Evidence Based Dentistry

Quality of Clinical Practice Guidelines

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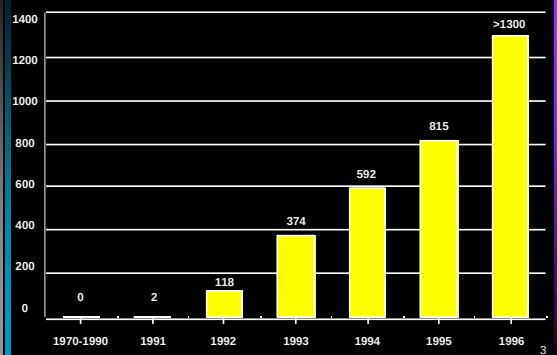
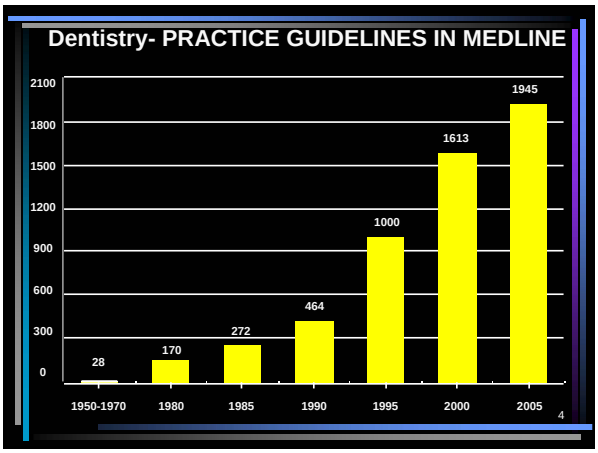
Justification for developing guidelines

- Demand for effectiveness and efficacy studies increasing
- Outcome measures needing to be developed and utilized
- Guidelines development reveals gaps in scientific justification
- Quality assessment integral to contracts with payers (including government)

PRACTICE GUIDELINES IN MEDLINE




Dentistry- PRACTICE GUIDELINES IN MEDLINE
2100
1800
1500
1200
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28
170
272
464
1000
1613
1945
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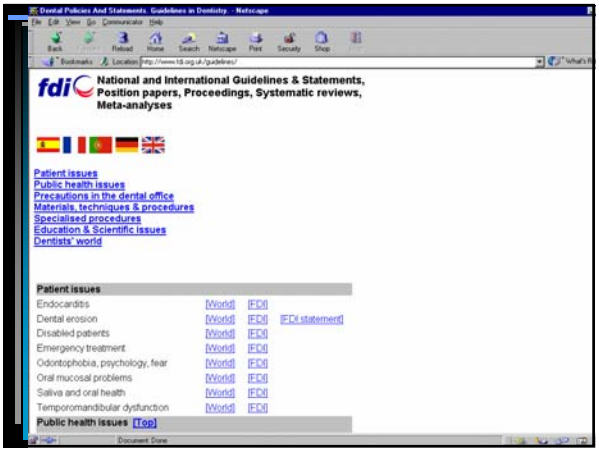
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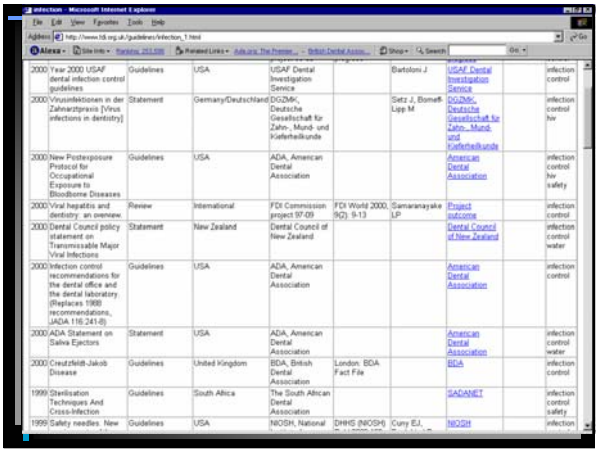
National and International Guidelines & Statements,
Position papers, Proceedings, Systematic reviews,
Meta-analyses
Patient issues
Public health issues
Precautions in the dental office
Materials, techniques & procedures
Specialised procedures
Education & Scientific issues
Dentists' world
Patient issues
Endocarditis [World] [FDI]
Dental erosion [World] [FDI] [FDI statement]
Disabled patients [World] [FDI]
Emergency treatment [World] [FDI]
Odontophobia, psychology, fear [World] [FDI]
Oral mucosal problems [World] [FDI]
Saliva and oral health [World] [FDI]
Temporomandibular dysfunction [World] [FDI]
Public health issues [Top]



Guidelines - old taxonomy

Practice Standards : Based on strong evidence; Accepted principles of patient management that reflect a high degree of clinical certainty

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Practice Standards : Based on strong evidence; Accepted principles of patient management that reflect a high degree of clinical certainty

Practice Guidelines: Based on weaker evidence; Recommendations for patient management that reflect a particular strategy or range of management strategies that themselves reflect a moderate degree of clinical certainty

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Guidelines - old taxonomy

Practice Standards : Strong evidence; Accepted principles of patient management that reflect a high degree of clinical certainty

Practice Guidelines: Weaker evidence; Recommendations for patient management that reflect a particular strategy or range of management strategies that themselves reflect a moderate degree of clinical certainty

Practice Options: Weakest evidence. Other strategies for patient management for which the clinical utility is uncertain (i.e., based on inconclusive or conflicting evidence or opinion)

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Canadian Task Force on periodic health examinations (1979)

A: Good evidence to intervene
B: Fair evidence to intervene
C: Insufficient evidence to recommend for or against intervention
D: Fair evidence to observe or ignore
E: Good evidence to observe or ignore

Good evidence = strong research-based: directly based on clinical evidence from randomised clinical trials or systematic reviews (recommendation strength A & E)
Fair evidence = moderate research based: directly based on well conducted clinical trials or extrapolated recommendations based on A (recommendation strength B & D)
Insufficient evidence = limited research-based: directly based on data from non experimental clinical studies, relevant laboratory studies or extrapolated recommendations based on A and B (recommendation strength C)
No scientific evidence = expert committees, reports, concensus, clinical experience or extrapolated recommendations based on A,B and C.

Recommendation grades

Practice Standards	**A At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation.** *(Evidence levels Ia, Ib)*	Explicit evidence based Evidence based
Practice Guidelines	**B Availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.** *(Evidence levels IIa, IIb, III)*	
Practice Options	**C Obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality.** *(Evidence level IV)*	Consensus based
(old taxonomy)	*AHCPR, 1993*	*New Zealand Guidelines Group*

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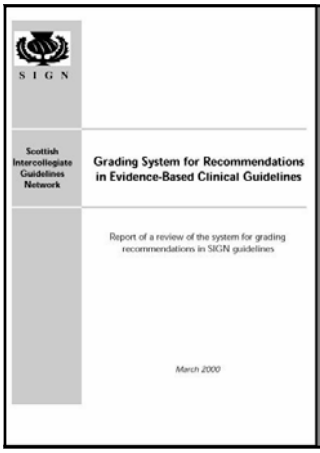

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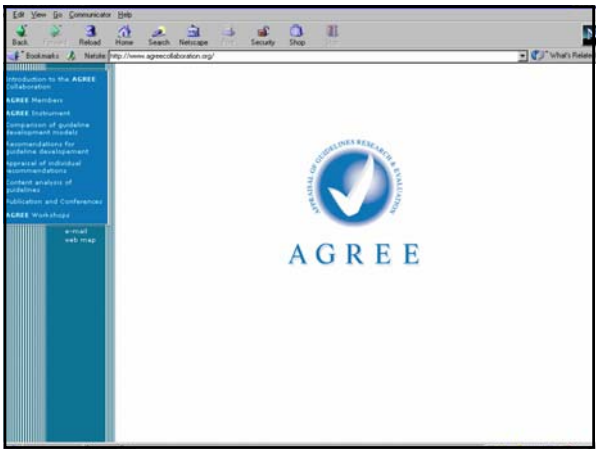

SIGN - GRADES OF RECOMMENDATIONS

A

- **At least one meta analysis, systematic review, or RCT rated as 1 ++ , and directly applicable to the target population*n; 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 result*s; 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 result*s; or***
- **Extrapolated evidence from studies rated as 2 ++**

D

- **Evidence level 3 or *4; or***
- **Extrapolated evidence from studies rated as 2 +**

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Guidelines appraisal questions

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New Zealand Guidelines Group

- Who developed the guidelines?
- Why did they develop the guideline?
- Is the guideline development process described? (if so, what process was used?)
- What is the strength of the evidence?
- Does the guideline possess the attributes of a good guideline?
- Has the guideline been successfully piloted or implemented?

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Guidelines appraisal questions

1. Are the clinical practice guidelines valid?
2. What are the recommendations?
3. Will the recommendations help locally?

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Are the clinical practice guidelines valid?

1. Were all important options and issues clearly specified?
2. Was an explicit and sensible process used to identify, select and combine evidence?
3. Was an explicit and sensible process used to consider the relative value of different outcomes?

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Are the clinical practice guidelines valid?

4. Is the guideline likely to account for important recent developments?

5. Has the guideline been subject to peer review and testing?

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What are the recommendations?

6. Are practical, clinically important recommendations made?
7. How strong are the recommendations?
8. What is the impact of uncertainty associated with the evidence and values used in the guidelines?

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Will the recommendations help locally?

9. Is the primary objective of the guideline consistent with my objective?

10. Can the recommendations be applied to my local population?

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Developing clinical practice guidelines - selection of evidence

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PROCESS

- Formulate the clinical question
- Search the literature for evidence
- Choose papers to be evaluated
- Critically evaluate the papers
- Classify by level of evidence

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Practice Guidelines - types of articles and reports

Therapeutic effectiveness

Diagnostic test evaluation

Natural history/prognosis studies

Outcome measure evaluation

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Relationship between Guidelines and Evidence

- Guidelines should be related to scientific and clinical evidence
- Empirical evidence should take precedence over expert judgement
- A thorough review of the literature should precede guideline development
- The scientific literature should be evaluated and weighted
- Evidence must be ranked and linked to strength of guidelines

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Articles and Reports Used in Developing Practice Guidelines for Therapeutic effectiveness

Randomized controlled trials

Non-randomized cohort studies
Case-control studies

Case series
Case reports
Expert opinion

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Definitions of types of outcomes

Surrogate

A laboratory measurement or a physical sign used as a substitute for a clinically meaningful endpoint that measures directly how a patient feels, functions or survives. Changes induced by a therapy on a surrogate endpoint should be expected to reflect changes in a clinically meaningful endpoint (Temple 1995).

Clinical

Outcomes that tend to be defined on the basis of the disease being studied; for example, survival in cancer, occurrence of vertebral fractures in treatments for osteoporosis, ulcer healing, walking distance or microbiological 'cure' in the treatment of infections.

Patient-relevant

Outcomes that matter to the patient and their carers. They need to be outcomes that patients can experience and that they care about (eg quality of life, return to normal function). Patientrelevant outcomes may also be clinical outcomes or surrogate outcomes that are good predictors (in a causal sense) of outcomes that matter to the patient and their carers.

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Articles and Reports Used in Developing Practice Guidelines for Diagnostic test evaluation

Sensitivity
Specificity
Positive predictive value - PPV
Negative predictive value - NPV
Likelihood ratio - LR

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RECOMMENDATIONS FOR THE USE OF DIAGNOSTIC TESTS ARE BASED ON DIAGNOSTIC ACCURACY AND NOT ON PATIENT OUTCOME

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Articles and Reports Used in Developing Practice Guidelines for Natural history/prognosis studies

- Longitudinal
- reliable outcome measures
- good follow-up
- uniform cohort
- etc.

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RECOMMENDATIONS BASED ON PROGNOSIS STUDIES ARE NOT POSSIBLE, THEY SIMPLY GIVE AN IDEA OF OUTCOME AND THE STRENGTH OF THE EVIDENCE PROVIDING THAT IDEA

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	Strength of evidence
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The *P*-value or, alternatively, the precision of the estimate of the effect (as indicated by the confidence interval).
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

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2. Resolving these discrepancies should be viewed as an important task in the compilation of an evidence summary.
3. Biostatistical and epidemiological advice may be needed on how to search for possible explanations for the disagreements before data are rejected as being an unsuitable basis on which to make recommendations.

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3. Advice may be needed on how to search for possible explanations for the disagreements before data are rejected as being an unsuitable basis on which to make recommendations
4. It may not be feasible to undertake an RCT in all situations. But, regardless of the clinical context, guidelines should be based on the best available evidence and if this evidence is suboptimal (eg based on observational data because an RCT, although feasible, has not been done) then this should be acknowledged.

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4. It may not be feasible to undertake an RCT in all situations. But, regardless of the clinical context, guidelines should be based on the best available evidence and if this evidence is suboptimal
5. It may be necessary to use evidence from different study designs for different aspects of the treatment effect. In general, there should be studies providing higher level evidence on the benefits.

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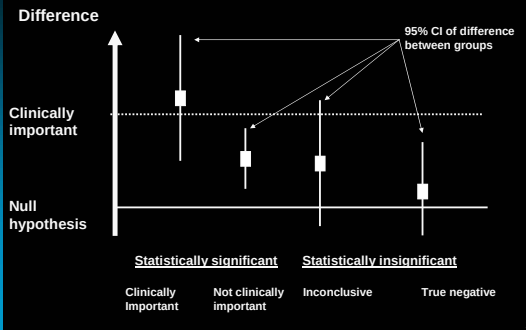
Statistical significance and clinical importance



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2 The point estimate of effect is clinically important BUT the confidence interval includes clinically unimportant effects

3 The confidence interval does not include any clinically important effects

4 The range of estimates defined by the confidence interval includes clinically important effects BUT the range of estimates defined by the confidence interval is also compatible with no effect, or a harmful effect

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Classifying the relevance of outcomes

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4 Evidence of an effect on proven surrogate outcomes but for a different intervention and population.

5 Evidence confined to unproven surrogate outcomes.

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Format for evidence checklist

Strength of evidence	
Level	Level I, II, III, etc
Quality	Score from quality assessment
Statistical precision	*P*-value and width of confidence interval
Size of effect	Summary estimate (eg RR) and 95% confidence interval, plus score for clinical importance of benefit
Relevance of evidence	Score from relevance assessment

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