



OFFICE OF THE CHIEF NURSING OFFICER

Guide
to the
Development of Clinical Guidelines
for
Nurse Practitioners

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Introduction

The guideline based approach to health care originated in the United States in the 1990s. Since that time it has been demonstrated repeatedly that the use of guidelines by hospitals and other healthcare providers is an effective way of achieving consistency in the provision of high quality health care. Today, guidelines are produced at international and national levels by clinical associations (e.g. Royal College of Obstetricians and Gynaecologists) and government bodies (e.g. Mid Yorkshire NHS Health Evidence Support Service) for use in a wide variety of clinical settings.

In addition to this more global approach, local health care providers are now producing their own guidelines, or adapting existing top-level guidelines for use in their own settings. This guide has been written to assist those health care professionals charged with the responsibility of developing and/or adapting guidelines for their own agency or speciality to produce feasible, appropriate, meaningful and effective clinical guidelines for patients and clients in their care.

What is a Clinical Guideline?

Clinical guidelines are systematically developed statements that assist members of the health care team and their patients to make appropriate decisions about a specific condition or treatment (American Federation for Ageing Research, n.d.) They arise following an examination of the current best evidence, and other knowledge relevant to a specific health problem (Field & Lohr, 1990; Sackett, Straus, Richardson, Rosenberg & Haynes, 2000).

Clinical Guidelines are not:

- step-by-step 'recipes' for assessment and treatment
- nursing procedures that most nurses in the specialty already perform
- standing orders
- simple descriptions of aetiology, prevalence and assessment.

What do Clinical Guidelines look like?

The format of a clinical guideline is usually determined by the particular aspect of care or condition it addresses and by the target patient population. Sometimes the guidelines may give a broad objective for care and criteria sets for its achievement. At other times guidelines may provide greater detail and specificity including more information about the patient's condition and treatment options.

Deterministic Guidelines

Deterministic guidelines comprise fixed lists, which describe aspects of care that should be followed, irrespective of the information available to the practitioner. They may be used to define minimum levels of care but are limited in their usefulness, as they do not allow for appropriate decision making.



Branching Guidelines

Branching guidelines are usually represented as algorithms. The recommended course of action at each stage depends on critically assessing and evaluating the clinical information gathered from the patient and then deciding on a course of action outlined in the guideline.

Attributes of a Good Clinical Guideline (New South Wales Department of Health, 2005)

Good guidelines:

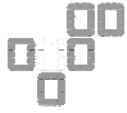
- have been developed using high levels of evidence of best practice (where it exists)
- are valid and relevant to the practice setting where they will be used
- have included all stakeholders in the development
- meet multiprofessional consensus in the clinical setting
- use unambiguous language in a user-friendly format
- incorporate precise definitions
- identify the range of potential decisions
- appraise each decision in terms of its feasibility, appropriateness, meaningfulness and effectiveness in the intended practice setting
- provide the evidence which, when added to clinical judgment and patient values and expectations, assist nurse practitioners and other health care professionals to make decisions about the care of individual patients - rather than prescribing a specific course of action.

They are appraised with regard to their potential to:

1. improve the quality of health care
2. reduce the use of unnecessary, ineffective or harmful interventions
3. facilitate the treatment of patients with maximum chance of benefit [and] with minimum risk of harm.

Use of Clinical Guidelines

Where there is evidence of variation in practice that affects patient outcomes, and a strong research base providing evidence of effective practice, clinical guidelines can assist health care professionals in making decisions about appropriate and effective care for their patients (Scottish Intercollegiate Guidelines Network [SIGN], 2004). It must be remembered however that professional judgement should not be replaced by reliance on a guideline. Thus, guidelines should identify exceptions to recommendations, which reflect clinical judgement or patient preference.



In addition to providing detailed information for health care practitioners regarding the most appropriate management of specific clinical presentations/ circumstances, it is claimed clinical guidelines have the potential to:

- standardise medical care
- raise the quality of care
- reduce the risk to the patient, healthcare provider and medical insurers
- achieve the best balance between cost and medical parameters such as effectiveness, specificity, sensitivity, resoluteness, etc.

Caution

Although clinical guidelines are an increasingly familiar part of clinical practice, they do have potential benefits and harms. While rigorously developed evidence-based guidelines minimise the potential for harm, it must always be remembered that they are only one option for improving the quality of care (Woolf, Grol, Hutchinson, Eccles & Grimshaw, 1999).

Variations from the guideline, which take into account individual circumstances, clinical judgement and patient choice, may also be appropriate. Thus, it is strongly recommended that users:

- confirm by way of independent sources that the information contained within the clinical guideline is correct
- remember that clinical guidelines are NOT a substitute for proper diagnosis, treatment or the provision of advice by an appropriate health professional.

Clinical Protocols (*also known as Procedures*)

Clinical protocols are precise and detailed plans for the study of a medical or biomedical problem and / or plans for a regimen of therapy (Primary Care Electronic Library [PCEL], 2007). Designed to be user-friendly and as a guide for daily clinical care, clinical protocols are summaries of the most important sections contained in the relevant clinical guideline. They are practice-area specific and specify details concerning the treatment and / or procedure endorsed by the employing agency.

Distinctions Between a Clinical Protocol and a Clinical Guideline

While guidelines are usually extensive and detailed documents, they do not contain detailed recommendations about drug duration, dose, (drug formularies) or how to accomplish an actual procedure. The information specified in a clinical protocol builds on that provided in the clinical guideline and directs the care provider on specific elements of the recommended care (Hommersom, Groot, Lucas, Marcos, & Martinez-Salvador, 2006).



Many sections in a clinical protocol may replicate related sections in a clinical guideline and differences in opinion between the clinical guideline designers and clinical protocol designers, may result in some differences between the two

documents. Distinction between clinical guidelines and protocols is provided in Table 1.

Table 1 Distinction Between Clinical Guidelines and Protocols

Clinical Guidelines	Clinical Protocols
Composed of elements describing different aspects of the patient's condition and the care given.	Specify details concerning the treatment/and or procedure endorsed by the employing agency. Vary in the degree to which they are optional.
Recommendations for management are supported by evidence.	Vary in the specificity and quantity of operational information they contain. Contextual and not always evidence-based.

(NSW Department of Health, 2005, p 7)

Local Protocols

Local protocols include patient group directions and referral advice and usually include decision-support systems (Mid Yorkshire Hospitals - NHS, n.d.). They are designed at a local level to implement national standards or, if national standards are not available, to determine care provision by using best available evidence.

Local protocols provide detailed descriptions of the steps taken to deliver specific care or treatment to patients in a given setting. As such they reflect local services, resources and staffing, and integrate the care provided by multidisciplinary teams.

Implementing Evidence-Based Practice

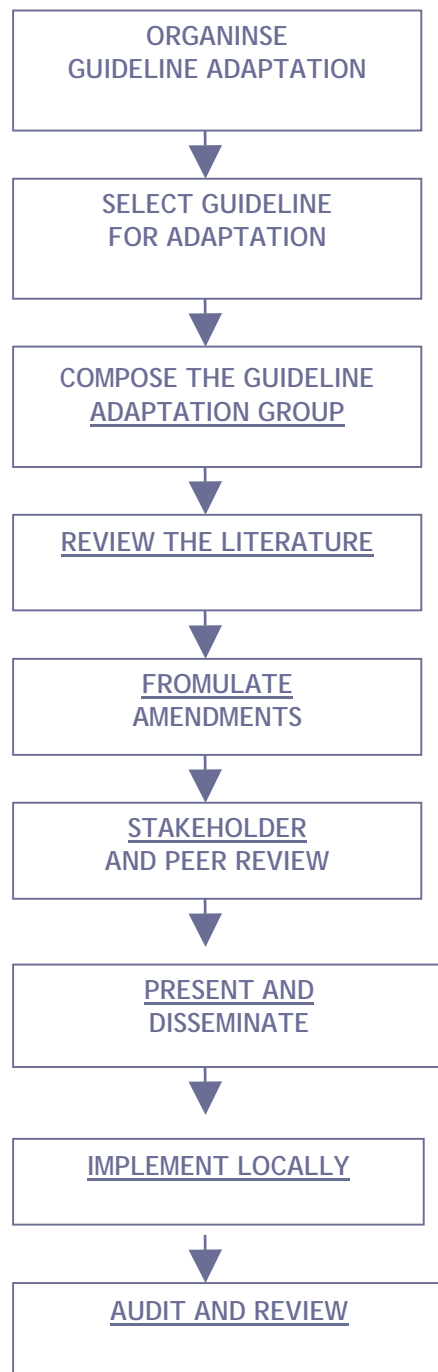
When determining the elements of care that will ultimately comprise their particular scope of practice, nurse practitioners have two options. The first, and increasingly popular option is to adapt existing guidelines for use in their practice setting. The second is to develop a new guideline.



Adaptation of Existing Clinical Guidelines (The AGREE Collaboration, 2001)

The difficulty in getting all stakeholders together may be minimised if pre-existing best practice clinical guidelines are adapted. It may only be necessary to meet with each stakeholder individually to explain the extent of the nurse practitioner's role - rather than trying to get all stakeholders together to write a new set of clinical guidelines.

Figure 1 Adaptation of Existing Clinical Guidelines





Locating Existing Guidelines

Guidelines are not usually identified as being only for the use of one particular profession, and the importance of multi-professional development of guidelines cannot be overstated. Listings (electronic clearinghouses) for guidelines often are listed under “hospitals” or “professional organisations”.

Published guidelines are based on a thorough review of scientific studies on the topic being addressed. On-line medical literature databases (e.g. PubMed) and evidence-based medicine databases (e.g. Cochrane Collaboration) and printed and electronic publications (e.g. Joanna Briggs Institute) exist in large numbers for this purpose.

A growing number of best practice guidelines are also being developed by professional colleges and other consortia. The Joanna Briggs Institute maintains a large database of clinical information to facilitate development of clinical guidelines by nurses and allied health professionals. Also available from the Medical Journal of Australia website (www.mja.com.au/public/guides/guides.html) are guidelines that represent the consensus opinion of experts based on review of the scientific literature.

In the USA, the National Guideline Clearinghouse maintains a catalogue of high quality guidelines published by various organisations (mostly health care professional organisations). In the United Kingdom, clinical practice guidelines are published primarily by the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guideline Network (SIGN) (Scottish Intercollegiate Guidelines Network (SIGN), 2004).

Resources such as the National Health and Medical Research Council (NH&MRC) Guide to Development, Implementation and Evaluation of Clinical Practice Guidelines (National Health & Medical Research Council, 1998) which uses the AGREE (Appraisal of Guidelines Research and Evaluation) tool are also available to assist teams to develop and evaluate their guideline/s.

Choosing a Guideline to Adapt

First Test - Answer Yes to all

- Does the existing clinical guideline provide best practice information about a particular clinical presentation that the nurse practitioner will be treating?
- Are there current references to justify the investigations, interventions and expected outcomes?
- Do the recommendations for management of the patient fall within the endorsed scope of practice of the nurse practitioner?



Second test - Highlights areas to be amended or added

- Which parts of the guideline are relevant to the nurse practitioner's practice?
- What are the gaps (if any) that need to be addressed (e.g. drug formulary to identify the drugs the nurse practitioner will be prescribing)?
- Will the guideline be acceptable to the employer and the multidisciplinary team that the nurse practitioner will/may be working with (feasibility, accountability, meaningful and effective)?

Note: Many papers on the development of clinical guidelines give much information about the development of them from scratch including a multidisciplinary development group, levels of evidence, clinical questions posed regarding intervention and prognosis. Much of this information is not relevant when you are adapting existing guidelines.

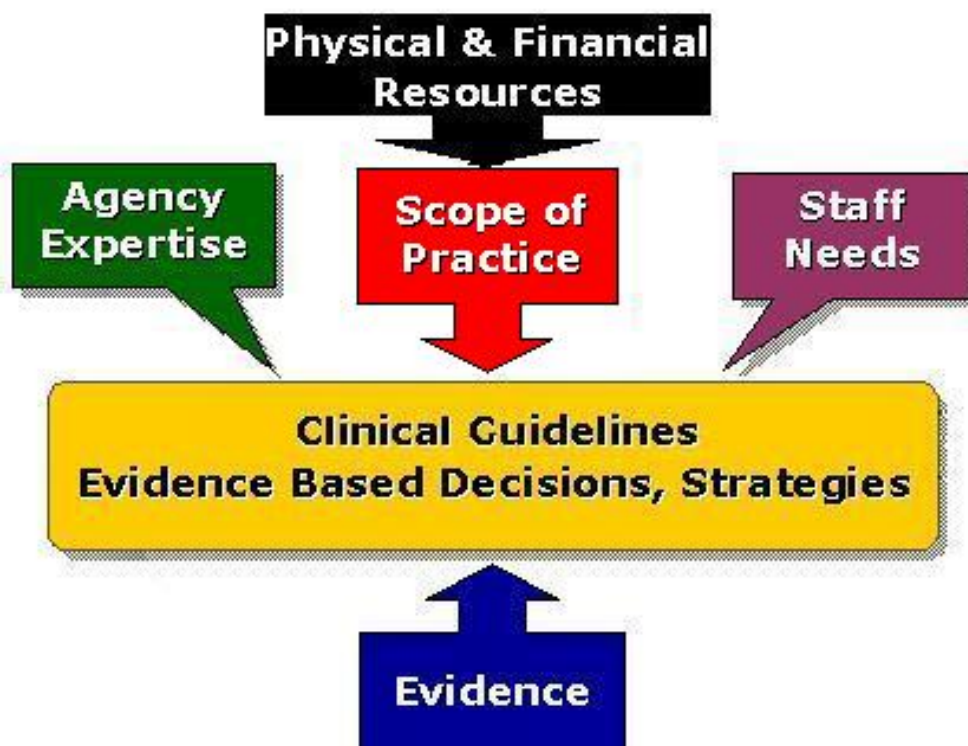
Advice on levels of evidence can be largely summarised by stating that the highest level of evidence should be used.

Developing Clinical Guidelines (Scottish Intercollegiate Guidelines Network [SIGN], 2004)

Development of a clinical guideline is usually initiated by and conducted under the auspices of a local, national or international authority in response to an identified need for standardisation of or improvement in care. Most commonly guidelines are developed by a panel of experts involved in the management of the condition/presentation addressed in the guideline.

The process is similar to, but more complex than, the guideline adaptation process, as a new guideline must be developed from the current evidence, which is considered in the light of the factors represented in Figure 2.

Figure 2 Developing Clinical Guidelines





Guideline Review and Endorsement

Local Review of Guidelines

To practise effectively, it is important that nurse practitioners have the support of local stakeholders for their guidelines and formulary. It is therefore important that all members of the health care team understand how the nurse practitioner will practise within the service. In this regards, briefings, either for individuals or groups, may clarify the work of the nurse practitioner in relation to their own roles.

It is the responsibility of the health service to decide upon the procedure to be followed to endorse a guideline or protocol for use by a nurse practitioner in that service. Ideally this process will be determined before commencing work on the development or modification of a guideline.

In addition to agreement by the guideline developers, endorsement is normally required from those likely to use or be affected by the guideline. These stakeholders may include - but are not limited to:

- Medical officer/s
- Radiographer
- Consumers
- Pharmacist or drug committee
- Pathologists
- Nurse/nurse managers

Conflict of Interest?

Depending on the location, the nurse practitioner may be expected to follow other protocols / guidelines in these instances (e.g. Remote Area Nursing Guidelines). Decisions about compliance with existing guidelines are made at a local health service level with the Nurse Practitioner - but not before the service has a clear understanding about relevant practice issues.

Review by Clinical Expert/s

The health service may decide to have a new guideline reviewed by an external agency prior to final signoff. The role of the clinical expert in reviewing the guidelines is crucial to ensure best practice is encapsulated in each guideline **Assessing the Quality of Your Clinical Guideline (National Health & Medical Research Council, 1998)**.



If considering adapting an existing clinical guideline for a nurse practitioner role, the following issues must be considered:

- The area of patient management is one of the hallmarks of the nurse practitioner's role. Is the recommended management feasible in the proposed practice setting? Is it relevant to the proposed client group?
- Expert decision making is a quality required of the nurse practitioner. Does the guideline incorporate details of the need to use this skill?
- Clinical guidelines do not indicate an exclusive course of action, or serve as a definitive mode of patient care. Does the clinical guideline show evidence of the need for clinical judgment in individual cases?
- Does the clinical guideline specifically identify the areas of limited prescribing, the initiation of diagnostic investigations and patient referral?
- Are likely variations in practice documented - including the rationale/s for doing so?
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Note: The description of patient management presumes advanced practice and expert clinical decision-making skills. Therefore, it is not necessary to have an exhaustive list of possible options for treatment but rather a description of the usual ones.

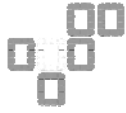
Table 2 Checklist for the Appraisal of a Clinical Guideline

	Yes	No	Unclear	Not App
The guideline is based on best available evidence.				
The choice of the patient population in terms of acuity and severity falls within this nurse practitioner's scope of practice.				
There is a concrete and precise description of the appropriate management in each specified situation as permitted by the body of evidence and this nurse practitioner's scope of practice.				
There is a concrete and precise description of the appropriate management for each patient group as permitted by the body of evidence and this nurse practitioner's scope of practice.				
The guideline clearly identifies those patients or conditions that need referral (urgent or otherwise) to medical practitioners.				



Endorsement of a Guideline

Guidelines and the formulary may be sent to each stakeholder for comment with a required response date. Following a consideration of the feedback and amendments to the guideline, the document is recirculated for endorsement. Majority consent is required for endorsement. If this is not forthcoming it is recommended that a meeting of stakeholders be convened to decide upon points of difference. Final sign off will normally include the signed agreement of the each individual stakeholder. It should also state the date of issue and make it clear that the information is correct only to that date (National Health & Medical Research Council, 1998).



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