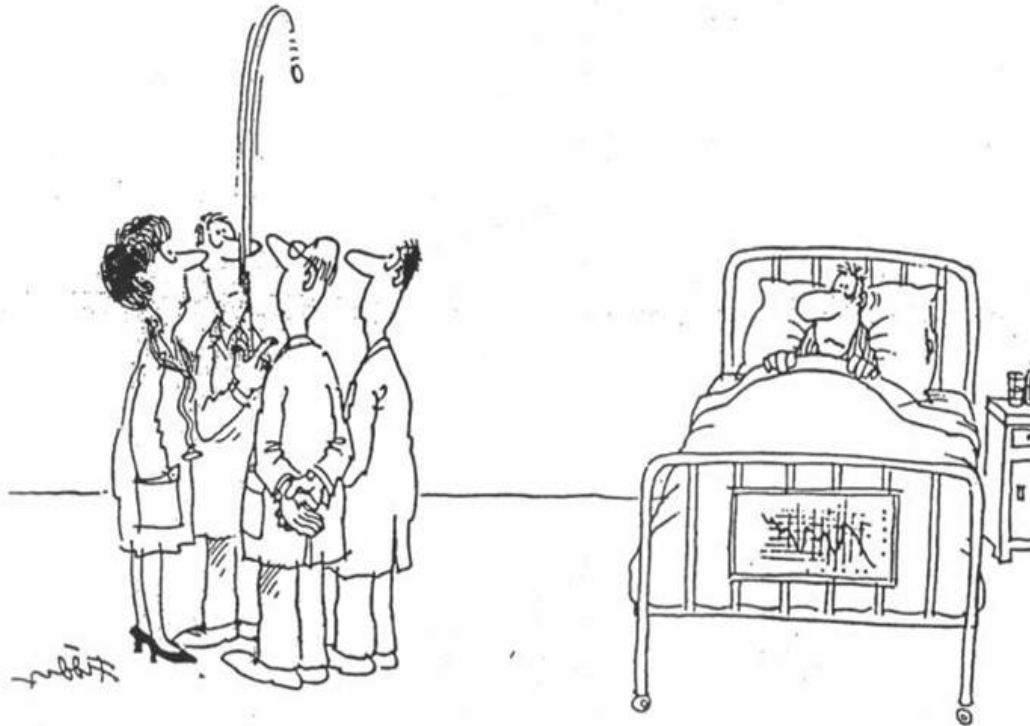


CLINICAL PRACTICE GUIDELINES



A GUIDE FOR CLINICIANS

Developed by Clinical Quality and Safety
The Royal Children's Hospital
Melbourne, Australia

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If you are interested in contributing to Clinical Practice Guidelines or have other queries, please contact:

Jody Smith
Clinical Guideline and Pathway Coordinator
Tel (03) 9345 6956
Pager 6956
Email: jody.smith@rch.org.au
Clinical Quality and Safety
Royal Children's Hospital

Renata Kukuruzovic
Evidence Based Clinical Practice (EBCP) consultant paediatrician
Email: renata.kukuruzovic@rch.org.au
Clinical Quality and Safety
Royal Children's Hospital

1. INTRODUCTION

What are Clinical Practice Guidelines?

Clinical Guidelines are systematically developed statements based on the best available evidence designed to assist practitioners with decisions about appropriate health care practices for specific clinical circumstances. The process used to develop guidelines involves a thorough evaluation of evidence based on outcomes of treatment or other health care procedures. Where research based evidence is not available, consensus by experts forms the basis of the guideline.

The Hospital Clinical Guidelines have been developed in accordance with the National Health and Medical Research Council (NHMRC) published recommendations^{1, 2, 3} to support clinicians, with an emphasis on the ongoing management of patients.

Why are these guidelines needed?

There has been a widespread move towards developing clinical practice guidelines, which are designed to:

- ❖ Improve the quality of health care.
- ❖ Reduce the use of unnecessary, ineffective or harmful interventions.
- ❖ Facilitate the treatment of patients with maximum chance of benefit, with minimum risk of harm, and at an acceptable cost.

Recent research has shown that clinical practice guidelines can be effective in bringing about change and improving health outcomes. They are underpinned by the evidence based clinical practice principles of good decision making which takes account of patients' preferences and values, clinicians values and experience, the best available evidence and the availability of resources.¹

Key principles for developing guidelines (NHMRC)¹

There are nine key principles for developing guidelines these include:

1. Process for developing and evaluating clinical practice guidelines should focus on outcomes.
2. Clinical practice guidelines should be based on the best available evidence and should include a statement about the strength of their recommendations. Evidence can be graded according to its level, quality, relevance and strength.
3. Taking the evidence - of whatever level, quality, relevance or strength - and turning it into a clinically useful recommendation depends upon the judgement, experience and good sense of the group developing the guidelines.
4. The process of guideline development should be multidisciplinary and include consumers. Involving a range of generalist and specialist clinicians, allied health professionals and consumers will improve the quality and continuity of care and will make it more likely that the guidelines will be adopted.
5. Guidelines should be flexible and adaptable taking into account clinical settings, costs and constraints. Provision should be made for accommodating the different values and preferences of patients and families.
6. Guidelines should be developed with research constraints in mind.

7. Guidelines are developed to be disseminated and implemented taking into account their target audiences. They should also be disseminated in such a way that practitioners and consumers become aware of them and use them.
8. The implementation and impact of guidelines should be evaluated.
9. Guidelines should be revised regularly.

WRITING CLINICAL PRACTICE GUIDELINES

Aims

The aim of this document is to facilitate staff at RCH in the development, writing and evaluation of multidisciplinary clinical practice guidelines.

Why do we develop a Clinical Practice Guideline?

The need for a Clinical Guideline is identified as a result of:

- Reflective practice
- Variations of practice within the hospital
- New study findings
- An adverse event or potentially dangerous practice

Who can write Clinical Practice Guidelines?

Development of Clinical Guidelines within the Royal Children's Hospital requires multidisciplinary involvement at all levels to ensure the clinical guideline encompasses the requirements of relevant clinicians and patient groups.

Clinical Guidelines can be written by:

- Clinicians
- Working Groups e.g. a multidisciplinary team managing a patient group
- Specific departments e.g. Haematology, Dermatology, General Surgery

Consumer involvement (Family Centred Care)

For guidelines to have a Family Centred Focus consumer involvement is recommended in the development process from the outset. Consumer input focuses on incorporating the core concepts of Patient and Family Centred Care including:

Dignity and Respect

- Respect family knowledge, values, beliefs and cultural backgrounds in the delivery of care.

Information Sharing

- Providing families with timely, accurate and complete information enabling them to participate in and care and decision making.

Participation

- Patients and families are encouraged and supported in participating in care and decision making at their chosen level.

Collaboration

- Facilitate patients, families, clinicians and leaders to work collaboratively in the development, implementation and evaluation of guidelines, education and the delivery of care.
(Institute for Family Centered Care <http://www.familycenteredcare.org/>).

Consumer input is not intended to focus on clinical recommendations based on the best available evidence.

The consumer approach should be individualised for each guideline and authors should contact us for assistance with this aspect of guideline development.

References

1. National Health and Medical Research Council (NHMRC) 1999. A guide to the development, implementation and evaluation of clinical practice guidelines.
2. National Health and Medical Research Council (NHMRC) 2000. How to use the evidence: assessment and application of scientific evidence.
3. National Health and Medical Research Council (NHMRC) 2000. How to put evidence into practice: implementation and dissemination strategies.

2. THE PROCESS FOR CLINICAL PRACTICE GUIDELINE CONTENT DEVELOPMENT

If you are intending to develop a clinical practice guideline contact Clinical Guideline and Pathway Coordinator on ext/page 6956 to learn more about the process.

Step 1	Determine topic Identify author/s
Step 2	Author discusses proposed topic with Guideline development team (Renata Kukuruzovic & Jody Smith).
Step 3	Download the 'Clinical Guideline Development Tools' including: a guide for clinicians, guideline template, evidence table, checklist for the guideline development and implementation.
Step 4	Consult with appropriate key stakeholders (medical, allied health, nursing and consumers). Involve them in the revision of drafts and consensus of opinion where there is a lack of evidence
Step 5	Review guideline websites and current practice.
Step 6	Contact RCH library complete a literature search.
Step 7	Author meets with Guideline Team to present evidence
Step 9	Attend next available guideline development workshop
Step 10	Formulate draft, utilising feedback from key stakeholders, evaluate evidence using table.
Step 11	Guideline team review draft content using PAED agree tool
Step 12	Clinical Guideline approval once suggested changes are made to satisfactory level.
Step 13	Clinical Guideline Approved (Signed off by relevant Dept Heads and CQS guideline team)
Step 14	Guideline published on the intranet
Step 15	Review of implementation and dissemination of the guideline (approximately 3 months post implementation)
Step 16	Author conducts a post implementation evaluation at 12 months evaluating health outcomes for patients and changes in clinical practice
Step 17	Guideline to be reviewed every 3 yrs +/- audit

3. CONTENT DEVELOPMENT (more information on some of the steps)

Step 4: Key Stakeholders

The overseeing multidisciplinary panel should include representatives from all relevant groups e.g. clinicians (nurses, doctors, and allied health) with specialist expertise and clinicians with general expertise, other relevant health professionals, representatives from consumer groups, professionals with expertise in guideline development.

Step 5: Search Existing Material

Review relevant current practice, guidelines, clinical pathways, and educational resources relating to the topic within the Royal Children's Hospital.

Search evidence based CPG websites nationally and internationally for guideline topic. Critique Guidelines, take note of the level of evidence used to develop guideline content and recommendations and the method of evidence collection utilised by the guideline site.

Guideline Sites include:

- National Guideline Clearing House <http://www.guideline.gov/>
- National Institute for Health and Clinical Excellence (NICE) <http://guidance.nice.org.uk/CG/published>
- New Zealand Guidelines Group <http://www.nzgg.org.nz/>
- Scottish Intercollegiate Guidelines network <http://www.sign.ac.uk/guidelines/published/>
- British Medical Journal <http://bmj.bmjournals.com/cgi/collection/guidelines>
- Royal College of Nursing <http://www.rcna.org.au/site/search.php>
- Royal Australian College of Physicians <http://www.racp.edu.au/hpu/evidence/index.htm>
- UK NHS <http://libraries.nelh.nhs.uk/guidelinesFinder/>
- National Institute of Clinical Studies <http://www.nhmrc.gov.au/nics/asp/index.asp>
- National Health and Medical Research Council <http://www.nhmrc.gov.au/publications/categories/index.htm>

Step 6: Evidence Based Literature Searching and Formulating the Evidence table

Identify clinical questions to identify key search term using PICO format to complete a thorough literature search e.g.

- **Population** – e.g. children with bronchiolitis
- **Intervention** – e.g. do bronchodilators
- **Comparator** – e.g. compared with placebo, or other treatments e.g. glucocorticoids
- **Outcome** – e.g. show improved clinical scores, reduced hospital stay etc.

Evidence based literature databases can be accessed through 'Library Services' on the RCH Intranet Site.

<http://www.rch.org.au/library/dbases.htm>.

Databases include:

- Clin-eguide (formerly ClinicalResource@Ovid).
- MDConsult
- SUMSearch
- The Cochrane Library
- Clinical Evidence
- EBM Reviews - ACP Journal Club

A copy of the literature search strategy and results should be saved and must be submitted to CQS with the final draft of the guideline to assist future guideline review.

The RCH library in conjunction with CQS facilitates a literature search to assist in finding the evidence (this is a prerequisite for developing a Hospital Clinical Guideline). Contact Jody Smith on 6956 or via email jody.smith@rch.org.au to make a booking.

Step 7: Grade and Record level of evidence in the evidence table

- Refer to Evidence table template in the resource section of this booklet or on the website under development resources <http://www.rch.org.au/emplibary/rchcpg/HCGEvidenceTable.doc>
- CQS facilitate a Clinical Practice Guideline development workshop on a regular basis to assist in the development of guidelines including searching and critiquing the evidence.
- Please record details on the evidence table and return to Clinical Quality and Safety (CQS) with guideline draft **electronically**.

The Hierarchy of evidence is based on the National Health and Medical Research Council (2000) and Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level I	Evidence obtained from a systematic review of all relevant randomised control trials.
Level II	Evidence obtained from at least one properly designed randomised control trial.
Level III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternative allocation or some other method).
Level III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised cohort studies, case control studies, or interrupted time series with a control group.
Level III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
Level IV	Evidence obtained from case-series, either post-test or pre-test and post test.
Level V	Expert opinion without critical appraisal, or based on physiology, bench research, or historically based clinical principles.

Please note: Clinical guidelines are based on reviews of the best available evidence. *Level 1 evidence represents the gold standard for intervention studies*; however it is not available for all areas of practice and frequently guidelines will use lower levels of evidence or consensus opinion where no studies are available.

This NHMRC Hierarchy can be used to grade the “*level of evidence*” however it does not give information about the “*quality of evidence*”, e.g. an RCT is level II evidence, however an RCT may be of poor quality and therefore this evidence would not be included in a guideline or review.

NB: Short courses are also available through CQS and CEBU (University of Melbourne) in critical appraisal. We strongly suggest that the main author take the opportunity to undertake one of these courses if they are unfamiliar with different study types and critical appraisal of studies.

Step 9: Formulate draft

- Refer to Clinical Practice Guideline template in the resource section of this booklet or on the website under development resources
http://www.rch.org.au/emplibrary/rchcpag/Guideline_template.doc
- Use the template to structure guideline. This encourages uniformity but it can be modified slightly to suit guideline content requirements.

Content

- Keep the *audience* in mind when writing guidelines. Guideline topics are rarely restricted to one discipline so they must be relevant to medical staff, nursing staff and allied health.
- The guideline also needs to include content specific to the variety of settings in which the target patient group or clinical practice is present. For example, does the guideline include management in the community, in the ward environment and/or the acute care setting?
- Work out what content is *essential to the guideline* and what content can be part of a *resource document*, a *link* to another site or a link to a PDF document etc.
- If a consensus of expert opinion is used to determine Guideline content due to an absence of available evidence or if there is discrepancy in evidence this should be stated in the Guideline and reflected in the evidence table.

Steps 10 to 13: Clinical guideline review process

- The draft Clinical Guideline needs to be circulated to relevant stakeholders for feedback and approval.
- If the guideline has hospital wide implications to practice and/or resources the guideline should be presented/discussed at Executive Clinical Leadership level.
- The final draft is returned to CQS and reviewed by the Clinical Guideline and Pathway Coordinator and Evidence Based Clinical Practice (EBCP) Consultant using the PAED-AGREE tool to appraise the content of the guideline.
- The guideline will then be presented to the Clinical Guidelines Reference Group*
- Feedback from the appraisal is presented to the author
- The Clinical Guideline is again reviewed and once satisfactory signed off by relevant Departmental Head/s, and the EBCP consultant and Clinical Guideline and Pathway Coordinator
- Once approved the Clinical Guideline will then be published on the Clinical Guidelines Site on the RCH Intranet.

Steps 14 to 16: Evaluation of clinical practice guidelines

The purpose of evaluating clinical practice guidelines is to assess the validity of the guidelines and the effectiveness of their dissemination and implementation.

An evaluation plan should be generated when guidelines are being developed, and this plan should take into account what data the evaluation will require e.g. data on processes, practices and outcomes.

The Royal Children's Hospital in accordance with NHMRC¹ recommends that Clinical practice guidelines are evaluated at least once every three years. RCH also recommends that the author/s of Clinical Practice Guidelines conduct a post implementation evaluation at 12 months evaluating health outcomes for patients.

An evaluation plan of clinical practice guidelines should consider some or all of the following: ¹

- Assessment of guideline dissemination
- Assessment of whether or not clinical practice is moving towards the guidelines' recommendations
- Assessment of whether or not health outcomes have changed
- assessment of the guidelines' impact on consumer' knowledge and understanding
- an economic evaluation of the guideline process

Evaluations may include conducting audits on patient files, audits of other relevant clinic records, customised surveys and other data collection initiatives. It may be appropriate to also collect data that can be usefully compared against national data.

For assistance in developing an evaluation plan and conducting evaluations, please contact the Evaluation and Analysis Coordinator in CQS on ext 5153 or email nichole.lister@rch.org.au

Useful resources for evaluation:

¹ National Health and medical Research Council (NHMRC) 1999. A guide to the development, implementation and evaluation of clinical practice guidelines.

Available at: <http://www.nhmrc.gov.au/publications/synopses/cp30syn.htm>

Date accessed: 22-06-07

² Eccles M and Grimshaw J. 2004. Selecting, presenting and delivery clinical guidelines: are there any "magic bullets"? MJA 80 (6 Suppl): S52-S54

Available at: http://www.mja.com.au/public/issues/180_06_150304/ecc10749_fm.html

Date accessed: 22-06-07.

RESOURCES:

Clinical Guideline Template

Clinical Guideline Evidence Table

Clinical Guideline Development Form

Clinical Guideline Implementation and Evaluation Form

The 'AGREE' Tool – Appraisal of Guidelines for Research and Evaluation (HCG Use only)

Appendix 1:

***Clinical Guidelines Reference Group**

The Hospital Clinical Guidelines Reference Group facilitates best practice in patient management via the process of facilitating multidisciplinary evidence based clinical practice guidelines at The Royal Children's Hospital. They are directly accountable to the Royal Children's Hospital (RCH) Quality and Safety Committee.

The objectives of the Hospital Clinical Guidelines Reference

- Guide the process of development, implementation and publication of guidelines at RCH (except those managed by the Clinical Practice Guideline group).
- Ensure the quality of guideline content is maintained, based on the best available evidence and the development, review and approval processes are consistent.
- Encourage all disciplines at RCH to be involved in guideline development.
- Ensure there are appropriate processes for adequate communication with all stakeholders involved in the guideline development including consumers.
- Work collaboratively with other guideline authorship groups (e.g. Clinical Practice Guideline group) to enhance organisational processes for Evidence Based Clinical Practice (EBCP).
- Review guideline drafts and initiate the revision of existing Hospital Clinical Guidelines 3rd yearly or more frequently as indicated.

Meetings

The Hospital Clinical Guidelines Reference Group meets on the second Monday of the Month over a 12 month period.

A Quorum will compromise of 50% of the reference group members.