PCORI Methodology Standards: Academic Curriculum
Module 6: Step 4—Extract Data

Category 11: Systematic Reviews

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Presented by Eric Bass, MD, MPH
Step 4: Extract Data

- Study characteristics
  - Population
  - Interventions and comparisons
  - Outcome measurement methods
  - Timing and setting

- Study results
  - Pertinent to key question(s)

- Study methods
  - Features that could influence outcomes
# Checklist of Items to Consider Extracting

- **Source**
  - Study and report ID
  - Reviewer ID

- **Eligibility**
  - Reasons for exclusion

- **Methods**
  - Study design and duration
  - Sequence generation, blinding, etc.

- **Participants**
  - Number
  - Demographics
  - Diagnostic criteria and comorbidity

- **Interventions**
  - Number of groups
  - Intervention details
  - Fidelity

- **Outcome measurement**
  - Definition, unit of measurement

- **Results**
  - Number of participants in each group
  - Summary data for each group

- **Miscellaneous**
  - Funding source
  - References to other studies

Outline expected tables (study features, risk of bias, outcomes) and figures (study selection, forest plots)

Identify data elements, group them, identify best way to extract each

Develop and pilot test extraction forms for expected reporting formats

Train data extractors and prepare plan to monitor data quality

Export and clean data for analysis

Elements of a Well-Specified Outcome

- **Domain** (e.g., anxiety)
- **Measurement type** (e.g., rating scale)
- **Metric** (e.g., change from baseline)
- **Aggregation method** (e.g., mean)
- **Time points** (e.g., 3 months)

Systematic review software versus database software versus simple tables

- Consider complexity, consistency, and completeness of data
- Beware of using spreadsheets
- Electronic forms make it easier to process data
- Systematic review software is usually best for large-scale reviews or reviews that will need updating
- Look for innovations in data management
Potential Causes of Bias and Error in Extracting Data

- **Bias**
  - Reporting bias
  - Data dredging
  - Extractor influenced by conflict of interest

- **Error**
  - Sloppy or inconsistent reporting of results
  - Imperfect fit between study report and extraction form
  - Careless or rushed extraction
  - Inadequate training and auditing
Quality Control Issues in Data Extraction

<table>
<thead>
<tr>
<th></th>
<th>Minimal experience</th>
<th>Moderate experience</th>
<th>Substantial experience</th>
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</thead>
<tbody>
<tr>
<td>Total errors</td>
<td>30%</td>
<td>30%</td>
<td>29%</td>
</tr>
<tr>
<td>Errors of omission</td>
<td>12%</td>
<td>16%</td>
<td>14%</td>
</tr>
<tr>
<td>Errors of inaccuracy</td>
<td>18%</td>
<td>14%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Replication of Study-Specific Standardized Mean Differences

- Calculated standardized mean differences (SMDs) differed from that of authors by ≥0.1 for point estimate or 95% CI for at least one of two selected trials

<table>
<thead>
<tr>
<th>Meta-analysis</th>
<th>Trial</th>
<th>Trial SMD (95% CI)</th>
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<tbody>
<tr>
<td>Brosseau, et al., 2004</td>
<td>Steil, et al., 1992</td>
<td>Reported -1.04 (-1.75 to -0.33)</td>
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<tr>
<td></td>
<td></td>
<td>Recalculated -1.23 (-1.96 to -0.50)</td>
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<tr>
<td>Bülow, et al., 1994</td>
<td></td>
<td>Reported 0.20 (-0.14 to 0.75)</td>
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<td></td>
<td>Recalculated -0.30 (-1.04 to 0.43)</td>
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<tr>
<td>Edmonds, et al., 2004</td>
<td>Wearden, et al., 1998</td>
<td>Reported -0.05 (-0.56 to 0.46)</td>
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<td></td>
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<td>Recalculated -0.25 (-0.59 to 0.08)</td>
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<td>Powell, et al., 2001</td>
<td>Reported -1.54 (-2.09 to -0.98)</td>
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<td>Recalculated -1.66 (-2.11 to -1.20)</td>
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<td>Barclay-Goddard, et al., 2004</td>
<td>Sackley and Lincoln, 1997</td>
<td>Reported -0.54 (-1.35 to 0.26)</td>
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<td>Recalculated -0.42 (-1.21 to 0.38)</td>
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<td>Brady-Fryer, et al., 2004</td>
<td>Lander, et al., 1997</td>
<td>Reported -1.63 (-2.54 to -0.73)</td>
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<td>Chen and Liu, 2004</td>
<td>Roychowdhury, et al., 2002</td>
<td>Reported -0.21 (-0.96 to 0.54)</td>
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<td>den Boer, et al., 2004</td>
<td>Rosner, et al., 1999</td>
<td>Reported 0.06 (not stated)</td>
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<td>Frisina, et al., 2004</td>
<td>Richards, et al., 2000</td>
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<td>Hartling, et al., 2004</td>
<td>Abul-Ainine and Luyt, 2002</td>
<td>Reported -0.44 (-1.08 to 0.21)</td>
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<td>Patel, et al., 2004</td>
<td>Goebel, et al., 2000</td>
<td>Reported 0.79 (0.20 to 1.38)</td>
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<td>Recalculated -0.66 (-1.34 to 0.01)</td>
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<td>Ramakrishnan, et al., 2004</td>
<td>Lie, et al., 1993</td>
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</tbody>
</table>

What Can Be Done to Minimize Bias and Error in Data Extraction?

- Set priorities and resist temptation to extract too much

- Design forms with:
  - Clearly worded closed-ended questions
  - Options for “not applicable,” “can’t tell,” or “not reported”

- Dual review versus solo review
  - Dual review yields 22% fewer errors but requires 36% more time (Buscemi, et al., 2006)
  - Dual review could be independent or sequential

- Use early random sampling to estimate error rates
  - Discuss and adjudicate discrepancies!

- Keep good records of data extraction

■ **Standard 2.1: Establish a team with appropriate expertise and experience to conduct review**
  ► Include expertise in searching for relevant evidence

■ **Standard 2.3: Ensure user and stakeholder input as review is designed and conducted**
  ► Protect independence of team to make final decisions about design, analysis, and reporting

■ **Standard 2.4: Manage bias and conflict of interest for individuals providing input**
  ► Require individuals to disclose conflict of interest and professional or intellectual bias
  ► Exclude input from individuals whose conflict of interest or bias would diminish credibility in eyes of intended users
**Standard 2.6: Develop a systematic review protocol**

- Describe context and rationale for review from decision-making and research perspective
- Describe study screening and selection criteria (inclusion and exclusion)
- Describe which outcomes, time points, interventions and comparisons will be addressed
- Describe search strategy for identifying relevant evidence
- **Describe procedures for study selection and data extraction and how to identify and resolve disagreement between researchers in study selection and data extraction**
- Describe approach to critically appraising studies
- Describe method for evaluating body of evidence, including quantitative and qualitative synthesis
- Describe and justify planned analyses of differential treatment effects according to subgroups, how intervention is delivered, or how outcome measured
- Describe proposed timetable
**Standard 3.5: Manage data collection**

- At a minimum, use two or more researchers, working independently to extract quantitative and other critical data from each study.
- For other types of data, one person could extract data, while a second person independently checks for accuracy and completeness.
- Establish a fair process for resolving discrepancies (do not give final decision-making to the senior reviewer).
- Link publications from the same study to avoid including data more than once.
- Use standard data extraction forms developed for the specific review.
- Pilot-test the data extraction forms and process.

PCORI agrees that dual review is desirable, but fact-checking may be sufficient.

- Quality control is more important than dual review per se.