Summary with Critical Appraisal

Process

Updated: April 2015
Version 1.0
REVISION HISTORY

Periodically, this document will be revised as part of ongoing process improvement activities. The following version control table, as well the version number and date on the cover page, is to be updated when any updates or revisions are made.

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<tr>
<th>Section</th>
<th>Revision Number</th>
<th>Date</th>
<th>Description/Changes Made</th>
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<tr>
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<th>Full Form</th>
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<tr>
<td>AGREE II</td>
<td>Appraisal of Guidelines for Research and Evaluation II Instrument</td>
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<tr>
<td>CADTH</td>
<td>Canadian Agency for Drugs and Technologies in Health</td>
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<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>NIHR CRD</td>
<td>National Institute for Health Research, Centre for Reviews and Dissemination</td>
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<tr>
<td>QUADAS</td>
<td>Quality Assessment of Diagnostic Accuracy Studies</td>
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1. INTRODUCTION

1.1 About Product
CADTH’s Rapid Response Service offers Canadian health care decision-makers quick and efficient access to health technology information based on the best available evidence.

A Rapid Response Summary with Critical Appraisal is a written summary of the existing evidence on a topic that best addresses specific stakeholder research questions. For these reports, full-text documents are appraised using standardized, internationally recognized appraisal instruments such as AGREE II and QUADAS. The final report includes a summary of the evidence, study characteristics, and findings, as well as a brief statement on implications for decision- or policy-making. In exceptional circumstances, or if requested, a Summary with Critical Appraisal may be externally peer-reviewed, and if so, this will be clearly marked in the report heading as a “Peer-reviewed summary with critical appraisal”.

1.2 Scope
Topics suitable for Rapid Response Reports include evaluations of medical, surgical and dental technologies, such as:

- drugs
- devices
- diagnostic tests
- medical, surgical, and dental procedures.

Please talk to the Liaison Officer in your jurisdiction to clarify if a topic is suitable for Rapid Response, or if it is better suited to another product line offered by CADTH.

1.3 Audience

1.3.1 Primary Audience
Decision-makers from participating* Canadian publicly funded health care jurisdictions are eligible to request a Rapid Response Report from CADTH. These include the following stakeholders:

- federal, provincial, and territorial health ministries
- health authorities
- hospitals
- national health care programs and regional health care programs.

* Quebec and Ontario do not participate in CADTH’s Rapid Response service.

Rapid Response requests are made in confidence, and no identifying information is included when the reports are made public on cadth.ca.
1.3.2 Secondary Audience
Anyone can access and review published Rapid Response Reports (including Summaries with Critical Appraisal), which are freely available at cadth.ca.

1.4 Purpose and Application for Decision-Making
The purpose of a Summary with Critical Appraisal is to quickly identify, appraise, and summarize existing evidence on specific health topics to provide evidence-based support to policy and health care decision-makers. This product is particularly useful for providing an overview of the existing evidence on a topic and a brief background of possible implications for decision-making. When externally peer reviewed, Summary with Critical Appraisals also provide the context that external reviewers with expertise in the topic area can bring to the report.

While Summary with Critical Appraisal reports summarize available existing evidence, they should not be construed as a recommendation for or against the use of a particular health technology, nor are they intended to replace professional medical advice. Readers are also cautioned that a lack of good-quality evidence does not necessarily mean a lack of effectiveness, particularly in the case of new and emerging health technologies, for which little information can be found but which may, in future, prove to be effective.

1.5 Transparency
CADTH is committed to being as transparent as possible, while still meeting the demanding timelines inherent in the Rapid Response Service. Each Summary with Critical Appraisal includes the research questions, selection criteria, selection of included studies, as well as the methods and appraisal tools used. For reports entitled “Peer-reviewed summary with critical appraisal,” drafts are externally reviewed by a content expert and feedback is addressed. Timelines do not allow for stakeholder feedback during the production process for Summary with Critical Appraisal reports.

The evidence evaluated for possible inclusion in a Summary with Critical Appraisal is identified by CADTH using all reasonable efforts, within time constraints. The following are the main avenues used to identify evidence for these reports:

- Published literature is identified by searching major biomedical bibliographic databases.
- Grey literature (literature that is not commercially published) is identified by searching Canadian and major international health technology assessment agency websites, as well as by undertaking a focused Internet search.

Rapid Response Reports are made freely available on cadth.ca but in exceptional circumstances, embargo periods may be considered. All drafts, search strategies, and working documents used to produce Rapid Response Reports are archived for 15 years, and may be requested if required, with the exception of copyright-protected documents and information provided in confidence by customers, manufacturers, and other agencies.
### 1.6 Timelines

*Exact timelines will be negotiated between a CADTH representative and the customer at the time of topic refinement.*

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Deliverables</th>
<th>Approximate turnaround time</th>
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<tbody>
<tr>
<td>Summary with Critical Appraisal</td>
<td>Customer contacted</td>
<td>48 hours from submission of request <em>(depending upon customer availability)</em></td>
</tr>
<tr>
<td></td>
<td>Report Finalized</td>
<td>30 business days from point of topic refinement.</td>
</tr>
<tr>
<td>Peer-Reviewed Summary with Critical Appraisal</td>
<td>Customer contacted</td>
<td>48 hours from submission of request <em>(depending upon customer availability)</em></td>
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<tr>
<td></td>
<td>Report Finalized</td>
<td>2 to 3 months from point of topic refinement.</td>
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### 1.7 Roles and Responsibilities

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<thead>
<tr>
<th>Product Type &amp; Peer-Reviewed Summary with Critical Appraisal</th>
<th>Role</th>
<th>Responsibilities</th>
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<tbody>
<tr>
<td></td>
<td>Liaison Officer</td>
<td>Submits Rapid Response requests on behalf of the customer, facilitates knowledge mobilization and uptake of CADTH products, and gathers evaluation and impact data on completed reports.</td>
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<tr>
<td></td>
<td>Topic Refiner</td>
<td>Reviews request and follows up with customer to refine research questions and information needs.</td>
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<tr>
<td></td>
<td>Project Coordinator</td>
<td>Monitors timelines and deliverables and coordinates the following: • peer reviews <em>(if report externally reviewed)</em></td>
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<td></td>
<td>Information Specialist</td>
<td>Conducts literature search, writes search methods, and ensures reference citations are accurate and follow Citing Medicine standards. Assigns medical subject headings and keywords to document metadata.</td>
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<tr>
<td></td>
<td>Information Technician</td>
<td>Retrieves selected references and delivers the full text to authors according to CADTH's Access Copyright licence terms.</td>
</tr>
<tr>
<td></td>
<td>Author</td>
<td>Screens literature, selects and evaluates evidence, drafts report, addresses review comments (both internal and, if required, external) and makes revisions when needed.</td>
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<td></td>
<td>Internal Reviewer</td>
<td>Reviews draft, suggests or makes revisions, and provides final sign-off on the report.</td>
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<td></td>
<td>Peer-Reviewed</td>
<td>As the external content expert on the particular health technology</td>
</tr>
<tr>
<td>Product Type</td>
<td>Role</td>
<td>Responsibilities</td>
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</tr>
<tr>
<td>Summary with Critical Appraisal</td>
<td>Reviewer</td>
<td>being evaluated, he or she reviews the draft report and suggests revisions when required.</td>
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<tr>
<td></td>
<td>Internal Reviewer</td>
<td>Reviews external comments and ensures that they have been addressed appropriately.</td>
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</tbody>
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All Rapid Response products are supported by CADTH’s publishing and Web teams.
2. PROCESS

2.1. Flow Chart

*Ctrl click* on individual processes for details

- Request Submitted Independently
- Topic Identification
- Is Question in Scope and Needed?
  - YES: Request Refined
  - NO: Request Does Not Proceed
- Director Approval?
  - YES: Literature Search
  - NO: Final Draft (if peer-reviewed)
  - NO: Literature Screening & Appraisal
- Report Drafted
- Internal Review
- Revisions?
  - YES: All Drafts
  - NO: Final Draft
- Report Finalized
- External Peer-Review *Optional
  - YES: Report Posted on cadth.ca
  - NO: Evaluation
- Report Delivered to Customer

Flow Chart Legend
- Process =
- Decision Point =
- Document =
- Start/End =

*Externally peer-reviewed in exceptional circumstances or if requested.*
**Detailed Processes**

### 2.1.1. Topic Identification

Topics for Rapid Response Reports are submitted by decision-makers in Canadian publically funded health care organizations (see “1.3 Audience”). Submissions are made by contacting a CADTH Liaison Officer or by independently submitting a request on cadth.ca. Topics can also be suggested by CADTH’s Program Development Office in conjunction with stakeholder feedback.

#### 2.1.2. Request Refined

CADTH contacts the customer within 48 hours of receiving the request (depending upon customer availability). A Topic Refiner follows up with the customer to obtain additional details to ensure that the request, needs, and research questions are clearly understood. Before starting a project, CADTH confirms the research questions to be addressed, how the information will be used, and when the information is required in order to most effectively support health care and policy decisions. If the topic is not suitable for a Rapid Response request (see “1.2 Scope”), or the Topic Refiner is able to identify a previously published report that answers the customer’s research needs, the request does not proceed.

#### 2.1.3. Engage External Peer Reviewer (Optional)

If an external peer review is requested or required, a Clinical Research Manager identifies and contacts potential external reviewers with expertise in the topic area or subject matter. The Project Coordinator arranges the engagement of the reviewer and ensures that a conflict of interest form is filled out.

#### 2.1.4. Literature Search

A limited literature search is conducted on key resources, including PubMed, The Cochrane Library, NIHR Centre for Reviews and Dissemination (CRD) databases, and Canadian and major international health technology assessment agencies (UK, US, Australia, New Zealand). A focused Internet search is also conducted. All searches are limited to published English-language articles in the human population. A date range of five years is typically applied, however that range may be modified depending upon the amount of recent evidence identified. Rapid Response searches may also be limited by study design, including some or all of the following, as negotiated with the customer:

- systematic reviews, meta-analysis, or health technology assessments
- randomized controlled trials
- non-randomized studies
- economic evaluations
- evidence-based guidelines
- adverse events reports.

An overview of the literature search process is detailed in the Methods section of each individual Summary with Critical Appraisal.

From the terms used in the literature search, the Information Specialist assigns French and English medical subject headings and keywords to the document metadata to facilitate retrieval in both official languages once the document is posted on cadth.ca.
2.1.5. Report Drafted
Literature search results are screened by the author based on inclusion and exclusion criteria agreed upon with the customer. Once screened, selected references are sent to Information Technicians to retrieve full-text documents, as per CADTH’s Access Copyright licence terms. When the author receives the full-text documents they are appraised (when applicable) using standardized, internationally recognized appraisal instruments, such as AGREE II and QUADAS. Articles required for background information are also selected and read to help draft the Context and Policy Issues section of the report. Report examples can be found on cadth.ca.

2.1.6. Internal Review
Once the report is drafted, it is internally reviewed by the reviewer to ensure that all author requirements for a Summary with Critical Appraisal are followed. The reviewer also ensures that all the study types requested have been included and all research questions are addressed in the Conclusions and Implications for Decision- and Policy-Making section.

2.1.7. Revisions
The author addresses the reviewer’s comments and makes appropriate changes. When the reviewer is satisfied with the draft, it is sent to the Information Specialist to ensure citation details are accurate and references follow Citing Medicine bibliographic style guidelines. Both the reviewer and Information Specialist double-check that copyright guidelines were followed.

2.1.8. External Peer Review (Optional)
If an external peer review is requested or required, the Project Coordinator sends the internally reviewed draft to the previously identified external reviewer (see “2.1.3 Engage External Peer Reviewer”) for feedback. Comments from the external reviewer are forwarded to the internal reviewer, who reads the feedback and discusses required revisions with the author. The disposition form is filled out by the author to document feedback and CADTH’s response. The internal reviewer confirms that external feedback has been accurately addressed and documented. The reviewed draft is sent to the Information Specialist to ensure citation details are accurate and references follow Citing Medicine bibliographic style guidelines. Both the reviewer and Information Specialist check that copyright guidelines were followed.

2.1.9. Report Finalized
Once the report is finalized it is sent to the customer and posted to cadth.ca. Occasionally, if requested, knowledge mobilization tools such as “reports in brief” are created to help disseminate findings.

2.1.10. Evaluation
The Liaison Officer for the jurisdiction follows up with the customer to obtain feedback. All evaluation data is entered into the Rapid Response database and is shared with project team members, including the Rapid Response Manager, to inform lessons learned.