Setting Priorities in Clinical Research: Identification and Classification of Research Gaps from Evidence-based Guidelines

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What is a Research ‘Gap’?
A topic or area for which missing or inadequate information limits the ability of reviewers to reach a conclusion on a given question.

What is a Research ‘Need’?
A research gap which needs to be filled to help decision makers.

Note – Not all research gaps are research needs.

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Evidence-based Guidelines Development Cycle

- Systematic review and evaluation of evidence
- Development of recommendation statements
- Stakeholder feedback and refinement of recommendation statements
- Distribution and dissemination of guidelines
- Implementation of guidelines
- Assessment of guideline adherence and effectiveness
- Formation of multidisciplinary guideline development committee
- Definition of scope and refinement of questions
- Evaluation of need for updating or developing new guidelines
Potential for Use of Evidence-based Guidelines to Identify Research Gaps

- Multidisciplinary nature of guideline development committees
- Systematic consideration of evidence
- Explicit and transparent process

Objective

To pilot test a method to systematically identify and classify research gaps using evidence-based guidelines

Methods

Identification of Research Gaps
Audit of evidence-based guidelines developed by the Cystic Fibrosis Foundation to identify:

Topics with Insufficient Evidence
1. Topics for which recommendations could not be made
2. Topics for which consensus recommendations were made after consideration of evidence

Suggestions for Further Research
3. Topics specifically suggested by committees as "needing further research"

Methods (Contd.)

Classification of Research Gaps
(I) By type of management issue:

<table>
<thead>
<tr>
<th>Type of Management Issue</th>
<th>Definition / Examples</th>
<th>Typical Design of Study Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparative effectiveness</td>
<td>Comparisons of different interventions</td>
<td>Clinical trials</td>
</tr>
<tr>
<td>Long term effects / chronic interventions</td>
<td>Assessment of benefit of chronic treatment modalities</td>
<td>Observational studies</td>
</tr>
<tr>
<td>Implementation / Integration into practice</td>
<td>Order of treatment, individualization of treatments, etc.</td>
<td>Mixed – pragmatic trials; qualitative; QI</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>Specific diagnostic tests or specific clinical tests in the ongoing assessment of patients</td>
<td>Observational studies</td>
</tr>
</tbody>
</table>
### Methods (Contd.)

#### Classification of Research Gaps (Contd.)

(II) **By target population:**
- general cystic fibrosis (CF) population
- specific cystic fibrosis populations (e.g., asymptomatic, with nutritional/growth deficits, with acute pulmonary exacerbations)

(III) **By age:**
- any age group
- infants and children <6 years of age only
- older children (≥6 years), adolescents, and adults only
- adults only

### Results (Contd.)

Five evidence-based guidelines developed:

<table>
<thead>
<tr>
<th>Guideline Topic (Year of Publication)</th>
<th>Number of Original Questions</th>
<th>Overall Number of Statements*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Medications (2007)</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>Nutritional Management (2008)</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Airway Clearance Therapies (2009)</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Acute Pulmonary Exacerbations (2009)</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Care of Infants with Cystic Fibrosis (2009)</td>
<td>23</td>
<td>34</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>48</strong></td>
<td><strong>75</strong>*</td>
</tr>
</tbody>
</table>

*Includes - USPSTF grades A, B, C, D, and I; and Consensus statements made due to insufficient evidence

- 62 research gaps identified
- Median 6 per guideline (range 5 to 32)
Results (Contd.)

How Research Gaps Identified?

<table>
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<th>Evidence Basis of Recommendation Statements</th>
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<td>Acute Pulmonary Exacerbations (2009)</td>
</tr>
<tr>
<td>Care of Infants with CF (2009)</td>
</tr>
<tr>
<td>(34 statements)</td>
</tr>
</tbody>
</table>

Guideline Topic: (I) By type of management issue:

- Comparative effectiveness: 44 (71%)
- Long term effects / chronic interventions: 29 (47%)
- Implementation / integration into practice: 8 (13%)
- Clinical assessment: 6 (10%)

*Note – Where appropriate, research gaps were classified under more than one category.

Classification of Research Gaps

(i) By type of management issue:

- Comparative effectiveness: 44 (71%)
- Long term effects / chronic interventions: 29 (47%)
- Implementation / integration into practice: 8 (13%)
- Clinical assessment: 6 (10%)

*Note – Where appropriate, research gaps were classified under more than one category.

(ii) By target population:

- General cystic fibrosis (CF) population (40 research gaps, 65%)
- Specific CF populations (e.g., asymptomatic, with nutritional/growth deficits, with acute pulmonary exacerbations) (22 research gaps, 35%)

(iii) By age:

- Any age group: 20 research gaps, 32%
- Infants and children <6 years of age only: 34 research gaps, 55%
- Older children (≥6 years), adolescents, and adults only
- Adults only
Results (Contd.)

Explicitness of Research Gaps

Number of times specified:

- P – population – 53 research gaps (86%)
- I – intervention – 49 research gaps (79%)
- C – comparison – 4 research gaps (7%)
- O – outcome – 10 research gaps (16%)

Conclusions

- Total of 62 research gaps identified
- Median 6 (mean 10.3) research gaps identified from each guideline
- Majority of research gaps due to insufficient evidence
- Method successful in identifying research gaps
- Method may be applicable to other conditions

Limitations

- Small sample (5 evidence-based guidelines)
- Audit of published reports of guidelines
- Guidelines may not always address all the clinically relevant issues for a disease.

Process Outcomes

Time Taken
- On average, 3 days per guideline document

Challenges
- Characterization of gaps—only 7% had relevant comparisons
- “Further research needed” suggestions from committee members too general (difficult to characterize)
Future Directions

- Guideline committees should be explicit in stating future research needs

- Next step in current project - solicit input from CF community to prioritize identified research gaps

- Johns Hopkins University Evidence-based Practice Center (JHU EPC) project (AHRQ-funded) on identifying frameworks for the identification and presentation of research needs

Multi-step Process in Feedback of Research Needs to Stakeholders

1. Identify research gaps

2. Characterize gaps into standard and explicit format

3. Translate research gaps into research needs and prioritize them

4. Distribute and disseminate research needs to all stakeholders

Thank you!