DEVELOPMENT OF EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES FOR BEST PRACTICE: TOWARDS BETTER OUTCOMES

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“They are called wise who put things in their right order.” – Thomas Aquinas

Medicine ranks among the very earliest of professions and continues to hold a high but somewhat challenged place in our community. However, to remain relevant in an increasingly sceptical and demanding society, the profession has been required to probe and review its structure and the quality and outcomes of the services it provides. Medicine clearly needs to embrace new structural opportunities and reduce risks in its processes, while continuing to deliver the highest quality of clinical care to the community.

Accelerated societal change began to cause some discomfort for the medical profession several decades ago; renewed interest in evidence-based medicine was observed at about the same time. In a proactive step, professional leaders began to assess the successful response of business and industry to variation and quality, and review the relevance of these activities to clinical practice. This has meant embracing change where appropriate after careful review, reinforcing clinical activities that were supportable, shedding those that were marginal or dubious, and aiming to bring evidentiary material of a high level into clinical practice within a reasonable time frame.

This activity led to the embracing of evidence-based medicine, which has been defined as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients”. The use of evidence in clinical practice requires a marriage of clinical skill and experience with the best evidence that has been accrued from a systematic search of the literature, or even by carefully reviewing the structure of practice, process and outcomes in a quality milieu. This requires constant review and response to perceived variables if quality is to be reinforced and maintained.

The acknowledgment of these dynamic situations led to the elaboration of evidentiary material in areas related to clinical practice. These became crafted into “Guidelines”.

At this stage, late 1993, the Australian Cancer Network (ACN) was established and began to address guideline development as a major activity. The aim was to bring accurate material relating to the clinical care of cancer to clinicians, medical students and other interested people in a timely fashion.

Involvement with National Health and Medical Research Centre (NHMRC) guidelines, which had just commenced their development, was a useful supplementary activity. Pursuing this path the ACN has had some success in developing evidence-based documents (list of publications follows).

The National Breast Cancer Centre (NBCC) was established in 1994 and ACN has had involvement in several of the guidelines developed by the centre. This interaction has been of benefit to both bodies.

In the same time frame, NHMRC, through its Quality of Care and Health Outcomes Committee, established a working party to develop criteria for guidelines, and in 1995, “Guidelines for the Development of Clinical Practice Guidelines” were published. These have since been substantially revised and expanded and now represent the standard against which clinical practice guidelines endorsed by NHMRC are developed.

A prime purpose for guideline development was to establish not only an evidence-base, but also to provide a resource base against which personal outcomes would be monitored through an audit process.

“A good culture is maintained by designing a way for people to monitor their own behaviour. Everyone must know how they are doing if we expect them to assume accountability.” – James Champy.

The expanding issue of audit at a personal level and as group comparators is another clear advance in addressing variation in practice as has been seen and widely embraced in the Royal Australasian College of Surgeons breast audit. The ACN has been and continues to be highly supportive of this College endeavour.

What are clinical practice guidelines?

The most widely accepted definition is that of The Institute of Medicine: “Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances”. This definition provided the benchmark which ACN has established for its guideline development program.

What guidelines are not

While being a valuable resource of tested evidence and contemporary information, guidelines do not cover every aspect of medicine.

They leave room for, and in fact require, clinical experience and good doctoring if they are to be implemented effectively. Clinicians and others are encouraged to draw on their personal and communal reservoirs of clinical knowledge and not to ‘throw out the baby with the bath water’ by playing down these valuable skills.

Guidelines are not:
- Replacements for clinical decision-making
- Prescriptive – not a cook book, to be slavishly followed
- Coercive for patients
- Comprehensive
- Total cover for all clinical situations

Why clinicians benefit from guidelines?

Guidelines are likely to be helpful when there is a large health burden; when current clinical practice varies widely; when there are large cost differentials between alternatives; and when there is new evidence not yet widely implemented or
being slowly embraced3. If, however, it is viewed as a cookbook, reasoned application of the Guidelines should produce a “cordon bleu” result.

Their application is limited and their availability is of reduced relevance if the current forms of practice are of uniformly good quality, or if no effective evidence is available to raise the quality of clinical practice.

Guidelines are useful in addressing cost and quality issues, as good quality care is expensive and poor quality more expensive6.

Variations in clinical practice require monitoring, review and comparison of resource use if their effect is to be fully evaluated and changes introduced when necessary.

What types of guidelines are available?

There are several types of guidelines; two are more or less laid down and directive whereas the third results from systematic review of peer reviewed literature and provides the basis for best practice. This approach has added value when it identifies areas in which research would be appropriate to underpin areas of deficiency in clinical practice6. All ACN guidelines have been based on available evidence.

Types of guidelines

Prescriptive: these direct specific action, are developed by a controlling group and are not necessarily evidence-based.

Consensus: usually developed by a knowledgeable group, from personal preference and selected evidence.

Evidence-based: these are based on systematic review of scientific data with input from knowledgeable clinicians.

Guideline development and implementation process

Having recognised the value of applying evidence in clinical practice and choosing the type of guidelines to introduce, it is necessary to establish a working group to develop them. This group should meet a number of criteria: skill, representative role, gender and geography. The group needs to be committed to the work program, appreciate what is expected of it, members who get along with each other and allow leadership to be evinced through the Chair. It is a tall order and in the process “Justice should not only be done, but should manifestly and undoubtedly be seen to be done” (Lord Hewitt (1870-1943)). To demur or deviate can be fatal to the development process.

A suggested multidisciplinary panel would encompass at least the following range of contributors:

- Specialist clinicians
- General practitioners
- Consumer representative
- Allied health professionals
- Research methodologist
- Health economists
- Public policy analyst
- Other experts
- NGO representative
- Industry representatives
- Bioethicist
- Regulators

Working together, they make a powerful multidisciplinary group. It is preferable to promote sub-committee activity than have a large and unwieldy main panel.

The multidisciplinary working party has significant activity in systematically reviewing current literature, particularly when the 20,000 journals and 200,000 papers published annually is the possible review base. This explosion has led to development of special literature searches and collaborations (Cochrane), but there remains a substantial task for each working party to systematically search literature to draft the guideline documents. The drafting procedure is demanding and may require a number of revisions before going to public consultation, when they will be revised again. This work has

Not all guidelines will be at this “gold standard”, but it is necessary to have a commitment to eliciting the best available evidence and Figure 2 provides a range of approaches to achieving levels of evidence ranged in their order of strength. In 19986 level IV evidence was raised in strength as against that propounded in 19955. Level IV evidence still abounds in guidelines and indicates the clear need for research in many areas of clinical practice where a low level of strength of evidence leads to expression of opinion only.

Observing the rules for developing evidence through systematic review can be a most demanding process and one wonders whether Peter Mere Latham was preparing guidelines when he made the following observation:

“Truth in all its kinds is most difficult to win; and truth in medicine is the most difficult of all … People in general have no notion of the sort and amount of evidence needed to prove the simplest matter of fact.”

— Peter Mere Latham (1789-1875).

Guidelines and clinical decision making

For guidelines to be useful in clinical decision making they must meet criteria that relate to the level, quality and strength of evidence and be relevant to the clinical problem under review. Clinical experience and decision-making skills add further value in the introduction of guidelines to clinical situations4. The levels of evidence as now applied to guideline development have been clearly defined by the NHMRC in 1998 and are listed in Figure 1.

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been done pro-bono by a large body of devoted professionals from professional organisations or as individuals, and all should be recognised for their significant contributions.

The processes outlined in Figure 2 require to be followed if the guidelines are to be endorsed by the NHMRC and each is an important component if a quality document is to be prepared. There is no quick path and a lot remains to be learned about dissemination and implementation.

Monitoring activities, eg patterns of care studies measured at or before the publication of the guidelines (Hill and Spigelman), have yet to be repeated at a time following guideline publication and comparisons will be valuable documents when available.

**Concerns about guidelines**

The major concerns are that guidelines could compromise clinicians if patients choose a course of litigation when an outcome is less than satisfactory. There have been concerns raised from time to time all of which are realistic and cogent. Legal concerns have been raised in a highly litigious medical environment and have increased clinicians’ concerns of their vulnerability. However, with time the concern is diminishing and comfort with the guideline process and the resultant guidelines is increasing.

The view is being taken that the accrual of evidence in a transparent manner by a well-established multidisciplinary working group provides significant protection, and the view outlined by Crown Law authorities is also supportive. The paper by Peter Dwyer also has been helpful; viz “in considering the acceptance and use of clinical practice guidelines, the medical profession should not be distracted by speculation about legal implications”.

Concerns regarding loss of professional freedom are to a certain extent in the eye of the beholder, but at no point should guidelines be promulgated without the disclaimer prefaced in each set: “This document is a general guide to appropriate practice, to be followed only subject to the clinicians’ judgement in each individual case”.

The guidelines are designed to assist decision-making and are based on the best information available at the date of compilation and should allow the level of flexibility outlined in the disclaimer.

There is not and has never been any attempt to reduce the importance of clinical experience and decision-making in patient management.

For some, the introduction of guidelines will lead to a review of their practices, eg over half of surgeons answering a questionnaire would change practice in some way after reading the Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer. This may lead to shift of practice emphasis (as noted with introduction of laparoscopic surgery, or reduction of gastric surgery with knowledge of H. Pylori) and as a result, may lead to some reduction of income. It needs to be said, however, that new strong evidence could expand the clinician’s role, but may increase cost to produce better outcomes through expanding use of technology and more focused care. It is not a necessary outcome for guidelines to cut cost.

**Do guidelines work?**

There is evidence that clinical practice guidelines have had wide acceptance, eg Melanoma Guidelines 1995 were distributed on request and 25,000 volumes were requested. The same guidelines were requested to be translated into Spanish by The Argentine Institute of Piel and disseminated in both Argentina and Spain. The 1999 revision has enjoyed similar acceptance.

Furthermore Carrick et al revealed that more than 80% of surgeons who had read all or most of the Early Breast Cancer Guidelines believed “them useful in improving women's management and well being, easy to understand, evidence-based, a good summary of recent evidence and that they would assist agreement between women and health care providers”.

There have been comparisons of guidelines, but none of cancer outcomes. There has been insufficient time to assess the effects on cancer outcomes of locally produced guidelines. Overseas studies have shown some influence on practice.
process, demonstrated improvement in 55, and in 11 studies evaluating outcome, demonstrated nine improvements.

Ward 1997 studied responses from 69 (of 90) surgeons sent questionnaires on the NHMRC Clinical Practice Guidelines for Management of Early Breast Cancer and found that they had been relatively well received by the group of clinicians answering the questionnaire.

Grimshaw and Russell and Ward comment that careful dissemination and implementation are required to make any substantial impact with practitioners.

**Dissemination**

Guidelines should be made as available as possible to relevant groups of clinicians, clinical training programs and undergraduate programs, cancer organisations, professional colleges and consumer organisations.

General practitioners find a specially formatted laminated double sided A4 document to be readily accessible when consulting. In many instances a GP may see only one or two patients in a specific guideline category each year, eg breast cancer.

It is not sufficient to simply mail a document. There needs to be follow through to ensure not only that the document has been delivered, but that it has been received and read.

Telephone enquiry, academic detailing, presentations at hospital and local medical associations are useful measures to promote this activity.

**Implementation**

Some guidelines are purely clinical, being either observational or behavioural, and require no specific aids or technology for their acceptance. If they are not readily assessed, they may not have registered as part of a mind set to improve clinical practice. Guideline developers need to penetrate this barrier.

Some guidelines will be resisted as they attack the comfort zone of established behaviour, eg those for auxiliary management in breast cancer will require incentive(s), education and persuasion for them to be accepted.

Other guidelines will require cooperation with wide collaboration, the embracing of other disciplines and perhaps the relinquishment of the clinician’s own role in a particular activity to enhance a clinical process and outcome.

There are still system barriers to be overcome and incentives, persuasion and education will all play a role in effectively implementing guidelines as they are produced.

**How guidelines help in practice**

- The evidentiary base provides a sound foundation on which to introduce changes to resource allocation.
- The guideline process identifies hiati in knowledge or processes and so identifies opportunities for clinical research.
- To definitively change established treatment or define new treatment requires the highest level of evidence applicable to the problem, preferably level I or II evidence.

**Clinical best practice**

Guidelines are built on three pillars:

- Evidence
- Clinical Expertise
- Patient Choice

These principles, when introduced and reinforced at a high level, should help meet the demands modern society places on its clinicians.

In May 2001 the NBCC held a workshop on the guidelines process and developed conclusions to be considered in planning the way ahead.

**Focus issues**

- How can we best develop guidelines? (Embrace systematic reviews and evidence)
- How can we overcome system barriers to best practice? (Remember the Berlin Wall)
- How can we best implement and render guidelines accountable? (Open the gates to each other – now)
- How can we encourage best practice by “generalists”? (By adoption of multidisciplinary practices)

**Challenges**

- Best wording of guidelines (No ambiguity – simple)
- Identify groups who need the guidelines (Us as well as them)
- Appropriate information for all women and men (Of course!)
- Identify priorities for implementation strategies (Will not always avoid tos)
- Best way to revise guidelines in timely fashion (Running review, don’t delay)
- Managing the cost issues (Continue to give our time freely or lose leadership)

(The bracketed remarks are the personal views of the author.)

Guidelines in the future must address some of these issues if they are to remain relevant, the current processes for development are too slow and yet NHMRC endorsement is seen as an imperative if they are to be implemented. The NHMRC imprimatur is important to Australian clinicians.

More rapid updating may be achieved by circulating new evidence once evaluated by fax, email, Internet, phone calls, etc.

More rapid revision processes must be developed to ensure that guidelines remain contemporary. Revision probably should commence on the day guidelines are published. Development of easily accessed data banks is another option.

Guidelines and their evidentiary base could be directed into critical pathways and we should continue the effort to produce gold standard evidence.

**Conclusion**

The preparation of clinical practice guidelines from systematically reviewed literature and the marshalling of the evidence so it can be used effectively by clinicians has provided a new resource for clinical care in some cancers. With widening acceptance, clinicians will have found a ready source of sound information for guidance when making a diagnosis and caring for patients.

They will hopefully change in a constructive way and put an end to Bertrand Russell’s claim that “… the most savage controversies are about these matters as to which there is no good evidence either way.”
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References

6 NHMRC Quality of Care and Health Outcomes Committee. Guidelines for the development and implementation of clinical practice guidelines. AGPS, Canberra, October 1995.

List of ACN Publications

1 Breast Cancer Update – ACN, December 1994
2 The Pathology Reporting of Breast Cancer – ACN, May 1997
3 Guidelines for the Management of Cutaneous Melanoma – ACN, June 1997
4 Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer (CRC) – NHMRC endorsed, March 1999
5 Clinical Practice Guidelines - The Management of Cutaneous Melanoma – NHMRC endorsed, December 1999
7 The Pathology Reporting of Breast Cancer – ACN, October 2001
8 Familial Aspects of Bowel Cancer: a guide for health professionals – ACN, 2002
9 Guidelines for the Management of Localised Prostate Cancer (to be published)
10 Guidelines for the Management of Non-Melanoma Skin Cancer (at first stage public consultation)
11 Guidelines for the Management of Epithelial Ovarian Cancer (in preparation)
12 Guidelines for the Management of Lung Cancer (in preparation)
13 Guidelines for the Management of Non-Hodgkin’s Lymphoma (in preparation)