Clinical Effectiveness
Research

Relevant Evidence

Articles:
- **POEM**: Patient Oriented Evidence that Matters
- **DOE**: Disease Oriented Evidence

Problems:
- **Common**: conditions encountered at least every two weeks
- **Uncommon**: conditions encountered between one every two weeks and one every six months

*Slowson and Shaughnessy*
Examples of Hypothetical DOE and POEM studies

Drug A lowers cholesterol

Drug A lowers cardiovascular mortality

Drug A decreases overall mortality

PSA screening detects prostate cancer most of the time and at an early stage

PSA screening decreases mortality

PSA screening improves Quality of life

Tight control of type 1 diabetes mellitus keeps FBS<140mg/dl

Tight control of type 1 Diabetes decreases Microvascular complications

Tight control of type 1 Diabetes decreases mortality And improve quality of life
Research

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*Slowson and Shaughnessy*

% of relevant published articles

Six month survey of 90 journals, which identified 8047 articles and only 213 POEM:

- Over 97% of medical literature DOE
- About 2.6% of medical literature is POEM
“Critical appraisal is not just a fault finding exercise. It is a process of reviewing a paper to find information of value”. 

Crombie, 1996
Part of the article paid most attention to:
Validity VS. Clinical Relevance

- High validity and high clinical relevance: High quality relevant
- Low validity and low clinical relevance: Low validity and low clinical relevance
- High validity and low clinical relevance: High quality low relevant
- Low validity and high clinical relevance: Low quality high relevant
Systematic Review
- Comprehensive search of the relevant research
- Explicit selection criteria
- Critical appraisal of the primary studies
- If quantitative methodology applied: meta-analysis

Systematic Reviews of Interventions:
- Evidence of benefit (positive effect)
- Evidence of harm (negative effect)
- Evidence of no effect (no change)
- No evidence of effect (inadequate evidence)
Evidence-Based Practice Guidelines

- Critical analysis of primary evidence
- Considering local conditions
- Promise of consistency and optimal care
- Source, methodology, accessibility

Concept Map
Clinical Practice Guideline

A systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
Clinical Practice Guideline

CPGs should define clinical review criteria, clinical indicators and standards to allow those applying them to measure performance against the statements they contain.
Clinical Practice Guideline

The content of a CPG may be presented in different ways directed toward clinicians, patients or researchers and in a variety of formats, such as clinical tests, patient information, audit tools, background text, clinical algorithms, checklists and structured notes.
The term *protocol*, although in widespread use, is viewed by many clinicians as implying a prescriptive quality, contrary to the spirit in which CPGs are designed (Scottish Clinical Resource and Audit Group, 1993).
A flowchart is a sequential diagram employed to show the stepwise procedures used in performing a task, as in an algorithm.
Stage I. Selection of Topic & Formation of Work Group

Factors to consider when deciding priorities for CPG Development

1. Prevalence of condition
2. Established variation in practice
3. Potential to change health outcomes
4. Potential to change cost outcomes
5. Potential to change ethical, legal or social issues
6. Cost of developing CPG
Stage I. Selection of Topic & Formation of Work Group

- Work groups will assist the steering group to develop project plans for the development of individual CPGs, and then execute them. This will involve:

  A. The collection and appraisal of the scientific evidence.
  B. The production of recommendations explicitly linked to the scientific evidence.
  C. The consideration of modulating factors.
  D. The piloting of, and then monitoring of, the CPG in practice.
Stage I. Selection of Topic & Formation of Work Group

- The composition of work groups will vary with the CPG under development and should reflect the interests of all “stakeholders” in that particular clinical area.
- Where appropriate, consideration should be given to the inclusion of workers from other clinical disciplines, commissioners, service managers and users and carers or their advocates.
Stage I. Selection of Topic & Formation of Work Group

- The character of a group relates to its size as well as its composition.
- The size of work groups in other programs of CPG development varies from **four** (Royal College of Physicians) to **fifteen** (Agency for Health Care Policy and Research).
- Striking a balance between stakeholder interest and efficient working is ultimately a pragmatic decision.
- **Eight or nine** members has been suggested as an effective number (Chassin, 1989; Russell *et al.*, 1993).
Stage II. Recommendations linked to the evidence

- An early task for guideline developers is to weigh the soundness and relevance of the direct and indirect evidence.

- This would have been generated by processes of varying degrees of scientific rigour, and by studies of different design and detail.
Stage II. Recommendations linked to the evidence

The approaches used to develop recommendations linked to this research evidence will vary according to the strength and quality of available studies and may involve one or more of the following:

A. Expert opinion
B. Unsystematic, ungraded literature review
C. Unsystematic, graded literature review
D. Systematic, graded literature review
E. Meta-analysis.
Stage II. Recommendations linked to the evidence

This work may be undertaken by:

- “Analyst teams” (e.g. American College of Physicians),
- Members of a work group, each taking responsibility for a given area (e.g. Royal College of Physicians)
- Independent consultants conducting systematic overviews or meta-analyses (such as the Cochrane Centre).
Stage II. Recommendations linked to the evidence

► Several scales have been devised that use preset criteria to rank the strength of the evidence, and therefore of the recommendations
Stage III. Modulating factors

- The consideration of the relationship of clinical and non-clinical factors to the evidence-based recommendations may involve the use of:
  A. Peer groups
  B. Consensus conferences
  C. Delphi techniques
  D. A combination of these.

- Where the research evidence is strong, consensus is more easily established.

- It is inevitable that differences of opinion in interpreting the evidence will sometimes arise.
Stage IV. Validity review and pilot testing

- A CPG should specify the methods used in its construction, including who was involved and the weightings of the evidence upon which the recommendations are based.
- An external peer review of the methodology, as well as the content, of a CPG is desirable.
- An appropriate pilot study would be required to establish the effectiveness and acceptability of a CPG.
- Although a randomized controlled trial is the ideal test of a CPG, time constraints may not always permit this.
Stage V. Reporting

► The final product may have a range of formats, for various target audiences.

► These may include as patient information sheets, clinical algorithms (decision trees), audit tools, background texts, clinical ‘reminders’, and structured note formats.
Stage VI. Dissemination

- The distinction between implementation and dissemination strategies is often arbitrary.
- The purpose of dissemination is to ensure that those who have an interest in the CPG are aware of it, and understand it.
- Dissemination can include the use of mass media, peer review journal publication, targeted mailing, and promotion by respected opinion leaders.
Stage VII. Implementation

- Although the extent to which a guideline is implemented is the only true measure of its success, surprisingly little is understood about what enhances or inhibits implementation.

- Factors which may help include early and thorough consultation (to foster ownership and increase the relevance of a CPG to clinical reality), planned educational strategies and clinical reminders, both outside and within the consultation.

- Potential obstacles to implementation include concerns about the implications of CPGs, doubts over their relevance or feasibility, and inadequate dissemination.
Stage VIII. Review

- Mechanisms for prompt feedback assist in the detection of inconsistencies in CPGs. To facilitate this process, CPGs should specify:
  
  I. The date of issue
  II. The most recent published (or unpublished) evidence considered in formulating the recommendations
  III. Relevant trials in progress, where findings may effect the CPG content
  IV. A review or “sell by” date.
Importance of Implementation Strategy

► Field and Lohr make the important point that ‘guidelines do not implement themselves’ (1992).

► If guidelines are to be effective, their dissemination and implementation must be vigorously pursued.

► If not, the time, energy and cost devoted to the guidelines’ development will be wasted and potential improvements in consumer health will be lost.
Distributing Guidelines: No Effect
Implementation Panel

► A multidisciplinary panel should oversee the various steps needed to disseminate and implement the guidelines.

► The panel, which may be the same as the panel responsible for developing the guidelines, should also identify any barriers to the guidelines’ acceptance and implementation and work with members of target groups to develop ways of overcoming these barriers.
Barriers to Change

Identifying barriers to change requires an understanding of sociological and psychological factors: it is essential that the guideline development panel has expertise in these areas; otherwise, inappropriate or ineffective methods of dissemination and implementation may be advocated.
CME and Change

► Many studies have examined strategies for continuing medical education (Davis et al. 1995) and there is a considerable body of evidence on which to draw.

► The most striking finding is that the simple dissemination of guidelines is likely to have no impact at all on implementation (Oxman et al. 1995; Wise & Billi 1995).
Change Intervention

- Change will occur only if specific interventions designed to encourage it are used.
- The interventions most likely to induce change are those that require the clinicians’ participation in the change process (Wise & Billi 1995).
Publishing the Guidelines

1. As Booklets
2. In professional journals;
3. In professional associations’ newsletters and magazines;
4. In trade publications and industry newspapers;
5. In the popular media;
6. As brochures
7. On the Internet and linked to websites appropriate for the target audience;
8. As audio or video tapes;
1. Posting out guidelines
2. Using national, regional and local media;
3. Publicity in trade publications and possibly writing articles for them;
4. Publicity through professional associations and their publications
5. Publicity in professional journals;
6. Publicity through consumer groups and their publications;
7. Contact with undergraduate and postgraduate educators;
8. Contact with undergraduate and postgraduate students;
9. Publicity through institutions such as colleges, hospitals,
10. Discussion at conferences, seminars and professional meetings;
11. Using ‘champions’ or local authorities to promote the guidelines or to be interviewed;
1. Including in Undergraduate Medical Education
2. Continuous Medical Education
3. Educational Materials
4. Seminars and Conferences
5. Web Based Materials
6. Interactive Educational Meetings
1. Including only technically efficient drugs for each problem in “national pharmacopoeia”
2. “Insurance pharmacopoeia” according to allocative efficiency of interventions
3. Considering “Pharmacopoeia in use” through sophisticated drug logistic strategies
1. Perfect Practice Prize
2. Naming 5 Star GPs in Professional Media
3. Payment Bonuses
4. Incentives for organizations within them CPGs are adopted and implemented
5. Incentives for Provinces within them CPGs are mostly Implemented
1. Setting Regulatory Clinical Standards
2. Mandatory Registration of Patients with Disease of Interest in Registration Books
3. Performance Monitoring
4. Clinical Audit
5. Feedback Messages (according to audit results)
6. Practice Reminders (e.g., on report of laboratory or radiology orders)
7. Prescription Feedbacks
8. Re-evaluation and Re-certification
9. Contracts
Audit and Feedback

Requests for knee x-rays

- Number of practices
- Requests per 1000 patients

- Std. Dev = 16.93
- Mean = 15.8
- N = 247.00
Duration of Effect
Thank You!
Any Question?