

3. Practice guidelines and other support for clinical innovation

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The first two articles discussed how to formulate and pursue clinical questions and how to build a clinical reference library. Looking up clinical questions during or immediately after patient care can be an effective method of learning; however, you must first realize your ignorance, then formulate a searchable question, find the answer and change your practice as a result. Even when there is widespread knowledge about an important innovation in clinical practice, such as aspirin for patients with myocardial infarction (MI), many patients are still incorrectly managed. Practice guidelines—‘systematically developed advisory statements created according to validated methodologies’¹—act as a compact summary of the evidence and other factors guiding patient management so could be helpful in this context, but they are many and various^{2,3}.

HOW TO SELECT A GUIDELINE

Your consultant asks you to identify a guideline to increase the local use of aspirin after MI

As a perfectionist, you want to select the very best from the multitude of guidelines on management of MI. But what makes a good-quality guideline? Italian workers have proposed three criteria: whether the guideline (a) reports the range of professionals involved in development, (b) reports the strategy used to identify primary evidence and (c) explicitly grades the recommendations². Inspection of 431 specialty society guidelines published from 1988 to 1998 showed that 54% met none of the criteria, 34% met one, 7% met two and only 5% met all three. Seemingly, specialty guidelines have been dominated by ‘experts’, with little involvement of GPs and other users. Equally, most guidelines result from an informal *mélange* of opinion in the charged social atmosphere of a committee. One encouraging result in the Italian review was that the more recent guidelines were more likely to include details of literature search and graded recommendations.

A UK group has developed a checklist of thirty-seven questions exploring three dimensions (rigour of development, clarity of content and context, documentation of methods for application and monitoring) [www.sghms.ac.uk/phs/hceu/]. In a study in which six clinicians used this ‘St George’s checklist’ to assess 60 guidelines the inter-rater agreement was excellent⁴. However, even if a guideline is of high scientific quality, doctors may still not follow it. An observational study of Dutch clinicians suggested that key determinants of whether recommendations would be followed were that they were uncontroversial, specific, evidence-based and required no change to existing routine⁵.

Even when we locate a satisfactory published guideline, it often proves too bulky or inconvenient for use in routine patient care. Some guideline authors now offer support tools such as glossy laminated flowcharts, pocket prompt cards or wall posters. Such tools are discussed later.

HOW TO MAKE A GUIDELINE LOCALLY RELEVANT

Guidelines nearly always contain recommendations that cannot be universally adopted. For instance, certain tests or treatments may not be locally available, or a recommendation for specialist care may run counter, without supporting evidence, to a local tradition of community care. Thus, a national guideline commonly needs to be adapted if local clinicians are to get a feeling of ‘ownership’. Strategies can include:

- Summarizing the guideline in a standard short format for a house officers’ handbook
- Deleting the sections that do not apply locally (if there is no strong evidence that they should be retained)
- Adding information about local facilities and services, such as to whom to refer patients, which days the clinic takes place and what phone number to ring.

However, sometimes when scrutinizing and tailoring a guideline one realizes that the raw material is unsatisfactory and a new one is needed.

HOW TO WRITE A NEW GUIDELINE

After applying the St George's checklist to five guidelines on aspirin in MI, you find that none is satisfactory. You resign yourself to writing a definitive guideline

Writing a high-quality guideline is hard, especially if you mean it to score well on the St George's checklist⁴. Before writing a single recommendation you will have to set up a multidisciplinary group, conduct detailed searches, appraise and grade the evidence, and combine this with other information such as patient preferences and health economic data. Various bodies, including the Scottish Inter-collegiate Guideline Network [www.sign.ac.uk]⁸ and the North of England Group⁹, have developed and published rigorous methods. Lessons from such activities are that adherence to the methodology depends not only on clinical commitment but also on library and epidemiological support, that the evidence tends to be more abundant than expected but much of it is of low quality, and that the effort of reaching agreement is about twice that envisaged. You decide to go ahead; but you are stopped in your tracks by your clinical director who asks about the legal implications for guideline users, authors and publishers.

What is the legal position of guideline users and authors?

Despite worries that the introduction of guidelines would lead to a flood of negligence cases, guidelines play a part in only 7% of US malpractice claims. However, there is a sufficient body of cases to allow some general conclusions^{10,11}.

Differences between clinical and legal views

Guidelines are created for a medical purpose, so have no special legal status. To a doctor, practice guidelines are clinical guidance resting firmly on the authority of science. To a lawyer, a guideline advises health professionals to practise in one way rather than another. Courts are always wary of guidance that cannot be subjected to cross-examination; so, although guidelines may be used in court to support a negligence case, they cannot substitute for expert testimony. An expert witness is necessary to help the court interpret the relevance of a guideline, even when its recommendations are found to be representative of responsible practice. Thus, the legal status of each guideline must be decided afresh in each case¹⁰.

Liability of authors and publishers

As a matter of public policy and to encourage the dissemination of knowledge, book authors and publishers are 'never' found liable for negligence due to errors¹². However, guidelines may be treated differently¹⁰. There have been no UK negligence cases yet, but in American

courts the developers have been held liable for faulty guidelines. Commenting on the relevance of this to the UK, Hurwitz wrote: 'There appears to be no logical reason why similar liability could not attach to the originators and issuers of UK guidelines shown to cause patient harm as a result of faulty guideline development methods'¹⁰. Failure of the guideline user to protest about the guideline does not protect the developer from a claim of negligence. Even if patients generally fail in suing guideline authors, other parties (such as a company whose product is disadvantaged) may bring a case¹¹.

Guidelines are merely advice, so the language used should encourage and remind clinicians to exercise appropriate discretion, for example avoiding words such as 'never' and 'always'¹⁰. However, use of permissive language ('probably', 'sometimes') when directive terminology is more appropriate may not protect the developers from liability. Such permissive language would be troublesome if it encouraged users to assume that other actions were appropriate in circumstances when the evidence supported only one course of action.

Liability of doctors for adherence

Adherence to a guideline is not automatically evidence of reasonable clinical practice, so doctors cannot escape legal liability by claiming that adherence to a guideline has overridden their clinical judgment¹⁰. In the UK, even if a guideline has been agreed as a legal standard, appropriate application still requires discretion. For example, a Scottish man with congenital homonymous quadrantanopia successfully appealed for restoration of his driving licence even though it had been withdrawn on the basis of legally adopted guidelines. A clinician who complies without protest with an inappropriate guideline cannot then deny responsibility for patient harm. The test of reasonableness of medical treatment remains 'the standard of the ordinary skilled man exercising and professing to have that special skill . . . who acted in accordance with a practice accepted as proper by a reasonable body of medical men skilled in that particular art'¹³.

Liability of doctors for non-adherence

In determining the status of a particular guideline, courts are likely to consider its authority, flexibility and scope, whether its development and application had statutory backing, and whether it embodies practices accepted as proper by a responsible body of doctors. Clinical practice may be perfectly lawful when it does not comply with a guideline, even one issued with executive authority. As Lord President Clyde stated in 1957, 'There is ample scope for genuine difference of opinion and one man is not negligent merely because his conclusion differs from that of other professional men'¹⁰. One reason for writing guidelines is to encapsulate

Box 1 Definitions of clinical innovation techniques

Audit and feedback	Collection and feedback of pooled activity or outcome data (Ref 23)
Business process re-engineering	Analysing the fundamental aims of an organization and how best to meet them
Care pathways	Preprinted multiprofessional record forms for common conditions or procedures, incorporating reminders (Refs 6,7)
Case conferences	Multidisciplinary discussion of specific cases and how to manage them
Case finding	Identification by staff or computer of patients who fulfil criteria for specific actions
Checklists for patients/clinicians	Proformas for patients or clinicians to prompt for data to be collected (Ref 24)
Computer-based records	Use of computers to enable flexible data collection and to search coded data (Ref 25)
Continuing education	Shared seminars, workshops, conferences, etc. The most effective allow participants to determine the agenda
Continuing professional development	Encouraging clinicians to recognize and address their training needs through whatever means are feasible and appropriate
Decision support systems	Computer systems which use patient data and clinical knowledge to generate patient-specific information or advice (Ref 26)
Distance learning material	Printed, video or computer-based material used to support learning which is posted or made available over the Web (Ref 14)
Incentives	Financial or other (e.g. peer group recognition)
Modified request forms	Redesign of paper or computer request forms to capture the information needed to support the innovation and eliminate inappropriate options (Ref 27)
Opinion leaders	Those professionals to whom others turn for advice; giving relevant information and distance learning materials to these individuals (Refs 23,25)
Outreach visits (synonym: counter-detailing)	A knowledgeable person visits clinicians, discusses the innovation, answers questions and leaves behind distance learning material (Refs 19,23)
Patient information	Providing preformed, tailored paper or computer-based information about a condition or procedure
Patient-focused care	Redesign of a clinical function to provide a one-stop shop for patients, incorporating all the resources required for routine patient management
Practice-based network	A primary care network to discuss and disseminate research methods and results (Ref 29)
Prospective self-audit	A variant of audit using self-collected data to ensure confidentiality and ownership of results
Quality improvement	Use of continuing quality improvement techniques, including audit, incident monitoring and definition of targets (Ref 30)
Record redesign	Redesign of paper or computer records to present critical patient data and other information in a suitable format to support the innovation (Ref 31)
Remedy perverse incentives	For example, reducing fees for unnecessary services (Ref 28)
Reminders to clinicians	Collection and feedback of patient data, clinical knowledge or advice relevant to individual patients by record inserts, stickers, stamps, etc (Refs 16,32)
Reminders to patients	Reminder letters or phone calls to patients about their treatment, appointments, diet etc; may be combined with case finding, checklists, decision support systems (Ref 33)
Shared decision-making	Active involvement of patients and carers in choosing management options. Synonym: patient participation (Ref 34)
Social marketing	Survey, involve, provide information to and educate people in the community by health promotion techniques, advertising, telephone help lines, walk-in health shops, etc. (Ref 35)
Staff substitution	Substituting new staff, often more junior or more specialized, for some patient care activities
Telemedicine	Use of electronic media to communicate between patients and clinicians or between clinicians on more than one site (Ref 36)

recent innovations in clinical science. However, the existence of such a guideline does not make every clinician liable. Lord Denning stated in 1955 that 'It would be quite wrong to suggest a medical man is negligent because he does not at once put into operation the suggestion that some contributor or other might make in a medical journal'¹⁰. Guidelines designed to hasten the adoption of recent evidence would not reflect customary professional care.

Once your guideline group has taken these lessons to heart, it moves fast to produce a high-quality guideline which you succeed in publishing in a journal. The major question, now, is how to ensure that your guideline exerts the desired effects on clinical practice.

HOW TO PROMOTE A CLINICAL INNOVATION

You spend a year developing a definitive guideline on aspirin and MI which you publish in a journal and also circulate locally. However, six months later local clinicians are still not advising patients to take aspirin after MI

Publication in a journal or circulation by mail is seldom sufficient^{14,15}. Part of the challenge is to get clinicians to read the guideline, and strategies include filing a summary of the recommendations in patient notes, producing a summary card for clinic room desks or a wall poster, composing a page for the junior doctors' handbook, and making slides for continuing education. Techniques less specific to guidelines¹⁶ include patient information leaflets,

Table 1 Barriers to clinical innovation and possible techniques to overcome them

Stage in the PRECEDE model	Documented barrier to innovation	Possible innovation techniques
1. Predispose to innovation (staff unwilling to change)	Clinicians do not know about it	Outreach visits; opinion leaders; wall charts; distance learning material; informal continuing education
	Apathy or lack of interest	Outreach visits; opinion leaders; incentives; audit of existing practice; provide information to patients; informal continuing education
	Concern about peer resistance	Target opinion leaders; informal continuing education; arrange focus group or survey of peers; provide distance learning materials
	Concern about patient resistance	Survey, involve and educate patients; social marketing techniques
	Conflicting financial interest	Remedy the perverse incentive: eliminate fees for obsolete services
	'We do it already'	Prospective self-audit (e.g. log book)
	'We're too busy'	Analyse, revise and agree job content; substitute staff; obtain more resources
2. Enable innovation (staff willing to change, 'system' is against them)	Too many innovations already in progress	Identify other staff to take the necessary action; prioritize and schedule innovations
	Poor access to high quality patient data	Case finding, care pathways, checklists for patients or clinicians; redesigned or computer-based records
	No access to detailed knowledge about innovation	Printed or computer-based guidelines or reference material; informal continuing education, opinion leaders, outreach visits
	Difficult to synthesize patient data with clinical knowledge	Informal role-playing seminars; case conferences; decision support systems
	Staff do not have the physical skills	Organize training courses; substitute staff who do have skills
	Staff do not have necessary space, staff, drugs, equipment	Identify and obtain the necessary resources
	'No money'	Reallocate funds from ineffective activities; seek increased budget (via managers, opinion leaders, patients, media)
3. Reinforce innovation (staff need continued encouragement)	Medicolegal or risk management concerns	Seek clarification; involve patients, support groups, self-help groups
	Other organizational problems	Analyse and streamline care process (e.g. patient-focused care, re-engineering, quality improvement approaches)
	Forgetting	Reminders; audit and feedback; staff rotation; refresher courses; incentives. Redesign tasks to eliminate memorization
	Simple mistakes caused by action slips or capture errors	Establish blame-free culture; log errors and near misses in an incident reporting system (Ref 22). Re-engineer care processes to make errors less likely, e.g. staff substitution, redesigned records and request forms

financial incentives and use of opinion leaders (see Box 1 for definitions).

Before the innovator can select the appropriate technique or combination of techniques, he or she must understand the barriers to change. Some clinicians may need to be persuaded or actually helped to do what is recommended; moreover, waverers will require continuing encouragement if they are to persevere with the innovation in the face of counter-pressure from patients¹⁷ or peers. These stages are summarized in the PRECEDE model¹⁸—predisposing people to innovation, enabling the innovation and reinforcing the innovation (Table 1).

Identification of barriers to innovation requires an understanding of where each individual or group lies in the innovation process and is fundamental to selection of appropriate techniques. Methods such as outreach visits¹⁹

contain multiple elements effective against many barriers. As with broad-spectrum antibiotics we can say that they often work though we seldom know exactly why. Innovation techniques can be expensive and have serious unwanted effects. Again as with antibiotics, precise diagnosis beforehand will help in choice of a suitable agent. Table 1 links the three innovation stages, some specific barriers at each stage and appropriate techniques.

Effectiveness

A difficulty in determining the effectiveness of an innovation technique is the large number of variables. For example, the intended result may be to introduce a new procedure or to lessen use of an outmoded one. The clinical behaviour targeted may be ordering of laboratory tests (to aid diagnosis²⁰, screening or disease monitoring), prescribing, referral, hospital discharge or counselling²¹. A technique which works well in one of these areas may not be effective in another. Techniques may be used singly or in combination, and with or without an attempt to identify the barriers to innovation. A systematic review of 99 randomized trials, examining 160 innovation techniques¹⁶, indicated that 70% of techniques improved clinical practice and 48% improved patient outcomes. A rough idea of the effectiveness of these innovation methods along four dimensions can be had from Table 2, though the comparisons are almost never within a single study and the number of studies is often too small to provide a reliable estimate.

The next article will examine continuing education activity in more detail; patient information will be discussed in article 6 and decision support systems in article 9.

Table 2 Effectiveness of innovation techniques according to four dimensions (data from Ref 16)

Dimension	Aspect	Effectiveness as per cent (no.) of techniques studied
Type of clinical behaviour targeted	Procedural skills	25% (1/4)
	Enhanced diagnosis	50% (2/4)
	General management of a problem (e.g. asthma)	55% (32/58)
	Resource utilization, including test ordering	71% (17/24)
	Preventive care activities	74% (40/54)
Type of innovation technique studied	Prescribing	79% (11/14)
	Formal continuing education course	14% (1/7)
	Educational materials	36% (4/11)
	Audit and feedback	42% (10/24)
	Patient mediated (e.g. leaflets)	78% (7/9)
	Reminders to clinicians	85% (22/26)
Number of innovation techniques used	Outreach visits	100% (7/7)
	Opinion leaders	100% (3/3)
	One innovation technique	60% (49/81)
Method used to identify barriers to innovation	Two techniques	64% (25/39)
	Three or more techniques	79% (31/39)
	No identification of barriers	42% (5/12)
	Literature showed need	53% (18/34)
	National guideline showed need	61% (25/41)
	Local consensus process	58% (26/45)
	A study to identify local barriers	89% (25/28)

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