

Guideline Development

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Outline

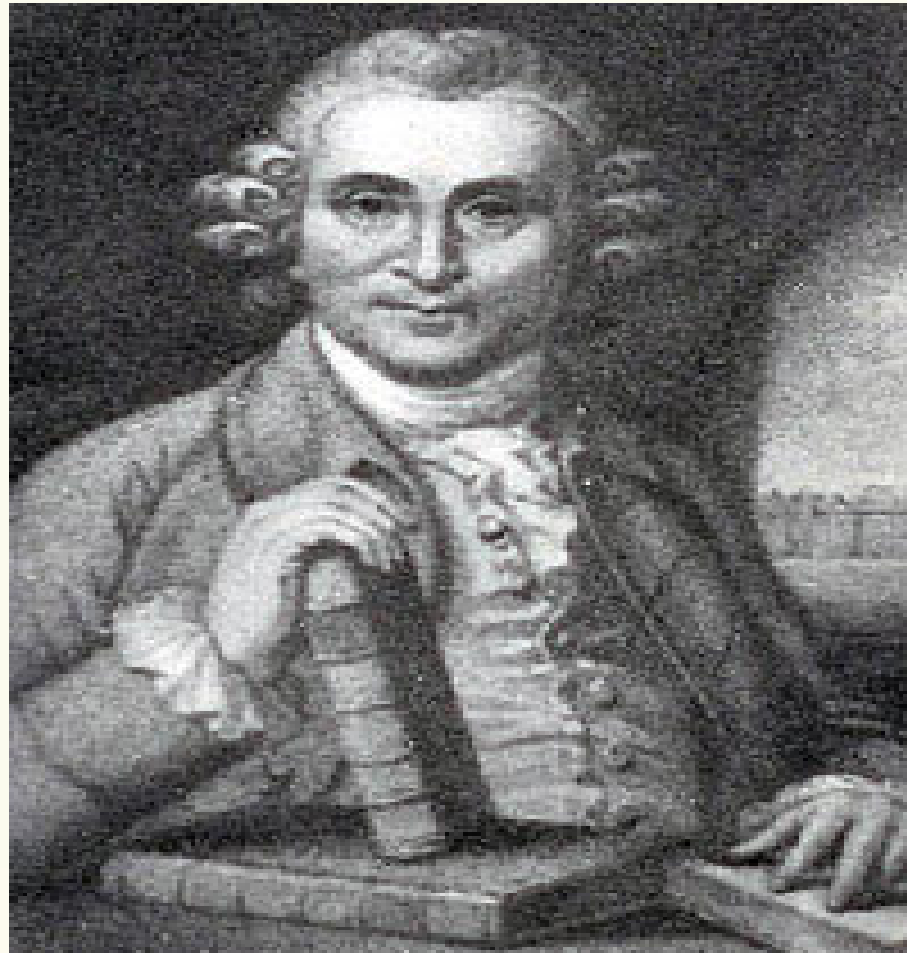
- Context
 - Evidence based medicine
 - Where do guidelines fit?
- How are they developed?
 - a brief introduction to the SIGN process
- Current issues in guideline development
- Future developments

What is good clinical practice?

Clinical decisions can be based on:

- Guesswork
- Opinion
 - Personal or collective (informal consensus)
 - Clinician or patient (or both)
 - Formal consensus
- Experience
- Evidence

Evidence based medicine isn't a new concept



Scurvy trial (1747)

12 men had “putrid gums, spots and lassitude, with weakness of their knees” and were treated in the same place, with a similar diet except:

- Quart of cider
- Elixir vitriol
- Vinegar
- Sea water
- Two oranges and one lemon
- Nutmeg, garlic, mustard concoction

Evidence based medicine....

- Clinical decisions should be based on the results of high quality clinical trials and observational studies
- Mathematical estimates of risk and benefit more valid than “anecdotal” evidence

‘Evidence Based Medicine (EBM) is the integration of best research evidence with clinical expertise and patient values’

Sackett DL et al. How to practice and teach EBM. 2nd Ed. Churchill Livingstone, 2000

But...

- Evidence isn't always high quality
- Evidence isn't assumption free
- Not everyone has the skills to critically appraise evidence
- There's a lot of it about...
 - Medline contains more than 13 million citations from more than 4600 biomedical journals

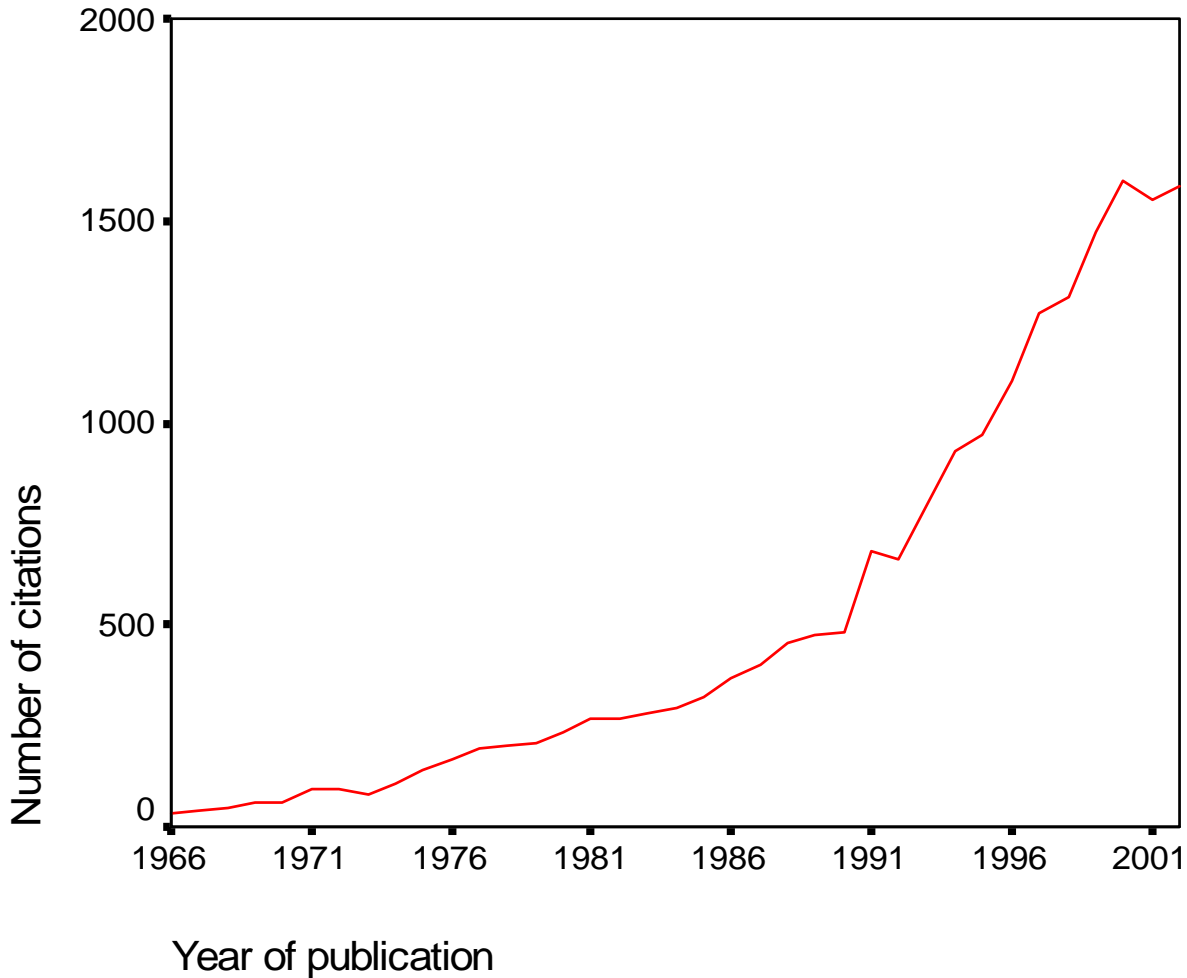
Leading to...

- Need for some way to collate evidence to answer important questions
- Guidelines arriving on the scene

Background to growth of guidelines

- ✓ development evidence based medicine
- ✓ growing concern about variation in clinical practice and need for evidence of effectiveness
- ✓ economic crisis in Western health care and focus on cost containment
- ✓ extra-professional interest: purchasers (governments, insurance companies) and patients
- ✓ national or regional government funding of guideline programmes

Citation of 'guideline(s)' in PubMed



What are clinical guidelines?

- Defined in the dictionary as ‘*an indication of a course to be followed*’
- Statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances

What they are not...

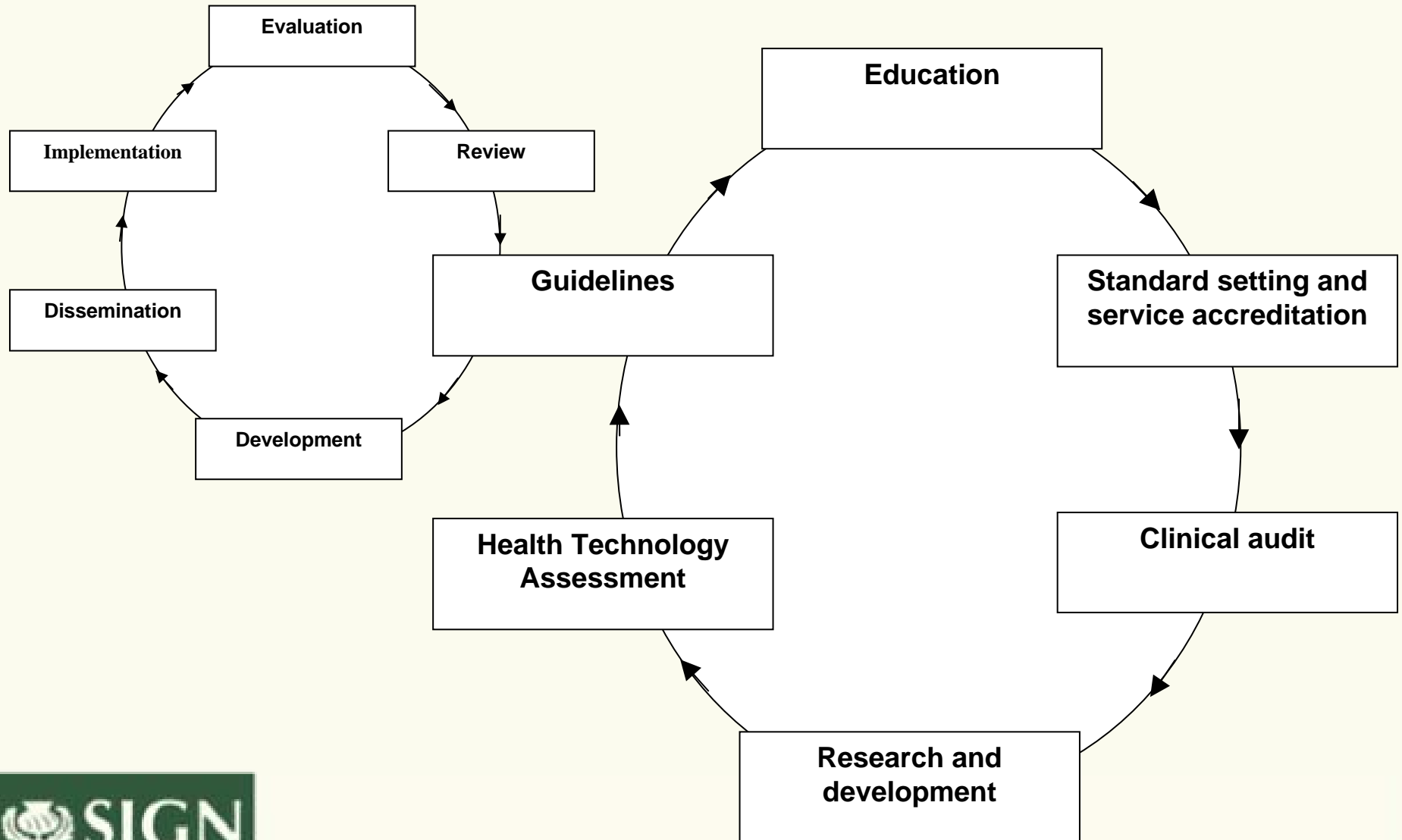
- Clinical protocols
 - Precise and detailed guidance on the management of a specific clinical condition or the undertaking of a specific clinical intervention
- Care pathways
 - Plans that specify the process of care from end to end for a particular condition, including expectations of sequencing of care and elapsed time for the components of care

Statement of Intent

- The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the appropriate healthcare professional(s) in the light of the clinical data presented by the ***patient*** and the diagnostic and treatment options available

Printed in every SIGN guideline

The clinical effectiveness cycle



Methods of guideline development I

- Expert opinion
 - guideline reflects the views of opinion leaders / specialist societies
 - inexpensive
 - high potential for bias
 - potential for hidden conflicts of interest

Methods of guideline development II

- Formal consensus
 - A number of methods exist, including Delphi, nominal group technique and consensus conferences
 - Results may be affected by way in which questions are posed, selection of participants and methods used
 - Some potential for bias

Methods of guideline development III

- Evidence based clinical guidelines
 - systematically developed statements to help professionals assimilate and evaluate the ever-increasing amount of information on best practice in the management of conditions
 - less susceptible to bias in their conclusions and recommendations than those based on consensus or a non-systematic review of the evidence

Why may evidence based guidelines be useful in practice?

- Guidelines provide an easily accessible summary of current evidence and recommended practice based upon that evidence
- They allow clinicians from different specialties easy access to best practice in other areas
- They provide good source of information for others (including patients, carers, politicians etc)

Factors influencing validity of guidelines

- Composition of guideline development group
- Identifying and synthesising evidence
- Methods of developing guideline

Grimshaw and Russell (Quality in Health Care 1993; 2(4):243-8)

The SIGN process



SIGN guideline development

- Guidelines are developed by *multidisciplinary*, nationally representative groups
- A *systematic review* is undertaken to identify and critically appraise the scientific literature
- *Recommendations* are explicitly linked to (and graded according to the strength of) the supporting *evidence*

1. Selection of guideline topics



2. Composition of the guideline development group



3. Systematic literature review



4. Formation and grading of recommendations



5. Consultation and peer review



6. Publication and dissemination



7. Implementation



8. Review

Setting up the group

Multidisciplinary participation is essential to ensure:

- Proper evaluation and interpretation of specialty-specific evidence
- Relevance to the realities of everyday practice
- Ownership and cooperation of all stakeholder groups
- Identification of relevant clinical and patient questions to be answered

Key question setting

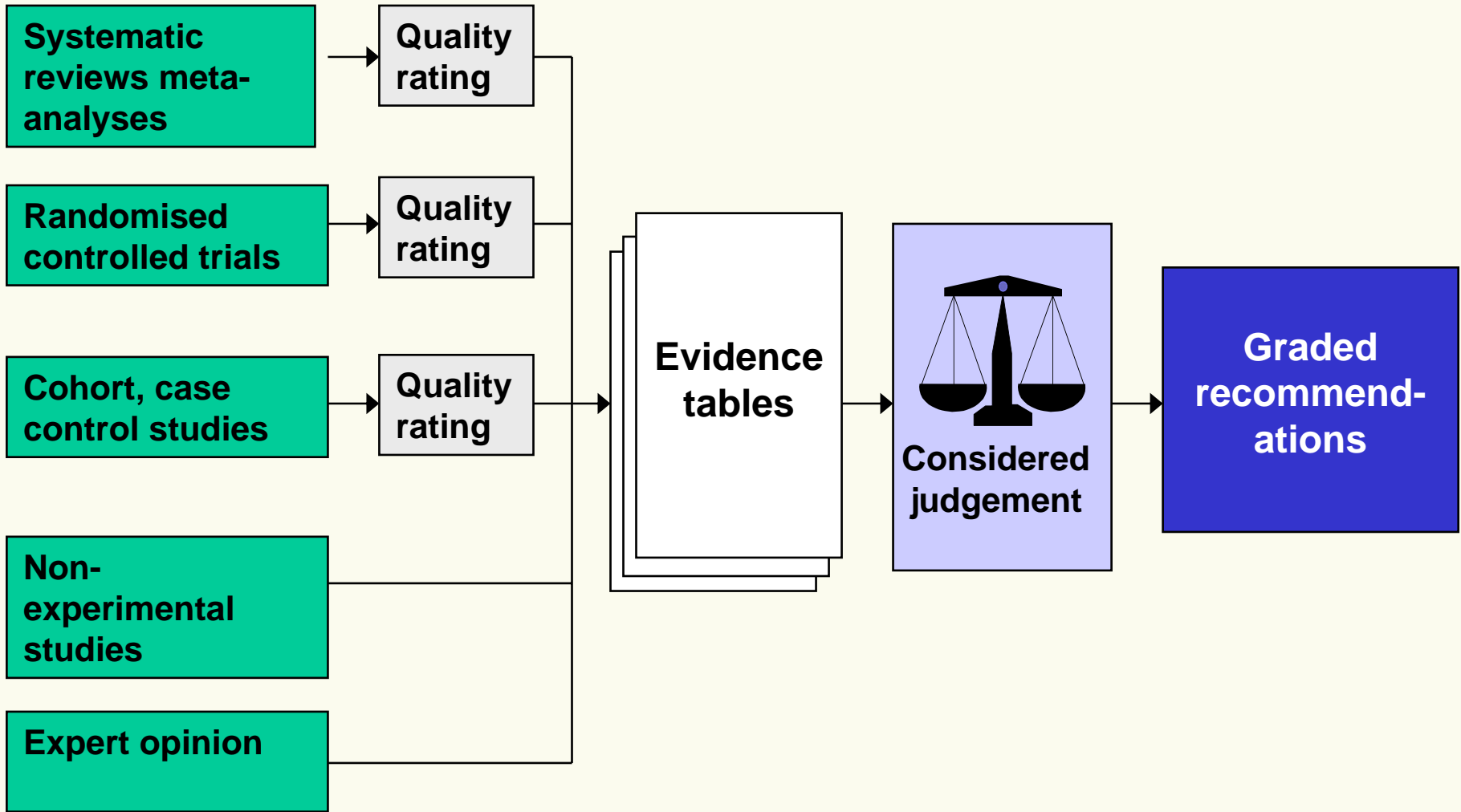
- These need to be clearly specified
- Need to be precise to allow searches to be focused on the important issues
- PICO (Patients, Intervention, Comparison and Outcome) format is useful

Systematic literature review

- Explicit search strategies are used to identify relevant studies
- Explicit inclusion/exclusion criteria are agreed to select studies for review
- Explicit quality assessment criteria are applied to evaluate the selected studies

Forming and grading of recommendations

- Explicit linkage of recommendations and evidence
- Involves explicit statement about quality of supporting evidence alongside key recommendations
 - As a result the likelihood of bias in the recommendations is reduced and the decision making process is more explicit.



SIGN levels of evidence

1 ⁺⁺	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1 ⁺	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 ⁻	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2 ⁺⁺	High quality systematic reviews of case-control or cohort or studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2 ⁺	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2 ⁻	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

SIGN grades of recommendation

A

At least one meta analysis, systematic review, or RCT rated as 1⁺⁺, and directly applicable to the target population;

or

A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1⁺, directly applicable to the target population, and demonstrating overall consistency of results

B

A body of evidence including studies rated as 2⁺⁺, directly applicable to the target population, and demonstrating overall consistency of results;

or

Extrapolated evidence from studies rated as 1⁺⁺ or 1⁺

C

A body of evidence including studies rated as 2⁺, directly applicable to the target population and demonstrating overall consistency of results;

or

Extrapolated evidence from studies rated as 2⁺⁺

D

Evidence level 3 or 4;

or

Extrapolated evidence from studies rated as 2⁺

Consultation and peer review

- Widening participation
 - National open meeting
- Expert consultation
 - Extensive peer review
- Quality control
 - SIGN Editorial Board

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Management of obesity in children and young people
A national clinical guideline

1. Introduction	1
2. Definition and prevalence of obesity and overweight in children and young people	2
3. Complications of childhood obesity	4
4. Diagnosis	6
5. Treatment	10
6. Key messages for patients and parents	13
7. Development of this guideline	14
8. Areas in development	17
9. Areas of health, safety and changing behaviour	18
10. References	22

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Management of cataplexis
A national clinical guideline

1. Introduction	1
2. Risk factors for cataplexis	2
3. Assessment, diagnosis and monitoring	3
4. Management of cataplexis	4
5. Key messages for patients and parents	5
6. Development of this guideline	6
7. Areas in development	7
8. Areas of health, safety and changing behaviour	8
9. References	10

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Management of Obstructive Sleep Apnoea/Hypopnoea Syndrome in Adults
A national clinical guideline

1. Introduction	1
2. Definition and prevalence	2
3. Signs and symptoms	3
4. Complications of OSA	4
5. Sleep studies	5
6. Management of OSA with CPAP	6
7. Management of OSA with oral appliances	7
8. Management of OSA with surgery	8
9. Management of OSA with weight loss	9
10. Key messages for patients and parents	10
11. Development of this guideline	11
12. Areas in development	12
13. Areas of health, safety and changing behaviour	13
14. References	15
15. Bibliography	16



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Using others' guidelines

- Many countries do not have resources to produce their own guidelines
- Instead they need to review and evaluate those produced elsewhere
- What questions should be posed of guidelines from elsewhere?

Appraisal of Guidelines, Research and Evaluation for Europe (AGREE Instrument, 2001)

- Covers six domains (23 items) looking at the quality of reporting and the quality of some aspects of the recommendations
- Provides an assessment of the likelihood that the guideline will achieve its intended outcome
- Does not assess the impact of a guideline on patient outcomes

Other questions to ask

- Does the guideline answer questions relevant for my own situation?
- Is it up to date?
- Will the recommendations be accepted and implemented locally?
 - Are there cultural differences which would prevent local implementation?
 - Are there other barriers to implementation?

Current issues in guideline development

- Guideline development
 - Increased role of consumers
 - Increased role of economic evaluation
- Types of guidelines
 - Living guidelines
 - Patient versions
 - Adaptation of other's guidelines
- Grading systems
 - Incorporation of effect size, harms and burden of care information
- Increased international collaboration
- Implementation

Thank you!
Contact SIGN at www.sign.ac.uk

