

Coding of Records in CENTRAL as CCTR and Correction of Records

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Minor Updates by the US Cochrane Center: 14 February 2005

Archived
1 Jan 2006

1. Introduction

The aim of this part of the CENTRAL Management Plan is to describe the processes by which records in CENTRAL will be included in the Cochrane Controlled Trials Register (CCTR) and by which errors in CENTRAL and CCTR will be corrected. The definitions of the two “registers” are that:

- Records included in CCTR should meet the requirements presented in Appendix 5b.1 of the Cochrane Reviewers’ Handbook (“CCTR definition”), i.e., they describe randomized, quasi-randomized, and possibly randomized or quasi-randomized trials
- CENTRAL will contain CCTR records, as well as records for studies about which there is less certainty regarding the study design, and records for studies which use designs appropriate for some Cochrane Reviews but which are neither randomized or quasi-randomized trials

The CENTRAL database currently exists and from this resource we will build CCTR. In this document, we first describe three categories of records that will be “grandfathered” from CENTRAL into CCTR; that is, we will assume they meet CCTR requirements. This is followed by a summary of the methods by which each new Cochrane submission will be deemed eligible for CCTR; a description of how CCTR eligible records will be coded as such on CENTRAL; and finally, procedures for users to follow when reporting errors on CENTRAL and CCTR, and methods by which these reported errors are corrected.

2. Assessment of records for CCTR

2.1 Assessment of existing CENTRAL and MEDLINE records for CCTR

The CCAG (CENTRAL/CCTR Advisory Group) has agreed that for there to be sufficient confidence that a record meets the “CCTR definition” of an included trial, the full content of the related report should have been checked. However, as an interim measure, records in CENTRAL that are most likely to meet the “CCTR definition” will be “grandfathered” into CCTR.

The following categories of records are considered for grandfathering:

- Records indexed in MEDLINE with the Publication Type RANDOMIZED-CONTROLLED-TRIAL;
- Records on CENTRAL that describe the reported study as “randomized” or “randomised” in the title or abstract
- Records on CENTRAL that describe the reported study as “quasi-randomized (or quasi-randomised)” (e.g., allocation by alternation or date of birth) in the title or abstract
- Records in hand search results submitted prior to October 2001, the date of the introduction of this ‘CCTR Coding and Error Removal’ document

If resources allow, a sample of the records in each of the four categories above will be assessed to confirm that they merit “automatic” grandfathered inclusion in CCTR. If the error rate is 10% or greater (i.e., if $\geq 10\%$ of the sampled citations do not meet the Cochrane definition for inclusion in CCTR), the CCAG will discuss possibly not “grandfathering” trial reports in that category.

2.2 Newly submitted records

2.2.1 Specialized Registers that contain only citations of trials

When a Review Group’s Specialized Register contains exclusively records that meet the “CCTR definition,” all records within the register will be included in CCTR. This will be determined by a positive response to the question on the *Submission Form for CENTRAL Specialized Registers* as to whether the submitted register contains exclusively records that conform to the “CCTR definition.”

2.2.2 Specialized Registers that contain some citations of non-trials

Some Review Groups maintain registers that contain records of reports that do not conform to the “CCTR definition.” For example, for Issue 4, 2004, *The Cochrane Library*, there were 12 registers submitted that contained other citations in addition to RCTs and CCTs. Review Groups maintaining such registers would be asked to inform the US Cochrane Center (USCC) which records within their registers are eligible for CCTR and which are not, as described in Section 3 below. Records eligible for CCTR will be included, after appropriate quality checks.

2.2.3 Hand search results – Center, Field, and Review Group submissions

Citations to reports of trials meeting CCTR criteria may also be submitted to the USCC as hand search results. There are three categories of hand search results citations: 1) citations identified by a Cochrane Center or Field; 2) citations identified by a Review Group that are not relevant to the Group’s scope and thus not eligible for the Group’s Specialized Register; and 3) citations identified by a Review Group that are included on the Group’s Specialized Register, and/or are submitted as hand search results expressly for MEDLINE retagging. The *Submission Form for Hand Search Results* should accompany all hand search submissions, whether they come from Centers, Fields, or Review Groups, and this Form should record whether all citations within the submission conform to the “CCTR definition.” As described in the *Guide for Submission of Hand Search Results for CENTRAL/CCTR*, all hand search results are expected to conform to the “CCTR definition”. CCTR eligibility of hand search results is confirmed by TSCs on the *Submission Form for Hand Search Results*.

3. Coding records: CCTR or CENTRAL

Individual records that the submitter has judged eligible for inclusion in CCTR and, as appropriate, have been quality checked for accurate classification, will be identified by displaying [CCTR] next to the record's CENTRAL identifier in *The Cochrane Library*. These [CCTR] tags will be supplied either by the CENTRAL publisher or by the USCC. The majority of submissions to CENTRAL/CCTR would be expected to conform to the "CCTR definition" and would be assigned the [CCTR] tag. The only exception expected is Specialized Registers that contain non-trial reports. [COMMENT FROM MIKE: Should something be added here about the records that get into CENTRAL from the automatic download from MEDLINE? For example, the audit of issue 1, 2002 of CENTRAL revealed that records in MEDLINE that were tagged with the Publication Type CONTROLLED CLINICAL TRIAL by NLM had too high an "error rate" to be automatically tagged as CCTR. The error rate was over 30% for records published after the mid 1990s (tables 4 and 4a of the report I prepared in 2002).]

Those Specialized Registers that also include non-randomized studies (e.g., interrupted time series) as well as RCTs and CCTs will be dealt with differently, as described below. TSCs who oversee registers containing non-randomized studies should contact the USCC directly to receive guidance before submitting their files. Generally, the TSC will create a "clean" file of only records judged eligible for CCTR and this is submitted to the USCC. RCT/CCT study design classification codes applied by the TSC indicate to the USCC staff which records are eligible. The TSC will also submit a separate file for records that have been assessed and judged ineligible for CCTR because they used a study design other than randomised or quasi-randomized; for these records the tag [CENTRAL] will be displayed next to the record's CENTRAL identifier in *The Cochrane Library*.

As resources permit, the USCC staff will perform quality checks on a sample of records within each register submitted for CCTR eligibility, and remove the CCTR tag from records that do not meet eligibility requirements. If < 10% of citations reviewed do not conform to the "CCTR definition," the CCTR tag will be removed only from these non-conforming citations. If \geq 10% of citations reviewed do not conform, the CCTR tag will be removed from all the citations in a Specialized Register, or the hand search submission.

4. Procedures for reporting errors and duplicates in CENTRAL and CCTR

Errors may be typographical, or involve incorrect citation information, or inclusion of citations not meeting the CCTR definition in CCTR. (Citations to reports of non-trials on CENTRAL should not be reported as errors.) Users of CENTRAL/CCTR who identify suspected errors should take the following actions:

- **Records downloaded from MEDLINE, as indicated by the 8 digit unique identifier in the CENTRAL/CCTR 'AN' field:** the suspected error (typographical ONLY) should be reported to the National Library of Medicine (NLM). Please use the following E-mail

address: custserv@nlm.nih.gov. (The USCC should be copied on these E-mails using the E-mail address Cochrane@brown.edu.). Faulty RCT or CCT MEDLINE Publication Type codes on CENTRAL/CCTR records downloaded from MEDLINE should not be reported to the NLM, but should instead be reported to the USCC staff, who will keep a list and send a yearly report to the NLM. (MEDLINE Publication Type codes are stored in the CENTRAL/CCTR PT field.) Please accompany the report of an error with supporting documentation, as listed on page 10. *Please note: citations that carry the subset [SB] tags 'premedline', (for PubMed - in process), or 'publisher', (for PubMed - as supplied by publisher), have not yet gone through NLM's quality control procedures and indexing process. It is during this process that NLM identifies errors and corrects them. On average, it takes approximately 4-6 weeks for a citation to go through the indexing process and become a full MEDLINE record. It is not necessary to notify NLM of an error at this stage.*

- **Records from Specialized Registers, as indicated by the SR Code accompanying the record in the CENTRAL/CCTR 'CC' field:** the suspected error should be reported to the relevant Review Group's TSC. The USCC (Cochrane@Brown.edu) should be copied on these communications. The Review Groups corresponding to the SR codes are listed in Appendix 2 of the *Guide for Submission of Specialized Registers to CENTRAL*. The name and contact information of the relevant Group's TSC can be found on the Group's module on *The Cochrane Library*. If a record from a Specialized Register is a MEDLINE record, as indicated by the 8 digit unique identifier in the CENTRAL/CCTR 'AN' field, typographical errors and errors involving incorrect citation information should be reported to NLM, as described above.
- **Records from other sources:** the suspected error should be reported to the USCC (Cochrane@Brown.edu), who will maintain a file of error reports and determine the processes by which the error can be confirmed and, if necessary, corrected.
- **Reporting suspected duplicates:** If a user notices that a record from a Specialized Register is slightly different from the corresponding MEDLINE record (typically indicating a handkeyed record), this discrepancy should be reported to the relevant TSC, who can replace a hand keyed record with the MEDLINE record in the next submission of their Specialized Register, and thereby assist in the duplicate removal from CENTRAL.

Whether you are sending a message to the NLM, the USCC, or a TSC please include the following items in your message:

- The journal name, volume, issue and page number
- The title of the article, or the MEDLINE UI (e.g., UI: 12345678), or the MEDLINE PMID number (e.g., PMID: 1234567)
- A description of the error

Note: Errors in the use of the CCTR tag (i.e., for records not meeting CCTR eligibility criteria) should also be reported to the USCC and the relevant TSC, if applicable.

Records are uploaded to CENTRAL/CCTR by the publisher according to the following specified order of precedence: MEDLINE, EMBASE, hand search results, and Specialized Registers. That is, a record in both MEDLINE and a Specialized Register is preferentially

uploaded from MEDLINE. Therefore, errors should be corrected on the highest precedence source to ensure record correction in CENTRAL/CCTR. The publisher will be asked to add appropriate reporting instructions, such as outlined above, to *The Cochrane Library's* Comments and Criticisms facility.

5. Removal or correction of records in CENTRAL/CCTR

Cochrane Review Group TSCs are responsible for the continued maintenance of their registers and the removal or correction of errors. Each submission of a register for CENTRAL/CCTR replaces the register previously submitted. When a record is removed from a Specialized Register, it is also removed from the CENTRAL/CCTR register, unless it also came to CENTRAL/CCTR from a source other than this Specialized Register.

All decisions on the removal of individual records from the cumulative hand search file need to be agreed by at least two people (one from the USCC and one from the UKCC), unless the removal arises from an electronic search designed to identify duplication of records (see Section 6, **Removal of Duplicates from CENTRAL and CCTR**). Decisions on the removal of entire categories of records that were grandfathered into CCTR, as described in Section 2.2 above, will need to be agreed by the CCAG. The USCC staff will keep a file of reports of records in CCTR downloaded from other sources (e.g., MEDLINE, EMBASE) that were deemed to be non-trials by CENTRAL users. The most appropriate means for removing these citations from CCTR will be determined by negotiations between the publisher and the USCC staff.

6. Removal of duplicates from CENTRAL and CCTR

Systems are being developed by the CENTRAL publisher for removing duplicate records from CENTRAL/CCTR, and these systems should continue to be refined. To determine the effectiveness of these de-duplication programs, the USCC staff will maintain a file of duplicates detected by users, and periodically review CENTRAL/CCTR to determine whether the duplicates are being removed. Upon request, the USCC staff would submit a list of these compiled duplicates to the CENTRAL publisher.
