

**Final Report Form**

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It is a condition of projects funded by the Collaboration that a Final Report is submitted before the final funding instalment is paid. The purpose of submitting a report is to enable the Collaboration’s Steering Group to assess whether the work for which the grant was awarded has been completed, and whether value for money has been achieved. It also facilitates the Steering Group’s discussions on how to ensure the results of projects are effectively used and communicated to the Collaboration at large.

**PROJECT DETAILS**

FUNDING PROGRAMME (e.g. Opportunities Fund 2008):

|  |
| --- |
| **Part of Cochrane Diagnostic Test Accuracy Reviews funding programme** |

TITLE OF PROJECT:

|  |
| --- |
| **Cochrane Register of Diagnostic Test Accuracy Studies** |

PRINCIPAL INVESTIGATOR:

|  |
| --- |
| **Jonathan Craig** |

STAFF ON PROJECT (Please differentiate between staff working on the project and staff employed through the project’s funding):

|  |
| --- |
| **Ruth Mitchell – employed through project funding** |

AWARD HOLDING COCHRANE ENTITY/ENTITIES:

|  |
| --- |
| **Cochrane Renal Group** |

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| --- | --- | --- | --- |
| Start date | 24th October 2008 | Duration of grant (months), including agreed extensions | 36 months |
| End date | 23rd October 2011 | Total grant value (in currency awarded) | AUS$233,490 |

**INTRODUCTION**

A detailed Final Report was submitted at the end of the first two years of funding for this project (October 2006-October 2008), so reference to activities relating to that period will be brief.

At the start of the project Ruth Mitchell (RM) invited several people with expertise in search strategy development and diagnostic test accuracy systematic reviews to form a Reference Group to provide advice and support. These generous and enthusiastic people are:

Mariska Leeflang (ML - Continental European Support Unit, Cochrane DTA Reviews, Netherlands)

Julie Glanville (JG – Project Director, Information Services, York Health Economic Consortium Ltd, UK )

Marie Westwood (MW – Kleijnen Systematic Reviews Ltd, UK)

Anne Eisinga (from 2007) (AE – UK Support Unit, Cochrane Systematic Reviews of DTA, UK)

The Screening and Test Evaluation Program, University of Sydney, Australia provided funding for the development of the proposal for the Register.

For the last nine months we have been fortunate to have the help of a student, Tom Rogerson, for one day per week to assist on the register, funded through the University of Sydney.

**OBJECTIVES**

The main objectives for the project are:

The development of a clean and comprehensive register of reports of diagnostic test accuracy studies (DTAS) that will provide:

1. Education and training for Trials Search Co-ordinators (TSCs) in recognising DTAS / principles of searching for DTAS
2. A body of diagnostic test accuracy studies to support education and research in the field of diagnostic accuracy reviews
3. Support for Cochrane review authors and TSCs regarding individual reviews
4. A mechanism for retagging DTAS in Medline with a searchable field e.g. diagnostic accuracy.pt.

**SUMMARY OF METHODS**

1. **Education and training for Trials Search Co-ordinators (TSCs) in recognising DTAS / principles of searching for DTAS**

Two main strategies have been followed: the provision of workshops for TSCs (mainly in collaboration with and/or co-facilitation by members of the Reference Group), and the development of an on-line education package for “just in time” training.

* 1. **Workshops**

These are workshops on various aspects of searching for, and identifying diagnostic test accuracy studies, designed specifically for TSCs. They are based in part on Chapter 7 *Searching for studies* of the *Cochrane handbook for systematic reviews of diagnostic test accuracy.* The workshops include a mix of presentation and practical exercises. One workshop has been held at each Colloquium since 2008. Two workshops, one in Freiburg 2008 and in Birmingham 2010 (a two-day workshop) also included an introduction to diagnostic test accuracy, the design of DTA studies and measures of test accuracy.

* Three workshops have been submitted and accepted for the 2011 Colloquium:

1. Developing search strategies for systematic reviews of diagnostic test accuracy (facilitators: RM, AE, JG)
2. Peer reviewing the search strategy for a Cochrane diagnostic test accuracy systematic review (faciltators: RM, AE, JG)
3. Searching for diagnostic test accuracy studies: review authors and TSCs working in partnership (facilitators: AE, RM)

(Full list of workshops is under Results and Deliverables below).

* 1. **Education package**

Most work has been carried out over the last eighteen months:

A detailed *Competencies / Skills / Required Training & Resources* document has been developed by RM covering three main aims:

1.Understanding the basics of diagnostic test accuracy, DTA studies and   
 measures of test accuracy

2. Constructing search strategies for identifying DTA studies in

Medline and other electronic databases

3. Understanding the range of resources available to search, and  
 methods for searching them

This was circulated to all members of the Reference Group for detailed comment and input. From this was developed a plan for the contents of the training package. The draft package has been sent to the Reference group for comment. It consists of 120 slides and exercises relating to each section of the package. The content is based on that developed for recent workshops by all members of the Reference group. It has also been sent to Miranda Cumpston, Training Coordinator, to keep her in the loop concerning DTA training.

Once further revisions have been made, TSCs will be invited to trial the package and suggest

further improvements. It will then be submitted to the SDTMG and IRMG for their final approval.

* 1. **Additional activities**

2007 RM contributed to the editing of Chapter 7 *Searching for studies* in the *Cochrane handbook for systematic reviews of diagnostic test accuracy*

1. **A body of diagnostic test accuracy studies to support education and research in the field of diagnostic accuracy reviews**

From 2006 -2008 work for this aim concentrated on setting up the Register framework (currently in Reference Manager) and testing out methods for populating it.

Special fields have been set up for Target Condition, Index Test, Reference Standard, and Population (Patient Characteristics).

RM and members of the Reference Group undertook a project in 2007 to understand the challenges in screening for DTA studies. 900 references retrieved from b. (below) were each screened by 3 people. Differences between screeners in assigning Yes, Maybe or No to records were discussed . Results were presented at 2007 Colloquium.

Development of the Register has involved several aspects.

1. Populating the Register

2 main methods have been used to populate the Register

* + 1. Finding and downloading included studies from non-Cochrane DTA systematic reviews. A search of MEDLINE yielded 1,500+ possible reviews. These were screened and narrowed down to 950, from which those available in full-text are being progressively screened for relevance and availability, and studies extracted. Studies from these reviews are downloaded from MEDLINE (1st preference) or EMBASE or hand-entered.

Including studies from published Cochrane reviews is also underway. As reviews are published the included studies are added to the Register. A protocol guiding TSCs is available on the TSC Forum in Archie.

* + 1. Screening records from MEDLINE indexed with the MeSH “Sensitivity and Specificity”.

This was the method chosen to source DTA records directly from MEDLINE.

Records entered into MEDLINE during 2005 and indexed by “Sensitivity and Specificity” are being progressively screened by RM and relevant studies added to the Register.

* 1. Other strategies
     1. Individual researchers have sent records for inclusion. Contributors include ML and Regina Kunz from the Basel Institute of Clinical Epidemiology and Biostatistics. 1,000 records to be downloaded from MEDLINE.
     2. A database of 806 studies from a register of renal-related studies already compiled by the Cochrane Renal group was added
     3. A pilot handsearch project was begun in November 2009 with members of the Diagnostic Test Accuracy Working Group (DTAWG) and AE. The aim was to develop handsearching methods for DTA and broader “clinical test evaluation” studies so that people could be encouraged to contribute to the Register via handsearching. It could also assist with the debate over whether to ask for a DTA study or “clinical test evaluation” study publication type in MEDLINE. (see 4. below). RM developed a decision tree for handsearching for DTA studies with input from DTAWG. Members were paired to handsearch the same issues of journals so that disagreement between handsearchers could be ascertained, and discussion about disagreements could clarify issues and improve the decision tree. Unfortunately the project has stalled due to the time involved in handsearching DTA studies. Volunteers need to be found to conclude the project.
     4. The possibility of using text-mining as a means of more quickly identifying DTA studies has been discussed. It depends on funding to take the idea further.

1. Maintaining data from Register to support development of methods to search for DTA studies

Data on methodological MeSH, EMTREE terms and textwords used in Register studies have  
 been used in the submissions to the National library of Medicine and Elsevier for a study type  
 keyword for DTA studies (see 4. below)

1. Coding studies

It is known that the indexing for target condition and test names is not optimal, and similarly author descriptions can be extremely varied. This is one of the main challenges in searching for DTA studies. To make the Register more easily searchable, coding for Target Condition and test names needs to be standardised.

Studies are coded with the author term for Target Condition, and some have also been coded for Index Test, Reference Standard and Population. An Excel list of terms is being kept. These can also help inform the development of search strategies for individual reviews.

1. **Support for Cochrane review authors and TSCs regarding individual reviews**

RM provides support for authors and TSCs by:

* 1. Searching the register for any studies that might be relevant to a review being undertaken. Relevant studies can provide information on likely MeSH and text words to use in a search strategy.
  2. Searching the database of potential non-Cochrane systematic reviews, as these can be a good source of studies to assess for inclusion. In 2011 RM has also searched the ARIF and Medion databases for relevant reviews for TSCs requesting Register searches.
  3. Assisting TSCs with development of DTA search strategies
  4. Peer reviewing search strategies of Cochrane review protocols for the DTA Editorial Unit. This usually involves two iterations – a first peer review, followed by reading the authors’ response to see if they have adequately addressed comments made.

1. **A mechanism for retagging DTA studies in MEDLINE with a searchable field e.g. diagnostic accuracy.pt.** *(EMBASE was later included in this objective as they expressed an interest to ML in this initiative)*
2. **MEDLINE**

A submission to the National Library of Medicine (MEDLINE) was prepared by RM in consultation with the Reference Group, and finalised in January 2009. In addition a letter was drafted to be sent to potential supporters of this proposal (researchers, clinicians etc. working in the area of diagnostic testing) asking for their endorsement, so that these could be sent with the proposal. At this stage some members of the Diagnostic Test Accuracy Working Group (DTAWG) expressed concern, as they felt that the submission might not succeed, and that we would not get a second chance. After considerable discussion it was decided to try to modify the proposal to propose a more general publication type (.pt.) such as *clinical test evaluation* that would cover a range of test evaluation studies including prognostic, predictive etc. This has proved difficult as the research on which much of the submission is based, has been on developing and testing methodological search filters for diagnostic test accuracy studies. It was hoped that the handsearching pilot mentioned in 2. c) (above) would help clarify the feasibility of this alternative approach, but the pilot has not yet been completed. The submission is being redeveloped this year in conjunction with a group from North America, including people from the Hedges team. It is planned to make a submission to the NLM by the end of this year. It is hoped that the decision by Elsevier to introduce *Diagnostic Test Accuracy Study* as an EMTREE check tag in EMBASE (see b. below) will strengthen the submission.

1. **EMBASE**

A submission was prepared for Elsevier (EMBASE), and discussions were held between two members of the Reference Group, DTAWG and a representative of Elsevier in May 2009. These seemed promising, but did not progress. Discussions were revived in July 2010, and after considerable preparation of additional supporting documents and training materials by RM and the Reference Group, Elsevier agreed to introduce *Diagnostic Test Accuracy Study* as an EMTREE check tag for EMBASE by December 2010.

**COMMUNICATION AND COLLABORATION**

Communication and collaboration has been undertaken with a range of groups and individuals to further the aims of the Register project:

1. Cochrane Collaboration. The initial proposal for a Register was widely circulated to all email lists for comment.
2. Register Reference Group. As mentioned in the Introduction, a Reference Group was formed at the start of the project to provide advice and support to RM on its development. The Reference Group has been involved in many aspects of the project, but in particular has been integral to the development of methods for populating the Register, to developing the submissions to the NLM and Elsevier for introduction of a DTA study indexing term; to the development of training opportunities for TSCs and other information specialists; to the development of the education package for TSCs. Members of the Reference Group have put considerable enthusiasm, time and effort into these initiatives even when they have not been part of their core, funded duties.
3. Trials Search Coordinators. A formal report on the Register is made at the TSC annual general meeting each year. TSCs attending training workshops on searching for DTA studies have provided valuable feedback to improve workshops. A protocol has been set up to guide TSCs in sending included studies from published reviews related to their CRG.
4. Steering Group. Open access progress reports have been submitted as required to each meeting of the CCSG since funding was granted, including a final report on the first two years of funding.
5. Screening & Diagnostic Test Methods Group. Informal reports on the progress of the Register have been made at meetings as scheduled at Colloquia.
6. Diagnostic Test Accuracy Working Group. The main collaborations with the DTAWG have been on the initial development of the proposal for the Register, and on the development of the Handsearching pilot (2.B.III above). The DTAWG has also provided comment on the submission to the NLM for a DTA study indexing term in MEDLINE, and was part of the initial discussion with Elsevier on introducing a DTA study check tag into EMBASE. RM has also contributed to discussions by DTAWG members on the future model of management for the production of DTA reviews by the Collaboration.
7. Elsevier. Elsevier is the publisher of EMBASE. Negotiations with Elsevier about the introduction of a DTA study check tag into EMBASE were held over two years (2009 – 2010) with a positive outcome by December 2010. News of their decision to introduce the new check tag was widely disseminated through CCInfo, Cochrane news, and various email lists.
8. Central Register of Studies. RM has provided input to the development of the CRS through comment on the model as it progresses, comment on the document concerning fields for the CRS, testing of scripts and testing of the Beta version.
9. Wiley was consulted during 2008 as to their views on eventual publication of a DTA register in the Cochrane Library. Their response was positive.
10. Cochrane Renal Group – the Renal Group has provided a supportive and stable base for RM and the Register.
11. Future communication/collaboration – Miranda Cumpston and Steve McDonald of the Training Working Group have been kept informed of progress regarding the training package. The Web team will need to be included in consultation regarding its development as an online training package.

**RESULTS AND DELIVERABLES**

1. **Education and training for Trials Search Co-ordinators (TSCs) in recognising DTAS / principles of searching for DTAS**
   1. **Workshops**

2007 Sao Paulo Colloquium

* + - Searching for Studies section of SDTMG introductory workshop on Cochrane DTA reviews (RM)

2008 Freiburg Colloquium

* Searching for Studies section of SDTMG introductory workshop on Cochrane DTA reviews (RM)
* How to search for studies for inclusion in Cochrane diagnostic

test accuracy reviews (AE, MW, RM)

2009 DTA training, Melbourne

* Searching for studies section of DTA training day (RM)

2009 Singapore Colloquium

* Developing search strategies for Cochrane systematic reviews of diagnostic test accuracy (RM, AE)

2010 Birmingham, July 5th and 6th

* Identifying studies for systematic reviews of diagnostic test accuracy (AE, JG, RM)

2010 Keystone Colloquium

* Developing search strategies for systematic reviews of diagnostic test accuracy (Advanced) (RM, JG, AE)

2011 Madrid Colloquium - three workshops have been submitted and accepted:

* Peer reviewing search strategies for Cochrane diagnostic test accuracy reviews (RM, AE, JG)
* Searching for Cochrane diagnostic test accuracy reviews (RM, AE)
* Searching for diagnostic test accuracy studies – review authors and information specialists working in partnership (AE, RM)
  1. **Education package** 
     + Under development – first draft completed, now under review by members of the Reference group

1. **A body of diagnostic test accuracy studies to support education and research in the field of diagnostic accuracy reviews**
   1. Populating the Register

4007 references from 133 non-Cochrane & 3 Cochrane reviews

806 references from Cochrane Renal Group database

853 references from screening approx. 6,000 MEDLINE records

112 references contributed by Regina Kuntz

Total as at 8/09/2011 5522 (there is overlap between these sets)

* 1. Maintaining data from Register to support development of methods to search for DTA studies
  2. Coding Studies

85% of studies are coded for Target Condition

51% of studies are coded for Index Test

It was difficult to set a target number of studies that the Register would hold by the end of the project

as the targets estimated in funding submissions (for funding for two people) could not be met by

one person. Screening titles and abstracts for DTA studies in downloaded MEDLINE records is much more difficult and time-consuming than for RCTs, especially when there is no specific index test and target condition being screened for. Authors often describe their studies badly, so that the full-text is required, and even then it can be difficult to tell. Experienced DTA reviewers involved in the handsearch project, who had to read the full text, commented that it was often difficult to judge studies outside their clinical domain, especially studies involving laboratory tests. Records screened for the Register are coded as YES Maybe or NO, and there are double the number of Maybes awaiting further assessment than YES records added to the Register. Some level of uncertainty will remain about many studies in the Register until they are assessed for inclusion in a review.

Other strategies need to be investigated for more quickly populating the Register. Text-mining has been mentioned earlier in this report as a possibility. Another strategy could be some test-based term searching, combined with the DTA terms, for DTA studies of tests that are used across a range of conditions e.g. for imaging tests.

1. **Support for Cochrane review authors and TSCs regarding individual reviews**
2. TSCs from the following 14 CRGs have been supported through a search of the Register (R) for relevant articles (also ARIF and Medion databases in 2011), and/or search strategy assistance (SS) (October 2008 – present):

Acute Respiratory Infections Group (R)

Anaesthesia Group (R)

Back Group (SS x 1)(R)

Bone, Joint and Muscle Trauma Group (R)

Depression Anxiety and Neurosis Group (R)

Dementia and Cognitive Improvement (R)

Ear Nose and Throat Disorders Group (R)

HIV Group-SACC (R)

Menstrual Disorders (SS x 2)

Neuromuscular Diseases (R)

Oral Health Group (R)

Schizophrenia Group (R)

Skin Group (R)

Upper Gastrointestinal and Pancreatic Diseases Group (R)

In addition the Eyes and Vision Group TSC was given advice on handsearching for DTA studies

1. RM has peer-reviewed 11 search strategies for the DTA Editorial team (October 2008 – present)
2. RM assisted an information specialist from the Centre for Reviews and Dissemination, York University, with development of a DTA search strategy for an HTA review.
3. Renal Group (SS x 6)
4. **A mechanism for retagging DTAS in MEDLINE and EMBASE with a searchable field e.g. diagnostic accuracy.pt.**

Elsevier has introduced *diagnostic test accuracy study* as a check tag.

Approx. 5,000 studies have since been given *Diagnostic Test Accuracy Study* as a  
 check tag in EMBASE since early December 2010.

* A revised draft for the submission to the NLM for a MEDLINE publication type is under preparation.

**DISSEMINATION AND IMPLEMENTATION**

The results of the Register relate to the four objectives, and specific dissemination undertaken is listed under each one where applicable:

1. Education and training for Trials Search Co-ordinators (TSCs) in recognising DTAS / principles of searching for DTAS

* Formal educational opportunities for TSCs have been provided for the last three years at Colloquia (see list of workshops under RESULTS and DELIVERABLES above)
* Future projects: The education package is under development and will be available to all TSCs by the end of 2011.

1. A body of diagnostic test accuracy studies to support education and research in the field of diagnostic accuracy reviews

* A report of the initial set-up of the register, and the results of the screening project undertaken by RM and the Reference group were presented at the 2007 Colloquium as an oral paper:

Mitchell RL, Glanville J, Leeflang MMG, Westwood M, Craig JC. 2007. Building a clean and comprehensive study based register of reports of diagnostic test accuracy studies [abstract 066]. 15th Cochrane Colloquium, Sao Paulo, Brazil. 23-27 October 2007.108

* There is the potential for presentations at future Colloquia on the results of the handsearch pilot when finished, and on the accuracy of use of the DTA study check tag in EMBASE.

1. Support for Cochrane review authors and TSCs regarding individual reviews

* Section 7.3.1 of Chapter 7 *Searching for studies* in the *Cochrane handbook for systematic reviews of diagnostic test accuracy* invites people to contact RM for a search of the Register for relevant studies, and for people in the Australasian region to contact her for search strategy advice. The training programme for CRGs also includes this advice. To date 15 TSCs have contacted RM for assistance with Register searches.

1. A mechanism for retagging DTAS in Medline with a searchable field e.g. diagnostic accuracy.pt.

* The news that Elsevier had agreed to introduce a check tag for DTA studies was widely published across the Collaboration (CC Info, Cochrane News, news page on Cochrane.org, Cochrane email lists) from the 8th November 2010 onwards.

The progress of the Register project as a whole is also communicated to the wider Cochrane Collaboration community as follows:

* Twice-yearly open access progress reports on the Register are submitted by RM to the Steering Group each year.
* RM reports on the Register at each Colloquium to the annual general meeting of the TSCs.
* RM reports on the Register to the annual meetings of the SDTMG as required.

While the aims under 1, 3 and 4 will have been largely met by the end of the project, the slow rate of populating the Register is of concern. Many DTA reviews involve a massive effort in screening thousands of records. The time spent on screening records for intervention reviews has been significantly reduced by the development of CENTRAL. If the amount of time that reviewers have to spend on screening records for DTA reviews can be reduced it will benefit everyone involved. To do this, other techniques of retrieving records that are likely to be DTA studies, as mentioned in RESULTS AND DELIVERABLES point 2. (above), need to be investigated.

**FUNDING**

Funding applications to the CCSG for both stages of the Register requested enough funding for two full-time information specialists, but funding for one person was granted each time. The Register project involved four objectives, and it has been difficult for one person to maintain equitable progress for all. For the Register to continue effectively more than one FTE is required.

**Future management**

The Register would be best managed where enough funding exists to provide the resources for it to grow properly. This will depend on how the management of Cochrane DTA reviews is funded. The Register would benefit from having more than one person whose core functions include the Register. If the funding model chosen includes funding for search specialists to support DTA reviews then the Register could be a part of their role. The development of the Cochrane Register of Studies provides an opportunity for DTA studies to be held in a discrete Register that can be accessible to TSCs both for searching and to contribute records as they are included in reviews. The CRS is a relational database which will enhance the ability to extract data from DTA records to inform further development of searching techniques. However it is important that there is someone responsible for managing the process of contributing records so that the integrity of its data is maintained.

**YOUR VIEWS**

I would like to thank the Collaboration very much for providing the opportunity for me to be engaged in such an interesting and challenging project. I have learnt a great deal from my involvement, and I hope have contributed. I would like to continue to be involved with Cochrane DTA review search strategy development and education activities, and the Register too if possible, as I believe that I have developed some expertise in this area.

I would also like to thank the many people and groups who have collaborated with me, including my colleagues in the Reference group, Anne Eisinga, Julie Glanville, Mariska Leeflang, and Marie Westwood; Les Irwig and Petra Macaskill from STEP at the University of Sydney; Jon Deeks and his team in Birmingham; Rob Scholten, Patrick Bussuyt and their colleagues in the Netherlands; the many other people in the Cochrane DTA community who I have met over these last few years; my TSC colleagues who are becoming more and more involved in DTA reviews; and not least, my colleagues in the Renal Group, who have encouraged and supported me.

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