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Guidelines Development: The United Kingdom Story

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CLINICAL PRACTICE GUIDELINES IN SURGERY

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There is a growing demand from government and public that health care treatments should be evidence-based. Alongside the demand for evidence-based treatment there is an anxiety about quality assurance, equity of access and other factors that may influence the outcome of treatments; knowing that effective treatments exist does not guarantee that all practitioners use the treatments, or that practitioners who do use them do so with adequate levels of competence. The rapidly expanding number of clinical practice guidelines both describe and disseminate best evidence-based practice.

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Objectives:

- to describe the UK approach to the development of clinical practice guidelines
- to discuss limitations of this approach, especially in relations to surgery
- to describe a possible alternative approach

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1 The UK approach to guidelines

Based on the principles of
evidence based healthcare:

- Primary evaluations ('evidence') of the effectiveness of a treatment
- Systematic review of the evidence
- Practice guidelines, based on the findings of systematic review and expert opinion

The traditional model for evidence-based health care has 4 key features:

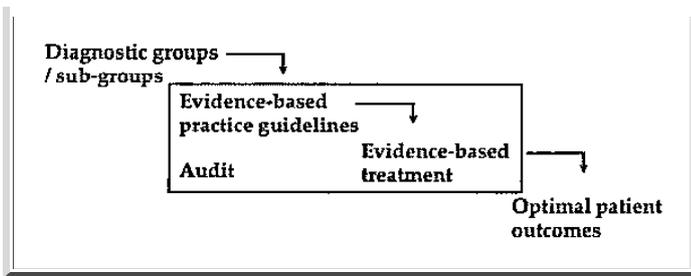
1. primary evidence of the effectiveness of treatments;
2. systematic review of the primary evidence about effectiveness;
3. clinical guidelines based on systematic reviews and expert consensus opinion;
4. clinical audit of 'compliance' with clinical guidelines.

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Quality assurance in health care

Relies primarily on auditing compliance with practice guidelines:

In this model, clinical audit focuses on compliance with the guidelines about management; this makes audit relatively easy, and works because of well established links between the use of articular interventions and improved outcomes (when they exist).



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UK surgical guidelines

Surgical practice guidelines based on systematic reviews of the available evidence:

- Cleft lip and palate
- Colorectal cancer
- Lung cancer
- Groin hernia in adults
- Bladder outflow obstruction in men
- Orthodontics
- Paediatric dentistry
- Restorative dentistry
- Dental public health
- Third molar teeth

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2 Limitations to the 'evidence-based' approach

- requires treatments to be defined and consistently applied
- requires high quality evidence about effectiveness
- requires evidence to be widely applicable

For some interventions, the usefulness of this traditional model is limited. It requires clear definitions of the interventions on which guidance is being formulated, high quality evidence about the effectiveness of the intervention, and high quality evidence that is widely applicable in different settings. These requirements are rarely met by surgical interventions.

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Surgical procedures are difficult to define and apply consistently

- many procedures are 'black box' interventions
- guidelines tend merely to specify the 'black box'
- no guarantee that the components of 'black box' are the same for all surgeons

Surgical procedures are often difficult to define. A procedure may be given a name, and there may be recognised 'variants', or alternative ways of achieving the same ends; yet there may still be considerable variation between surgeons in the way the procedure is carried out.

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Surgical procedures are difficult to define and apply consistently

Practice guidelines that specify 'black box' interventions are only credible if:

Surgical guidelines that make recommendations about procedures can only be credible if there is no variation between surgeons in the way the intervention is carried out, or if any variation that exists is unimportant and not associated with patient outcome. Both of these possibilities seem implausible.

- there is no variation inside the 'black box', or
- variation inside the 'black box' is irrelevant

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Total hip replacement 'black box'?

-
- type of femoral prosthesis?
 - modular or monoblock design?
 - cement centraliser fitted?
 - surgical approach?
 - trochanteric osteotomy carried out?
 - Femoral bone grafting carried out?
 - Type of distal femoral plug used?
 - Method of bone preparation?
 - Greater trochanteric bone removal by curette?
 - Lesser trochanteric bone removal by curette?
 - Prophylactic antibiotics given?
 - Make of cement used?
-

There are also concerns about the applicability of evidence about the effectiveness of surgery, a problem that exists for almost all RCTs but which is likely to be especially serious in surgery, where individual surgeons vary. An individual surgeon may be unwilling to trust high quality evidence obtained by someone else.

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Lack of high quality evidence about effectiveness of surgical procedures

Despite pressure for evidence-based surgery, quality of evidence not improving:

	1980	1990
% comparative studies	16%	17%
% RCTs	7%	7%
average qual. comp studies	5.49	6.04

Solomon & McLeod 1993

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Lack of high quality evidence about effectiveness of surgical procedures

Possible reasons for the lack of RCTs of surgical procedures include:

- lack of perceived need for evaluation
- lack of consensus about key variables inside the 'black box'
- lack of equipoise amongst surgeons
- difficulty in recruiting patients

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Colorectal cancer guidelines

Preparation for surgery (evidence grade A, B or C):

- Mechanical bowel preparation prior to surgery is recommended (C)
- All patients should have antibiotic prophylaxis (A)

Elective surgical treatment (evidence grade B or C):

- Surgeons should expect to achieve an overall curative resection rate of 60% (but will depend on stage ...)(B)
- Cytocidal washout prior to anastomosis should be used (B)

Adjuvant chemotherapy (evidence grade A):

Adjuvant radiotherapy (evidence grade A):

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Limited applicability of evidence about effectiveness in surgery

- highly selected nature of patients studied in RCTs is widely acknowledged
- in addition, applicability of surgical RCT evidence limited by heterogeneity of interventions
 - different level of competence
 - different components in 'black box'

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Limited applicability of evidence about effectiveness in surgery

Variation in 30-day mortality following carotid endarterectomy:

30-day mortality in RCTs	~ 0.5%
30-day mortality in RCT Medicare hospitals	1.4%
30-day mortality in non-RCT Medicare hospitals	1.7-2.5%

Wennberg et al., 1998

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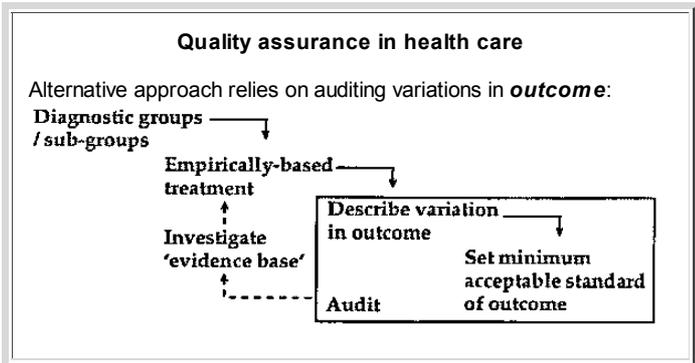
3 An alternative approach to surgical guidelines

Evidence based healthcare approach flawed because:

- poor quality or insufficient evidence
 - difficult to set practice guidelines
 - practice guidelines can be challenged
- interventions are imprecisely defined
 - difficult to know what to audit

The traditional evidence-based approach may therefore be inappropriate in surgery. Focusing on the outcomes of surgery offers an alternative approach.

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For example, it may be possible to set a 'minimum acceptable' standard for different case-mix groups; the minimum acceptable standard becomes, in effect, the guideline.

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'Epidemiology' of surgical outcome

Investigate variation in outcome:

- as a function of the attributes of patients, surgeons / physicians, and hospitals
- focus on variation in mean outcome for surgeons / physicians, and hospitals
- gives potential insights into key variables associated with variation in outcome

Having high quality data about patient outcomes also permits study of the 'epidemiology' of outcome, that is investigation of factors associated with variation in patient outcome, be they patient characteristics, clinician characteristics and features of the way they carry out procedures, or hospital characteristics. Knowledge of 'risk factors' for poor outcome can be used to set research questions that may need more formal evaluation.

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Quality assurance in health care

The outcome approach is not without its own limitations.

Important that minimum acceptable outcome is based on representative sample:

Primary arthroplasty, 5 year failure rate - UK specialist centres	~ 4%
Primary arthroplasty, 5 year failure rate - UK regional register	~ 8%

Gregg, 1998 (pers. comm.)

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Quality assurance in health care

Outcome-driven approach to setting of standards requires:

- infrastructure for high quality data collection of case-mix and outcome
- valid and relevant measure of outcome
- valid models for case-mix adjustment
- statistical methods for hierarchical analysis

It depends on high quality, complete data. It depends on relevant, valid and repeatable measures of outcome. It depends on relevant, valid and repeatable measures of case-mix, and knowledge of what are the important case-mix variables. It depends on sophisticated statistical methods for modelling multi-level or hierarchical datasets. These are not trivial requirements, which should not be underestimated.

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Conclusions:

- **The traditional evidence-based approach to practice guidelines and clinical audit is not always feasible**
- **An outcome-driven approach offers an alternative way of setting and auditing standards of high quality health care**
- **The data requirements of an outcome-driven approach should not be underestimated**

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