

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'?

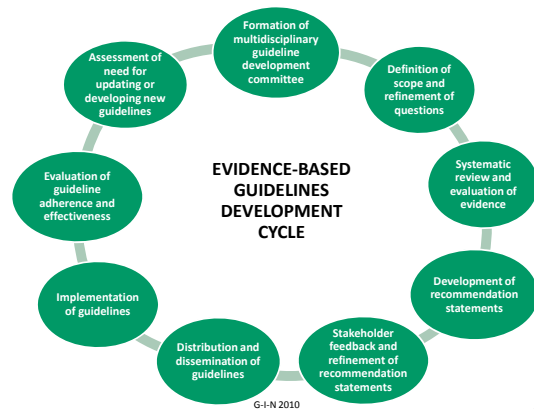
A research gap which needs to be filled to help decision makers.

Note – Not all research gaps are research needs.

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Evidence-based Guidelines Development Cycle



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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

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Objective

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

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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”

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Methods (Contd.)

Classification of Research Gaps

(I) By type of management issue:

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

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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

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Methods (Contd.)

Explicitness of Research Gaps

Research gaps assessed for number of times the following were specified:

- P – population
- I – intervention
- C – comparison
- O – outcome

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Results

Five evidence-based guidelines developed:

Guideline Topic (Year of Publication)	Number of Original Overall Questions	Overall Number of Statements*
Chronic Medications (2007)	5	17
Nutritional Management (2008)	4	10
Airway Clearance Therapies (2009)	8	4
Acute Pulmonary Exacerbations (2009)	10	10
Care of Infants with Cystic Fibrosis (2009)	21	34
TOTAL	48	75*

*Includes - USPSTF grades A, B, C, D, and I; and Consensus statements made due to insufficient evidence
 Excludes – Consensus statements made without evidence consideration (n=10) and registry data-based statements (n=4)

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Results (Contd.)

Number of Research Gaps

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

Guideline Topic (Year of Publication)	Number of Research Gaps
Chronic Medications (2007)	14
Nutritional Management (2008)	5
Airway Clearance Therapies (2009)	5
Acute Pulmonary Exacerbations (2009)	6
Care of Infants with Cystic Fibrosis (2009)	32
TOTAL	62

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Results (Contd.)

How Research Gaps Identified?

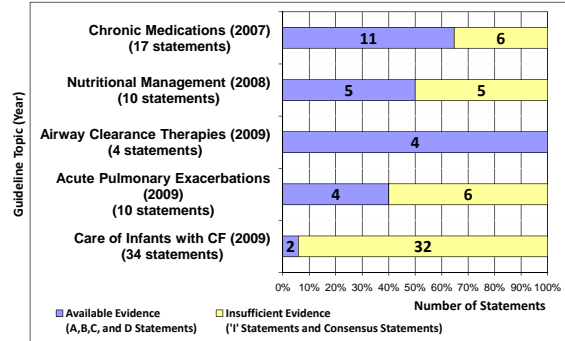
	Number (%) of Research Gaps
Insufficient Evidence	
1. Topics for which recommendations could not be made	22 (35%)
2. Topics for which consensus recommendations were made after evidence consideration	27 (44%)
Suggestions for Further Research	
3. Topics specifically suggested by committees as "needing further research"	13 (21%)
TOTAL	62

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Results (Contd.)

Evidence Basis of Recommendation Statements



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Results (Contd.)

Classification of Research Gaps

(I) By type of management issue:

Type of Management Issue	Number of Research Gaps*
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.

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Results (Contd.)

Classification of Research Gaps

(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

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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%**)

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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

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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.

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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)

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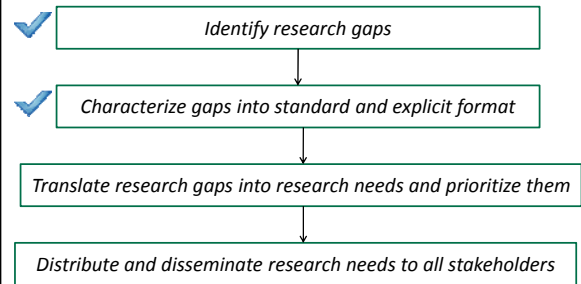
Future Directions

- 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

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Multi-step Process in Feedback of Research Needs to Stakeholders



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Thank you!