

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

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Scientific summary

EUnetHTA JA: a process evaluation

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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.

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The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

This report

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