Do we need a rapid review reporting guideline?

Is PRISMA-P helpful when generating a RR protocol?

David Moher
senior scientist, Ottawa Hospital Research Institute
associate professor, Department of Epidemiology and Community Medicine, University of Ottawa

4th February 2015
CADTH Rapid Review Summit: Then, Now, and in the Future
Vancouver, Canada
Competing interests

• Intellectual
  – Co editor-in-chief Systematic Reviews
    ▪ And will be peddling the journal
  – Principal developer, PRISMA and PRISMA-P
  – Member of the PROSPERO advisory group
  – Lead editor for a book I’ll be peddling

• Fiscal
  – None
Key questions to consider

- Is there evidence/rationale for developing RRRG?
  - Popularity or small niche market
  - Examining the publication record
Organizations producing Rapid Reviews

ISCRRA
Penn Medicine
Centre for Addiction and Mental Health
IHE
INSTITUTE OF HEALTH ECONOMICS
Kaiser Permanente
Cochrane Innovations
Canadian Agency for Drugs and Technologies in Health
CADTH
United States Department of Veterans Affairs
KCE
Health Canada
THE COCHRANE COLLABORATION COLLEGE FOR POLICY AT GEORGE MASON UNIVERSITY
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• High visibility – 800,000 article accesses in 2014
• Promotes sharing of data, and registration of systematic reviews

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The publication record

- It’s tarnished 😞😞😞😞😞
- There is considerable avoidable waste in the biomedical research industrial complex
What is a rapid review? A methodological exploration of rapid reviews in Health Technology Assessments

Julie Harker MRes1 and Jos Kleijnen MD PhD1,2

1Kleijnen Systematic Reviews Ltd, York, UK and ‘School for Public Health and Primary Care (CAPHRU), Maastricht University, Maastricht, The Netherlands

Abstract

Aim: Commissioners of Health Technology Assessments require timely reviews to attain efficacious decisions on healthcare and treatments. In recent years, there has been an emergence of ‘rapid reviews’ within Health Technology Assessments; however, there is no known published guidance or agreed methodology within recognised systematic review or Health Technology Assessment guidelines. In order to answer the research question ‘What is a rapid review and is methodology consistent in rapid reviews of Health Technology Assessments?’, a study was undertaken in a sample of rapid review Health Technology Assessments from the Health Technology Assessment database within the Cochrane Library and other specialised Health Technology Assessment databases to investigate similarities and/or differences in rapid review methodology utilized.

Method: In a targeted search to obtain a manageable sample of rapid reviews, the Health Technology Assessment database of The Cochrane Library and six international Health Technology Assessment databases were searched to locate rapid review Health Technology Assessments from 2000 onwards. Each rapid review was examined to investigate the individual methodology used for searching, inclusion screening, quality assessment, data extraction and synthesis. Methods of each rapid review were compared to investigate differences and/or similarities in methodologies used, in comparison with recognised methods for systematic reviews.

Results: Forty-six full rapid reviews and three extractable summaries of rapid reviews were included. There was a wide diversity of methodology, with some reviews utilising well-established systematic review methods, but many others diverging in one or more areas, that is searching, inclusion screening, quality assessment, data extraction, synthesis methods, report structure and number of reviewers. There was a significant positive correlation between the number of recommended review methodologies utilised and length of time taken in months.

Conclusions: Despite the number of rapid reviews published within Health Technology Assessments over recent years, there is no agreed and tested methodology and it is unclear how rapid reviews differ from systematic reviews. In a sample of Health Technology Assessment rapid reviews from 2000 to 2011, there was a wide diversity of methodology utilised in all aspects of rapid reviews. There is scope for wider research in this area to investigate the diversity of methods in more depth during each stage of the rapid review process, so that eventually recommendations could be made for clear and systematic methods for rapid reviews, thus facilitating equality and credibility of this type of important review methodology.

Key words: Cochrane Library, health technology assessment, methodology, rapid review, timeline plot.

Background

Over recent years, there has been demand from commissioners of Health Technology Assessments (HTAs), healthcare guidance and guidelines for reviews that are able to answer the stipulated research question rapidly, efficiently, competently and satisfactorily. While systematic reviews (SRs) remain the methodology of choice when summarising evidence by identifying, selecting, appraising and synthesising research findings in health and medical research, they can often be time-consuming using many human and financial resources. There have been several HTA reports published by...
NIH plans to enhance reproducibility

Francis S. Collins and Lawrence A. Tabak discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

A growing chorus of concern, from scientists and laypeople, contends that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring. As leaders of the US National Institutes of Health (NIH), we share this concern and here explore some of the significant interventions that we are planning.

Science has long been regarded as self-correcting, given that it is founded on the replication of earlier work. Over the long term, this principle remains true. In the shorter term, however, the checks and balances that ensure scientific fidelity have been hobbled. This has compromised the ability of today’s researchers to reproduce others’ findings.

Let’s be clear: with rare exceptions, we have no evidence to suggest that irreproducibility is caused by scientific misconduct. In 2011, the Office of Research Integrity of the US Department of Health and Human Services pursued only 12 such cases. Even if this represents only a fraction of the actual problem, fraudulent papers are vastly outnumbered by the hundreds of thousands published each year in good faith.

Instead, a complex array of other factors seems to have contributed to the lack of reproducibility. Factors include poor training of researchers in experimental design, increased emphasis on making provocative statements rather than presenting technical details, and publications that do not report basic elements of experimental design. Crucial experimental design elements that are all too frequently ignored include blinding, randomization, replication, sample-size calculation and the effect of sex differences. And some scientists reportedly use a ‘secret sauce’ to make their experiments work — and withhold details from publication or describe them only vaguely to retain a competitive edge. What hope is there that other scientists will be able to build on such work to further biomedical progress?

Exacerbating this situation are the policies and attitudes of funding agencies, academic centres and scientific publishers. Funding agencies often uncritically encourage the overvaluation of research published in high-profile journals. Some academic centres also provide incentives for publications in such journals including promotion and tenure, and in extreme circumstances, cash rewards.

Then there is the problem of what is not published. There are few venues for researchers to publish negative data or papers that point out scientific flaws in previously published work. Further compounding the problem is the difficulty of accessing unpublished data — and the failure of funding agencies to establish or enforce policies that insist on data access.

**Preclinical Problems**

Reproducibility is potentially a problem in all scientific disciplines. However, human clinical trials seem to be less at risk because they are already governed by various regulations that stipulate rigorous design and independent oversight — including randomization, blinding, power estimates, pre-registration of outcome measures in standardized public databases such as ClinicalTrials.gov and oversight by institutional review boards and data safety monitoring boards. Furthermore, the clinical trials community has taken important steps towards adopting standard reporting elements.

Preclinical research, especially work that uses animal models, seems to be the area that is currently most susceptible to reproducibility issues. Many of these failures have simple and practical explanations: different animal strains, different lab environments or subtle changes in protocols. Some irreproducible reports are probably the result of coincidental findings that happen to reach statistical significance, coupled with publication bias.
FIGURE 2. Star chart depicting proportions of adequately reported PRISMA items. A higher proportion meant that item was better reported.
80 consecutive studies

- Subsequently published in Evidence Based Medicine (Oct 2005 for 12 months)
  - 55 RCTs; 25 SRs

- intervention information missing from 41/80

- retrieved through additional methods

Key questions to consider

- Are there scientific barriers to development?
  - Terminology
  - Diversity of product
### Spectrum of Rapid Review Products

<table>
<thead>
<tr>
<th>i. Evidence brief (snapshot)</th>
<th>ii. Rapid Evidence Map (scoping) (primary studies and/or SRs, HTAs, or CPGs)</th>
<th>iii. Rapid Evidence Map (SRs, HTAs, or CPGs)</th>
<th>iv. Rapid Review (Primary studies only)</th>
<th>v. Rapid Review (SRs, HTAs, or CPGs + primary studies)</th>
<th>vi. Rapid Review (SRs, HTAs, or CPGs)</th>
<th>vii. Traditional SR – done quickly (shortened timeframe only)</th>
</tr>
</thead>
</table>

**Evidence Briefs** - 24 hrs-3 wks; short and concise

**Variety of rapid review products**
- from a rapid evidence map or scoping (ii-iii) based on ‘**off the shelf evidence**’ +/- primary studies to rapid reviews using ‘off the shelf sources of evidence’ +/- primary studies

**Traditional SR**
- but within a shortened timeframe – no corners cut (but report format)
Key questions to consider

- What’s the best practice for developing the RRRG?
WHAT IS A RAPID REVIEW?

There is broad agreement as to what is a systematic review
### Spectrum of Rapid Review Products

| i. Evidence Brief (snapshot) | ii. Rapid Evidence Map (scoping) (primary studies and/or SRs, HTAs, or CPGs) | iii. Rapid Evidence Map (primary studies only) | iv. Rapid Review (SRs, HTAs, or CPGs + primary studies) | v. Rapid Review (SRs, HTAs, or CPGs) | vi. Traditional SR – done quickly (shortened timeframe only) |

**Evidence Briefs** - 24 hrs-3 wks; short and concise

**Variety of rapid review products** – from a rapid evidence map or scoping (ii-iii) based on ‘off the shelf evidence’ +/- primary studies to rapid reviews using ‘off the shelf sources of evidence’ +/- primary studies

**Traditional SR** but within a shortened timeframe – no corners cut (but report format)
• Scientific content
• Format of product(s)
Defining a reporting guideline

- “a checklist, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology”
Guidance for Developers of Health Research Reporting Guidelines

David Moher1,2,*, Kenneth F. Schulz3, Iveta Simera4, Douglas G. Altman4
1 Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada. 2 Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada. 3 Family Health International, Research Triangle Park, North Carolina, United States of America. 4 Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom.

Introduction

Publishing health research is a thriving, and increasingly, enterprise. On any given month about 65,000 new articles are indexed in PubMed, the United States National Library of Medicine's public access portal for health-related publications. However, the quality of reporting in most health care journals remains inadequate. Gaglione and colleagues [1] assessed descriptions of given treatments in 80 trials and systematic reviews for which summaries were published during one year (October 2005 to October 2006) in Evidence-Based Medicine, a journal that is aimed at physicians working in primary care and general medicine. Treatment descriptions were inadequate in 41 of the original published articles, which made their use in clinical practice difficult if not impossible to replicate. This is just one of numerous examples of a large and disturbing literature indicating the general failure in the quality of reporting health research [2–6]. Many publications lack clarity, transparency, and completeness in how the authors actually carried out their research.

Inadequate reporting is problematic for several reasons. If authors do not provide sufficient details concerning the conduct of their study, readers are left with an incomplete picture of what was done. As such, they are not able to judge the reliability of the results and interpret them. There are also ethical and moral reasons for reporting research adequately [7].

Table 1. Recommended steps for developing a health research reporting guideline.

<table>
<thead>
<tr>
<th>Step</th>
<th>Item Number</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial steps</td>
<td>1</td>
<td>Identify the need for a guideline</td>
</tr>
<tr>
<td>1.1</td>
<td>Develop new guideline</td>
<td></td>
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<tr>
<td>1.2</td>
<td>Extend existing guideline</td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Implement existing guideline</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Review the literature</td>
<td></td>
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<tr>
<td>2.1</td>
<td>Identify previous relevant guidance</td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Seek relevant evidence on the quality of reporting in published research articles</td>
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<tr>
<td>2.3</td>
<td>Identify key information related to the potential sources of bias in such studies</td>
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<tr>
<td>3</td>
<td>Obtain funding for the guideline initiative</td>
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<tr>
<td>Pre-meeting activities</td>
<td>4</td>
<td>Identify participants</td>
</tr>
<tr>
<td>5</td>
<td>Conduct a Delphi exercise</td>
<td></td>
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<tr>
<td>6</td>
<td>Generate a list of items for consideration at the face-to-face meeting</td>
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<tr>
<td>7</td>
<td>Prepare for the face-to-face meeting</td>
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<tr>
<td>7.1</td>
<td>Decide size and duration of the face-to-face meeting</td>
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<tr>
<td>7.2</td>
<td>Develop meeting logistics</td>
<td></td>
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<tr>
<td>7.3</td>
<td>Develop meeting agenda</td>
<td></td>
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<tr>
<td>7.3.1</td>
<td>Consider presentations on relevant background topics, including summary of evidence</td>
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<tr>
<td>7.3.2</td>
<td>Plan to share results of Delphi exercise, if done</td>
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<tr>
<td>7.3.3</td>
<td>Invite session chairs</td>
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<tr>
<td>7.4</td>
<td>Prepare materials to be sent to participants prior to meeting</td>
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<td>7.5</td>
<td>Arrange to record the meeting</td>
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<tr>
<td>The face-to-face consensus meeting itself</td>
<td>8</td>
<td>Present and discuss results of pre-meeting activities and relevant evidence</td>
</tr>
<tr>
<td>8.1</td>
<td>Discuss the rationale for including items in the checklist</td>
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<tr>
<td>8.2</td>
<td>Discuss the development of a flow diagram</td>
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<tr>
<td>8.2</td>
<td>Discuss strategy for producing documents; identify who will be involved in which activities; discuss authorship</td>
<td></td>
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<tr>
<td>8.4</td>
<td>Discuss knowledge translation strategy</td>
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<tr>
<td>Post-meeting activities</td>
<td>9</td>
<td>Develop the guidance statement</td>
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<tr>
<td>9.1</td>
<td>Pilot test the checklist</td>
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<tr>
<td>10</td>
<td>Develop an explanatory document (R&amp;I)</td>
<td></td>
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<tr>
<td>11</td>
<td>Develop a publication strategy</td>
<td></td>
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<tr>
<td>11.1</td>
<td>Consider multiple and simultaneous publications</td>
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<tr>
<td>Post-publication activities</td>
<td>12</td>
<td>Seek and deal with feedback and criticism</td>
</tr>
<tr>
<td>13</td>
<td>Encourage guideline endorsement</td>
<td></td>
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<tr>
<td>14</td>
<td>Support adherence to the guideline</td>
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<tr>
<td>15</td>
<td>Evaluate the impact of the reporting guideline</td>
<td></td>
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<tr>
<td>16</td>
<td>Develop Web site</td>
<td></td>
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<tr>
<td>17</td>
<td>Translate guideline</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Update guideline</td>
<td></td>
</tr>
</tbody>
</table>
Five stages

- **Initial steps**
  - Seek relevant evidence on the quality of reporting in published research articles

- **Pre-meeting activities**
  - Conduct a Delphi exercise
  - Involve decision makers and patients

- **Face-to-face meeting**
  - Discuss the development of checklist (and flow diagram)

- **Post meeting activities**
  - Pilot test checklist
  - Publication

- **Post publication activities**
  - Develop a toolkit
Describing reporting guidelines for health research: a systematic review

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\textsuperscript{b}Research and Clinical Epidemiology, Canadian College of Naturopathic Medicine, Toronto, Ontario, Canada
\textsuperscript{c}Conway Medical Library, Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canada
\textsuperscript{d}Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom
\textsuperscript{e}Quantitative Sciences, Family Health International, Research Triangle Park, NC, USA
\textsuperscript{f}Department of Anesthesia, The Ottawa Hospital, Ottawa, Ontario, Canada
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Accepted 29 September 2010

Abstract

Objective: To describe the process of development, content, and methods of implementation of reporting guidelines for health research.

Study Design and Setting: A systematic review of publications describing health research reporting guidelines developed using consensus.

Results: Eighty-one reporting guidelines for health research were included in the review. The largest number of guidelines do not focus on a specific study type (n = 35; 43%), whereas those that do primarily refer to reporting of randomized controlled trials (n = 16; 20%). Most of the guidelines (n = 75; 94%) include a checklist of recommended reporting items, with a median of 21 checklist items (range: 5–61 items). Forty-seven (58%) reporting guidelines were classified as new guidance. Explanation documents were developed for 11 (14%) reporting guidelines. Reporting-guideline developers provided little information about the guideline development process. Developers of 50 (62%) reporting guidelines encouraged endorsement, most commonly by including guidelines in journal instructions to authors (n = 18; 36%).

Conclusions: Reporting-guideline developers need to endeavor to maximize the quality of their product. Recently developed guidance is likely to facilitate more robust guideline development. Journal editors can be more confident in endorsing reporting guidelines that have followed these approaches. © 2011 Elsevier Inc. All rights reserved.

Keywords: Systematic review; Reporting guidelines; Research methodology

1. Introduction

More than 60,000 articles are indexed monthly in PubMed, the United States National Library of Medicine’s public access portal to the health-related journal literature.

Given the large and growing volume of published articles, readers commonly find research reports that fail to provide a clear and transparent account of the methods and adequate reporting of the results. If authors do not provide sufficient details concerning the conduct of their study, readers

Financial disclosure: Funding support was obtained from the Canadian Institutes of Health Research (http://www.cihr-icr.gc.ca). Professor Altman is supported by Cancer Research UK. Dr Moher by a University of Ottawa Research Chair, and Dr Schulz by Family Health International. The funders had no role in study design, data collection, and analysis, decision to publish, or preparation of the manuscript. All researchers are independent from relevant funding agencies.

Author contributions: Dr Moher, Sampson, Altman, Schulz, Miller, Simera, Grimshaw, and Hoey contributed to the design and planning of the systematic review, including securing funding. Dr Weeks and Seely and Ms Ocampo conducted data screening and extraction and prepared the results, with assistance from Dr Moher. Dr Moher prepared the first draft of this manuscript, and all coauthors contributed to revised drafts and have approved this final version. Dr Moher is the guarantor.

Competing interests: Drs Moher, Schulz, Simera, Hoey, and Professor Altman are all members of the EQUATOR (Enhancing the QUality and Transparency Of Health Research) Network Steering Group.

* Corresponding author. Clinical Epidemiology Program, Ottawa Methods Centre, Ottawa Hospital Research Institute, The Ottawa Hospital, General Campus, Critical Care Wing, Fire Station Building, 661 Smyth Road, Ottawa, Ontario K1H 8L6, Canada. Tel.: 613-737-8899 ext. 79425; fax: 613-737-9230; e-mail: dmoher@obri.ca (D. Moher).

Moher D et al. JCE 2011; 64(7):718-42
Multiple journals versus a single one
  - Diversity of audience (multiple)
• Translation policy
• 5-10 minute Youtube for each item
• Link to bank of examples
• Link ‘appropriate’ creative commons licence
• More clearly outline optimal endorsement and implementation strategies for individual and group journals
  – Example letters
  – Example communication strategy across journals
Evolving format

Primary research question as the title

Informative sidebar outlines the program; PICOTS framework; and our group as the producer

“Key messages” section aims to summarize overall findings

Brief context, objectives, plus, a section on economic & policy implications

Reference to the disclaimer (versus full disclaimer upfront)
Specifics of PICOTS elements (in detail)

Key question(s)

Snapshot of evidence (literature search findings)

Abbreviations (front & centre)

PRIMSA Flow diagram (anchors the report)
Results:

Listed as ‘Summary of Findings:
- Aim is to limit text

For each key question the following are highlighted:

a) Evidence based identified (by study design; region)
b) Risk of bias assessment findings
c) Population

In tabular format, outcomes are listed alongside their findings

---

### Summary of Findings

**How do rapid-acting insulin analogues compare with short-acting insulin?**

**Evidence base:** 7 RCTs (n = 444; France, India and United States)\(^1\,^2\,^3\,^4\,^5\,^6\,^7\) and 1 Cohort Study (n = 35,049; United States)\(^8\)

**Risk of bias assessment:** RCTs - No obvious concerns but missing information precluded full assessment; Cohort – 8/9

**Population:** Type 1 or 2 DM; DKA

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycemic Control</td>
<td>Inconclusive (4 RCTs meta-analyzed and 1 large cohort study)</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>Inconclusive: Number of patients with hypoglycaemia (4 RCTs meta-analyzed and 1 large cohort study)</td>
</tr>
<tr>
<td></td>
<td>Inconclusive: Number of hypoglycaemic events (3 RCTs meta-analyzed)</td>
</tr>
<tr>
<td>Duration of Hospital Stay</td>
<td>Inconclusive (5 RCTs meta-analyzed) – favours analogue in subgroup of patients with Type 2 diabetes (non-DKA population) MD (days) = -1.06, 95% CI -1.22, -0.90</td>
</tr>
<tr>
<td></td>
<td>Favours analogue (1 large cohort study) MD (days) = -1.00, 95% CI -1.14, -0.86</td>
</tr>
<tr>
<td>Mortality</td>
<td>Zero events (4 RCTs)</td>
</tr>
<tr>
<td></td>
<td>Favours analogue (1 large cohort study): Crude RR = 0.44, 95% CI 0.39, 0.50</td>
</tr>
<tr>
<td>Postoperative Complications/Wound Infections</td>
<td>No evidence available</td>
</tr>
<tr>
<td>Utilization/Cost/CEA</td>
<td>Similar utilization patterns across treatment arms (7 RCTs)</td>
</tr>
<tr>
<td></td>
<td>Lower cost with Lispro SC vs. Regular IV for treatment of DKA (1 RCT) MD (S) = -1299.00, 95% CI -1843.40, -754.60</td>
</tr>
<tr>
<td></td>
<td>Lower cost with analogue vs. human bolus (1 large cohort study) Crude MD (S) = -12 197.00, 95% CI -13 084.92, -13309.08</td>
</tr>
</tbody>
</table>

*After adjustment for confounders, the lower bound reduction in duration of hospital stay was as low as 11 hours and as high as 21 hours.*

**How do basal-bolus analogues compare with basal-bolus insulin?**

**Evidence base:** 4 RCTs (n = 547; India and United States)\(^9\,^10\,^11\,^12\) and 1 Cohort Study (n = 22; United States)\(^1\)

**Risk of bias assessment:** RCTs – No obvious concerns but missing information precluded full assessment; Cohort – 4/9

**Population:** Type 2 DM with majority undergoing surgery; DKA; non-critically ill diabetic patients

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycemic Control</td>
<td>Favours analogue for treatment of DKA (1 RCT) MD (mmol/L) = -3.60, 95% CI -4.74, -2.46</td>
</tr>
<tr>
<td></td>
<td>Favours non-analogue when regular insulin is administered three times daily (1 RCT and 1 cohort)</td>
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<tr>
<td></td>
<td>Severe hyperglycaemia: 28.9% analogue vs. 12.9% non-analogue Values in target range (7.8-10 mmol/L): 24% analogue vs. 69% non-analogue</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>Inconclusive: Number of patients with hypoglycaemia (2 RCTs meta-analyzed) – favours analogue in subgroup of patients with DKA: RR = 0.36, 95% CI 0.14, 0.88</td>
</tr>
<tr>
<td></td>
<td>Inconclusive: Number of hypoglycaemic events (3 RCTs meta-analyzed) for &lt;2.2 or &lt; 2.8 mmol/L and 2 RCTs meta-analyzed for &lt;3.9 mmol/L or 2.2-3.8 mmol/L) – favours analogue in subgroup of patients with DKA: Rate Ratio = 0.35, 95% CI 0.16, 0.77</td>
</tr>
</tbody>
</table>
Brief summary of the methods used:
- searches; sources;
- eligibility criteria;
- screening/extraction methods;
- study types included; dates;
- risk of bias assessment

Acknowledgements

Collaborators

Additional documents available upon request

Report Citation information including authors

Shorter disclaimer
Effects of Performing Complex Pediatric Intracavitary (IC) Surgical Procedures in Specialized versus Non-specialized Centers in High Risk Children: Cochrane Response Rapid Review

Context
This review is being conducted as part of Cochrane Innovations Rapid Response program. The Children’s Hospital Association (CHA) has undertaken an initiative to develop a system of care for infants, children, adolescents and their families with surgical needs. The aim is to optimize outcomes by matching patient needs prospectively defined with appropriate resources, and by improving the coordination of care for surgical patients within a given region. As such, the CHA has requested a rapid review to assist in informing pediatric surgical initiatives. Findings from this exercise will inform the U.S. Task Force for Children’s Surgical Care discussions.

Objectives
CHA is interested in development of a rapid review that addresses the effects of performing certain pediatric surgical procedures in specialized centers. The population of interest would be children who are at high risk because of their age or co-morbidities, primary condition requiring surgery, or because the procedure they require is rarely performed or highly complex.

Key Messages
- From this rapid review of observational studies, the identified evidence signals that specialization compared with non-specialization may be generally effective for reducing mortality after pediatric cardiac surgery.
- For other outcomes and surgeries findings are ambiguous because:
  1. Results were inconsistent across studies (i.e., a mix of positive, negative, or non-significant findings); or
  2. There was a lack of clarity as to whether the results favored specialization, non-specialization, or showed equivalence of surgical services (i.e., the majority of studies were statistically non-significant)
- Given the potential shortcomings of the rapid review process, and the limitations of analyses from observational studies, conducting a full systematic review in order to confirm our findings may be warranted.

Policy Implications
- Given the findings with cardiac surgery, policy decision-makers need to determine whether to generalize these findings to other complex, high risk (non-cardiac) conditions in the pediatric population.
- Further investigation may be needed to determine if other ‘lower acuity’ conditions (e.g., appendicitis) requires surgical specialty care.

Disclaimer: While every effort has been made to reflect all scientific research available, this document may not fully do so. Please refer to the full disclaimer on pg. 12 for more information.
"It's come to my attention that you have a life outside the office."
Is PRISMA-P helpful when generating a RR protocol?
Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement

David Moher1*, Larissa Shamseer2, Mike Clarke3, Davina Ghersi4, Alessandro Liberati5, Mark Petticrew6, Paul Shekelle7, Lesley A Stewart8, and PRISMA-P Group

Abstract
Systematic reviews should build on a protocol that describes the rationale, hypotheses, and planned methods of the review; few reviews report whether a protocol exists. Detailed, well-described protocols can facilitate the understanding and appraisal of the review methods, as well as the detection of modifications to methods and selective reporting in completed reviews. We describe the development of a reporting guideline, the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols 2015 (PRISMA-P 2015). PRISMA-P consists of a 17-item checklist intended to facilitate the preparation and reporting of a robust protocol for the systematic review. Funders and those commissioning reviews might consider mandating the use of the checklist to facilitate the submission of relevant protocol information in funding applications. Similarly, peer reviewers and editors can use the guideline to gauge the completeness and transparency of a systematic review protocol submitted for publication in a journal or other medium.

Background
Systematic reviews are the reference standard for synthesizing evidence in health care because of their methodological rigor. They are used to support the development of clinical practice guidelines and inform clinical decision-making. They are becoming increasingly common; in 2010, 11 new reviews were estimated to be published daily [1]. Ideally, systematic reviews are based on pre-defined eligibility criteria and conducted according to a pre-defined methodological approach as outlined in an associated protocol.

The preparation of a protocol is an essential component of the systematic review process; it ensures that a systematic review is carefully planned and that what is planned is explicitly documented before the review starts, thus promoting consistent conduct by the review team, accountability, research integrity, and transparency of the eventual completed review. A protocol may also reduce arbitrariness in decision-making when extracting and using data from primary research, since planning provides an opportunity for the review team to anticipate potential problems. When clearly reported protocols are made available, they enable readers to identify deviations from planned methods in completed reviews and whether they bias the interpretation of a review results and conclusions. Bias related to the selective reporting of outcomes has been characterized as a serious problem in clinical research, including systematic reviews [2-7].

Until recently, systematic review protocols were generally available only through select organizations, such as The Cochrane [8] and Campbell Collaborations and the Joanna Briggs Institute, for which the preparation of a protocol is mandatory. Outside of these organizations, the existence of a protocol is infrequently reported in completed reviews [9,10]. Fewer than half of 300 systematic reviews indexed on MEDLINE in November 2004 (most recent generalizable sample; 2014 update underway) report working from a protocol [10], 80% of which are non-Cochrane affiliated. Of the non-Cochrane therapeutic reviews, only 11% mentioned the existence of a protocol [10]. The majority of reviews in health care are...
<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item #</th>
<th>Checklist Item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADMINISTRATIVE INFORMATION</strong></td>
<td>1a</td>
<td>Identify the report as a protocol of a systematic review</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>If the protocol is for an update of a previous systematic review, identify as such</td>
</tr>
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<td></td>
<td>2</td>
<td>If registered, provide the name of the registry (e.g., PROSPERO) and registration number</td>
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<tr>
<td></td>
<td>3a</td>
<td>Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author</td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Describe contributions of protocol authors and identify the guarantor of the review</td>
</tr>
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<td></td>
<td>4</td>
<td>If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td>5a</td>
<td>Indicate sources of financial or other support for the review</td>
</tr>
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<td></td>
<td>5b</td>
<td>Provide name for the review funder and/or sponsor</td>
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<tr>
<td></td>
<td>5c</td>
<td>Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td>6</td>
<td>Describe the rationale for the review in the context of what is already known</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICOS)</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Specify the study characteristics (e.g., PCO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review</td>
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<td></td>
<td>9</td>
<td>Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage</td>
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<td></td>
<td>10</td>
<td>Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be reproduced</td>
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<tr>
<td><strong>Study records</strong></td>
<td>11a</td>
<td>Describe the mechanisms that will be used to manage records and data throughout the review</td>
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<tr>
<td></td>
<td>11b</td>
<td>State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)</td>
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<tr>
<td></td>
<td>11c</td>
<td>Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators</td>
</tr>
<tr>
<td><strong>Data Items</strong></td>
<td>12</td>
<td>List and define all variables for which data will be sought (e.g., PCO items, funding sources), any preplanned data assumptions and simplifications</td>
</tr>
<tr>
<td><strong>Outcomes and prioritization</strong></td>
<td>13</td>
<td>List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale</td>
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<tr>
<td><strong>Risk of bias in individual studies</strong></td>
<td>14</td>
<td>Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis</td>
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<tr>
<td><strong>Data</strong></td>
<td>15a</td>
<td>Describe criteria under which study data will be quantitatively synthesized</td>
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<td></td>
<td>15b</td>
<td>If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I², Kendall's τa)</td>
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<td>15c</td>
<td>Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)</td>
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<td></td>
<td>15d</td>
<td>If quantitative synthesis is not appropriate, describe the type of summary planned</td>
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Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation

Larissa Shamseer 1, David Moher 1, Mike Clarke 2, Davina Ghersi 3, Alessandro Liberati (deceased) 4, Mark Petticrew 1, Paul Shekelle 2, Lesley A Stewart 3, the PRISMA-P Group

1Ottawa Hospital Research Institute and University of Ottawa, Canada; 2Queen’s University Belfast, Ireland; 3National Health and Medical Research Council, Australia; 4University of Modena, Italy; 5London School of Hygiene and Tropical Medicine, UK; 6Southern California Evidence-based Practice Center, USA; 7Centre for Reviews and Dissemination, University of York, UK

Introduction
Systematic reviews hold a unique place in healthcare. They help form the basis for developing practice guidelines and they provide information on gaps in knowledge, thus informing future research efforts. This information is relevant to stakeholders across the health system. The rigour and trustworthiness of systematic reviews is, in large part, based on the a priori planning and documentation of a methodological approach to conduct (that is, a protocol).

A systematic review protocol is important for several reasons: (1) it allows systematic reviewers to plan carefully and thereby anticipate potential problems; (2) it allows reviewers to explicitly document what is planned before they start their review, enabling others to compare the protocol and the completed review (that is, to identify selective reporting); (3) it provides a framework for managing data and evaluating results; (4) it allows reviewers to document the review process and its outcomes; and (5) it facilitates the publication of systematic reviews and their interpretation by other researchers.

The PRISMA-P 2015 checklist contains 17 items considered to be essential and minimum components of a systematic review or meta-analysis protocol. This PRISMA-P 2015 Explanation and Elaboration paper provides readers with a full understanding of and evidence about the necessity of each item as well as a model example from an existing published protocol. This paper should be read together with the PRISMA-P 2015 statement. Systematic review authors and assessors are strongly encouraged to make use of PRISMA-P when drafting and approving review protocols.
ADMINISTRATIVE INFORMATION

- **Title**
- **Identification**
  - 1a Identify the report as a protocol of a systematic review
- **Update**
  - 1b If the protocol is for an update of a previous systematic review, identify as such
- **Registration**
  - 2 If registered, provide the name of the registry (e.g., PROSPERO) and registration number
Eligibility criteria

- 8 Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review

- Information sources
  - 9 Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage

- Search strategy
  - 10 Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
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QUESTIONS