What are clinical guidelines? The theory behind guidelines, and their development
Background
Evidence-based practice

• ‘the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients’ Sackett et al (1996)
  – There is a belief that treatment based on evidence produces more predictable and better health outcomes than non-evidence-based treatment

If you read only one published study, how sure are you that it is the highest quality (best) study? will reflect the findings of all other relevant studies on the same topic? will provide best clinical guidance?

Well, you really don’t know for sure!!
• Produce and/or use secondary evidence
  – Rapid reviews
    • most recent, highest hierarchy literature, usually SRs or MAs
  – Meta-analysis
    • Comprehensive search, appraisal & synthesis of experimental studies related to your question
  – Systematic reviews
    • Comprehensive search and appraisal of all the relevant literature related to your question
• Secondary evidence (constructed well) **minimises** the biases incurred from single primary studies
  – Systematic literature reviews and Meta-analyses use a non-biased, transparent approach to collating and evaluating evidence from primary research
  – Secondary evidence produces summary findings ‘on balance’
• An emerging area of technical writing merged with clinical experience
  – The focus is on providing clinical guidance which will influence practice decisions
  – Clinical Practice Guidelines: “Systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances”

Key guideline development bodies around the world have their own processes

- Scottish Intercollegiate Guidelines Network (SIGN)
  - http://www.sign.ac.uk/
- National Institute for Health and Clinical Excellence (NICE)
  - http://www.nice.org.uk/
- National Health and Medical Research Council (NHMRC)
- New Zealand Guidelines Group (NZGG)
• Confusion in terminology / nomenclature
  – **Guideline** provides recommendations for public/community health or safety issues (e.g. infection control)
    • **Clinical guideline** provides recommendations for diagnosis & management of a clinical condition
  – **Care pathways** specify multidisciplinary processes of care for specific conditions
    (usually tracking care from admission through to discharge)
  – **Practice protocols** are pre-agreed processes of delivering specific aspects of care
    (e.g. injecting, prescribing)
• **Guidelines** provide *guidance* for clinicians in the form of *evidence-underpinned recommendations for care*
  – one guideline will usually contain multiple recommendations related to the purpose of the guideline

• The evidence-underpinnings (strength) of the recommendations is reflected in the use of words
• Clinicians can choose to deviate from care pathways, or not comply with recommendation in guidelines, if there are sound clinical reasons, or patient preference, for doing so

• Clinicians should not vary from any step in a protocol
  – These specify minimum care expected in terms of quality and safety
  – Protocols are often embedded in clinical competencies
• Usually written in chapters
• Each chapter deals with a key question or area of concern (practice)
  – Each chapter may address a number of sub questions
    • Each sub question will be answered by recommendations which are derived from the best available literature
    • Each recommendation should be underpinned by the evidence sources from which it was derived
      – The quality of the evidence sources should be reported
Guideline recommendations may be based on different levels of evidence:

- The current best available evidence should be sought for each question.
- If there is equivocal published evidence for the question, there will be no preferred practice.
- If there is NO published evidence, you may need to frame a recommendation on consensus expert or peer opinion.

Opinion is NOT a substitute for available published evidence.
Developing Guidelines
• Synthesised best available evidence for care of a specific condition
• Presented in different forms
  1. Case management
    • Processes to assist decision making
      (operationalise the guideline)
  2. Care management
    – Statements of effective care
      (recommendations)
For each clinical guideline recommendation:

- At least one answerable question is required (using the PICO/PECOT method)

\[
P = \text{Population} \quad E = \text{Exposure} \\
I = \text{Intervention} \quad C = \text{Control} \\
C = \text{Comparison} \quad O = \text{Outcome} \\
O = \text{Outcome} \quad T = \text{Timeframe}
\]
• The evidence sources need to be specified as in a systematic review
• The resultant literature needs to be considered in terms of the **evidence dimensions**
• Evidence summaries are made for each question
• An answer to each question (recommendation) is made on the strength of the available evidence

**Basically, multiple Systematic reviews are undertaken of the literature to answer each guideline question**
1. Hierarchy level
   • study design

2. Study Quality
   • how good is the study?

3. Statistical precision of results
   – statistical significance (p value, confidence limits)

4. Effect size
   • how clinically important are the findings?

5. Relevance
   • usefulness of results in clinical practice

NH&MRC (1998)
<table>
<thead>
<tr>
<th>Component</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence Base</td>
<td>several level I or II studies with low risk of bias</td>
<td>one or two level II studies with low risk of bias or a SR/multiple level III studies with low risk of bias</td>
<td>level III studies with low risk of bias, or level I or II studies with moderate risk of bias</td>
<td>level IV studies, or level I to III studies with high risk of bias</td>
</tr>
<tr>
<td>Consistency</td>
<td>all studies consistent</td>
<td>most studies consistent and inconsistency may be explained</td>
<td>some inconsistency reflecting genuine uncertainty around clinical question</td>
<td>evidence is inconsistent</td>
</tr>
<tr>
<td>Clinical impact</td>
<td>very large</td>
<td>substantial</td>
<td>moderate</td>
<td>slight or restricted</td>
</tr>
<tr>
<td>Generalisability</td>
<td>population/s studied in body of evidence are the same as the target population for the guideline</td>
<td>population/s studied in the body of evidence are similar to the target population for the guideline</td>
<td>population/s studied in body of evidence different to target population for guideline but it is clinically sensible to apply this evidence to target population*</td>
<td>population/s studied in body of evidence different to target population and hard to judge whether it is sensible to generalise to target population</td>
</tr>
<tr>
<td>Applicability</td>
<td>directly applicable to Australian healthcare context</td>
<td>applicable to Australian healthcare context with few caveats</td>
<td>probably applicable to Australian healthcare context with some caveats</td>
<td>not applicable to Australian healthcare context</td>
</tr>
</tbody>
</table>
Distilling this into NH&MRC recommendation grading...

A. Body of evidence can be trusted to guide practice
B. Body of evidence can be trusted to guide practice in most situations
C. Body of evidence provides some support for recommendation(s) but care should be taken in its application
D. Body of evidence is weak and recommendation must be applied with caution
Clinical Guidelines usually only incorporate..

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>treating the right patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>treating the right patient right</td>
</tr>
<tr>
<td><strong>Organisation</strong></td>
<td><strong>treating the right patient right at the right time</strong></td>
</tr>
</tbody>
</table>

_This is often called ‘operationalisation’ and is usually based on expert/ peer opinion (Level IV)_.

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[Image]
How do I find good guidelines?

- Search the internet
  - Established guideline sites
    - NICE
    - SIGN
    - NHMRC
    - National Guidelines Clearing House
    - NZGG
  - using google.com........‘Clinical guidelines & ..........’

- Guidelines are rarely published in peer-reviewed journals (volume of work is too great)
  - Summaries might be published in journals

- Critically appraise the quality of the full text guideline using critical appraisal tools
• Well known trusted guideline developers (they use standard development processes)
  – NICE, SIGN, NZGG, NHMRC,

• Less trustworthy developers (variable developmental processes and purposes)
  – Guidelines Clearing House
  – National / state Departments of Health
  – Industry (insurers, hospitals)
• Do not recreate the wheel (use others’ work)
• Become aware of available clinical guidelines
  – Critically appraise their methodological quality
  – Consider their recommendations in light of current practice and contexts
• Improve availability of high quality research literature that reflects clinical practice
• Develop consensus evidence to underpin guideline development where there is no current research evidence
• For iCAHE Guidelines Clearinghouse, go to www.unisa.edu.au/cahe
• iCAHE critically appraises guidelines on its website so that readers can make quick decisions about which guidelines to pursue reading
1. Critiquing guideline quality

- Similar to scoring methodological quality of primary or secondary studies
  - quality scores on aspects of construction
    - Who
    - When
    - How
    - Why
    - What

The AGREE instrument (2008)
www.agreecollabotration.org

iCAHE scoring system (2009)
Evidence of reliability of construction in……

- Decisions regarding study inclusion
- Classification of included studies into hierarchy of evidence
- Quality scoring of study methodology
- Extraction of relevant findings
- Grading strength of evidence

This requires evidence that independent developers participated in producing literature reviews that underpin recommendations.
• Variability
  – Study design quality
  – Availability of research into guideline topics
  – Primary & secondary study findings
• Discipline-focus in reference and stakeholder groups
• Clinician versus research perspectives
• Lack of common understanding of research quality
• Turning research into defensible clinical recommendations
• No agreed mechanism of obtaining consensus opinion where no evidence exists
• Minimal support to test uptake or impact of guidelines
Process

– Barriers to uptake by clinicians
  • Differences from usual care
  • Compliance
  • Incentives
– Acceptability to patients
  • No increased cost or effort
– Monitoring processes
  • Delivery of care
  • Decision-making regarding guideline implementation
<table>
<thead>
<tr>
<th>Factor</th>
<th>Potential barrier(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Patients expectations</td>
</tr>
<tr>
<td>EBP process</td>
<td>Identification and implementing EBP is a difficult process</td>
</tr>
<tr>
<td>Team Issues</td>
<td>Multidisciplinary teams, uniformity of approach</td>
</tr>
<tr>
<td>Care process</td>
<td>Lack of uniformity, range of service delivery models</td>
</tr>
<tr>
<td>Management Support</td>
<td>Changes in leadership</td>
</tr>
<tr>
<td>Time/facilities/cost</td>
<td>Time pressures, cost effectiveness, structural limitations</td>
</tr>
<tr>
<td>Health System</td>
<td>All stakeholders having similar expectations</td>
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Outcome

- Requires prospective concurrent use of randomly selected control and guideline patients
  - Do guidelines produce better health outcomes more consistently than ‘usual’ care?
    - Short and long term
  - Is guideline care no more costly than ‘usual’ care?
    - Short and long term
  - Is guideline care seen to provide value for money?
The “change” problem

• Current ideas of logistics of putting evidence into practice draws on questionable assumptions about human behaviour
  – Health professionals are sensitive to “evidence” for and against treatment

• This statement is only true for some, and in only in specific instances
Take home messages

• Clinical guidance should
  – have a clear purpose
  – have clearly defined end-users
  – be accompanied by an implementation plan
  – be evaluated in the short and long term for
    • Uptake and compliance
    • Clinician and patient concern
    • Impact on health and cost outcomes
    • Local adaptations
Evidence-based recommendations are only as good as their uptake and application.