Principles of Evidence Based Clinical Guidelines (EBG)

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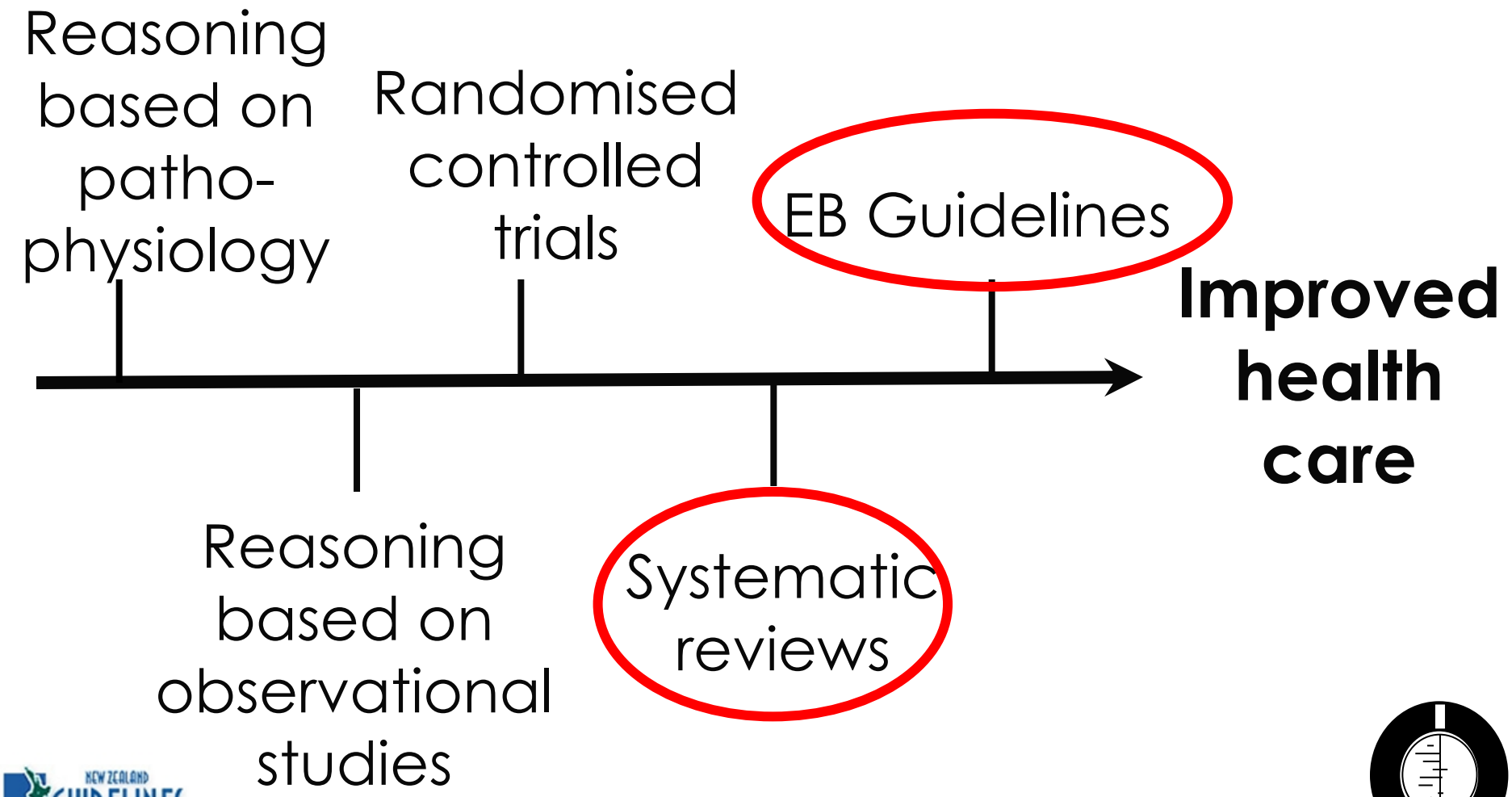
Outline

- Definition of evidence based guidelines (EBG)
- Purpose of EBG
- The AGREE guideline appraisal tool
- The New Zealand Guideline Group development process

Background to EB clinical guidelines

- EB clinical guidelines have grown from the evidence-based medicine movement.
- The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research.
- **Clinical guidelines have systematised this practice**

Moving towards evidence-based care



Definition of clinical guidelines

‘systematically developed statements to assist practitioner and patient **decisions** about appropriate health care for specific clinical circumstances’

guidelines are decision-aids

Purpose of clinical guidelines

- Guidelines contain recommendations (statements) for best practice, based on the systematic identification, selection and critical appraisal of the available evidence.
- **While it is intended that these recommendations should provide an evidence-based foundation for health care decision-making, they should not prescribe it**
- **Guidelines are recommendations, not rules**
- **The 80:20 rule**

Purpose of clinical guidelines

- it is intended that guidelines influence more than just the individual practitioner
- they seek to move practice in the more general sense, to close gaps between current and optimal practice, and
- **to improve the quality of health care, and decrease costs and utilisation**

What makes guidelines evidence-based?

- developed after systematic searching, selection & critical appraisal of information from literature
- includes strategies for describing strength of evidence
- clearly separates opinions from evidence
- focused on giving information on differences between different options, including benefits and harms
- should adhere to standards e.g. those set by the AGREE collaboration, which is an international collaboration of researchers and policy makers who seek to improve the quality and effectiveness of clinical practice guidelines.

AGREE (Appraisal of Guidelines for Research and Evaluation in Europe)

- Scope and purpose
- Stakeholder involvement
- Rigour of development
- Clarity of presentation
- Applicability
- Editorial independence

The AGREE criteria provide a set of principles for EB guidelines

Scope and purpose

1. The overall objective(s) of the guideline should be specifically described.
2. The clinical question(s) covered by the guideline should be specifically described.
3. The patients to whom the guideline is meant to apply should be specifically described.

should be very focused!

Stakeholder involvement

4. The guideline development group should include individuals from all the relevant professional groups.
5. The patients' views and preferences should be sought.

Not just specialists! (80:20 rule)

Rigour of development

6. Systematic methods should be used to search for evidence.
7. The criteria for selecting the evidence should be clearly described.
8. The methods used for formulating the recommendations should be clearly described.
9. The health benefits, side effects and risks should be considered in formulating the recommendations.
10. There should be an explicit link between the recommendations and the supporting evidence.
11. The guideline should be externally reviewed by experts prior to publication.
12. A procedure for updating the guideline should be provided.

explicit, transparent, systematic processes

Clarity of presentation

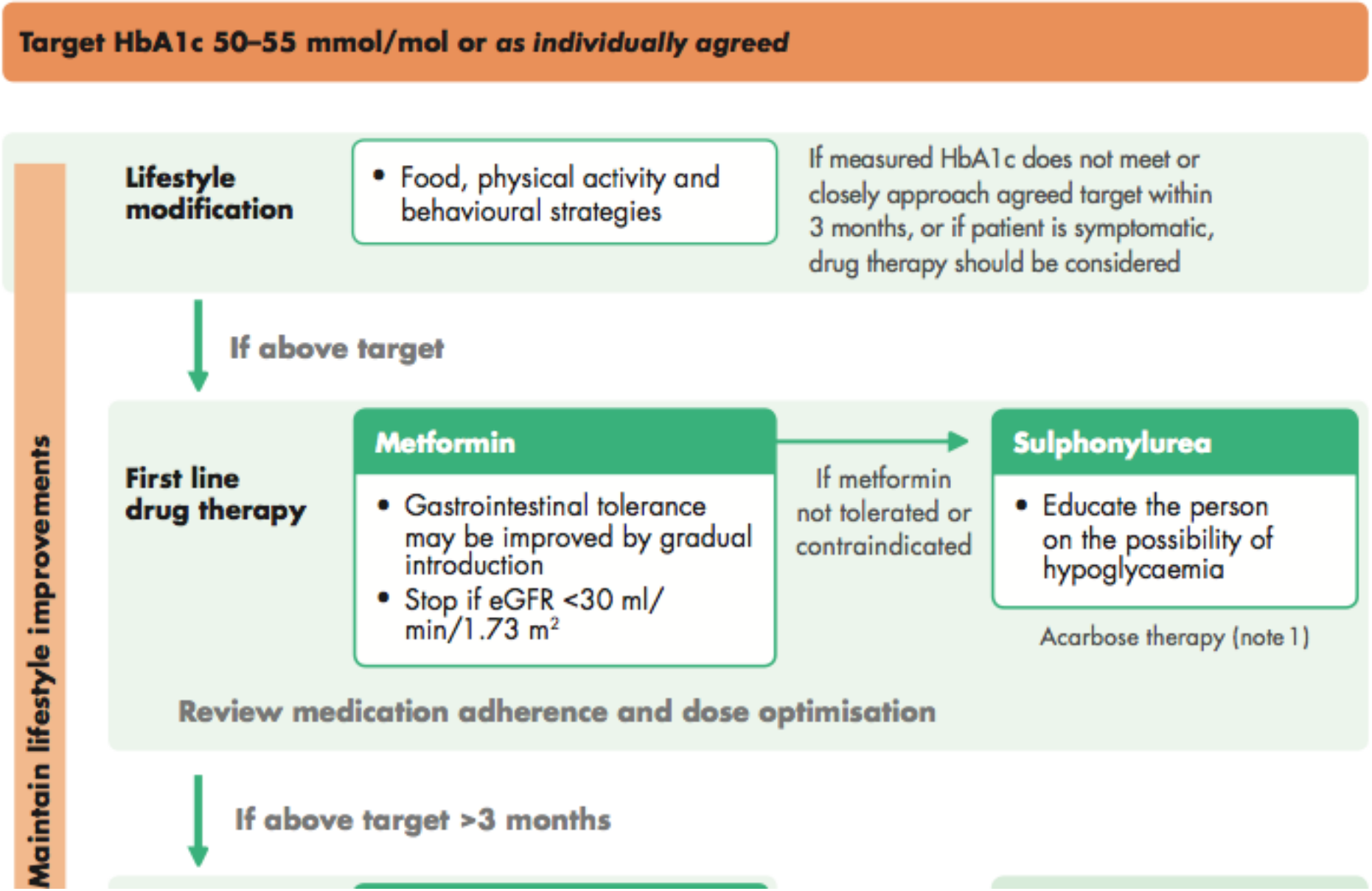
13. The recommendations should be specific and unambiguous.

14. The different options for diagnosis and/or treatment of the condition should be clearly presented.

15. Key recommendations should be easily identifiable.

present recommendations as decision algorithms

Figure 4 Management of glycaemic control



Applicability

16. target users should be clearly defined.

17. potential organisational barriers in applying the recommendations should be discussed.

18. potential cost implications of applying the recommendations should be considered.

19. guideline should be supported with tools for application.

20. guideline should present key review criteria for monitoring and audit purposes

21. guideline should be piloted among end users.

link development & implementation

Editorial independence

22. The guideline should be editorially independent from the funding body.

23. Conflicts of interest of guideline development members should be recorded.

beware of influence of vested interests!

The New Zealand Guideline Group (NZGG) development process

www.nzgg.org.nz

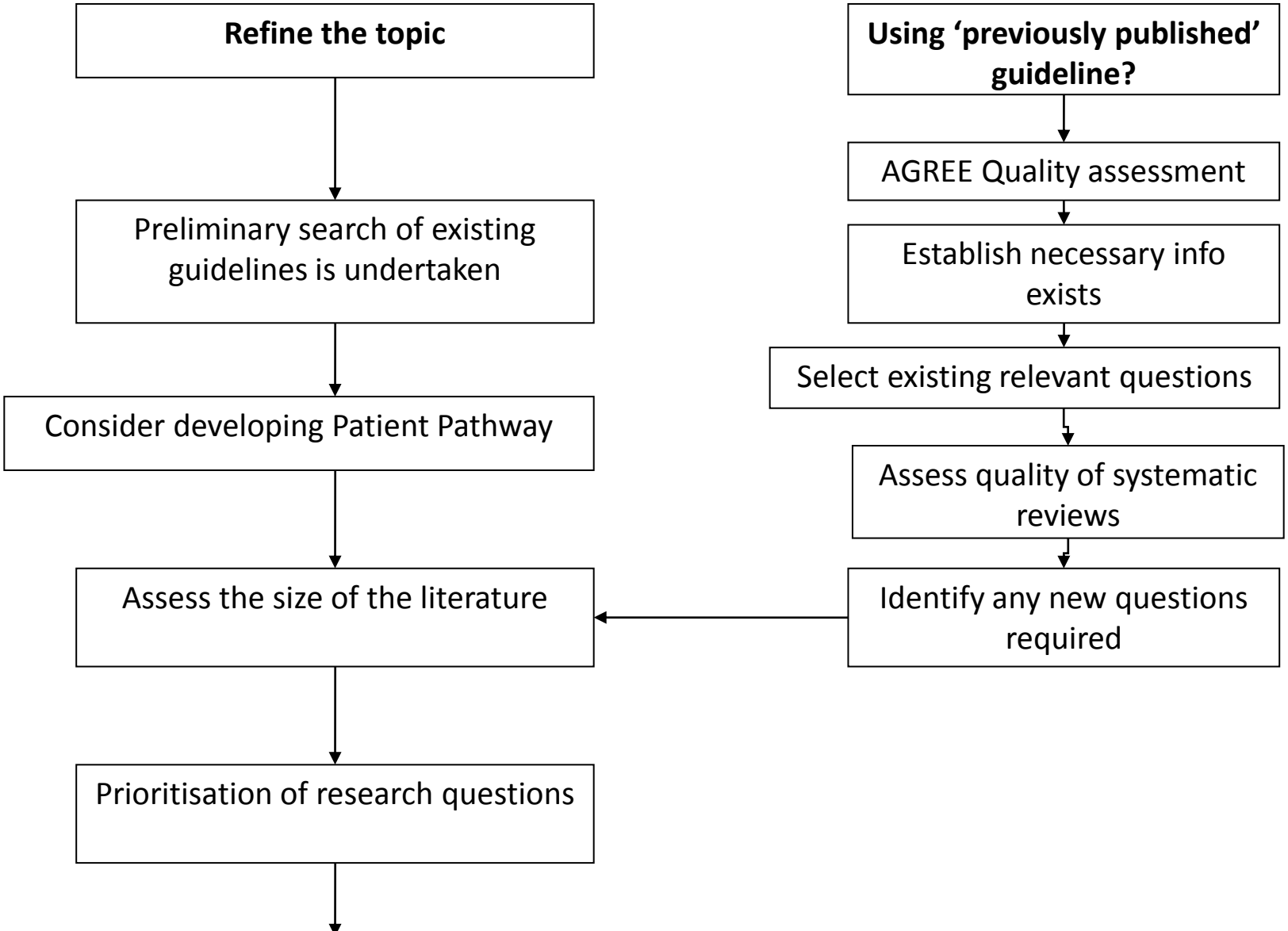
Ensuring the Topic is Appropriate for a Guideline

- A topic is appropriate for a guideline if documented evidence exists that there is a gap between the evidence and what is being currently practiced.
- This potential for ‘improvability’ must be present to ensure quality improvement programmes are effective

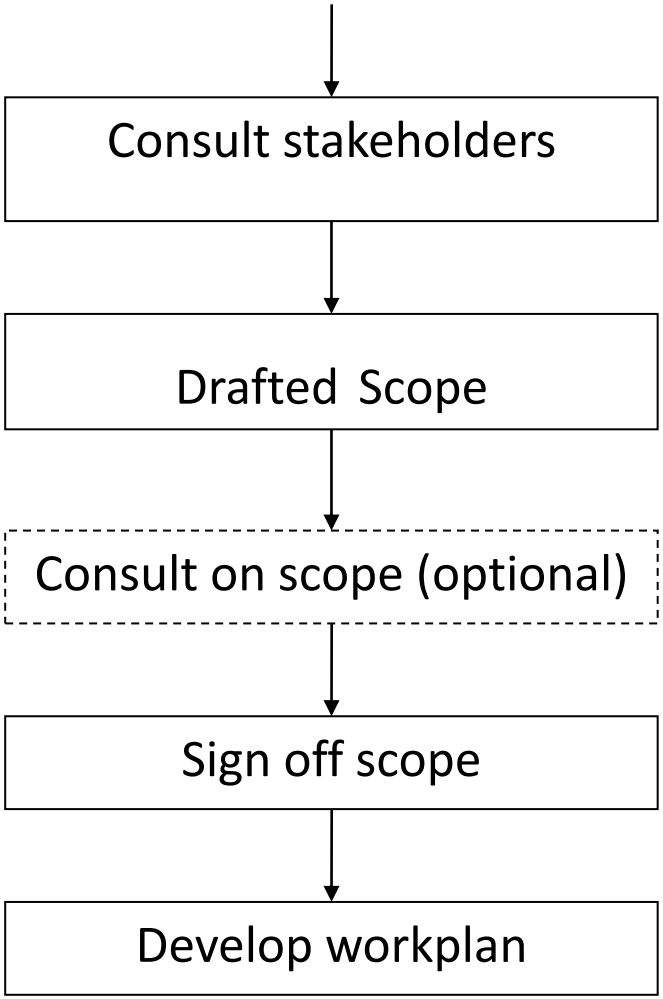
Scoping a Guideline and Developing a Work plan

- Development of a guideline's scope (the parameters of the topics and issues dealt with in the guideline) is informed by early development work called scoping
- Scoping is particularly focused on what is to be EXCLUDED from the guideline to make it manageable and relevant
- Results of the scoping phase are used to plan in detail the guideline work

Scoping


Refine the topic
Preliminary search of existing guidelines is undertaken
Consider developing Patient Pathway
Assess the size of the literature
Prioritisation of research questions
Using 'previously published' guideline?
AGREE Quality assessment
Establish necessary info exists
Select existing relevant questions
Assess quality of systematic reviews
Identify any new questions required

Scoping


Consult stakeholders
Drafted Scope
Consult on scope (optional)
Sign off scope
Develop workplan

Involving Consumers in Guideline Development

- Consumers are at the heart of all guidelines
- Consumer views should be represented on every guideline
- Consumer representatives need to have skills relevant to guideline development

Establishing the Guideline Development Team (GDT)

- The GDT contains representatives from a number of different disciplines, including methodologists
- The chair is selected after an interview
- A manageable group size is no more than 15 people
- The number of meetings is dependent upon the size of the guideline and ranges from four to eight over the course of the guideline

Function of a Guideline Development Team

The translation of the evidence into recommendations by GDT requires important judgments to be made about:

- the expected effects of the different options of care
- factors that might modify the impact of these options of care
- needs, risks and resources in the setting in which a recommendation is to be implemented
- ethical, political and legal constraints
- the balance between the expected benefits and harms

Developing Key Research Questions

Review questions direct the guideline

- Not all questions of interest can be researched due to time and budget constraints and the GDT will need to prioritise those of most importance
- 15–20 questions can be answered in a 2-year timeframe
- All review questions need to be in a PICO framework
- There is a difference between research review questions and implementation questions

Identifying and Selecting the Evidence

- A high quality literature search is essential in good guideline development
- A high quality literature search relies on the identification of all relevant search terms as well as the best study designs to answer each key clinical question
- Some studies are more susceptible to bias because of the way they are designed. A hierarchy of evidence is used to identify which study designs will best answer each key question while reducing the likelihood of bias
- The hierarchy of evidence is then used to select studies from the identified body of evidence and these are appraised by the researchers

Assessing & Summarising the Evidence

- Assessment of evidence must be objective and systematic
- Standardised appraisal checklists & evidence tables are used
- A level of evidence is assigned to each study based on how well the design eliminates bias
- Different quality checklists are used for different study designs
- Characteristics of the studies are summarised in evidence tables
- The whole evidence base for each key question is summarised by NZGG researchers of the GDT to facilitate the development of recommendations
- Where a high quality systematic review is identified for use, the individual studies contained in that review will not be individually appraised

Developing Recommendations

- Good recommendations are a combination of an interpretation of the evidence base and clinical judgment
- A clinically useful recommendation depends on the judgment and experience of the GDT
- Some people only read the recommendations so they must be clearly stated and easily understood without reference to supporting text
- Strength of the recommendation is indicated by a grading system that is based on the level and quality of the evidence reviewed
- Guidelines are only effective if they are used so recommendations must be relevant and practical

Writing the guideline

- Guidelines contain brief reviews of the pertinent evidence with recommendations; they are not textbooks for treatment
- NZGG follows a standard guideline structure (with a few exceptions)
- There are eight main sections to a guideline document
- NZGG guidelines are written by NZGG Staff with contributions from others

Structure of guideline

An NZGG guideline consists of eight main parts in the following order:

1. Introduction
2. Key messages, algorithms and summary of recommendations
3. Background (where relevant)
4. Evidence reviews: summary and recommendations
5. Implementation Issues
6. General section (includes relevant tools etc)
7. Guideline development process (includes the GDT, the methods and review questions)
8. Appendices (including glossary)

Consultation and Peer Review

- All major guidelines require a public consultation
- There are some stakeholders from whom it is more important to seek feedback and these groups are termed the ‘Key Stakeholders’
- All guidelines will have a professional peer review completed during the consultation phase

Presentation & Dissemination of a guideline

- Following recommendation development there are activities that are undertaken to improve the presentation and usability of a guideline
- Most NZGG guidelines are published as a full guideline with subsidiary documents (e.g. consumer and practitioner summaries)
- Dissemination of the guideline is important but without specific implementation activities is unlikely to improve practice

Implementation of Guideline Recommendations

- Implementation of guidelines and recommendations is a complex process
- Implementation activities are guideline and recommendation specific and not all approaches work for all guidelines
- There are five activities that NZGG undertakes in implementation

Development of implementation plan

1. identification at an early stage of those review questions and subsequent recommendations that may need research into how to best implement
2. consideration of cost-effectiveness analysis of high-cost interventions that may be recommended
3. the development of review questions aimed specifically at identifying barriers and enablers for the implementation of recommendations for high risk groups
4. identification of key recommendations following the completion of the guideline
5. development of implementation plans for all guidelines.

Updating and Replacing Guidelines

- NZGG assesses currency of a guideline five years following publication
- Currency and guideline replacement is an evolving field
- Updating a guideline requires access to the original review questions, search strategies and evidence tables
- Replacing a guideline may involve developing new scope, review questions and search strategies
- The ultimate decision to update or review a guideline will be made by the original commissioning body

Extra slides

ideas

- 80:20 rule
- AGREE tool provides framework
- Recommendations need to be algorithm-based
- Accessible/buy-in/users must be members of guideline dvpt teams – not just experts
- Integrate guideline development with implementation