Harmonising content in the Cochrane Register of Studies: the HarmoniSR project

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Background

HarmoniSR (**Harmoni**sing **S**pecialised **R**egisters) was formed to standardise the format and content of reference records and study records in the Cochrane Register of Studies (CRS).

Some Cochrane Groups have maintained study records in their Registers for many years, however, there isn't an agreed standard set of Cochrane study fields.

Defining a core set of fields to describe a study consistently across Groups is important for other Cochrane initiatives such as the Linked Data project, where PICO elements of a study will be annotated in reviews, as well as for improving the content and value of the CRS.

Objectives

We had two main objectives. Firstly, to develop guidance for the formatting of reference records in CRS; and secondly, to develop a core set of study fields, consistent with corresponding fields in the Linked Data PICO annotator. We are presenting the results of this second strand of work.

Methods

We conducted consultation and discussions on current and preferred field mappings, followed by webinars, presentations, and workshops at Cochrane meetings looking at both reference and study records. Two documents were subsequently developed, one looking at reference fields and one at study fields. These were circulated to the Trials Search Co-ordinators mailing list for feedback. We collated all the feedback, and convened a group of six people to work through each field one by one for each record type until a consensus was reached.

Results & conclusions

We reached agreement on 19 core study fields to describe a study in the CRS. We identified which fields were consistent across the Linked Data annotator tool, and which fields could be automatically populated from ClinicalTrials.gov. (Table 1) This will enrich the data held in CRS, capture the metadata created as part of the Linked Data project, and aid study discoverability. Once implemented in CRS, the core fields can be used as standard across CRGs by Groups who currently maintain study records, and provide a starting point for those who wish to do so in the future.

Cochrane core study field	ClinicalTrials.gov Data Element Definitions[i]	Cochrane Linked Data PICO annotation field[ii]
CRS study ID		
Study name (Cochrane style guide convention)		
Study full name (expanded acronym)		
Study acronym	Title acronym	
Study Title (Public)	Public title	
Study Title (Official)	Official title	
Study registration ID	NCT number	
Other study IDs	Other IDs	
URL to study registration	URL	
Study design (Cochrane definition)		
Healthcare condition		Condition
ClinicalTrials.gov health care condition	Conditions	
Intervention type		Intervention classification
Interventions		Intervention materials
ClinicalTrials.gov intervention	Interventions	
Participants (number)	Number enrolled	
Study Outcomes		Outcomes
Expected end date of study	Estimated Study Completion Date	
Data extraction status		

Table 1: Cochrane core study fields compared with ClinicalTrials.gov and Cochrane Linked Data annotator fields.

i. ClinicalTrials.gov Protocol Data Element Definitions. 2014. Available from: https://prsinfo.clinicaltrials.gov/definitions.html [Accessed 18 Sept 2015]
ii. Cochrane Linked Data PICO Ontology. Available from: http://linkeddata.cochrane.org/pico-ontology [Accessed 18 Sept 2015]

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