Clinical Study Reports within Cochrane Reviews
Consultation Meeting

MINUTES

Thursday, May 16th, 2019, 10:00-16:30

William Goodenough Large Common Room
William Goodenough House, Mecklenburgh Square, London, WC1N 2AB

Minutes/Notes

Meeting objectives:
1. A needs assessment that builds on the findings of the previous Cochrane-funded project that assessed when clinical study reports (CSRs) would be valuable.
2. Reflection on the experiences of individuals and teams that have used CSRs as the basis for reviews and exploration of the practical feasibility of using CSRs in Cochrane.
3. Explore access and other major obstacles to CSRs, as well as discuss how Cochrane could help overcome these (potential support unit with established links to places of access?). Consider what on-going support would be needed – non-financial/human and financial.
4. Plan potential pilots and begin considering the development of how-to guidance on using CSRs in Cochrane Reviews.

Preparation for the meeting:
- Read ‘Interim guidance on how to decide whether to include clinical study reports (CSRs) and other regulatory documents into Cochrane reviews’ (Attached MIF Report)
- Familiarise yourself with what CSRs looks like with the ‘Tamiflu (oseltamivir) clinical study reports via Figshare’.

Core planning team members: Rachel Churchill, Kerry Dwan, Ella Flemyng, Toby Lasserson, Joerg Meerpohl, Nicole Skoetz, Lesley Stewart, David Tovey.

Minutes: Froeks Kamminga

Full attendee list at the end of the agenda

1) Introduction and meeting objectives - see meeting slides.

Questions/comments following presentation:
CSR appendices include the most useful information as spin can occur in the CSR summary, e.g. slant towards certain outcomes or under-reporting of adverse events. CSR synopsis is still better than a journal article. Suggestion: two days per CSR to extract data, starting with summary and appendices. Peter Doshi found medium of 135 pages for the summary of the efficacy in a CSR (see BMJ Open paper here).

Chair: Ella Flemyng
Presenter: David Tovey

2) Overview of the project ‘Interim guidance on how to decide whether to include clinical study reports (CSRs) and other regulatory documents into Cochrane reviews’ - see meeting slides.

Chair: Ella Flemyng
Project initiated in 2014, when there was relatively low awareness of CSR use.
It involved defining the rationale; glossary of terms used in CSRs; interim guidance; consultation with Cochrane community; raising awareness - talks at Colloquium and survey.

Overall, the outcomes of consultation and awareness raising was positive, and experience of those involved in systematic CSR reviews showed they should not add greatly to the time taken for a systematic review (unless you want to go in forensically). CSR reviews shouldn't need specialist skills. However, there is a need for guidance on how to use them to address needs and concerns in the review community.

Other than benefits in terms of outcome and reporting bias, CSRs provide useful data on sub-populations not seen elsewhere. Challenges with CSRs: they can be incomplete and have internal inconsistencies.

Problems occur when they aren't publicly available, the process to get them is very long, with legal issues on data sharing agreements, issues of exclusivity, or time limits on use of a CSR. Even though there is a global trend towards open access and data transparency, Cochrane would need to develop advocacy around gaining access to CSRs and invest in infrastructure to enable it.

**Questions/comments following presentation:**
David Tovey highlighted that the Director of ClinicalStudyDataRequest.com is keen to work with Cochrane on sharing CSRs.
Question on what CRGs can do and what needs to be done by Cochrane centrally. Example: CSRs were refused to some teams in Canada. Would need to define who and how to respond in this situation.

3) Presentations from authors who have used CSRs in Cochrane, or other types, of reviews - see [meeting slides](#).

**Highlights/questions/comments following presentations:**

**Kerry Dwan**
CSR content and size will vary depending on manufacturer.
Benefits include structured nature of CSRs, ability to check data in MA or NMA and reduced selective reporting.
Challenges include the length of the document (searchable PDFs help).
Protocols will need to describe how discrepancies between data sources will be dealt with.

**Tianjing Li and Evan Mayo-Wilson**
Reiterated: hard and time-consuming process to access CSRs. Flagged as major issue for Cochrane going forward.
Using CSRs requires more time but same expertise compared with journal articles.
CSRs helped better define risk of bias - most went from unclear to low when CSRs were available (some went to high).
CSRs include more outcomes and results: 75% of the outcomes were only available in CSRs (only 25% reported publicly) - four outcome domains led to over 214 outcomes. Highlights a very important need to have a robust protocol that clearly defines the outcome of interest.
CSRs provide most reliable information about harms. Difference between systematically reported harms and non-systematically collected/reported harms. Non-systematic harms are messy (those captured with results - not those specified a priori with case reports, etc.). Most names of non-systematic events are never mentioned publicly. This is the same for serious adverse events. They are not reported in journal articles even though they are found in CSRs: multiple selection criteria are
used to report non-systematic harms. In short, journal articles are not adequate for harms/adverse events reporting.
Also noted: lot of inconsistencies within and across sources.
To overcome obstacles, main ingredients are funding and having a plan.

Lars Jørgensen
Reiterated: Challenge in accessing data, e.g. EMA initially rejected requests for CSRs. Also encountered heavily redacted sections. Overwhelming amount of data is invisible. Need to have full access to start using them.
Once you gain access it saves time: no need to contact trial authors etc.
Only a third of harms were found in the registry and journal articles, compared to CSRs.

Bernd Richter
ICH guidance highlights the structure for CSRs.
EMA, FDA and Canada are now releasing CSRs.
Germany does not have guidelines for accessing CSRs. The German institute IQWiG uses CSRs for assessment of new drugs and has agreements with pharmaceutical companies, to use CSRs in-house.

Main observations: Appendices contain wealth of information; Be clear on the question you want to ask; It takes time to access CSRs.
Advantages of CSRs: Simple structure; All end points reported; Methodology can be compared with study protocol. Time specific date for end points and participants; No author requests necessary; Easy navigation.
Challenges and how to overcome them: Use a top-down approach to overcome the frightening size; Needs piloting in house (CRG), suggest by highly experienced and enthusiastic author groups only; Contract/access requests should be done by Cochrane centrally, not individual reviewers.

Lesley Stewart
Case study of YODA (Yale Open Access Data) comparing multiple sources on product promoting spinal fusion (CSR with published journal articles). Outcomes of study itself were fairly similar across all sources, i.e. effectiveness. However, very little was reported on adverse events. The typical iceberg scenario of adverse events where most remain hidden under water.

Benefits of using CSRs highlighted across the talks included:
- Clearer understanding of methodology so facilitates risk of bias assessments.
- Helps highlight selective reporting.
- Harms reporting.
- Clearer efficacy estimates.
- Simple structure, easy to use.
- Include all endpoints with time-specific data points (facilitate RoB 2).
- Include more detail on sub groups.

Challenges highlighted across the talks included:
- Time and access: It can take 9+ months to get an answer of ‘no’ for a CSR request.

Main observations from group discussion:

General brainstorm
- Level of pressure from regulatory context. Does this impact CSR access? Three types of CSRs: Approved indications; other trials that do not have regulatory approval; CSRs for seedling trials. CSRs do not often get in to public domain.
- Pros and cons of mixing up different types of sources (CSRs, journal articles, other sources) in a single review. Expect differential access and have a plan. CSR preferred over journal article. Look for systematic differences.
- Academic trials do not produce CSRs but do produce a similar type of document. Should we look at and include academic trials as well? Different standards for industry and academic reviews. Different standards for collecting information on harms and adverse effects. Quality of documentation and data quality will vary.
- Including CSRs does not mean we really get to the truth as they still have an agenda they are furthing (the drug tested in clinical trial) So: all sources have limitations which need to be properly communicated in every Cochrane review.
- Addressing biases is one thing, but including CSRs helps to highlight fundamental design issues (e.g. inappropriate choice of comparator, duration of follow-up, choice of outcome). Exposes important problems.
- Challenge of implementation. Reviewers do need guidance and definitions.

Adverse events and harms
- Adverse events are major consideration in using CSRs.
- Anticipated/expected harms and unexpected harms. Different sources will give information on different adverse effects. E.g. clinical trials vs long term observational studies.
- Harms - should we have an omnibus? Need to be careful in the changing/junking existing benefits/harms approach. Approaches needed for taking account of where regulation is not common, or scrutiny lower, than in Europe and North America.
- Discussed splitting up Cochrane reviews into separate benefits reviews and adverse effects/harms reviews. General consensus was no as there’s a risk people will just ignore the harms reviews and only look at benefits reviews! There needs to be balance.
- Don’t forget drug interaction effects.

Cochrane and advocacy
- Cochrane centrally to develop strategic advocacy approach, central coordinating role to engage with pharmaceutical companies, come up with ways to help reviewers request CSRs, templates etc. Facilitate access. In-house piloting?
- Should Cochrane have a database of open and accessible CSRs? As an addition to CENTRAL?

Summary thoughts and areas of agreement
- CSRs are structured, searchable, summarised and we do have basic guidelines and experience.
- Have funding and a plan.
- Will need to consider longer-term plans and how CSR implementation work will link with other Content Strategy projects, including living systematic reviews.

4) Group breakout to discuss how Cochrane could overcome the obstacles and challenges faced by authors and editors.

**Group 1 = Access to CSRs** – facilitated by Joerg Meerpohl

Challenges include:
- How to deal with delays to the systematic review process due to requests for non-publicly available CSRs? How much time and how many resources should we devote to requesting and tracking down these reports?

Need to build delays into the process; planning and coordination; requests for CSRs would need to go out at the time of protocol/title registration; amount of resource we allow should depend on the priority.

- There is a general lack of knowledge in how to obtain CSRs and where to begin.

CENTRAL should be updated to highlight which trials have CSRs; advocacy would be key – Cochrane should discuss with EMA, FDA etc. to agree how to overcome barriers in accessing usable CSRs. This
would disrupt ‘fake transparency’ and blocks can be deliberated. Discuss IQWIG’s agreements with
them; could there be issues with conflicts of interest and expectations to not go too hard for
continued access (Cochrane vs pharmaceutical companies) (not the experience of IQWIG); off-patent
drugs, much easier to get the data; with actively marketed drugs they have a tendency to drag their
feet; different companies can have different attitudes, e.g. GSK had an incentive to support
transparency and by working with them there was a positive outcome. Develop guidance based on
experience to date. Chapter of the new Intervention Handbook (Chapter 4 – Searching for and
selecting studies) does cover parts of this but we need something a little more comprehensive: what
are the likely requirements, for protocol/CV of authors; could we include Cochrane Response? Start
with Networks and CRGs, not individual authors. Longer term develop (interactive) learning
modules.

- How to identify when a CSR exists for a specific trial?

Sometimes stated on trial registry/company sites; fewer CSRs for devices; if submitted for market
approval you should know a CSR exists; CCD-Module 52 is a document listing all trials; should it be
assessed on an individual review basis; could it link to CENTRAL (meta-data on CENTRAL about
existence and on an individual review basis authors could try to get access to CSRs; CSRs should be
used in situations where there are suspicions; worth trying to get access to all of the company’s CSR;
issues with regulators, e.g. less information from FDA; should consider a Cochrane unit that could
provide admin support with finding and approaching companies; Cochrane should develop letter
templates; Cochrane central has a role in obtaining and maintaining the infrastructure for CSR
requests (would need to be those with methodological experience), this could be a project in itself to
investigate access to data to make it auditable; platforms like vivli (IPD data sharing) is where you
request data but doesn’t hold the data, just does transfer when requested.

- Advocacy (additional from the discussion)

Cochrane Central to take the lead on advocacy, e.g. with pharmaceutical companies; foster
agreements with them about CSRs that exist, directly or via regulatory bodies. Inventory of relevant
websites. Be clear on what we are asking and who we are asking, have a multi-pronged approach
(companies, regulators, trial registers). Sharing data, open access etc., many commitments are on
paper; need to develop standard engagement protocol that everyone will follow. If this is something
Cochrane will invest in, can a business case be made that is relevant to Cochrane’s continued quest
for sustainability?

**Group 2 = Data sharing agreements - facilitated by Lesley Stewart**

- If a CSR isn’t not publicly available, what agreements need to be in place and who is responsible?

Unlike that agreements via email will be applicable – things have moved on.
Issues: Many agreements are not applicable for systematic review use (usually just an agreement to
look at one trial, esp. the sharing platforms); agreements would be with the pharma company (not
regulatory agency): issues with language in the agreements; huge varieties in data agreements;
restrictions in use and sharing, the pharma companies want exclusivity; time limitations on use; who
should be the signatory on the agreement; complicated agreement clauses.

- CSR records management within an author group - how should we create, manage and share
CSR records?

Issues with what’s included within agreements: Could we share information on trials via CENTRAL
and issues with managing a CSR within an author team within a single review, e.g. how can
Information Specialists use CSRs to facilitate screening within a review via metadata.

Priorities for Cochrane going forward:
1) Cochrane should develop data sharing template agreements - would allow Cochrane to ensure it's applicable to systematic review use and onward sharing/publication in Cochrane Library. Should consider differing levels on the use, ideally Cochrane would want to use CSRs across all CRGs (not just one review – would reduce duplication of effort). Could include rights to describe a CSR in a Review, as well as rights to use the CSR metadata. Plain language needed.

2) Central person to take legal responsibility to sign the agreements; Cochrane to develop relationships with regulatory agencies and pharma to make CSRs available and usable in Cochrane review. Legal risk would be low. Authors may leave CRGs and a central effort would reduce duplication of efforts. Could be kept in a shared folder in CRS so different CRGs could use it with restricted access for the users.

3) Longer term would be advocating for open CSRs (open access and use).

**Group 3 = Considerations for protocols and implementation of SR analysis plans – facilitated by Tianjing Li**

- Plans for extracting and analyzing non-systematic harms (adverse events).

Review protocols should include plans for extracting, analyzing, and presenting the substantially greater amount of information about non-systematic harms in CSRs compared with other sources (e.g., journal articles). Harms are vastly underreported in journal articles, and information about harms in journal articles is often useless because articles (a) do not describe the methods used to collect data about harms, (b) do not describe the methods used to analyze harms, (c) do not describe the criteria used to select harms for inclusion or exclusion in journal articles, and (d) report incomplete statistical information. By contrast, CSRs often contain detailed and analyzable information about hundreds of potential harms. Relevant results from the MUDS study are: [http://bit.ly/2VpDiYf](http://bit.ly/2VpDiYf) and [http://bit.ly/2E6fJZ5](http://bit.ly/2E6fJZ5).

- Plans for extracting and analyzing multiple results for benefits and systematic harms.

Many Cochrane reviews define their outcomes at the level of “domain”. While a journal article might include a handful of results associated with a given domain, a CSR might contain dozens of results for a single outcome domain related to potential benefits or systematic harms. This occurs because CSRs include multiple outcomes that differ in five elements: domain, measure, metric, method of aggregation, and time point. CSRs also contain multiple results for a single outcome because CSRs include multiple analyses that differ in: analysis populations, methods for handling missing data, methods for adjustment. Whether or not Cochrane reviews use CSRs, review protocols should explain how they will handle multiple outcomes for the same domain and multiple analyses of the same outcome. Particularly when they include CSRs, plans for data extraction are needed to keep the task manageable/efficient, and plans for selection and analysis are needed to prevent cherry-picking (bias). See: [http://bit.ly/30jWqFj](http://bit.ly/30jWqFj), [http://bit.ly/2E9G1Km](http://bit.ly/2E9G1Km), and [http://bit.ly/2Vq90PB](http://bit.ly/2Vq90PB).

Priorities for Cochrane going forward: Use CSRs are the primary data source when they are available. The data extract and analysis can be done more reliably and accurately. The plan to extract and analyze systematic adverse events (AEs) should be the same as any efficacy outcome. For non-systematic AEs, it may not be possible/feasible to analyze all of them.

- It’s important to analyze all serious AEs and patient-important AEs.
- When possible, share the remaining non-systematic AEs (not analyzed) with the public.
- Be transparent about the methods and rationales used to decide which AEs to analyze.

RoB assessment for non-systematic AEs is a different animal.

**Group 4 = Assessing and extracting data from a single CSR – facilitated by Nicole Skoetz**

- Difficulties in understanding how CSRs are organised.
Once structure understood quite easy (even from different manufacturers). More difficult for older trials. So many data: structured review protocol with clearly defined domain outcomes are necessary. Prioritise for Cochrane going forward could include automatic data extraction (tools, Adobe helpful to extract into Excel (for newer trials).

- How to overcome issues that using shortcuts to assess CSRs create and dealing with discrepancies within a single CSR, e.g. extracting data from the Synopsis when a deeper read might reveal reporting bias in the Synopsis. Also, how to proceed if you only receive partial CSRs or CSRs with redacted details, e.g. appendices removed (IPD, case report forms, etc.)? Especially when you are not informed that certain aspects are missing or have been removed.

Use a hierarchical approach: appendices, CSR report (helpful for methods assessment), CSR synopsis, and finally journal publication.

- How to proceed when you have restricted access to CSRs, e.g. view only, no print, as is the case with platforms like ClinicalStudyDataRequest.com.

Double data extraction, solving disagreements difficult without highlights. Tag where data came from so that double-checking can be carried out.

**Group 5 - Using CSRs with other data sources within a single review** - facilitated by Kerry Dwan

- How to proceed if you can only access a subset of CSRs for the studies you wish to include in a review?

Maximise use of information, make use of whatever you can. Look at totality of the evidence; Study centric – complete picture; Sensitivity analyses; Hierarchical model of putting them together – similar to combining non-RCTs and RCTs, or IPD and aggregate. Test for consistency and inconsistency – is the combined model any good?; Do not exclude studies without CSR.

- Extent of search required if a review is to be based purely on CSRs. Will it be necessary to conduct full multi-database searches as well?

Reviews that include CSRs may not be able to access all CSRs that are potentially available; Review should include standard searches; Trial registry searches; CSR searches; Guidance or template should be developed – if someone has done it before, tell information specialists; HPV index has many duplications. They also searched trial registries of manufacturers; Dangerous to focus on CSRs only; Help to establish an index is needed – a lot of resource; Consider another resource similar to CENTRAL to store ‘studies’ including records of CSRs. Use a PICO framework and automation to search. If you do this recruit good quality authors. CENTRAL is moving towards this – may run into problems with the record as CENTRAL is published. Helpful to know that it’s there. Exposes us to not sharing data etc. Could possibly store in CRS – depending on permissions.

- How to deal with data discrepancies between data sources (CSRs, journal publications, trial registry records, etc.) and which take precedent?

CSR on top of hierarchy? Then results on clinicaltrials.gov, journal publications; Look at in context – why are they different? Do not base it on the format; From a pragmatic point of view it’s difficult. Regular authors wouldn’t do this; Pilot – what’s the short-term gain. Could this be a methodological project? Pilot should consider - what does a reader experience? In terms of using a hierarchical model. How do they interpret it? How you present will impact how people interpret. This is important as people may think CSRs are the best information; Where there are differences, reviewers will need to define why there may be differences – similar to contacting authors. Readers may gloss over that;
Demonstrate best use of what we have; Be transparent about where information is from; CSR – most accurate. Problem is comparing across trials; Would need sensitivity analyses; Not a one size fits all approach – driven by the question; Heterogeneity will be a consideration; State in protocol how you plan to address discrepancies.

- Documenting information sources.

Tagging the source of trial information included in a review could facilitate reconciliation between extractors and improve auditing. That is, it can be difficult to reconcile or audit the information included in systematic reviews when information is derived from multiple sources (e.g., journal articles, conference abstracts, CSR) and combined / presented at the level of the “trial”. For a single trial, reviewers and readers might notice discrepancies among 10 journal articles, 5 conference abstracts, and a 5,000-page CSR. When reviewers use data from multiple sources, including CSRs, it would be helpful to extract information at the level of the “source” rather than the “trial”, or to otherwise tag the source from which the information was obtained. See [http://bit.ly/2VEVsow](http://bit.ly/2VEVsow) and [http://bit.ly/2W4C5Vh](http://bit.ly/2W4C5Vh).

Documenting and checking – when concerns are exposed we can go back and double check. If CSRs are only available to authors – how do we do this? Cochrane to do this centrally to allow authors and editors access; Tamifu – all on figshare – were they allowed? Tag to say published/unpublished/communication and CSR. Additional tabs where different sources are from should be included in the published review; Consider a flowchart like the study flow diagram; Could we use a structured spreadsheet; How would this be presented in the Cochrane Library? Could link out of the review as a workaround – link to an Additional file (Excel file). Consider a central repository, a stable repository; this overlaps with Group 3.

5) Presentation to outline a proposal for the conducting pilots in Cochrane reviews (aiming for three pilots in 2019) followed by group discussion - see [meeting slides](#). Chair: Toby Lasserson

**Highlights/questions/comments following presentation:**
We will need early engagement with advocacy in the pilot.
Need to consider how long you wait to not get the CSRs.
Should the pilot state that a Review has two searches – the standard MECIR search and a CSR search. Useful to have a mix of pilot groups with experience and inexperienced reviewers as will help understand training needs.
Will need to ensure an emphasis on a very robust protocol.
Key to taking the project forward will be an open network of those with experience and those who are interested, with CET support.
Will need project manager, project team and key stakeholders to ensure the project delivers (groups that are too big struggle to complete work).
Communication between the pilot groups will be key for shared learning and prevent duplication of effort.

When considering which Reviews for the pilot:
- The pilot should include examples of Reviews where we have the CSRs and ones where we have to request them from the beginning of the process (can consider how the request impacts on the 12 months search time).
- Only sponsor-run trials for approval with CSRs, e.g. drugs that are on the market.
- Seeding trials.
- Try to find a Review with a new drug on the market
- Peter Doshi has a list of publicly available CSRs.
- Need to ensure the Review is for a priority question for a Network/CRG.
- Should consider a replication Review so we can assess the incremental gain from using CSRs as part of the pilot.
Identifying Reviews for the pilot:
- Contact the Network Senior Editors/CRGs with the ‘when’ criteria for using CSRs developed by the MIF 2 project and ask for suggestions.
- Cross-reference with the list of priority Reviews (high priority/high impact Reviews – speak to Tarang Sharma).
- Cochrane Metabolic and Endocrine Disorders - Bernd Richter has a potential Review in which the author group also wants to use RoB 2.
- Cochrane Common Mental Disorders – this CRG would like to propose titles for the pilot, e.g. a potential Review on all anti-depressants vs placebo using CSRs.
- Cochrane Cancer Network - Nicole Skoetz mentioned a Living NMA on renal cancer and would like to identify CSRs as the Review includes new drugs; however, may be getting a little complicated in terms of methodology.
- Cochrane Children and Families Network - Robert Boyle mentioned three potential Reviews and will speak to the author groups to see if they are interested.

Timelines – pilot Reviews should be confirmed before the 2019 Colloquium.

**Attendees**

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<td>Olivia</td>
<td>Wu</td>
<td>Director, NIHR Complex Reviews Support Unit</td>
</tr>
</tbody>
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