Development and use of Evidence-Based Clinical Practice Guidelines

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Outline

- Definition and aim
- Key principles for developing guidelines
- Development of CPG
- Adaptation of CPG
- Local example

Clinical Practice Guidelines (CPG):

A systematically developed statements designed to assist clinician and patient decisions about appropriate health care for specific clinical circumstances

Field and Lohr, 1990

Aim of Clinical Practice Guidelines:

To facilitate more consistent, effective and efficient practice and improve health outcomes for patients

Key principles for developing guidelines

- Processes for developing and evaluating clinical practice guidelines should focus on outcomes. Outcome measures can range from survival rates to quality-of-life attributes.

- Clinical practice guidelines should be based on the best available evidence and should include a statement about the strength of their recommendations.

NHMRC, 1998

Key principles for developing guidelines

- The method used to synthesise the available evidence should be the strongest applicable.
- The process of guideline development should be multidisciplinary and should include consumers.
- Guidelines should be flexible and adaptable to varying local conditions.
- Guidelines should be developed with resource constraints in mind.

NHMRC, 1998

Key principles for developing guidelines

- Guidelines are developed to be disseminated and implemented taking into account their target audiences.
- The implementation and impact of guidelines should be evaluated.
- Guidelines should be revised regularly.

NHMRC, 1998

Is a CPG needed?

Generally, a CPG has the potential to play an important role when:

- There is uncertainty or a difference of opinion about what care should be provided, as evidenced by wide variation in practice or outcome
- There is proven treatment for a condition and mortality or morbidity can be reduced
- There is a need to bring together scientific knowledge and expertise on a subject
- There are iatrogenic diseases or interventions carrying significant risks or costs.

Eccles MP, Implement Sci 2006;1:28
Grimshaw J, J Gen Intern Med 2006;21:S14–20

Identifying a particular topic to promote best practice

If a CPG is appropriate for a given topic, the topic itself must be focused

Table 2.1: Practical considerations for focusing the CPG topic

Which patients or practice settings do you want to look at?	• What inclusion or exclusion criteria might you apply to this question?
Which diagnostic tests or interventions will be covered by the CPG?	• What is the focus of this CPG—therapeutic agents, diagnostic/screening techniques, surgical procedures, others? What evidence exists about the effect and application of these interventions?
What outcomes do you want to change?	• Patient outcomes (e.g., mortality, morbidity, complications, quality of life)? • Organizational outcomes (e.g., rate of hospital readmissions)? • Public health outcomes?
Who are the target users of the CPG?	• Which health care professionals and other employees will be affected by the CPG? • Will patients be targeted as CPG users?
What resources are available for the CPG initiative?	• What resources exist to support the development and implementation of the CPG? (Issues to consider: administrative costs, meeting costs, honorariums to participants, implementation budget, etc.) • Do you have the commitment of major agencies for dissemination and uptake?

Canadian Med Assoc, 2007

Convence a CPG group
How will the CPG working group operate?

- Clinicians from all disciplines with relevant specialist expertise
- Clinicians with general expertise
- Other relevant health professionals
- Representatives of consumer groups
- Experts in research methods relevant to guideline development
- Health economists
- Representatives of regulatory agencies

Review the scientific evidence

Clinical practices guidelines usually include three sources of evidence:

- Evidence based on the outcomes of systematic reviews
- Evidence based on clinical experience, or
- Evidence adopted from well established guidelines

Steps in developing scientific evidence based on systematic review:

- Formulation of the evidence analysis question
- Search the literature for each question
  - ✓ Search plan needs to be developed with inclusion and exclusion criteria
  - ✓ Search words need to be identified
  - ✓ Databases to search should be identified
  - ✓ Initial search should be conducted using the search words
  - ✓ Titles and abstracts need to be reviewed first
  - ✓ Gather articles and reports meeting the inclusion criteria and determine the study design and level of quality for each study
- Write the evidence summary

Development of consensus statements

- **Delphi technique**
  - ✓ Determination and formulation of questions
  - ✓ Selection of Delphi experts
  - ✓ Formulation of a first questionnaire that is sent to the experts
  - ✓ Analysis of the answers to the first questionnaire.
  - ✓ Formulation of a second questionnaire that is sent to experts
  - ✓ Sending of a third questionnaire

Development of consensus statements

- **Advantages of Delphi technique**
  - ✓ Participants who cannot come together physically can be involved in the process.
  - ✓ Allows participants to remain anonymous
  - ✓ Inexpensive
  - ✓ Participants send their contribution when they want to and only contribute to those aspects that they feel best able to contribute

Development of consensus statements

- **Nominal group technique (NGT)**
  - ✓ Introduction and explanation
  - ✓ Silent generation of ideas
  - ✓ Sharing ideas
  - ✓ Group discussion
  - ✓ Prioritizing the ideas

CPG adaptation

The adaptation phase consists of the following steps:

- Determine the health question (s) to be addressed.
- Search for guidelines and other relevant documents.
- Screen retrieved guidelines.
- Select guidelines for review from the larger number retrieved by title or abstract search.
- Assess guideline quality, currency, content, consistency.
- Assess acceptability and applicability of the recommendations.
- Review and balance assessments.
- Select from the guidelines and recommendations to create an adapted guideline.

ADAPTE Group, 2007

CPG adaptation

The adaptation phase consists of the following steps:

- Prepare a draft adapted guideline.
- Test the adapted guideline locally to get feedback on its use and endorsement of the final product

CPG adaptation

Assessing guideline quality :

Appraisal of Guidelines Research & Evaluation (AGREE) instrument .

The instrument contains 23 items grouped into 6 quality domains with a 4-point Likert scale to score each item

The domains are

- Scope and purpose
- Stakeholder involvement
- Rigour of development
- Clarity and presentation
- Applicability
- Independence editorial

AGREE Collaboration, 2003

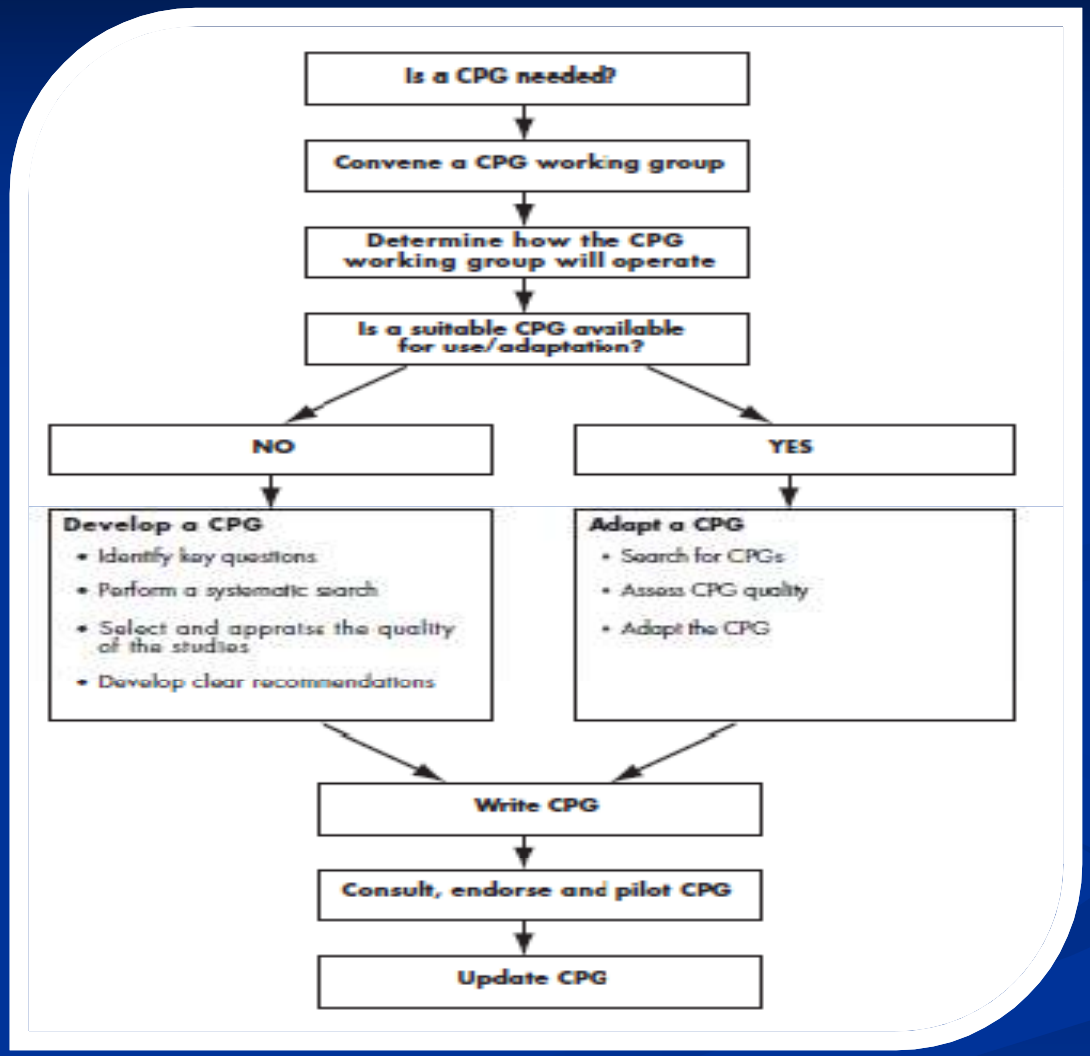
CPG adaptation

The ADAPTE approach outlines the following 5 options for CPG adaptation.

- Reject the entire guideline.
- Accept the entire guideline and all of its recommendations.
- Accept the evidence summary of the guideline.
- Accept specific recommendations.
- Modify specific recommendations.

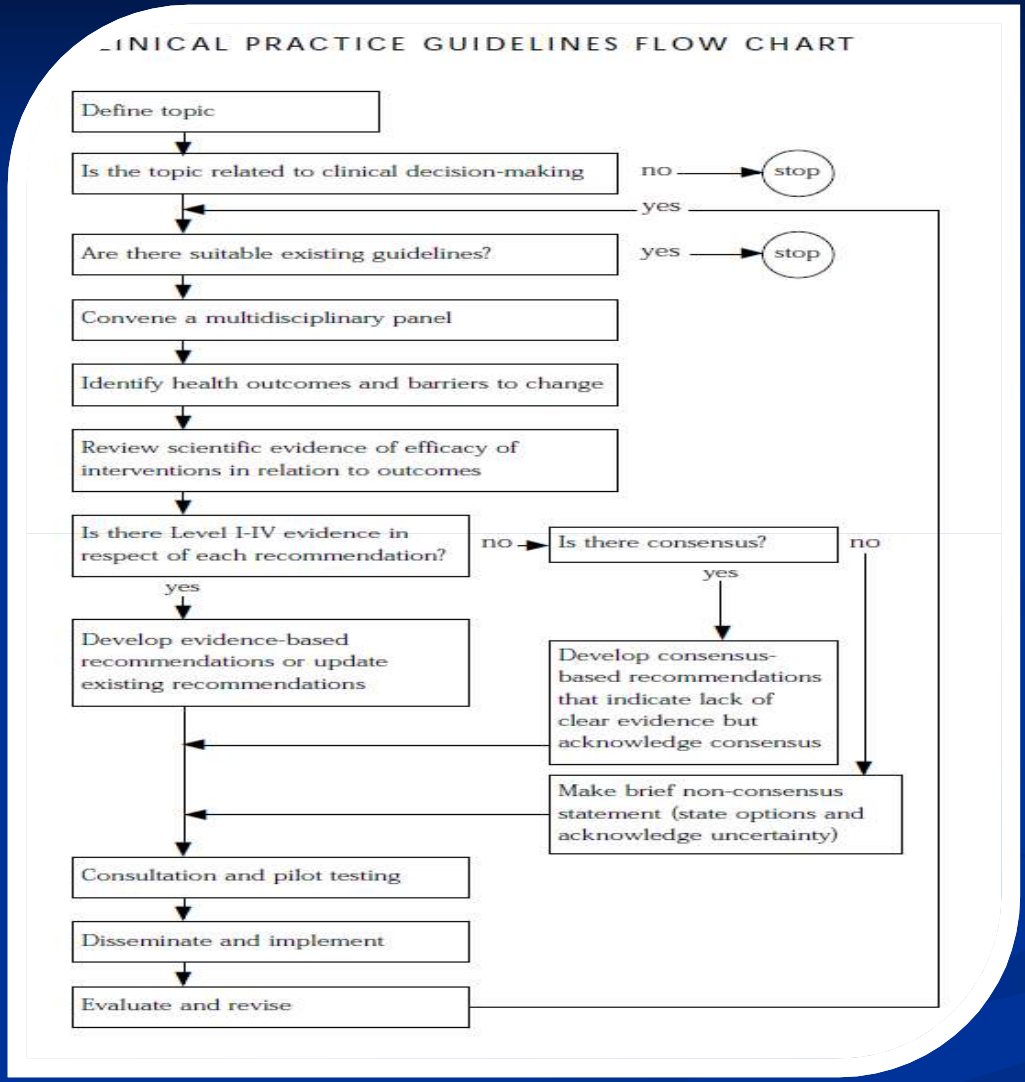
ADAPTE Group, 2007

Major steps in CPG development



Canadian Med Assoc, 2007

Major steps in CPG development

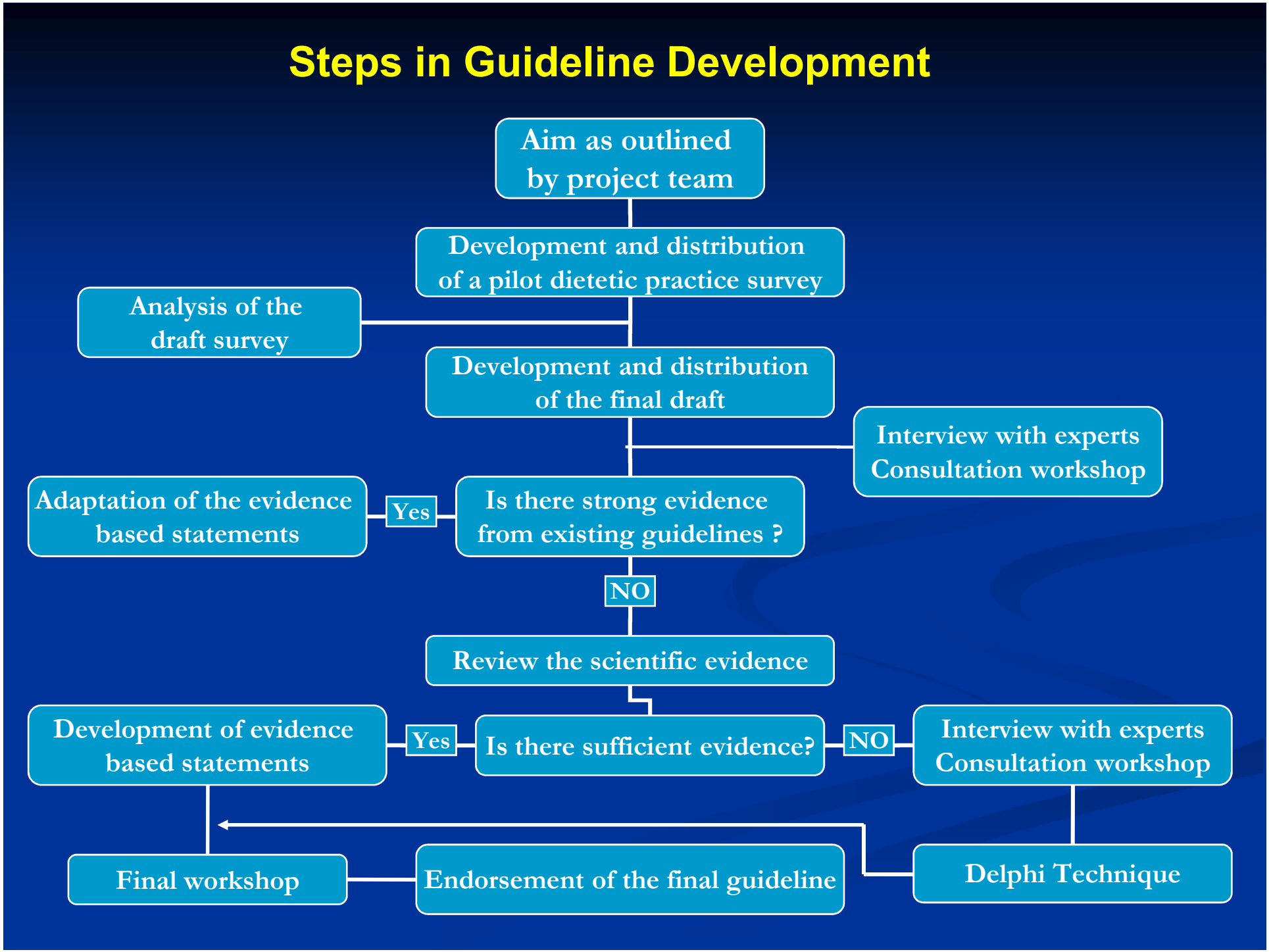


NHMRC, 1998

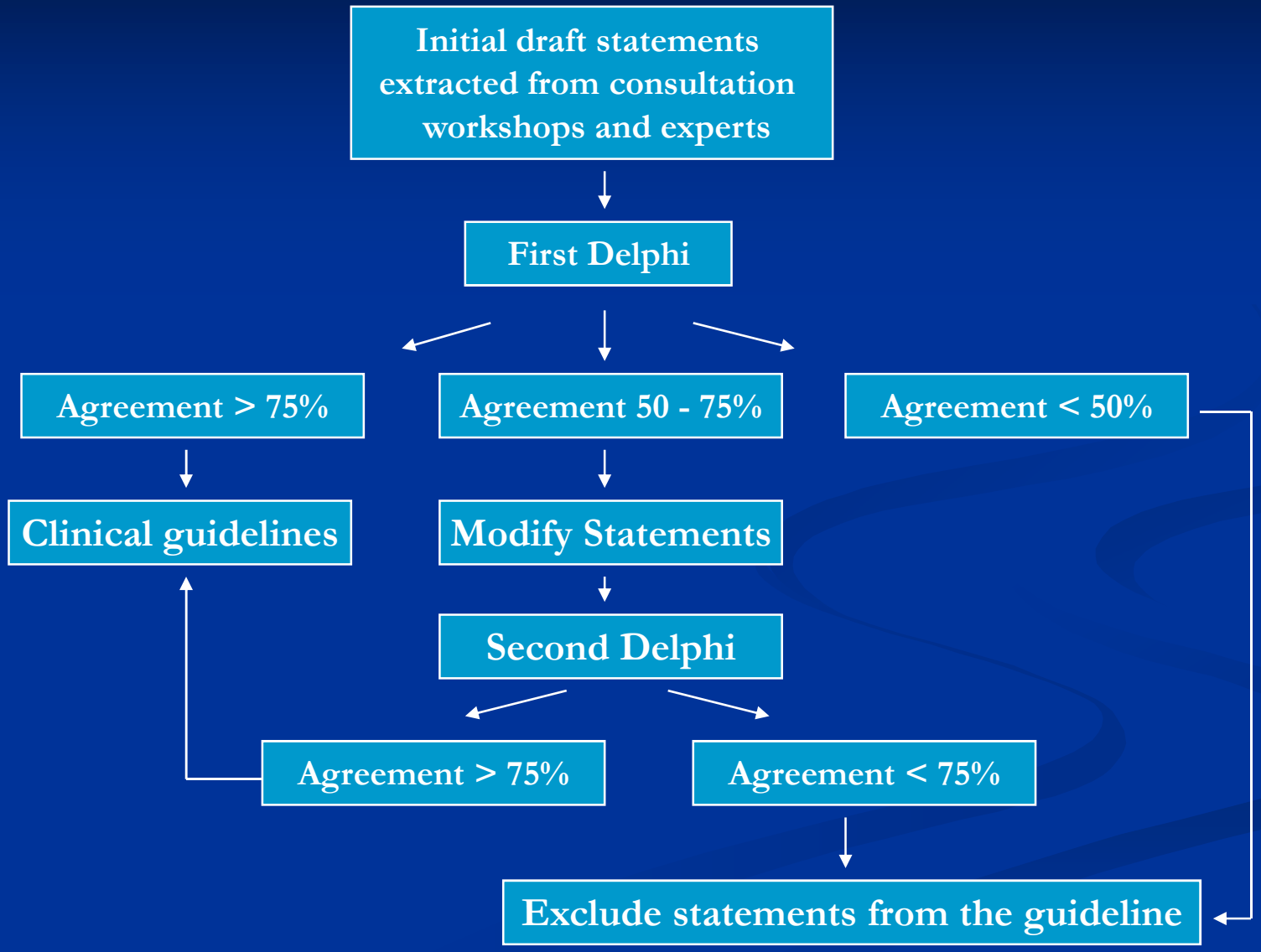
Example

Saudi evidence based CPG for nutritional management of obesity

Steps in Guideline Development



Delphi technique procedures



Evidence Summary: Higher Calcium or dairy intake support weight loss in adults

	Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
12	Zemel MB, 2000(4)	Cross sectional study	High	7114 men (mean age 43.5 ±0.44) and 380 women (mean age 28.7±0.4)	Cross sectional survey of adult subjects. Dietary consumption was measured in servings/month. Multiple logistic regression analysis was used.	The regression model for men and women indicated an inverse relationship between calcium and dairy intakes and body fat (multiple $R^2 = 0.20$; $P = 0.0009$ for men, $R^2 = 0.40$; $P = 0.0006$ for women)	Supportive: increased calcium and dairy intakes is inversely associated with body fat
13	Lovejoy JC, 2001(8)	Cross sectional study	Medium	97 white and 52 African American women (mean age 47.4±0.2 years)	Data were collected from the Health Transitions Study. Dietary intake was assessed by 4-day food record.	Body fat was inversely associated with fiber and calcium intake and positively correlated with total, saturated, and monounsaturated fat intakes ($P<0.05$)	Supportive: Calcium intake is inversely associated with body fat in African American women
14	Jacqmain M, 2003(7)	Cross Sectional Study	Medium	470 men and women aged 20-65 years	Data were collected from the Quebec Family Study Sample who regularly used vitamin or mineral supplements. Participants were divided into 3 groups based on calcium intake.	- In women: calcium intake was inversely correlated with % body fat ($r = -0.19$), fat mass ($r = -0.17$, $P < 0.05$), BMI ($r = -0.07$), and waist circumference ($r = -0.07$) - In men: there were no significant differences	Supportive: Calcium intake is inversely associated with body weight and fat mass but these findings observed in women only.
15	Marques-Vidal P, 2006(19)	Cross sectional study	High	17,771 men and 19, 742 women aged > 18 years	Data were collected from the Portuguese Health Interview Survey. Average daily milk intake was calculated by a frequency questionnaire that also assessed the average volume of one serving	- In men, milk intake was inversely related to BMI ($r = -0.10$, $P<0.001$), whereas the relationship in women was weaker ($r = -0.06$, $P< 0.001$). - In women younger than 55 y, milk intake decreased with increased BMI categories (291±9, 271±10 and 269±11 ml/day for normal, overweight and obese subjects, respectively, $P<0.001$), whereas no relationship was found in the older group.	Supportive: increased calcium intake is inversely associated with BMI in men and premenopausal women but no associated observed older women.

Type, quality and number of supportive and non supportive studies*

Study type	*Study quality*	*Number of supportive studies*	*Number of non supportive studies*
Review articles	*High*	*0*	*1*
	Medium	*1*	*1*
	Low	*0*	*1*
RCTs	*High*	*0*	*1*
	Medium	*4*	*0*
Cohort studies	*High*	*0*	*1*
	Medium	*4*	*1*
Cross-sectional studies	*High*	*2*	*0*
	Medium	*2*	*0*
Total		**13**	**6**

* *Review articles and high quality RCTs do not support the hypothesis*

Evidence-based statement:
Increased intakes of calcium or dairy products are associated with weight loss.

Level of evidence: Low

Quality Criteria Checklists

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS					
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes	No	Unclear	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes	No	Unclear	N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes	No	Unclear	N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes	No	Unclear	N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
1.	**Was the research question clearly stated?**	Yes	No	Unclear	N/A
	1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?				
	1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?				
	1.3 Were the target population and setting specified?				
2.	**Was the selection of study subjects/patients free from bias?**	Yes	No	Unclear	N/A
	2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?				
	2.2 Were criteria applied equally to all study groups?				
	2.3 Were health, demographics, and other characteristics of subjects described?				
	2.4 Were the subjects/patients a representative sample of the relevant population?				
3.	**Were study groups comparable?**	Yes	No	Unclear	N/A
	3.1 Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)				
	3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?				
	3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)				
	3.4 If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?				
	3.5 If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)				
	3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?				
4.	**Was method of handling withdrawals described?**	Yes	No	Unclear	N/A
	4.1 Were follow up methods described and the same for all groups?				
	4.2 Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)				
	4.3 Were all enrolled subjects/patients (in the original sample) accounted for?				
	4.4 Were reasons for withdrawals similar across groups?				
	4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?				
5.	**Was blinding used to prevent introduction of bias?**	Yes	No	Unclear	N/A
	5.1 In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?				
	5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)				
	5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk				

Am Diet Assoc, 2008

APPENDIX 5: *QUALITY CRITERIA CHECKLISTS*: PRIMARY RESEARCH

	factors blinded?		
	5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?		
	5.5 In diagnostic study, were test results blinded to patient history and other test results?		
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**	Yes No Unclear N/A	
	6.1 In RCT or other intervention trial, were protocols described for all regimens studied?		
	6.2 n observational study, were interventions, study settings, and clinicians/provider described?		
	6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?		
	6.4 Was the amount of exposure and, if relevant, subject/patient compliance measured?		
	6.5 Were co-interventions (e.g., ancillary treatments, other therapies) described?		
	6.6 Were extra or unplanned treatments described?		
	6.7 Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?		
	6.8 In diagnostic study, were details of test administration and replication sufficient?		
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes No Unclear N/A	
	7.1 Were primary and secondary endpoints described and relevant to the question?		
	7.2 Were nutrition measures appropriate to question and outcomes of concern?		
	7.3 Was the period of follow-up long enough for important outcome(s) to occur?		
	7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?		
	7.5 Was the measurement of effect at an appropriate level of precision?		
	7.6 Were other factors accounted for (measured) that could affect outcomes?		
	7.7 Were the measurements conducted consistently across groups?		
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes No Unclear N/A	
	8.1 Were statistical analyses adequately described the results reported appropriately?		
	8.2 Were correct statistical tests used and assumptions of test not violated?		
	8.3 Were statistics reported with levels of significance and/or confidence intervals?		
	8.4 Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?		
	8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?		
	8.6 Was clinical significance as well as statistical significance reported?		
	8.7 If negative findings, was a power calculation reported to address type 2 error?		
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes No Unclear N/A	
	9.1 Is there a discussion of findings?		
	9.2 Are biases and study limitations identified and discussed?		
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes No Unclear N/A	
	10.1 Were sources of funding and investigators' affiliations described?		
	10.2 Was there no apparent conflict of interest?		

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Quality Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Quality Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Quality Worksheet.

Am Diet Assoc, 2008

Thank You