Clinical practice guidelines: on what evidence is our clinical practice based?

Sarah Marriott and Claire Palmer

Many sources of evidence inform clinical practice, including research findings, patients' views, and clinical experience. This article describes recent progress in developing what will be the College's first guideline, *The Assessment and Management of Violence in Clinical Settings*. The design of the programme acknowledges the diversity of evidence in this area, by drawing a distinction between different types of evidence. Evidence is systematically identified and its quality appraised by the Work Group, through commissioning literature reviews. Initial recommendations will be based on experimental data. The methods used to consider non-experimental data, particularly expert opinion, will be described in more detail in a later article in this series.

The Clinical Practice Guidelines Programme's aim is to influence routine health outcomes by supporting clinicians' decisions about patient care. A cornerstone of the programme is the task of gathering the evidence on which clinical practice is based, and bringing it to the attention of clinicians. Sources of evidence include the basic sciences, patient-centred research findings, the law, medical ethics, patients' views, and clinical judgement and experience. The topic for the first clinical practice guideline, *The Assessment and Management of Violence in the Clinical Setting*, was selected following a survey of those involved in mental health care (Palmer, 1995).

A diverse range of evidence supports clinical practice

There are many different types of evidence which inform clinical practice. Evidence can be described as either experimental or non-experimental. Experimental evidence may be of either a quantitative or qualitative nature. Where quantitative data is sought, there is a burgeoning methodology of trail designs, all varying considerably in their 'power', or the extent to which they are likely to minimise both the operation of systematic bias and the opportunity for chance findings. The use of a control group, and methods which randomly allocate participants to a treatment group strengthen the trial design. A randomised controlled trial (RCT) combines both of these features. It is widely regarded as the 'gold standard' of quantitative research methods.

However, the quality of a controlled experiment does not depend solely on its design, but also on how it is conducted. Important questions in appraising a controlled study include those relating to systematic bias in the match between control populations and the treatment group, in the care provided to each aside from the intervention being evaluated, in those lost to follow-up during the course of the experiment, and in the assessment of outcome. Methods of allocation are also important, particularly the extent to which those who evaluate outcomes are unaware (blinded) of the process or intervention preceding it. Where a number of RCTs address a virtually identical hypothesis, the results can be pooled into a meta-analysis. If this is well designed, it provides still stronger evidence because it summarises findings from substantially larger populations.

Unfortunately, there are neither sufficient well-designed controlled trials to provide a comprehensive evidence base for the increasingly complex world of routine practice, nor is their design always appropriate for this purpose. For instance, to test the hypothesis that restriction of the most acutely disturbed patients is associated with an increased risk of harm to others, it would obviously be practically difficult, as well as unethical, to randomise patients at the time of admission (including those on a section of the Mental Health Act), between a treatment group which received nursing care in a ward environment and another nursed in a community setting. Other quantitative designs can be adopted, and although not as robust, the findings from non-RCT designs can be so dramatic that it does not make sense to ignore them.

Good clinical practice is not only a matter of what is done, but also of how and why it is done

Qualitative research. Qualitative research designs are concerned with making sense of information,

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Table 1. Criteria for evaluating the quality of a controlled study

Is the study hypothesis clearly defined?
Is the study population a representative one?
Was the assignment of patients to treatment randomised?
Were patients, practitioners, assessors blind to the experimental intervention?
Were the groups similar at the start of the trial?
Aside from the experimental investigation, were the groups treated equally?
Were all those who entered the trial accounted for at its conclusion?
Was this in the groups to which they were originally allocated?
Are all clinically important outcomes considered?
Whose perspective do they reflect?
Are the techniques used for data analysis appropriate?
What is the size, and precision of the treatment effect?
Do the likely benefits outweigh the harms and risks?
Is the conclusion supported by the results?

Table 2. Criteria used to classify research studies

Evidence obtained from a controlled study

(I) Meta-analysis of 2 or more randomised controlled trials
(II) Single randomised controlled trial
(III) Controlled trial with partial randomisation
(IV) Prospective controlled cohort study
(V) Retrospective controlled cohort study

(hierarchical)

Evidence obtained from a non-controlled study

- Evidence from multiple time series, across time and/or place
- Longitudinal quantitative study
- Systematic qualitative research studies
- Systematic, evidence based guidelines based on a thorough review

(non-hierarchical)

Authoratative reports

- Consensus statements
- Reports of expert committees
- Unsystematic overview other

(to be excluded from evidence based recommendations of the review, but brought to the attention of the Work Group when guidelines are developed)

(Adapted from Deeks & Sheldon, 1995).

and as much with generating hypotheses as with answering them. As a result, quantitative and qualitative approaches are often complementary. Methods include delphi-techniques, in-depth interviews, and preference surveys.

Non-experimental evidence. This includes the beliefs, convictions, and judgements of individuals or groups, including clinicians, patients, and expert committees.

Unfortunately, whether or not evidence conclusively supports one course of action rather than another usually is influenced by a range of considerations rather than just one. For instance, an important question is not just whether the expected outcome is good, but whether it is good *enough* when the possible risks are taken into account. Even with sophisticated appraisal methods, the distinction between experimental and non-experimental, qualitative and quantitative studies, fact and opinion is not always crystal clear. Employing advanced statistical analyses may not be sufficient to support a confident conclusion from a study's findings. A degree of judgement is always involved, and there is no substitute for common sense.

The quantitities of evidence are enormous, and can be hard to track down

The sheer volume of supporting evidence also poses difficulties. For instance, the first issue of the *British Journal of Psychiatry* this year contained 20 scientific papers, two editorials, one review article, five letters, and five book reviews, each on topics related to clinical practice. It also reproduced the index for the most recent issue of the *American Journal of Psychiatry*, which included approximately the same number of items. These are just two of at least 1700 scientific and medical journals listed on the Medline database alone. Other databases, such as Embase or PsychLit, include a significant number of additional journals published at weekly, monthly or quarterly intervals.

The inexperienced electronic database user can expect to find less than 20% of the information relevant to her search task, and a more experienced searcher will approach 50%. Systematic search techniques, employing a comprehensive range of subject headings (called MeSH in Medline) and using specialist operator functions appropriately across the range of relevant databases are recommended. When these are supplemented with efforts to identify high quality, unpublished material, as well as material printed in unlisted publications, the sensitivity and specificity of searching can be improved substantially (Dickersin *et al*, 1994). Hand-searching journals is very time consuming, but sometimes reveals material 'concealed' from a searcher by inappropriate indexing terms.

Table 3. Quality and quantity of evidence identified by systematic search of Medline (adapted from Pereira, 1995)

	Controlled trials, e.g. RCTs, cohort studies, etc.	Other quantitative data	Reviews (included MeSH term systematic review)	Opinion based articles, e.g. editorials
Violence prediction (included MeSH, heading and author search)				
Long-/short-term prediction	***	****	***	****
Risk assessment	**	***	****	***
Violence intervention (included MeSH heading search only)				
Use of seclusion	*	****	***	**
Use of medication	*	**	***	**
Use of psychotherapy	*	*	*	*
Other strategies	*	***	*	***
Guidelines		*	*	**

No. of articles: *, 1–5; **, 6–10; ***, 11–20; ****, 21–40.
RCTs, randomised controlled trials.

Collating the evidence

The Work Group has met regularly since its first meeting in November 1995. It is chaired by Professor John Wing, and includes members from a range of professional backgrounds, and a service user[1]. It is supported by the members of the Clinical Practice Guidelines Project Team, based in the College Research Unit[2].

The Work Group's first task was to 'scope' the clinical topic. It adopted a definition for violence, 'physically destructive or damaging behaviour'; for the settings in which the guideline might be applied, 'settings in which clinicians provide care'; and a clearly defined clinical scenario, 'a person who is actively violent, for example attacking others, breaking objects, or on the brink of such behaviour'. The clinical skills and decisions demanded by this clinical situation were considered in a wide range of practice settings, together with the desired (and possible undesired) outcomes. The resources and structures which might influence clinical processes and promote better outcomes were also explored.

Four project modules have been developed which together outline the guideline's content. These are prediction, prevention, assessment, and intervention. Before commissioning literature reviews, the Work Group required an estimate of the quality and quantity of relevant data. An overview of published literature was commissioned, and conducted by systematically searching a single electronic database (Medline).

Literature reviewers have been recruited from a wide range of multidisciplinary backgrounds. Training in the techniques of developing and conducting a systematic literature review, systematic search and quality appraisal skills are provided by the programme, through the Clinical Practice Guidelines Office Team[3]. So far, six reviews have been commissioned, across the prediction and intervention modules. These are short- and long-term prediction of violence (prediction module), psychological intervention, seclusion and physical restraint, the human environment, the physical environment, and pharmacological intervention (intervention module). The protocol for each of these reviews is developed in consultation with the Work Group membership.

1. The Work Group members are Professor John Wing (Chair, and previously Director, College Research Unit), Dr Zerrin Atakan (Consultant Psychiatrist), Dr David Ndegwa (Consultant Forensic Psychiatrist), Dr Brian Kidd (Senior Registrar), Dr Martin Ward (Lecturer in Nursing), Dr John Deeks (Medical Statistician), Dr Brian Thomas-Peter (Clinical Forensic Psychologist), Ms Nina Rideout (Service User), Mr David Leadbetter (Approved Social Worker).

2. The Clinical Practice Guideline Project Team includes Ms Claire Palmer (CPG Programme Facilitator), Ms Victoria Thomas (Administrator), Dr Paul Lelliott (Director, College Research Unit), and Dr Sarah Marriott (Research Fellow).

3. The Clinical Practice Guidelines Office Team includes Ms Claire Palmer, Ms Victoria Thomas, and Dr Sarah Marriott.

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Table 4. Consecutive stages in undertaking a systematic review

- Hypothesis formulation
- Protocol development
- Searches for published and unpublished literature
- Assessment of quality and relevance of citations
- Obtain full texts
- Assessment of quality and relevance of citations of full texts
- Data collection
- Analysis
- Report preparation and presentation to the Work Group

(Adapted from Oxman, 1994).

The tasks ahead

The Clinical Practice Guidelines Programme is now in its second year. As its experience broadens, it is refining the framework within which practice guidelines can be developed and put to use (Marriott & Lelliott, 1994). This need not apply only to national projects, such as the College's programme. Many local clinicians are also keen to develop clinical systems, as well as the evidence base for the care they routinely provide. The Clinical Practice Guidelines Office Team is now working on educational and training materials covering multidisciplinary project development, literature searching and appraisal skills. Finally, the development of the College's first guideline, *Assessment and Management of Violence in Clinical Settings* is well under way. It is likely that the systematic approaches to establishing the evidence base for practice outlined here will reveal areas in which the research findings are far from robust. This alone will be valuable and will contribute to defining a future research agenda.

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