Module 5: Identifying Research Gaps

Category 1: Formulating Research Questions

Prepared by Zackary Berger, MD, PhD
Eric Bass, MD, MPH

Presented by Zackary Berger, MD, PhD
Identifying Research Gaps: Methodology

- Methodologies for research gaps overlap with literature reviews

- Tradeoffs between breadth, feasibility, and generalizability
  - For example, systematic review might not be appropriate if literature is lacking in high-quality studies

- “Scoping review” (e.g., Arksey and O’Malley, 2005)
  - Identifying the research question
  - Searching for relevant studies
  - Selecting studies
  - Charting the data
  - Collating, summarizing, and reporting the results
  - Consulting with stakeholders to inform or validate study findings

Identifying Research Gaps: Methodology

- Identify key questions for which evidence is of low quality

- Based on Cochrane reviews—e.g., whether ...
  - A recommendation for further research was made
  - Evidence was insufficient

- From insufficient evidence for given steps in care pathway

Identifying Research Gaps: Methodology

- Suggested framework of Robinson, et al. for reporting research gaps
  - PICOTS approach
  - Assess extent of gap
  - Characterize reason why gap exists

### Research Gaps Abstraction Worksheet

<table>
<thead>
<tr>
<th>Serial No.</th>
<th>Reason(s) for Gap*</th>
<th>Population (P)</th>
<th>Intervention (I)</th>
<th>Comparison (C)</th>
<th>Outcomes (O)</th>
<th>Setting (S)</th>
<th>Free Text of Gap</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example B</td>
<td></td>
<td>Women with gestational diabetes</td>
<td>Metformin</td>
<td>Any insulin</td>
<td>Neonatal hypoglycemia, NICU admissions</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Example D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>How should the physician assess asthma or bronchodilator responsiveness?</td>
<td></td>
</tr>
</tbody>
</table>

* Reasons for Gap:
A. Insufficient or imprecise information
B. Biased information
C. Inconsistency or unknown consistency
D. Not the right information.

Evaluating the Gap: Extent and Reasons

- Characterize gap using PICOTS elements (including setting)
- Identify the reason(s) why the gap exists
  - Insufficient or imprecise information
  - Biased information
  - Inconsistency or unknown consistency
  - Not the right information
- Reasons can be mapped to evidence grading systems
  - GRADE (Grading of Recommendations Assessment, Development, and Evaluation Work Group)
  - USPSTF (US Preventive Services Task Force)
  - SOE (strength of evidence; Agency for Healthcare Research and Quality Evidence-based Practice Center [EPC])
- A priori discussion can help consistency of grading

Characterizing Reason for Research Gaps: Insufficient or Imprecise Information

<table>
<thead>
<tr>
<th>EPC SOE</th>
<th>Precision is a required domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRADE</td>
<td>The GRADE Working Group advises decreasing the grade of the quality of the evidence if the data are “imprecise or sparse”</td>
</tr>
</tbody>
</table>
| USPSTF  | The following questions are considered while grading the evidence:  
|         | • “How many studies have been conducted that address the key question(s)?”  
|         | • “How large are the studies? (i.e., what is the precision of the evidence?)” |


Characterizing Reason for Research Gaps: Biased Information

<table>
<thead>
<tr>
<th>EPC SOE</th>
<th>Risk of bias is a required domain. It incorporates the elements of study design and aggregate quality of the studies under consideration.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRADE</td>
<td>Study quality and study design are key elements.</td>
</tr>
</tbody>
</table>
| USPSTF | The following questions are considered while grading the evidence:  
  - “To what extent are the existing studies of high quality? (i.e., what is the internal validity?)”  
  - “Do the studies have the appropriate research design to answer the key question(s)?” |


Characterizing Reason for Research Gaps: Inconsistency or Unknown Consistency; Not the Right Information

<table>
<thead>
<tr>
<th>EPC SOE</th>
<th><em>Applicability</em> is described as an “other pertinent issue.” <em>Directness</em> is a required domain. It also incorporates the element of surrogate versus clinical outcomes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRADE</td>
<td><em>Directness</em> is a key element, incorporating the elements of applicability and surrogate versus clinical outcomes.</td>
</tr>
</tbody>
</table>
| USPSTF  | The following question is considered while grading the evidence:  
- “To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)” |

*Consistency is part of all three grading systems*

Research Gaps, Example 1—Cardiac Resynchronization Therapy

- Systematic review of cardiac resynchronization therapy (CRT) in the elderly
  (Rickard et al., in preparation)
  - Population:
    - Patients with comorbidities excluded
    - Limited data on patients >85 years old
  - Comparator:
    - No head-to-head comparison of CRT-D (with defibrillator) versus CRT-P (with pacemaker only)
  - Outcomes:
    - Limited data on patient-reported outcomes

- Gaps from biased, incomplete, or nonexistent information

- Issue of limited generalizability
“Informed Consent and Methadone Management Plan: No study evaluated whether an informed consent process improves clinical outcomes, patient adherence to treatment, or patient satisfaction with regard to treatment of chronic pain or opioid dependence in patients prescribed methadone. No study evaluated effects of different educational strategies to inform patients about the indication for methadone treatment, goals of therapy, or availability of alternative therapies. No study evaluated clinical outcomes or patient satisfaction after instituting plans to monitor therapy, adjust doses, or manage potential adverse effects.”

“Initiation of Methadone: No study evaluated effects of different dosing strategies for initiation or titration of methadone on risk of harms. Evidence for recommended starting doses or titration of methadone is limited and based on expert opinion, conversion tables (with substantial variability in suggested conversion ratios) and previously published guidelines. Five retrospective studies found recent initiation of methadone use associated with increased risk of all-cause mortality. No study evaluated how quickly tolerance is lost after stopping methadone.”
Identify Research Gaps in Your Own Research Question

- Use the PICOTS framework or another framework here to identify research gaps in relevant domains

- Where are the gaps?

- What are the reasons for the gaps?

- How can your research question approach the gaps?