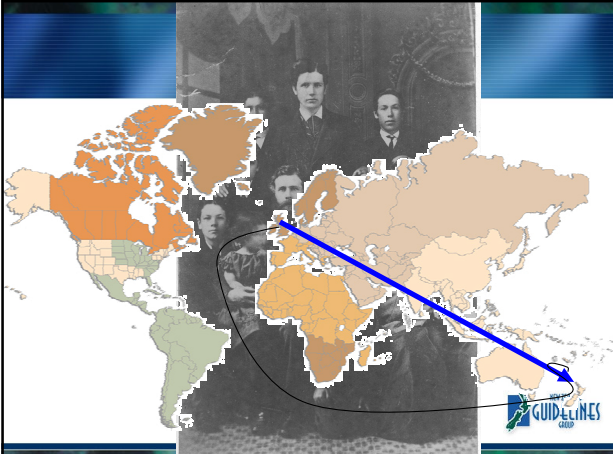



Promoting Effective Health and Disability Services


Guideline Development Methodology

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G-I-N Meeting
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Guideline Development Methodology

- International perspective
 - What is being done ?
- Steps in guideline methodology
 - Any evidence for what we do?
- What are the challenges ?
 - What could GIN do ?



History of Guideline Development

- Early guidelines
 - Consensus methods
 - Literature reviews not always systematic
 - Not many systematic reviews
- First evidence based guidelines
 - Searching for all the evidence
 - Systematic reviews
 - Recommendations linked to evidence
- Explicit evidence based guidelines
 - Benefits, harms and costs are presented



An International Perspective

- 19 guideline development programmes surveyed in 2000/2001
- 13 countries: UK, Spain, France, Italy, Netherlands, Finland, Germany, Sweden, Switzerland, Australia, Canada, NZ and the US

(Burgers 2002)



Reasons for guideline development

- Quality improvement of health care: 7
- Improving cost effective care: 6
- Supporting evidence based care: 6
- Contributing to more effective care: 3
(Burgers 2002)



Guideline Development Teams

- 10-20 members per team
- 3-5 disciplines per team
- Patient representatives: 11
- Methodological experts in most
- Permanent guideline staff: 14
(Burgers 2002)



Collection of Evidence

- Electronic
 - All programmes
- Handsearching
 - 14 programmes
- Patient registry data
 - 2 programmes
- Unpublished data
 - 4 programmes

(Burgers 2002)



Analysis of evidence

- Systematic reviews/metanalysis
 - 19 programmes
- Non systematic
 - 8 programmes
- Experienced based
 - 9 programmes
- Decision analysis
 - 3 programmes

(Burgers 2002)



Formulation of recommendations

- Evidence linked in most development programmes
 - Formal expert consensus in 8
 - Informal expert consensus in 13
(Burgers 2002)



Guideline Review Process

- Internal peer review: 11
- External peer review: 18
- Pilot testing: 4
(Burgers 2002)



The AGREE tool



- Provides a framework for assessing the quality of clinical guidelines
- Can be applied to guidelines in any disease area
- Can be used by: policy and decision makers, guideline producers



The Domains of the AGREE Tool

- 1 Scope & purpose
- 2 Stakeholder involvement
- 3 Scientific rigour
- 4 Clarity & presentation
- 5 Applicability
- 6 Editorial independence



Domain 3: Rigour of Development of Guideline

8. Systematic methods used to search for evidence.
9. The criteria for selecting the evidence are clearly described
10. The methods used for formulating the recommendations are clearly described
11. Health benefits, side-effects and risks considered when formulating the recommendations



Domain 3: Rigour of Development of Guideline

12. There is an explicit link between the recommendations and the supporting evidence.
13. External review of guideline by experts prior to publication.
14. Procedure for updating is described.



Steps in Guideline Development

1. Topic Identification
2. Suitability screen
3. Form a multidisciplinary working party
4. Formulate clinical questions
5. Identify evidence (internal and external)
6. Evaluate evidence
7. Develop balance sheet
8. Develop recommendations
9. Implementation and dissemination
10. Update (evaluate and improve)



1. Topic Identification

- What are the areas where there is a gap between the evidence and current practice ?
 - Health Status
 - Patient/Provider Satisfaction
 - Cost/Utilization
- The topic is complex and there is debate
- Implementation is feasible



2. Suitability Screens

- Does the project have a driver/owner?
- Is there evidence of a gap?
- Can we measure the proposed change?
- Is there a suitable guideline that could be identified?
- Is there adequate literature to make an evidence based decision about practice?
- How much effort would it take to close the gap?
- Is there a reasonable likelihood that we could implement the change?



3. Multidisciplinary team

- Clinicians
 - Primary and secondary care
 - Allied health care workers
- Consumers, patient representatives
- Epidemiologists
- Information experts
- Health economists
- Health managers



4. Developing clinical questions

- Well developed questions form the basis of the evidence-based guideline structure
- Focuses guideline team on important issues & the most relevant evidence
- Requires a structured approach (5 parts)
 - Patients
 - Exposure/Interventions
 - Comparison
 - Outcomes
 - Time



Framing a 5 part PECOT question

Participants	Exposure (eg. Cause, factor, Rx, disease)	Comparison	Outcome	Time
How would I describe a group of patients like mine?	Which main exposure am I considering?	What is the main alternative to compare with the exposure?	What can I hope to accomplish? What does this exposure affect?	Over what time period is it reasonable to expect an effect?



5. Identifying the evidence

- Comprehensive searching
- Avoid applying limitations to reduce publication bias
 - Non English studies included
 - Unpublished data sought
- Use PECOT framework to drive searching
- Also includes internal data



6. Evaluate the evidence

- Critical appraisal
 - Study quality checklists
- Develop evidence tables
 - Quantification
- Summarise outcomes



Scales for Quality Assessment?

- 35+ scales of composite scores published
- Generally agreed that they are not useful in differentiating high and low quality studies
- Better approach is to analyse the individual components of study quality
 - Blinding
 - Concealment of allocation
 - Intention to treat analysis



7. Balance sheets

- Benefits, harms (and costs) considered
 - for the current situation and if the guideline was implemented
- Not a full economic analysis
 - Simple analysis of projected costs if apply guideline
- Delivers the 'value' of the Guideline
 - Resource utilisation
- The 'final chapter' of an *explicit* evidence-based guideline



8. Developing the Recommendations and Algorithm

- Probably the part of the guideline most often read
- Considers applicability:
 - for whom will the intervention do more harm than good?
 - to whom should the recommended intervention be offered?
- Each recommendation should advise a course of action, followed by an indication of the strength of the recommendation



Considered judgment form*

For each clinical question:

- Volume of evidence
- Consistency of evidence
- Applicability of evidence
- Clinical impact of evidence
- Evidence Summary with levels/scores
- Recommendation with grade

*SIGN

9. Implementation & Dissemination and 10. Update

- Dissemination/Implementation
 - Increasingly electronic
- Target
 - Clinicians
 - Patients
 - Policy makers
- Update
 - Evaluation first (quality indicators?)



Steps in guideline development

	Systematic	Pragmatic	Evidence
Topic selection/SS	✓	✓	
M-D working party	✓	✓	
Clinical questions	✓	✓	?
Literature search	✓		✓ ✓
Critical appraisal	✓		✓
Balance sheets	✓	✓	?
Recommendations	✓	✓	?
Implementation			✓
Update		✓	✓?

Methodological Challenges in Guideline Development

- Incorporating patient preferences
- Dealing with uncertainty
- Grading levels of evidence/recommendations
- Adaptation of guidelines
- Updating of guidelines
- Incorporating quality indicators
- Electronic clinical decision support



Methodological Challenges in Guideline Development

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Patient preferences

- Research into barriers to successful guideline implementation
 - Patients don't want the recommended treatments
 - Patients want treatments not recommended by guidelines



How to get to patient preferences?

- Inclusion of consumer representatives on guideline development teams
- Formal surveys of patients opinions
- Focus groups to seek patient opinions on the clinical questions and implementation
- Decision analytic methods
- Qualitative approach



Example of need for more information on patient preferences

- Caesarean section: obstetricians report that pregnant women are asking for elective caesarean sections
- Survey data of women who had just given birth:
 - 50% of women felt that c-section was more convenient than normal birth
 - 30% felt that c-section was safer than normal birth
 - 15% were planning to ask for c-section in the future

(Australian data)



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Dealing with uncertainty

- If you need to make a recommendation when there is no evidence:
 - Consensus approach
 - Wide consultation
 - Be explicit about what we don't know
 - Advise need for more research
 - Caution



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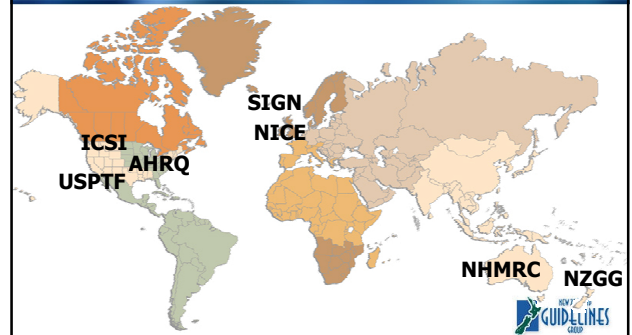


How to go from individual study components to a grade or level?

- Consistent and systematic approach needed
- Checklists, scores, individual study components?



Grading systems



Study design

Clinical Question

- Best treatment?
- Diagnosis
- Aetiology/risk factors
- Prediction and prognosis

Optimal Study Design

- RCT or SR
- Comparative study
- Cohort or case control
- Cohort or survival study



NZGG grading system for individual studies

Level of evidence	Assign scores that best fits*	Description of evidence/quality
+	Mostly ✓	Strong study with minimal bias
∅	Some ✓	OK - bias not likely to affect results
-	No or few ✓	Weak study with significant bias

* Using a checklist of ✓, ? X



The GRADE Project

- International group working on grading levels of evidence:

4 levels of quality

- High
 - Moderate
 - Low
 - Very low
- Lead by Andy Oxman and Gordon Guyatt



Grading systems for recommendations

2 tier approach:

1. Grade the *individual studies with the study design* (level of evidence - RCT+, SR \emptyset or COH+, 1++, 1+, 2++, 2+ etc)
2. Grade the *recommendations* based on the body of evidence (A, B, C etc)



NZGG Grading System

- A** Recommendation supported by **GOOD** (strong) evidence
- B** Recommendation supported by **FAIR** evidence
- C** Recommendation supported by **EXPERT OPINION** only
- I** No recommendation can be made - evidence is **INSUFFICIENT**



Taking evidence and turning it into recommendations

- Least systematic part of the process
- One persons evidence is another persons rubbish
- Group process requires skilled facilitation



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Potential Steps in Adapting Guidelines

1. Find guidelines
 - www.guideline.gov
 - HTA websites
 - GIN www.g-i-n.net
2. Appraise guideline
 - using the AGREE instrument



Steps in guideline adaptation

3. Analyse the content for scope and applicability
 - same health settings, professional groups
 - same patients, consumers
 - same interventions
 - same outcomes



Steps in adapting guidelines

4. Permission to use relevant parts
5. Look for the gaps
 - any clinical questions not covered
6. Look at sources of evidence
 - is the search strategy available?
 - any evidence tables?
 - links from evidence statements to references



Steps in guideline adaptation

7. Recommendations
 - are the recommendations valid and is the grading correct?
 - look at the controversial topics in particular
8. Re-run the search strategy
 - to include literature at least one year prior to the date of publishing
 - check if any large study would radically change the recommendations



Steps in guideline adaptation

9. Rewrite and regrade recommendations if necessary
 - what are the cultural and consumer issues particular to New Zealand?
 - are the practice points or grades appropriate?
10. Implementation
 - for the local circumstances



Methodological Challenges in Guideline Development

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Updating Guidelines

- Practitioners want up to date information
- AHRQ: research suggested that “as a general rule guidelines should be reassessed for validity every 3 years” (Shekelle 2001)



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Quality indicators

- Quality indicators are used for audit and evaluation
- Can they be used between countries?
 - US and UK indicators covering 18 conditions - 56% agreement (Marshall et al 2003)



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Electronic decision support

- Requires clear actionable statements from guideline developers
- How to integrate into the electronic medical record?
- How to deal with complexity and comorbidities of patients?



Potential for GIN Members to assist

- Harmonisation
 - Grading levels of evidence
 - Grading of recommendations
 - Quality indicators
- Assisting with the adaptation of guidelines
 - Avoiding duplication
 - “Globalise the evidence, localise the decisions”
- Anticipate AGREE assessments
 - Careful description of process and methodology (7 items)



