Guidelines, recommendations, etc. Based on eminence or evidence?

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In guidelines we cannot trust. Do you agree?

A number of terms exist

• Guidelines
• Recommendations
• Regulations
• Directives
• Standards
• Position papers
• Opinions
• Etc.

There is a distinction between these terms; often they are used interchangeably.

Some of them have the power of law in some, albeit not all, countries.
Eminence versus Evidence
What is ‘eminence based medicine’?

Making the same mistakes with increasing confidence over an impressive number of years....

Isaacs D, Fitzgerald D. BMJ 1999; 319: 1618
What is ‘eminence based medicine’?

• Relying on the opinion of a medical specialist or other prominent health official when it comes to health matters, rather than relying on a careful assessment of relevant research evidence.
‘Who am I to judge?’

Pope Francis, 2013

Who am I to question an ‘expert’ (especially a physician, a specialist or a prominent medical researcher who knows so much more than me)?
What is ‘evidence based medicine’?

Evidence based medicine: what it is and what it isn’t

It’s about integrating individual clinical expertise and the best external evidence

The use of current best evidence in making decisions about the care of individual patients.

Sackett D. BMJ 1996
Current situation

• Poor quality
  – Too often clinical practice guidelines, or similar documents, are of poor quality or are eminence-based

• Consequences
  – Health care decisions might be based on biased or erroneous information

Standards for the development of evidence-based guidelines

Institute of Medicine 2011
<table>
<thead>
<tr>
<th>Standard</th>
<th>Clause</th>
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<tbody>
<tr>
<td>1.</td>
<td>Establishing transparency</td>
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<td>2.</td>
<td>Management of conflict of interest</td>
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<td>3.</td>
<td>Guidelines development group composition</td>
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<td>4.</td>
<td>Clinical practice guideline-systematic review intersection</td>
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<td>5.</td>
<td>Establishing evidence foundations for and rating strength of recommendations</td>
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<td>6.</td>
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<td>External review</td>
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<td>Updating</td>
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1. Establishing transparency

The processes by which a clinical practice guideline is developed and funded should be described transparently.

2. Management of conflict of interest

There's no such thing as a free lunch

Milton Friedman, an American economist
What is a conflict of interest?

• A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

71% of chairs of clinical policy committees and 90.5% of co-chairs had financial conflicts

2. Management of conflict of interest

• Potential guideline development group members should declare conflicts.
• None, or at most a small minority, should have conflicts, including services from which a clinician derives a substantial proportion of income.
• The chair and co-chair should not have conflicts.
• Eliminate financial ties that create conflicts.

3. Guideline development group composition

As representative as possible

- The group should be composed of methods experts, clinicians, representatives of stakeholders, and affected populations.

4. Clinical practice guideline-systematic review intersection

Systematic reviews are essential to the process.

Standards for systematic reviews

Institute of Medicine

Cochrane Collaboration

Time-consuming and costly

Estimates vary from 216 to 2,518 h
(with a mean of 1,139 h)
and an average of approximately $104,750

(Petticrew & Roberts, 2006).
5. Establishing evidence foundations for and rating strength of recommendations

- Explain the reasoning behind each recommendation, summarize evidence for benefits and harms, characterize the quality and quantity of relevant evidence and the role of subjective judgments.

- Rate the level of evidence and the strength of the recommendation.

- Describe differences of opinion about recommendations.

# The GRADE system
to grade the strength of evidence and grades of recommendations

<table>
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<tr>
<th>Quality of evidence</th>
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<tr>
<td><strong>High quality</strong></td>
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<td><strong>Moderate quality</strong></td>
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<td><strong>Low quality</strong></td>
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<td><strong>Very low quality</strong></td>
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<th>Grade of recommendation</th>
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<tr>
<td><strong>Strong</strong></td>
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<tr>
<td><strong>Weak</strong></td>
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Guyatt et al. BMJ 2008;336:924-6
6. Articulation of recommendations

- Describe the action recommended by the guideline and when it should be used;

- wording should facilitate measurement of adherence.

7. External review

External reviewers....

.......... should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations, agencies, patients, and representatives of the public....

8. Updating

- Document the dates of the guideline, systematic review, and planned update;

- Monitor the literature and update the guideline when new evidence suggests the need for change.

Discussion on the guidelines development

BMJ 2013;346:f3830 doi: 10.1136/bmj.f3830 (Published 14 June 2013)

EVIDENCE BASED MEDICINE

Why we can’t trust clinical guidelines
Despite repeated calls to prohibit or limit conflicts of interests among authors and sponsors of clinical guidelines, the problem persists. Jeanne Lenzer investigates

Jeanne Lenzer medical investigative journalist
New York, USA
Public Private Collaboration in Clinical Research During Pregnancy, Lactation and Childhood. A Joint Position Statement of the Early Nutrition Academy (ENA) and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)

Koletzko, Berthold; Benninga, Marc A.; Godfrey, Keith M.; Hornnes, Peter J.; Kolacek, Sanja; Koletzko, Sibylle; Lentze, Michael J.; Mader, Silke; McAuliffe, Fionnuala M.; Oepkes, Dick; Oddy, Wendy H.; Phillips, Alan; Rzehak, Peter; Socha, Piotr; Szajewska, Hania; Symonds, Michael E.; Tamini, Jan; Thapar, Nikhil; Troncone, Riccardo; Vandenplas, Yvan; Veereman, Gigi
How good are guidelines if most published research is false?

**Essay**

*Why Most Published Research Findings Are False*

*John P. A. Ioannidis*
When the research findings are less likely to be true

- The smaller the studies
- The smaller the effect sizes
- The greater the number and the lesser the selection of tested relationships
- The greater the flexibility in designs, definitions, outcomes, and analytical modes
- The greater the financial and other interests
- The hotter a scientific field (with more scientific teams involved)

The potential benefits of practice guidelines are only as good as the quality of the guidelines themselves.

AGREE II is the international tool to assess the quality and reporting of practice guidelines.
The paths from research to improved health outcomes

Glasziou Evid Based Med. 2005
The paths from research to improved health outcomes

Evidence

Clinical outcome

<table>
<thead>
<tr>
<th>Aware</th>
<th>Accepted</th>
<th>Applicable</th>
<th>Able</th>
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<td>Physician</td>
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<td>Patient</td>
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Glasziou Evid Based Med. 2005
Take home messages

• **Variations in quality**
  – Clinical practice guidelines vary significantly in quality, therefore in the trustworthiness of the yielded recommendations.

• **Evidence versus eminence**
  – It is important that one can distinguish evidence-based clinical practice guidelines from guidelines that are not.

• **Standards available**
  – Standards for the development of evidence-based guidelines have been developed.
  – If adhered to, trustworthy guidelines should follow.
Do you remain sceptical?
A final comment....

Always listen to experts.

They’ll tell you what can’t be done and why.

Then do it.

Thank you for your attention.