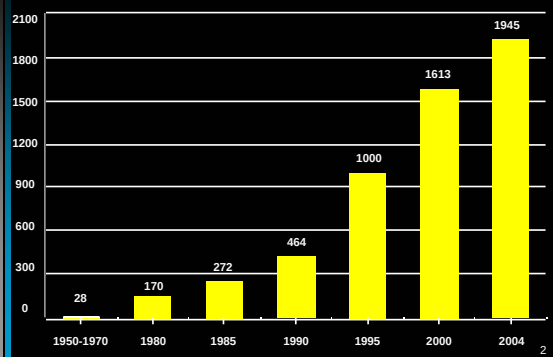
Evidence Based Dentistry

Implementing scientific evidence into clinical practice guidelines

Asbjørn Jokstad
University of Oslo, Norway

PRACTICE GUIDELINES IN DENTISTRY (Medline)



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)

From research to practice -

Steps
- Creating evidence
  - Basic science research
  - RCTs
  - Observational studies
- Summarizing evidence
  - EPCs
  - Published meta-analyses
  - Cochrane collaborators
  - Others
- Disseminating evidence
  - Clinical practice guidelines
  - Continuing medical education
  - Publications
  - Cochrane database
- Implementing evidence
  - Clinical pathways
  - Computer decision support systems
  - Automated MEDLINE searches
  - Academic detailing
  - Audit and feedback

Obstacles
- Paucity of clinical trials
  - Underfunding of research
  - Lack of trained clinical investigators
  - Frequency of small underpowered studies
- Heterogeneity of studies
- Inconsistency between meta-analyses and large RCTs
- Lack of awareness of existing efforts
- Access to evidence
- Information overload
- Format not helpful
- Labor-intensive
- Expensive
- Waning effectiveness

EPCs, Evidence-based practice centers
RCTs, randomized controlled trials;

Relationship between Guidelines and Evidence

- Guidelines should be related to scientific and clinical evidence
- Empirical evidence should take precedence over expert judgment
- 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

5

Initial system: 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.

SIGN - GRADES OF RECOMMENDATIONS

A

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

7

PROCESS

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

8

Guidelines appraisal questions

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

9

Are the guidelines valid? 1/2

1. Were all important options and issues clearly specified?

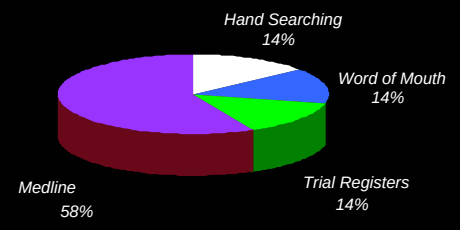
10

Are the guidelines valid? 1/2

1. Were all important options and issues clearly specified?
2. Was an explicit and sensible process used to identify, select and combine evidence?

11

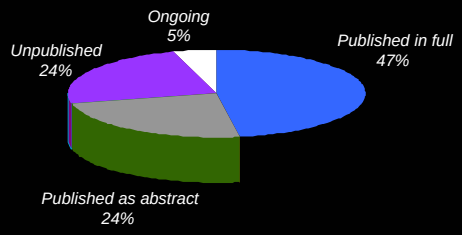
Typical identification of trials



E.g. chemotherapy for cancer.

12

Typical identification of trials



E.g. chemotherapy for cancer.

13

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.

15/07/2004

14

Key points for considering levels of evidence

1. Differences in the conclusions reached about effectiveness from studies at differing levels of evidence or within a given level of evidence need to be resolved.

15

Key points for considering levels of evidence

1. Differences in the conclusions reached about effectiveness from studies at differing levels of evidence or within a given level of evidence need to be resolved.

2. Resolving these discrepancies should be viewed as an important task in the compilation of an evidence summary.

16

Key points for considering levels of evidence

1. Differences in the conclusions reached about effectiveness from studies at differing levels of evidence or within a given level of evidence need to be resolved.
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.

17

Key points for considering levels of evidence

1. Differences in the conclusions need to be resolved.
2. Resolving these discrepancies is an important task
3. Biostatistical and epidemiological advice may be needed.

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.

18

Key points for considering levels of evidence

1. Differences in the conclusions need to be resolved.
2. Resolving these discrepancies is an important task
3. Biostatistical and epidemiological advice may be needed.
4. Guidelines should be based on the best available evidence and if this evidence is suboptimal then this should be acknowledged.
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.

19

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

20

Are the 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?

21

Types of outcomes

1. 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).

22

Types of outcomes

1. 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).

2. 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.

23

Types of outcomes

1. 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).

2. 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.

3. 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). Patient relevant 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.

24

Relevance of evidence of outcomes

1 An effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival

2 An effect on a surrogate outcome that has been shown to be predictive of patient-relevant outcomes for the same intervention

3 An effect on proven surrogate outcomes but for a different intervention

4 An effect on proven surrogate outcomes but for a different intervention and population

5 Evidence confined to unproven surrogate outcomes

25

Are the 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?

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

26

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

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

27

What are the recommendations?

6. Are practical, clinically important recommendations made?
7. How strong are the recommendations?

28

Clinical importance of benefit

1 A clinically important benefit for the full range of plausible estimates. The confidence limit closest to the measure of no effect (the 'null') rules out a clinically unimportant effect of the intervention

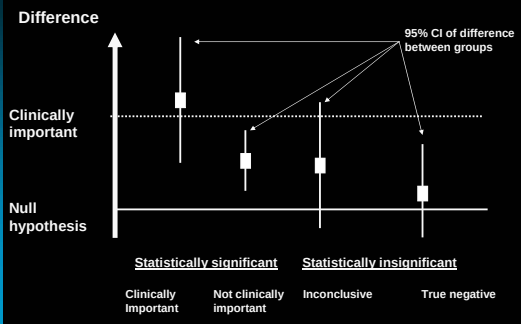
2 The point estimate of effect is clinically important BUT the confidence interval includes clinically unimportant effects

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

29

Statistical significance and clinical importance



30

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?

31

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?

32

DIAGNOSTIC TESTS:

RECOMMENDATIONS ARE BASED ON DIAGNOSTIC ACCURACY AND NOT ON PATIENT OUTCOME

33

PROGNOSIS :

RECOMMENDATIONS CANNOT BE PROVIDED. THE EVIDENCE SIMPLY GIVES AN IDEA OF OUTCOME AND THE STRENGTH OF THE EVIDENCE PROVIDING THAT IDEA

34

Therapy:
No evidence of effect

does not mean

evidence of no effect

35