3. Summarize and Assess Evidence for Each Outcome

Notes:

- Data from studies must be abstracted for each important outcome for an intervention. It is recommended that up to 7 outcomes (including both benefits and harms) be included for any comparison of interventions or exposures.
- Ideally abstracted data will come from high quality systematic reviews and meta-analyses, but may also come from primary studies if a systematic review is not available or if more recent primary research has been published.
- It is likely that not all studies in a systematic review will provide evidence for each pre-selected outcome; therefore abstract only the data related to the important outcome(s) identified. For example, the figure below shows that in this sample systematic review, the first study (S1) provides evidence for outcomes 1 and 2 (OC1, OC2); the second study (S2) provides evidence for the first 3 outcomes, etc. (2). Primary studies may provide evidence for different outcomes; therefore you should abstract all of the data from primary studies related to the outcome. For example, an RCT may provide evidence for benefits and a non-randomized study may provide evidence for rare adverse effects.

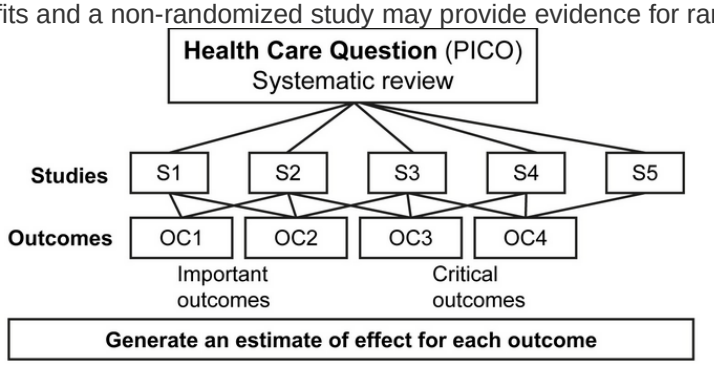

Figure – GRADE process of summarizing evidence based on outcomes – adapted from (2)

3.1 Abstract Data

1. Use the *Data Abstraction Spreadsheet* created in Excel (in Dropbox – PEN GRADE Process – Tools: PEN Data Abstraction Spreadsheet.xlsx). In the data abstraction workbook, there are separate excel sheets: one for randomized controlled trials (RCTs) and one for non-randomized studies (NRS).
2. Set up the Data Abstraction Spreadsheet by listing each outcome for the intervention/exposure identified for the PICO practice question (PQ).
3. For each PQ, if you have multiple systematic reviews (SRs), choose only one systematic review for each outcome (i.e. select the highest quality, or the one that most closely represents your PICO). Report the data as shown in the systematic review (e.g. pooled results or a narrative description of results if a meta-analysis was not done). It is generally not necessary to go to the primary studies included in SRs unless a risk of bias assessment was not conducted.
4. Under each Outcome, the minimum data abstracted should include: Study identifier (author, year), Participants and Results. Risk of bias will also be assessed with relevant tools (see section 3.2) and entered onto the Data Abstraction Spreadsheet.
5. Additional columns can be added to the spreadsheet to describe other study information but it is important to limit the amount of text describing the studies, and focus on objective, numerical data. Sometimes studies will not provide numbers for results, and instead report only significant changes. This should be recorded in the Comments as the information will be used to summarize the overall effect, e.g. *data from 4 studies were not pooled together since data was not available, but 3 showed improvement in cholesterol and 1 reported no difference.*
6. Study identification information from one publication can be copied into other rows if it provides data on more than one outcome.

7. References will not be included in the Data Abstraction Spreadsheet. References for SRs and primary studies should be cited on a separate document. See PEN Style Guide for formatting and acceptable reference style.

3.2 Assess Risk of Bias Within Studies

Notes:

The Data Abstraction Spreadsheet includes columns to document risk of bias for each domain, represented as: L for low, H for high, U for unclear.

- If a systematic review has assessed risk of bias of included studies, this information can be reported as such in the risk of bias domain headings on the Data Abstraction Spreadsheet. If a different risk of bias tool was used, record the name of the tool and indicate the overall risk of bias.
- For SRs and studies that have not assessed risk of bias, use the following tools to evaluate risk of bias and record the results on the Data Abstraction Spreadsheet under each domain heading (Comment: Abstracts are prone to selective reporting and it isn't usually possible to assess for risks of bias in abstracts, so if included, weight them less in the assessment):

Tools to evaluate risk of bias:

- For RCTs – Use the *Cochrane Risk of Bias Tool for RCTs*; (in Dropbox – PEN GRADE Process – Tools: Cochrane Risk of Bias Tool for RCTs.docx)
- For NRS – Use the *PEN version of the GRADE Risk of Bias assessment of NRS* (in Dropbox – PEN GRADE Process – Tools: PEN version ROB_NRSI tool.docx)

3.3 Recommended Resources / Readings for Assessing Risk of Bias

- GRADE training module: 'Assessing risk of bias': http://cebgrade.mcmaster.ca/index.html