have any concerns about the involvement of external stakeholders in the EUnetHTA JA?

	No	Yes	Don't Know
The principles of stakeholder involvement in the JA (Stakeholder involvement policy and SOP)	○	○	○
The actual involvement of stakeholders in the JA	○	○	○
The level of commitment of stakeholders in the JA	○	○	○

Please explain your answers, if you wish;

3. How has your organisation contributed to the EUnetHTA JA?

EUnetHTA JA Stakeholder Forum Final Survey 2012

4. Lead partners and Co-lead partners decided not to hold a conference at the end of the EUnetHTA JA. Instead there was one in 2011 in Gdansk. Was this the right decision?

- ○ No
- ○ Yes
- ○ Don't Know

Please explain your answer;

5. What have been the main CHALLENGES of being involved in the EUnetHTA JA?

6. What have been the main BENEFITS of being involved in the EUnetHTA JA?

7. How useful do you think the following will be for the work of professionals producing HTA?

	Not Useful	Of some use	Very useful	Don't Know
Networking with contacts made from participating in the EUnetHTA JA	○	○	○	○
The HTA Core Model (the online Tool & Service for producing, publishing, storing and retrieving HTA information) (WP4)	○	○	○	○
The HTA Core Model on screening (WP4)	○	○	○	○
A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals (WP5)	○	○	○	○
Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies (WP7)	○	○	○	○
Operational web-based toolkit including database containing information on evidence generation on new technologies (EVIDENT) (WP7)	○	○	○	○
Accessing the EUnetHTA tools by a single sign-on through the MO site (WP6)	○	○	○	○

Please add any comments;

EUnetHTA JA Stakeholder Forum Final Survey 2012

8. Would you like to improve your understanding by having training about developments from the project?

	No	Yes	Don't Know
The HTA Core Model (the online Tool & Service for producing, publishing, storing and retrieving HTA information) (WP4)	○	○	○
The HTA Core Model on screening (WP4)	○	○	○
A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals (WP5)	○	○	○
Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies (WP7)	○	○	○
EVIDENT (Operational web-based toolkit including database containing information on evidence generation on new technologies) (WP7)	○	○	○

Please add any comments;

9. Do you think that the EUnetHTA JA will be successful in achieving its 3 official objectives by the end of the project (December 2012)?

	No	Yes	Don't Know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA JA meeting its objectives;

10. Would a sustainable European collaboration add value?

	No	Yes	Don't Know
National level	○	○	○
Regional level	○	○	○
European level	○	○	○

Please explain what value would be added, or why no value would be added;

EUnetHTA JA Stakeholder Forum Final Survey 2012

11. What would make you know that a sustainable European Collaboration on HTA has been achieved?

12. Do you have any comments about how EUnetHTA JA has been promoted externally? (500 word limit)

e.g.the promotional leaflet, public website, groups on social networking sites, videos (on Youtube & website) and presence at conferences

13. Please complete the evaluation table for ALL the EUnetHTA JA workpackages;

	Do you have any concerns about this WP?	Will it achieve its objectives by the end of the EUnetHTA JA?	Have you received appropriate communication from this WP?	Has this WP been worth having in the EUnetHTA JA?
WP1: Coordination				
WP2: Dissemination				
WP3: Evaluation				
WP4: Core HTA				
WP5: Relative Effectiveness Assessment of Pharmaceuticals				
WP6: Information Management System				
WP7: New Technologies				
WP8: Strategy & Business Model Development				

Please explain your answers, if you wish;

EUnetHTA JA Stakeholder Forum Final Survey 2012

5. EUnetHTA Joint Action 2

This section asks for your opinions about the EUnetHTA JA2 and how experiences from the EUnetHTA JA can be used to inform it.

1. Do you think the EUnetHTA JA2 (2012-2015) will serve as a useful follow-up to EUnetHTA JA?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer;

2. What are the main learning points from the EUnetHTA JA that should inform the EUnetHTA JA2?

3. What can be learnt from EUnetHTA JA about how to best involve external stakeholders and/or experts in EUnetHTA JA2?

4. How can communication (internal or external) be improved in EUnetHTA JA2?

EUnetHTA JA Stakeholder Forum Final Survey 2012

5. Do you have any concerns about the planned EUnetHTA JA2?

- ○ No
- ○ Yes
- ○ Don't Know

Please explain any concerns and what could be done about them;

6. What would make ongoing European collaboration on HTA effective?

EUnetHTA JA Stakeholder Forum Final Survey 2012

WP4: Core HTA

This section asks for your evaluation of WP4: Core HTA.
Please answer the questions if your organisation feels it can take a view.

1. Has your organisation participated in a Stakeholder Advisory Group (SAG) for WP4?

- ○ No
- ○ Don't Know
- ○ Yes

2. How has WP4 progressed so far?

- ○ Poorly
- ○ OK (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP4's workplan lists 3 deliverables - we are interested in your views about them.

3. 'An online Tool & Service for producing, publishing, storing and retrieving HTA information' should be delivered in months 36 - December 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

EUnetHTA JA Stakeholder Forum Final Survey 2012

4. 'Screening application of the HTA core model' should have been delivered in month 15 - March 2011. Do you think this happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

5. 'A set of two core HTAs' should be delivered in month 36 - December 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

EUnetHTA JA Stakeholder Forum Final Survey 2012

WP5: Relative Effectiveness Assessment of Pharmaceuticals

This section asks for your evaluation of WP5: Relative Effectiveness Assessment of Pharmaceuticals.
Please answer the questions if your organisation feels it can take a view.

1. Has your organisation participated in a Stakeholder Advisory Group (SAG) for WP5?

- ○ No
- ○ Yes
- ○ Don't Know

2. How has WP5 progressed so far?

- ○ Poorly
- ○ OK (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP5's workplan lists 2 deliverables - we are interested in your views about them.

3. 'A relative effectiveness assessment of a (group) of pharmaceutical(s)' has been rescheduled to be delivered in month 30-31- June - July 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

EUnetHTA JA Stakeholder Forum Final Survey 2012

4. 'A methodological guidance that will be appropiate for the assessment of relative effectiveness of pharmaceuticals' should be delivered in month 36 - December 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

5. Is there anything else you want to say about WP5?

EUnetHTA JA Stakeholder Forum Final Survey 2012

WP7: New Technologies

This section asks for your evaluation of WP7: New Technologies.
Please answer the questions if your organisation feels it can take a view.

1. Has your organisation participated in a Stakeholder Advisory Group (SAG) for WP7?

- ○ No
- ○ Don't Know
- ○ Yes

2. How has WP7 progressed over the past year?

- ○ Poorly
- ○ OK (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP7's workplan lists 2 deliverables - we are interested in your views about them.

3. 'EVIDENT (EVidence Database on New Technologies)', containing information on evidence generation on new technologies, should be delivered in month 33-September 2012.
Do you think this database will be successful in facilitating additional evidence generation?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns;

EUnetHTA JA Stakeholder Forum Final Survey 2012

4. 'Criteria to select/prioritize health technologies in need of additional evidence generation' should be delivered in month 30 - June 2012.
Do you think these criteria will be useful?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns;

5. Is there anything else you want to say about WP7?

EUnetHTA JA Stakeholder Forum Final Survey 2012

Survey End

1. Is there anything else you would like to say about the EUnetHTA JA?

2. Please estimate the time it has taken you (in minutes) to complete this survey

Many thanks for completing this survey!

Please click on the 'Finished' button below to submit your answers.

Appendix 7 Questionnaire for stakeholders not admitted to the stakeholder forum 2010

EUnetHTA Joint Action survey

1. Introduction

We ask for your help in completing this baseline survey for organisations which were found eligible for membership of the EUnetHTA Joint Action Stakeholder Forum but were not offered a seat. This was due to a necessity of upholding a balanced representation of the interests and limited number of available seats in each stakeholder category

We are requesting ONE response from your organisation.

Your response may be attributed to you unless you indicate otherwise (when it would be kept confidential within the Stakeholder Forum, Executive Committee, Secretariat and the WP3 evaluation team). In exceptional cases we might contact you to ask you for further clarification about responses.

There is no word count limit for your answers and the reply boxes expand.

Please click NEXT when you have answered all questions on a page. You can click PREVIOUS should you wish to go back to the page before. Please click FINISHED at the end to submit your answers.

Many thanks for your help completing this survey!

Please complete this survey as soon as possible and by 3rd September.

EUnetHTA Joint Action survey

2. EUnetHTA Joint Action Stakeholders

Although your organisation does not hold a seat on the Stakeholder Forum, it is a Stakeholder for the EUnetHTA JA. We are interested in your views about the role of Stakeholders generally in the EUnetHTA JA.

What do you think you will offer by being a Stakeholder for the EUnetHTA Joint Action?

What do you think you will gain from being a Stakeholder for the EUnetHTA Joint Action?

Do you feel confident that the views of Stakeholders will be adequately considered in the EUnetHTA JA?

- ○ No
- ○ Yes
- ○ Don't know

Please explain any concerns about how Stakeholders' views will be considered;

EUnetHTA Joint Action survey

3. EUnetHTA Joint Action Stakeholder Forum

In this section we are interested in your views about the Stakeholder Forum of the EUnetHTA JA.

How did your organisation become aware of the EUnetHTA Joint Action Stakeholder Forum?

Why did your organisation apply to be a member of the Stakeholder Forum?

What did you think your role as a member of the Stakeholder Forum would have involved?

What will the Stakeholder Forum miss by your organisation not being a member of the Stakeholder Forum (but having access to documents and the opportunity to comment them in writing)?

EUnetHTA Joint Action survey

4. EUnetHTA Joint Action Stakeholder Forum

Was the process of setting up the Stakeholder Forum straightforward?

- ○ No
- ○ Yes
- ○ Don't know

Please explain any concerns about the setting up of the Stakeholder Forum;

Do you think your views will be adequately expressed in the Stakeholder Forum by your representative?

- ○ No
- ○ Yes
- ○ Don't know

Please explain any concerns about how your views will be expressed;

Do you have any comments about the Stakeholder Involvement Policy & Standard Operating Procedure documents as well as the expert involvement procedure?

EUnetHTA Joint Action survey

Do you feel confident that adequate feedback about the EUnetHTA JA will be provided to Stakeholders?

- ○ No
- ○ Yes
- ○ Don't know

Please explain any concerns you have about the provision of feedback to Stakeholders;

EUnetHTA Joint Action survey

5. EUnetHTA Joint Action

Do you think that the EUnetHTA Joint Action will be successful in achieving its objectives?

	No	Yes	Don't know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA Joint Action meeting its objectives;

What effect do you think organising the EUnetHTA Joint Action work in 8 workpackages will have?

- ○ Negative
- ○ Mixed (both negative & positive)
- ○ Positive
- ○ Don't know

Please explain any concerns & how the EUnetHTA Joint Action could have been better organised;

EUnetHTA Joint Action survey

Do you think that the EUnetHTA Joint Action could serve as a foundation for a sustainable European collaboration at the end of the project?

- ○ No
- ○ Yes
- ○ Don't know

Please explain your answer;

What do you think an ongoing European HTA collaboration should be doing?

EUnetHTA Joint Action survey

6. Work packages of the EUnetHTA Joint Action

WP4: Core HTA Model

What do you think are the aims of WP4?

Do you have any concerns about WP4?

- No
- Yes - please explain any concerns about WP4;

WP5: Relative Effectiveness Assessment of Drugs

What do you think are the aims of WP5?

Do you have any concerns about WP5?

- No
- Yes - please explain any concerns about WP5;

WP7: New Technologies

EUnetHTA Joint Action survey

What do you think are the aims of WP7?

Do you have any concerns about WP7?

- ○ No
- ○ Yes - please explain any concerns about WP7;

Do you have any other comments about any of the other EUnetHTA Joint Action workpackages?

Do you have any other comments about the EUnetHTA Joint Action 3-year work plan?

EUnetHTA Joint Action survey

7. Submission

Is there anything else you would like to add?

Many thanks for completing this questionnaire!

Please now click the 'Finished' button to submit your answers.

Appendix 8 Questionnaire for stakeholders not admitted to the stakeholder forum 2012

EUnetHTA JA Stakeholders' Final Survey 2012

Introduction

Please complete this 2012 survey for organisations which are external stakeholders of the EUnetHTA Joint Action. We ask for one response from your umbrella organisation.

The survey has been designed to be easily completed and should take you no longer than 30-45 minutes (depending on how much you write for the free-text questions).

Your response may be attributed to you unless you indicate otherwise (when it would be kept confidential within the EUnetHTA Joint Action Stakeholder Forum, Executive Committee, Secretariat and the WP3 evaluation team). In exceptional cases we might contact you to ask you for further clarification about responses.

There is no word count limit for your answers and the reply boxes expand.

The EUnetHTA JA Executive Committee requests your early response to this survey and by JUNE 19 at the latest please.

Please click NEXT when you have answered all questions on a page. Click PREVIOUS if you want to go back to the page before. Click FINISH at the end to submit your answers.

Many thanks for your help,
Eleanor Guegan (NETSCC, WP3 lead partner), e.guegan@soton.ac.uk

EUnetHTA JA Stakeholders' Final Survey 2012

2. EUnetHTA Joint Action (JA) Stakeholders

This section asks for your evaluation about the involvement of external stakeholders in the EUnetHTA JA.

1. Please indicate your agreement with the following statements;

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Being an external stakeholder of the EUnetHTA JA has been a good use of my organisation's time	○	○	○	○	○
My organisation has got what it hoped by being an external stakeholder of the EUnetHTA JA	○	○	○	○	○
The EUnetHTA JA Stakeholder Forum has fulfilled its purpose	○	○	○	○	○
The appropriate organisations were included in the Stakeholder Forum	○	○	○	○	○
The formation of a Stakeholder Forum was an effective way of organising Stakeholder input into the EUnetHTA JA	○	○	○	○	○
The Stakeholder Advisory Groups (SAGs) have been a good way of being involved in the EUnetHTA JA	○	○	○	○	○
Our organisation is aware who is our representative on the Stakeholder Forum	○	○	○	○	○
Our organisation has been kept updated by our representative on the Stakeholder Forum/the Secretariat	○	○	○	○	○

Please add any comments;

EUnetHTA JA Stakeholders' Final Survey 2012

EUnetHTA JA

This section asks for your evaluation of the EUnetHTA JA.

1. Please indicate your agreement with the following statements;

	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
The EUnetHTA JA has achieved what my organisation hoped	○	○	○	○	○
Stakeholders' views have been adequately considered in the EUnetHTA JA	○	○	○	○	○
Adequate feedback from the EUnetHTA JA has been provided to Stakeholders	○	○	○	○	○
My organisation's expertise has been appropriately used in the EUnetHTA JA	○	○	○	○	○
It would be useful to have a EUnetHTA conference on a regular basis	○	○	○	○	○

Please add any comments;

2. Do you have any concerns about the involvement of external stakeholders in the EUnetHTA JA?

	No	Yes	Don't Know
The principles of stakeholder involvement in the JA (Stakeholder involvement policy and SOP)	○	○	○
The actual involvement of stakeholders in the JA	○	○	○
The level of commitment of stakeholders in the JA	○	○	○

Please explain your answers, if you wish;

3. How has your organisation contributed to the EUnetHTA JA?

EUnetHTA JA Stakeholders' Final Survey 2012

4. Lead partners and Co-lead partners decided not to hold a conference at the end of the EUnetHTA JA. Instead there was one in 2011 in Gdansk. Was this the right decision?

- ○ No
- ○ Yes
- ○ Don't Know

Please explain your answer;

5. What have been the main CHALLENGES of being involved in the EUnetHTA JA?

6. What have been the main BENEFITS of being involved in the EUnetHTA JA?

7. How useful do you think the following will be for the work of professionals producing HTA?

	Not Useful	Of some use	Very useful	Don't Know
Networking with contacts made from participating in the EUnetHTA JA	○	○	○	○
The HTA Core Model (the online Tool & Service for producing, publishing, storing and retrieving HTA information) (WP4)	○	○	○	○
The HTA Core Model on screening (WP4)	○	○	○	○
A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals (WP5)	○	○	○	○
Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies (WP7)	○	○	○	○
Operational web-based toolkit including database containing information on evidence generation on new technologies (EVIDENT) (WP7)	○	○	○	○
Accessing the EUnetHTA tools by a single sign-on through the MO site (WP6)	○	○	○	○

Please add any comments;

EUnetHTA JA Stakeholders' Final Survey 2012

8. Would you like to improve your understanding by having training about developments from the project?

	No	Yes	Don't Know
The HTA Core Model (the online Tool & Service for producing, publishing, storing and retrieving HTA information) (WP4)	○	○	○
The HTA Core Model on screening (WP4)	○	○	○
A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals (WP5)	○	○	○
Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies (WP7)	○	○	○
EVIDENT (Operational web-based toolkit including database containing information on evidence generation on new technologies) (WP7)	○	○	○

Please add any comments;

9. Do you think that the EUnetHTA JA will be successful in achieving its 3 official objectives by the end of the project (December 2012)?

	No	Yes	Don't Know
Development of a general strategy & business model for sustainable European collaboration on HTA.	○	○	○
Development of HTA tools & methods.	○	○	○
Application and field testing of developed tools & methods.	○	○	○

Please describe any concerns about EUnetHTA JA meeting its objectives;

10. Would a sustainable European collaboration add value?

	No	Yes	Don't Know
National level	○	○	○
Regional level	○	○	○
European level	○	○	○

Please explain what value would be added, or why no value would be added;

EUnetHTA JA Stakeholders' Final Survey 2012

11. What would make you know that a sustainable European Collaboration on HTA has been achieved?

12. Do you have any comments about how EUnetHTA JA has been promoted externally? (500 word limit)

e.g.the promotional leaflet, public website, groups on social networking sites, videos (on Youtube & website) and presence at conferences

13. Please complete the evaluation table for ALL the EUnetHTA JA workpackages;

	Do you have any concerns about this WP?	Will it achieve its objectives by the end of the EUnetHTA JA?	Have you received appropriate communication from this WP?	Has this WP been worth having in the EUnetHTA JA?
WP1: Coordination				
WP2: Dissemination				
WP3: Evaluation				
WP4: Core HTA				
WP5: Relative Effectiveness Assessment of Pharmaceuticals				
WP6: Information Management System				
WP7: New Technologies				
WP8: Strategy & Business Model Development				

Please explain your answers, if you wish;

EUnetHTA JA Stakeholders' Final Survey 2012

5. EUnetHTA Joint Action 2

This section asks for your opinions about the EUnetHTA JA2 and how experiences from the EUnetHTA JA can be used to inform it.

1. Do you think the EUnetHTA JA2 (2012-2015) will serve as a useful follow-up to EUnetHTA JA?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain your answer;

2. What are the main learning points from the EUnetHTA JA that should inform the EUnetHTA JA2?

3. What can be learnt from EUnetHTA JA about how to best involve external stakeholders and/or experts in EUnetHTA JA2?

4. How can communication (internal or external) be improved in EUnetHTA JA2?

EUnetHTA JA Stakeholders' Final Survey 2012

5. Do you have any concerns about the planned EUnetHTA JA2?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns and what could be done about them;

6. What would make ongoing European collaboration on HTA effective?

EUnetHTA JA Stakeholders' Final Survey 2012

WP4: Core HTA

This section asks for your evaluation of WP4: Core HTA.
Please answer the questions if your organisation feels it can take a view.

1. Has your organisation participated in a Stakeholder Advisory Group (SAG) for WP4?

- ○ No
- ○ Don't Know
- ○ Yes

2. How has WP4 progressed so far?

- ○ Poorly
- ○ OK (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP4's workplan lists 3 deliverables - we are interested in your views about them.

3. 'An online Tool & Service for producing, publishing, storing and retrieving HTA information' should be delivered in months 36 - December 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

EUnetHTA JA Stakeholders' Final Survey 2012

4. 'Screening application of the HTA core model' should have been delivered in month 15 - March 2011. Do you think this happened?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

5. 'A set of two core HTAs' should be delivered in month 36 - December 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

EUnetHTA JA Stakeholders' Final Survey 2012

WP5: Relative Effectiveness Assessment of Pharmaceuticals

This section asks for your evaluation of WP5: Relative Effectiveness Assessment of Pharmaceuticals.
Please answer the questions if your organisation feels it can take a view.

1. Has your organisation participated in a Stakeholder Advisory Group (SAG) for WP5?

- ○ No
- ○ Yes
- ○ Don't Know

2. How has WP5 progressed so far?

- ○ Poorly
- ○ OK (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP5's workplan lists 2 deliverables - we are interested in your views about them.

3. 'A relative effectiveness assessment of a (group) of pharmaceutical(s)' has been rescheduled to be delivered in month 30-31- June - July 2012. Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

EUnetHTA JA Stakeholders' Final Survey 2012

4. 'A methodological guidance that will be appropiate for the assessment of relative effectiveness of pharmaceuticals' should be delivered in month 36 - December 2012.
Do you think this will happen?

	No	Yes	Don't Know
On time	○	○	○
To a good quality	○	○	○

Please explain any concerns;

5. Is there anything else you want to say about WP5?

EUnetHTA JA Stakeholders' Final Survey 2012

WP7: New Technologies

This section asks for your evaluation of WP7: New Technologies.
Please answer the questions if your organisation feels it can take a view.

1. Has your organisation participated in a Stakeholder Advisory Group (SAG) for WP7?

- ○ No
- ○ Don't Know
- ○ Yes

2. How has WP7 progressed over the past year?

- ○ Poorly
- ○ OK (but could be better)
- ○ Well
- ○ Don't Know

Please explain any concerns;

WP7's workplan lists 2 deliverables - we are interested in your views about them.

3. 'EVIDENT (EVidence Database on New Technologies)', containing information on evidence generation on new technologies, should be delivered in month 33-September 2012.
Do you think this database will be successful in facilitating additional evidence generation?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns;

EUnetHTA JA Stakeholders' Final Survey 2012

4. 'Criteria to select/prioritize health technologies in need of additional evidence generation' should be delivered in month 30 - June 2012.
Do you think these criteria will be useful?

- ○ No
- ○ Don't Know
- ○ Yes

Please explain any concerns;

5. Is there anything else you want to say about WP7?

EUnetHTA JA Stakeholders' Final Survey 2012

Survey End

1. Is there anything else you would like to say about the EUnetHTA JA?

2. Please estimate the time it has taken you (in minutes) to complete this survey

Many thanks for completing this survey!

Please click on the 'Finished' button below to submit your answers.

Appendix 9 Plenary assembly questionnaire

eunethta

NHS National Institute for Health Research

Plenary Assembly 20th-21st May 2010

1. Do you think the Plenary Assembly met its objectives?

O No O Yes O Don't know

Please explain your answer;

2. Overall, how satisfied were you with the conference venue/facilities?

O Not satisfied O Satisfied O Don't know

Please explain your answer;

3. What did you like MOST about the Plenary Assembly?

4. What did you like LEAST about the Plenary Assembly?

5. How could next year's Plenary Assembly be better?

Appendix 10 Plenary assembly questionnaire 2011

Plenary Assembly 2011. London

1. Were the meeting objectives met?

☐ No ☐ Yes ☐ Don't know-unclear what the objectives were

Please explain your answer;

2. What was the BEST thing about the meeting?

3. What was the WORST thing about the meeting?

4. How would you describe the following?

	Very poor	Poor	Acceptable	Good	Very good
Receiving documents in advance	☐	☐	☐	☐	☐
Leadership of the meeting	☐	☐	☐	☐	☐
Relevance of items discussed	☐	☐	☐	☐	☐
Meeting & networking with colleagues	☐	☐	☐	☐	☐
Venue & meeting facilities	☐	☐	☐	☐	☐
Social event	☐	☐	☐	☐	☐

Please write comments here;

5. How can the 2012 Plenary Assembly be better?

6. Please tick in the grid below to show when you received & read the meeting documents.

	1 week before meeting	1-3 days before meeting	During the meeting	I did not read them
When did you receive meeting documents?				
When did you read meeting documents?				

Please comment, if you wish;

7. Were you (or your organisation) involved in developing the meeting agenda with the Secretariat?
Please tick the appropriate box below.

Yes ☐ No ☐ Don't Know ☐

Please comment, if you wish;

Appendix 11 Plenary assembly questionnaire 2012

Plenary Assembly 2012, Lisbon

1. Were the meeting objectives met?

☐ No ☐ Yes ☐ Don't know-unclear what the objectives were

Please explain your answer;

2. What was the BEST thing about the meeting?

3. What was the WORST thing about the meeting?

4. How would you describe the following?

	Very poor	Poor	Acceptable	Good	Very good
Receiving documents in advance	☐	☐	☐	☐	☐
Leadership of the meeting	☐	☐	☐	☐	☐
Relevance of items discussed	☐	☐	☐	☐	☐
Meeting & networking with colleagues	☐	☐	☐	☐	☐
Venue & meeting facilities	☐	☐	☐	☐	☐
Social event	☐	☐	☐	☐	☐

Please write comments here;

5. How can Plenary Assemblies in EUnetHTA JA2 be better?

6. Please tick in the grid below to show when you received & read the meeting documents.

	1 week before meeting	1-3 days before meeting	During the meeting	I did not read them
When did you receive meeting documents?				
When did you read meeting documents?				

Please comment, if you wish;

7. Were you (or your organisation) involved in developing the meeting agenda with the Secretariat?
Please tick the appropriate box below.

Yes ☐ No ☐ Don't Know ☐

Please comment, if you wish;

Appendix 12 Introductory note sent to data set Delphi participants

Exploring a minimum dataset for policy relevant publically funded primary research in development, to facilitate data sharing amongst trial funders.

Background

1) Multiple registries exist for randomised controlled trials and observational primary studies – eg ClinicalTrials at the NIH[1], and CCT[2].
2) These enable, among other things
   a) Investigators to see what work is underway in their field.
   b) Clinicians to identify studies in which they might like to take part, or enrol their patients.
   c) Reviewers and policy makers to assess publication bias, by using registered studies as a denominator.
3) These uses have been reinforced by major journals encouraging trials towards early registration in a trials database in order to be eligible for publication.
4) Public funders have a duty to make best use of their limited resources by minimising accidental trial duplication. Existing registries go partway to addressing this duty by allowing funders to identify studies which are underway. There is however still a gap – there is no widely used registry which tracks studies in development – either in the form of an application from an investigator to a funder, or being planned internally by a funder running a commissioned programme such as the NIHR HTA programme[3]. Thus funders run the risk of developing studies in parallel, which may have been avoided or improved had they known of the parallel activity.
5) For example, in 2007 the NIHR HTA programme (the PERSEPHONE trial), the French Institut National du Cancer (the PHARE trial), and PHARMAC in New Zealand (the SOLD trial) all funded pragmatic clinical trials of herceptin in breast cancer. The agencies had been unaware of each other's plans until funding decisions had been made. Consequently the commissioned trials are comparatively 'stand alone'. It is likely that had the agencies been aware of these three trials in parallel development appropriate outcome measures could have been included to facilitate meta-analysis or other comparison between them.

The benefits of a widely used 'studies in development' database

6) Knowledge of studies in development, before funding decisions have been made could lead to several opportunities

[1] http://clinicaltrials.gov/
[2] http://www.controlled-trials.com/
[3] http://www.hta.ac.uk

a) Funders could commit to one multinational study, rather than multiple smaller studies, or

b) Funders could ensure that at least some outcome data in multiple studies would be directly comparable – thus facilitating meta-analysis.

c) On a global basis, it would facilitate an optimum distribution of research funding – eg knowledge of what each funder had planned could facilitate inter-funder discussion in order to get maximum value from the resources that each had to contribute.

d) With an indicative map of possible studies, systematic reviewers may be able to better plan when to conduct updates of existing reviews.

e) Similarly, policy makers may be able to plan when to consider updates of their guidance and other policy documents.

The Current Opportunity

7) As part of the EUnetHTA 2010-12 project[4], jointly funded by the European Commission and European Union member state governments, NETSCC[5] in the UK and HAS[6] in France have resources to explore a registry for publically funded studies in development, with an emphasis on pragmatic trials and studies expected to have an effect on policy. Such a registry would aim to enable funders to identify studies being planned or considered elsewhere. It would then be up to the relevant agencies to contact each other and cooperate if they wished.

8) This exploration will extend over 3 phases. The first two will be led by NETSCC, and the 3rd by HAS:

   a) **Phase one**, in 2010, will involve identifying interested organisation, and developing a minimum dataset for a registry.

      i) This dataset is likely to be small and contain data such as

         (1) Organisation considering the study

         (2) Study title and other characteristics such as the country that the study would be set in

         (3) The key elements of the study research question, laid out in PICO or EPICOT format [7]

      ii) Where possible elements will be recorded using a controlled vocabulary, such as MeSH. This would facilitate a computer run matching process should the registry be implemented.

      iii) The process will use a Delphi approach, probably of 2 rounds.

   b) **Phase two**, in the first half of 2011, will test the identified data set by asking partners to provide the dataset for studies they have undertaken

[4] http://www.eunethta.eu
[5] http://www.netscc.ac.uk
[6] http://www.has-sante.fr
[7] Brown, Brunnhuber, Chalkidou *How to formulate research recommendations* BMJ **333** p804-806 2006

within a particular clinical area, to be determined. We will then validate that the dataset is able to identify similar studies.

c) **Phase three**, extending through 2012, will explore an IT platform to run a database built on the dataset, building on HAS's experience with the EIFFEL toolkit[8].

9) While there are a number of organisations within EUnetHTA with an interest in this project, this is a tool which will be far more useful with a much wider involvement – and therefore we would like to invite any publically funded organisation which funds or commissions pragmatic trials expected to influence policy to take part in this development process, and to use the final produce should we be successful in developing a database.

10) It is envisaged that within phases one and two we'd ask for no more than a few hours input from each partner outside NETSCC and HAS. As planned, this would involve commenting on two drafts of a possible data set in phase 1, and identifying and completing the dataset on somewhere between 1 and 3 trials (either underway or planned) for phase 2.

11) Partners may also be asked to comment on the database tool as it is developed in phase 3 – again this is unlikely to need more than a few hours per organisation.

Likely characteristics of studies to be described by the dataset

12) The dataset will seek to describe a wide range of studies, the criteria will be (subject to review by Delphi process)

a) Publically funded primary research involving the generation of new data.

b) Likely to be directly relevant to policy. This implies certain study designs are more likely to be included than others:

i) Included

(1) Effectiveness and cost-effectiveness studies

(a) Pragmatic Trials, including cluster designs

(b) Observational studies

(i) cohort and registry designs, including long term followup designed to obtain safety and long term outcome data

(ii) natural experiments

ii) Excluded

(1) Efficacy and mechanism designs

(a) Explanatory trials

(2) Lower quality designs

(a) Case studies & case series

[8] http://www.eiffel.eunethta.has-sante.fr/

Further information

13) For further information or discussion, please contact either Eleanor Guegan (Senior Research Fellow at NETSCC, E.Guegan@soton.ac.uk) or Andrew Cook (Consultant in Public Health Medicine / Fellow in Health Technology Assessment at NETSCC, andrewc@soton.ac.uk)

Andrew Cook

July 2010

NETSCC Document Control

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Further copies from	andrewc@soton.ac.uk

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0.2	12th April 2010	Andrew Cook	Updated post ISG
0.3	6th May 2010	Andrew Cook	Updated post Eleanor G trip to HAS
0.4	1 July 2010	Andrew Cook	Updated post WP7a ftf meeting, Dublin

Appendix 13 First data set Delphi questionnaire October 2010

Dataset and registry for clinical studies in development

1. Introduction

Aim of the Dataset

To create a registry for primary clinical research studies which are being considered either by a public funder, or on the advice of a national appraisal body.

Such a registry would allow research funders and appraisers to consider changes to planned studies-eg to enable easier meta-analysis. For further information click here to access the introductory note.

Delphi Instructions

1. Please click here to review the dataset.
2. Then please answer the following questions about the dataset.

There are 4 sections; The WHOLE dataset, SPECIFIC data items, Missing information and Possible implementation of a registry.

Please click NEXT when you have answered all questions on a page. You can click PREVIOUS should you wish to go back to the page before. Please click FINISH at the end to submit your answers. Hyperlinked sites will open in new pages.

Please submit your responses by 29th October 2010.

Many thanks for your help with this project!

Dataset and registry for clinical studies in development

2. The WHOLE Dataset

The dataset suggests responses in 2 languages;
*'Natural language' - the native language of the organisation considering a study.
*'Common language' - either a default human language or a coding system (eg MeSH).

English is suggested as the default human language as it is the most common language used in the HTA community, HTAi and INAHTA.

1. What language(s) should be used in the dataset?

- ○ ONLY natural language
- ○ ONLY common language
- ○ BOTH natural language AND common language

Please comment if you wish;

2. If a COMMON language is to be used, what should this be?

- ○ English
- ○ Coding system (controlled vocabulary)
- ○ Both English & coding system
- ○ Not applicable - I don't think a common language should be used
- ○ Other

If 'Other' please specify what should be used;

Dataset and registry for clinical studies in development

3. The dataset suggests MeSH as the most appropriate coding system (controlled vocabulary). click here for MeSH information

Is MeSH the correct choice?

- ○ MeSH is appropriate
- ○ Other would be better

If 'Other would be better', please specify what would be better and why;

4. If MeSH should be used, would MeSH terms or codes be better?

- ○ MeSH terms
- ○ MeSH codes
- ○ Either MeSH terms or codes
- ○ Not applicable - MeSH is not appropriate

Please comment, if you wish;

5. The dataset has been based on PICO; Patient, Intervention, Control, Outcome.

Should the 'Intervention & Control' be combined into one section as 'Technologies'? Or would they be better separated?

- ○ COMBINE 'Intervention & Control' in 1 section
- ○ Keep 'Intervention' & 'Control' as 2 SEPARATE sections

Please explain any advantages of keeping Intervention and Control as separate sections;

Dataset and registry for clinical studies in development

3. SPECIFIC Data Items

1. Contact email

Is EMAIL the best default contact method?

- ○ YES
- ○ No

If 'No' please specify what would be better & why;

2. Study title

We suggest recording the study's title in English.
A native language title may capture subtleties lost in translation, although these would only be apparent to speakers of that language.

Should a description in native language also be included?

- ○ Yes
- ○ No - an English version is sufficient

Please comment, if you wish;

Dataset and registry for clinical studies in development

3. Internal Reference

Does your organisation use internal reference numbers for projects, that could be made public?

- ○ Yes
- ○ No

If 'No', please explain;

4. Apart from an internal reference number, are there any other points of identification which should be used to identify studies?

- ○ No
- ○ Yes

If 'Yes', please specify what else should be used;

5. Research question

Is there added value in recording the research question in native language as well as English?

- ○ Yes - would like native language too
- ○ No - happy with English alone

Please comment, if you wish;

Dataset and registry for clinical studies in development

6. Source of Research Question

Early discussion has shown that some organisations are interested in where a research idea has come from eg Government Report, HTA Organisation Report, etc.

Should we record this as a specific referenced source (eg NICE IPG 262, click here for NICE IPG 262), or according to a classification scheme?

- ○ Full referenced source
- ○ Classification scheme

If 'Classification scheme', please recommend which scheme would be best;

7. Outcome

We think that records should be closed once a decision has been made on whether or not to fund a project.

This set of outcomes are suggested;
*** Did not proceed - finished**
*** Did not proceed - alternative question identified**
*** Commissioned as RCT**
*** Comissioned as Observational Study**

Should any other outcomes be included?

- ○ No
- ○ Yes

If 'Yes' - please specify what other outcomes should be included;

Dataset and registry for clinical studies in development

8. Should extra information be included, such as the record number in a clinical trials registry (when this becomes available)?

- ○ No
- ○ Yes

If 'Yes', please specify what extra information should be included;

Dataset and registry for clinical studies in development

4. Missing Information

1. We aim to keep this dataset small - to allow users to identify potential overlaps between planned studies then discuss these in greater depth with the appropriate organisation(s).

However, is anything missing which would help identify studies?

- ○ No
- ○ Yes

If 'Yes', please specify what is missing;

Dataset and registry for clinical studies in development

5. Possible implementation of a register

1. Pre-registration

Should the dataset 'pre-register' participants – ie should participating organisations be coded, to include contact details?

Items 1 & 2 would therefore be replaced by a single code.
This would also imply one contact per organisation rather then one per study.

- ○ Yes
- ○ No

Please comment, if you wish;

Eligibility criteria

It is currently anticipated the following organisations would be accredited to enter policy relevant primary research on the register (and to use the register to match their research plans against those already registered);

Public appraisal and research funding agencies (organisations that supply funds for research or who have approval of research protocols) – who produce policy relevant primary research.

2. Can establishing the precise eligibility details be left until the 'register implementation phase', to be led by HAS from mid-2011?

- ○ Yes
- ○ No

If 'No', please explain why not;

Unit of Registration

A given grant (or potential grant or application) may contain a number of sub projects – eg a literature review, a survey and a trial.

We suggest that the unit of registration should be an **individual research question** (as each sub project should have it's own research question).

Therefore, in the above example only the trial and possibly the survey would be eligible to register. The literature review would not be - it should be registered in the registry for literature reviews click here for further information.

Dataset and registry for clinical studies in development

3. Is a separate research question an appropriate unit of entry?

- ○ Yes
- ○ No

If 'No', please explain what would be better;

Dataset and registry for clinical studies in development

6. End

1. Do you have any other comments on the dataset or the overall project?

Many thanks for your responses.

Now please click FINISH to submit your responses.

Appendix 14 Report following first Delphi questionnaire

Dataset for Trials in Development – a report on Delphi round 1 – October/November 2010

Background

1) In the summer of 2010, NETSCC and HAS set out to recruit organisations to contribute to a Delphi process to develop a dataset to inform a registry for policy relevant primary studies in development.

2) Thirteen organisations from nine countries agreed to participate in the first round.

3) The first round survey was sent to these participants in October 2010. By 8th November 12 (92%) had responded.

Survey Responses

Dataset as a whole

Issues of language

4) As the conductors of this survey are distinctly Anglophone, we wished to explore and get consensus on which language(s) should be used within the database.

5) Responders from other Anglophone countries exhibited similar anxieties – that an English only (or English first) dataset might not be manageable for organisations where English is not the first language.

6) All organisations from countries where English is not the common language of everyday use supported English being the main language used in the dataset. **We shall therefore adopt English as the default language for the dataset.**

7) ¼ of respondents suggested some kind of native (ie non-English) language involvement would be useful. **We shall explore this further in the next Delphi round.**

Coding Systems

8) One half of respondents recommended that a coding system / controlled vocabulary be used in addition to English.

9) Of the 10 respondents who expressed opinion on a coding system to use, all supported the use of MeSH. One commented that in some cases a code may not exist within an adopted coding system, in which case the human readable language would be the appropriate fall back.

10) Given 8) and 9) **we will allow entry of both English and MeSH**, but see 11) and 12) below.

11) All 10 respondents who expressed an opinion agreed that MeSH terms could be used, only one was also supportive of MeSH codes. **Therefore, we will suggest that any database using this dataset support entry and display of MeSH terms.** The

ability to do this will however depend on the implementation platform. One respondent indicated that using codes would require more work than using terms.

12) One respondent suggested we consider the use of ATC (the Anatomical Therapeutic Classification System - http://en.wikipedia.org/wiki/Anatomical_Therapeutic_Chemical_Classification_System) , a system currently in use by the European Medicines Agency. **We will explore the added value of adding this to MeSH in the next Delphi round.**

PICO

13) We were able to identify PICO as a structure for recording information, which would allow easy matching of overlapping planned studies. We asked the group if it is sensible to separate intervention and control under different headings.

14) 70% of responders favoured keeping them separate. The suggested advantages related to

a) clarity in the designs of trials, and the use of technologies in different countries

b) searching within the database for technologies which are being compared

c) the absence of comparator indicating that a study may not be comparative

15) **We will therefore maintain intervention and control as separate fields.** There is an implication for a database however that the records should be searchable by either of these fields individually, or both combined.

Specific Dataset Items

Contact

16) All respondents indicated that email is an appropriate default contact method. **We will therefore adopt email as the default contact method.**

Study Title and Research Question

17) We wondered whether, even if we were recording most data in English, there might be some added value of recording a study title in its native language – eg French for a study originating from France. We considered that there might be some subtlety of language which other co-language speakers might benefit from.

a) The majority of responders did not see a need for a native language title or research question.

b) The two responders who thought it might be useful were not native English speakers

c) **We will therefore give consideration to making a native language title and research question an optional part of the dataset.**

Unique Identifiers

18) It seemed to us that a unique identifier for each record in the database would be essential, to facilitate discussion between organisations once a study of interest had been identified.

a) We were surprised to discover that half of responding organisations do not use a unique identifier which they are able to share – this group includes organisations with an active primary research portfolio.

b) Some organisations indicated that collections of characteristics could be used to identify projects. One responder indicated that they fund 'collections of projects', and hence one unique identifier would refer to a collection, rather than a single research question.

c) **We will explore options for uniquely identifying projects with the database in the next Delphi round.**

Source of research idea

19) Of 10 responders to this question, 8 favoured giving the full referenced source of a research idea. **We will therefore include a field for a full referenced source for a research idea in the data set.**

Outcomes

20) Responders were in favour in including outcome information in the dataset. It was particularly stressed that a record should not be removed once an outcome is known.

a) Some suggestions were made for specific outcomes to be included in addition to those suggested in the question

i) Did not proceed due to lack of finance

ii) Did not proceed due to lack of researcher capacity

iii) Did proceed – likely timescale for results to be available

b) **We will develop a menu of outcomes.** This menu may need to be expanded based on experience with a functional database. **We will include a field in the outcomes section for a trial or other registry number.**

Other information

21) We received a number of suggestions for other information which could be included

a) A summary project description

b) Country details

c) Number of planned centres for recruitment

22) There was one comment that the dataset was not sufficiently flexible for all studies which might be included.

23) **We will explore these responses further in Delphi round 2**

Implementation of a register

24) Half of responders thought that organisations should be pre-registered. One suggested the ability to provide an additional project level contact could be appropriate. **We will follow this up with HAS, who will be implementing any register which arises from this work.**

25) All except one responder considered that leaving the precise eligibility details could wait for implementation. **We will follow this up with HAS, who will be implementing any register which arises from this work.**

26) While 8 responders agreed that the research question is an appropriate unit of entry, two raised issues. One in particular, which funds programme of research comprised of multiple questions, felt that they would find this too onerous. **We will explore the implications of using a study title as a unit of registration.**

Other comments

27) "We should not add more hurdles in the way of people doing research"

28) "there is a difficult balance to be drawn between (a) keeping the database very simple, but alerting funders to possible overlap, and (b) a fuller register with sufficient detail such that an alerted agency finds enough information to not to need to get further information from the second funder. "

Appendix 15 Second data set Delphi questionnaire December 2010

Dataset and registry for clinical studies in development #2

1. Introduction - 2nd Delphi round survey

Aim of the Dataset

This dataset aims to allow the creation of a registry for primary research studies which are being considered (either by a public funder or on the advice of a national appraisal body). Such a registry would allow research funders and appraisers to consider making changes to planned studies (eg to enable easier meta-analysis).

The registry would contain studies which funders are considering, but have not yet made a final decision on – ie in a state where the study could potentially still be changed. Once a study progresses sufficiently that it is funded, the record on this database should be updated with this relevant information.

Such a registry would be used by entering particular characteristics about a study - eg the population, intervention and comparator. The registry would then identify similar studies. It would contain contact details and sufficient information to allow the enquirer to contact the potential funder of the matched study for further discussion.

1st Delphi round survey report

We appreciate your response to the 1st Delphi round survey.
Please click here for the survey report.

2nd Delphi Survey Instructions

Following the 1st survey we have updated the dataset.
1. Please click here to review the updated dataset before answering the questions.
2. Then please answer the following questions about the dataset.
These are in sections; dataset as a whole, coding, unique identifiers, outcomes, validation, unit of registration and the overall project.

Please click NEXT when you have answered all questions on a page. You can click PREVIOUS should you wish to go back to the page before. Please click FINISH at the end to submit your answers. Hyperlinked sites will open in new pages.

Please submit your responses by 20th December 2010.
Many thanks for your help with this project!

Dataset and registry for clinical studies in development #2

2. The WHOLE Dataset

In the 1st survey about ¼ of responders favoured inclusion of some information in native language, as well as in English.

We have updated the dataset to include OPTIONAL fields for native language recording of the study title and research question.

1. Is this sufficient?

- ○ Yes
- ○ Too complicated - adds little value for increased complexity
- ○ No - suggest additional information

If applicable please identify what extra native language information you want included and why;

Dataset and registry for clinical studies in development #2

3. Coding

In the previous survey respondents agreed that MESH is the most appropriate coding system. However, one respondent suggested ATC codes would add value for pharmaceuticals (this is used by EMEA etc). For further information about ATC codes click here .

1. Are you familiar with ATC coding?

- ○ Yes
- ○ No

Please comment, if you wish;

2. Do you see any advantages in using ATC (or any other technology/disease related coding) in addition to MeSH?

- ○ Yes
- ○ No
- ○ Don't Know

Please explain your answer;

3. Is your organisation able to provide ATC coding for its projects within its current resources?

- ○ Yes
- ○ No

Please comment, if you wish;

Dataset and registry for clinical studies in development #2

4. Unique Identifiers

Unique identifiers would serve two roles within the database;
1. To uniquely identify individual records - this can be left to the implementation phase.

2. To improve the database for its users. The system should enable a user to identify a possible overlap. They can then contact the owner of the identified study, saying *'I would like to talk to you about your study'* and be easily able to identify the exact study which they want to discuss.

Different organisations use different ways to identify their projects. Some use code numbers, others use project titles, or other project characteristics.

We propose that two points of identification taken together will uniquely identify a project for database users - 1 AND (2 or 3) below;

1. The 'owning organisation' – which plans the study and entered the record on the database AND

2. A piece of information which is unique to the project within the organisation. This may be a code, or the title (if the institution is confident this will act as a point of identification as outlined above)OR

3. If the organisation is unable to identify an appropriate identifier for (2) above, the database will automtically supply one (much like a clinical trials registry supplies a registry number) – but the owning institution would need to ensure this number was noted on its own records.

1. Other organisations may identify projects from your portfolio via the database and contact your organisation to discuss them with you.

Would this system enable your institution to identify which projects from your portfolio they wanted to discuss with you? 1 AND (2 or 3) above.

- ○ Yes
- ○ No
- ○ Don't Know

Please explain your answer;

Dataset and registry for clinical studies in development #2

2. If your organisation does not use a unique code for your planned projects, each project would automatically be assigned one by the database (#3 above).

Will you be able to incorporate this registration number into your organisation's own records? (this will be necessary so that you can identify which project a caller wishes to discuss)

- ○ Yes
- ○ No
- ○ Don't Know

Please explain your answer;

Dataset and registry for clinical studies in development #2

5. Outcome for the planned study

The 1st survey emphaised the importance of keeping a record about what happened to each planned study;
1. If they went ahead - where further information can be found
2. If they did not go ahead - why this did not happen.

We suggest a menu of choices for what happens to a project. We are interested in your views about what should be included;

1. Studies that WENT AHEAD.

Which outcomes should be included for planned studies that went ahead?

	Yes	No	Don't Know
Funded as a **trial** (include trial reference number/other reference)	○	○	○
Funded as **another type of study** (include reference number/other reference)	○	○	○
Results likely to be available by **date** (note:does not mention trial registration)	○	○	○
Cofunded with a specified **public sector funder**	○	○	○
Cofunded with a specified **private sector funder**	○	○	○

Please add your comments;

2. Studies that DID NOT PROCEED.

Which outcomes should be included for planned studies that did not go ahead?;

	Yes	No	Don't Know
Lack of **clinical**, or other, need (eg no one cared sufficiently about the results to make it woth doing)	○	○	○
Lack of **researcher capacity**(ie a capable researcher could not be found to deliver the project)	○	○	○
Lack of **research funding**	○	○	○
Lack of **other funding** (eg the trial costs would be paid, but no one would pay for the drugs involved)	○	○	○

Please add your comments;

Dataset and registry for clinical studies in development #2

3. Should any other outcome measures be included?

Please specify them, and their value;

Dataset and registry for clinical studies in development #2

6. Other Information

The 1st survey identified other information that could be included in the registry. Please indicate whether you think they would be valuable.

1. A short summary of the planned research (eg up to 200 words).
This may allow exclusion of an overlap without the need to contact the study owner.
An example has been included at item 18 in the example dataset version 3.

- ○ Yes
- ○ No
- ○ Don't Know

Please explain your answer;

2. The country where a study is planed.
We thought this may be evident from the research funder - but this would be simple to add if it were useful.

- ○ Yes
- ○ No
- ○ Don't Know

Please explain your answer;

3. The number of planned centres for recruitment.
We considered that the planning stage is probably too early to know this, and it would not help in identifying planned similar studies. If occasionally important it could be entered in the summary field - do you agree?

- ○ Yes
- ○ No
- ○ Don't Know

Please explain your answer;

Dataset and registry for clinical studies in development #2

7. Validation

In 2011 we intend to undertake some validation of this dataset.

To validate efficacy we will invite participants to submit possible entries using this dataset in particular clinical areas. We will then explore how good the dataset is at identifying overlapping studies and excluding non overlapping studies. One clinical area we will look at is Breast Cancer and Herceptin (the issue which sparked the first thoughts about a registry).

To address this next year, we will ask you to submit any studies you have about Breast Cancer; those involving Herceptin, and one or two (if you have any) which don't include Herceptin.

1. We also aim to undertake similar validation in one or two other clinical areas. When selecting we will try to pick areas where multiple organisations have suggested an interest.

What clinical areas would you suggest?

2. Validation of effectiveness will need to wait until there is a reasonably well-populated registry. Then we will investigate characteristics of the registry and its search tools to try to identify diagnostic accuracy etc.

We believe that sensitivity should be favoured rather than specificity in searches. This would mean that the registry should tend to suggest more overlaps than there actually are-the excess would be trimmed by the user. We feel that a little more work to exclude non-overlapping studies would be better than a more specific search which would miss studies of interest.

Do you agree?

- ○ Yes
- ○ Don't Know
- ○ Other approach would be better

If you think other approach would be better - please specify;

Dataset and registry for clinical studies in development #2

8. Registration Unit

For most of the respondents one project contains approximately 1 or 2 studies – eg 1 RCT, or two RCTs with different eligibility criteria. However, one respondent indicated that in their organisation one project can contain many different studies using different designs.

We're looking for a solution which allows 'good enough' matching of similar studies, to allow organisations to engage in discussion.

1. We suggest that the unit of registration is the PROJECT, which may consist of one or more substudies (either in parallel or series). This may require multiple entries against the PICO fields. The summary field can then contain information about substudies (if any) to allow searchers to determine whether to make contact with the study owner to investigate further. This would have little impact for most organisations, but would help for organisations which fund programmes of research.

Would this work for your organisation?

- ○ Yes
- ○ No
- ○ Don't Know

Please explain your answer;

Dataset and registry for clinical studies in development #2

9. Information about this project

When we invited you to take part in this Delphi process, we suggested it would not take a large investment of your time. We'd like to check that our estimates were correct.

1. How many person-hours has your organisation taken to respond to round one of this Delphi process (the previous survey)?

2. How many person-hours has your organisation taken to respond to round two of this Delphi process (this survey)?

3. Is there anything else you would like to add, either about the current version of the dataset or the project as a whole?

Many thanks for your responses.

Now please click FINISH to submit your responses.

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