



A GUIDE FOR WRITERS

Thank you for agreeing to take part in the preparation of a CARI Guidelines document. We recommend that each guideline writer follows the process outlined below when writing their evidence-based guideline.

CARI Guidelines Office

Administrative support for the guideline writers and the overall development process is provided by the CARI Guidelines Office, which is part of the Centre for Kidney Research, located at the Children's Hospital at Westmead, NSW. The office has 4 staff members, whose contact details are as shown below:

Senior Project Officer Denise Campbell DeniseC2@chw.edu.au Ph: (02) 9845 1477	Administration Officer Julia Bambery Juliab3@chw.edu.au Ph: (02) 9845 1470	Research Officer Allison Tong AllisonT@chw.edu.au Ph: (02) 9845 1482	Implementation Research Officer Michelle Irving Michelli@chw.edu.au Ph: (02) 9845 1480
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Selection of Subjects and Writers

This task is undertaken each year by the Dialysis, Nephrology & Transplantation (DNT) Subcommittee, which is a joint committee of the Australian and New Zealand Society of Nephrology (ANZSN) and Kidney Health Australia (KHA). Guideline Group Convenors and Members are chosen based on their areas of interest, expertise, and availability. Convenors are chosen by the CARI Steering Committee subject to approval of the DNT Subcommittee. Members are chosen by Convenors from 1) a list of nephrologists who have registered their interest in being a guideline writer, and 2) from other disciplines as needed.

People who would like to contribute to the CARI Guideline process should contact the Chair of the CARI Guidelines Steering Committee, Dr Martin Gallagher. His telephone number is: (02) 9993 4552 and his email address is: mgallagher@george.org.au

Distribution of Background Material

Individuals who have agreed to become a member of a CARI Guidelines working group are provided with the following reading material:

- 3 extracts from the *JAMA 'Users' Guides to the Medical Literature'* (How to use an article about therapy or prevention; How to use an overview; How to use an article about a diagnostic test)
- a copy of the critical review form for a systematic review, randomized controlled trial, and a diagnostic test
- 4 useful reference articles (Grading quality of evidence and strength of recommendations; Practice guidelines developed by specialty societies: the need for a critical appraisal; Are guidelines following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medical literature; Changing clinical behaviour by making guidelines specific)
- copies of other clinical practice guidelines which may already exist in the subject area (e.g. the K/DOQI guidelines or the UK Renal Association guidelines)
- a copy of the CARI Guideline Writing Template as a guide to the required format of the final document

- a copy of a sample published CARI guideline
- a copy of the CARI Guideline Writer's Guide to Developing Searchable Questions, and
- a copy of the Literature Search Checklist for Writers of the CARI Guidelines.

Evidence-based Approach

The evidence-based approach used involves the systematic retrieval and appraisal of information from the literature. The intention is to write guidelines based on evidence derived from randomized controlled trials (RCTs) [i.e. Level I and II evidence]. When there is no such evidence, a summary of the available evidence and a note about the relevant level of evidence should be included. Suggestions for Clinical Care can be written based on Level III and IV evidence. The primary aim is to produce guidelines that are based on good quality evidence. Writers are expected to quantify the absolute differences in outcome, including both benefits and harms.

Levels of Evidence

We currently use the levels of evidence designated by the NHMRC*:

- **Level I:** evidence obtained from a systematic review of all relevant RCTs
- **Level II:** evidence obtained from at least one properly designed RCT
- **Level III:** evidence obtained from: well-designed pseudo-randomised controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group
- **Level IV:** evidence obtained from case series, either post-test or pretest/post-test.

(Source: NMHRC. How to use the evidence: assessment and application of scientific evidence. Canberra 2000)

GUIDELINE DEVELOPMENT PROCESS

The guideline development process includes an initial Guideline Group Meeting by Teleconference and 3 subsequent Face to Face Meetings (as per the timeline that will be distributed by the CARI Office). Minutes for each meeting will be distributed to all Guideline Group Members and the Convenor/s within 1 week of the meeting.

All Teleconferences and Face to Face Meetings will be organised by the CARI Administration Officer, with flights booked through Joanna Stoic at KHA. Because members usually come from various states, the Face to Face Meetings are usually held in one of the Qantas Meeting Rooms located on Level 2 in Domestic Terminal 3 at Sydney Airport. All travel and accommodation costs are covered by CARI.

Any newly developed CARI Guidelines will be presented and discussed at the next DNT Workshop, which is held in March every 2 years.

1st Guideline Group Meeting

Once a Guideline Group has been established, a meeting by teleconference is arranged to decide which topics will be covered within the general topic that has been identified by the DNT Subcommittee. If a group is revising a guideline, some subtopics previously covered may be deleted or merged. Responsibility for writing the first draft of each subtopic is also decided at this teleconference. A timeline for the Guideline development process will have already been sent to the Convenor and Members by the CARI Office. The Convenor of each Guideline Group

will need to submit a Work Plan to the CARI Office that outlines the subtopics the group plans to work on in the designated area. The process allows 12 months from the time of this meeting until the draft document is expected to be ready for external peer review.

Draft Mock Clinical Practice Guideline

Based on current content knowledge, writers are to draft mock guideline statements that specify what should be done to whom and how. Also need to define the population of interest (i.e. chronic kidney disease, dialysis, or transplantation) and clinically relevant, patient-centred outcomes.

Attend Critical Appraisal Workshop

Convenor/s and Members of new Guideline Groups will be invited to attend a 1-day Critical Appraisal Workshop at which the key quality indicators for an RCT, systematic review and study of diagnostic test accuracy will be taught and discussed. Following the Workshop, there will be time for each Guideline Group to have a Face to Face Meeting and further refine the scope of their activity, division of tasks, and develop draft guideline recommendations.

Develop Literature Search Questions

Guideline writers are asked to develop specific, searchable questions that will enable the Research Officer (Allison Tong) to design high-yield search strategies. The CARI Guideline Writer's Guide to Developing Searchable Questions describes this process, gives an example of a suitably structured question and includes a PICOM Table that writers can use to frame their search questions in. Alternatively, writers can use the Literature Search Checklist for Writers to frame their search questions.

Literature Search/Screen Abstracts

The CARI Research Officer will perform literature search/es for each guideline writer once their PICOM Table has been received. To ensure that as much relevant material as possible is retrieved, the Cochrane Renal Group's Specialised Register of Randomised Controlled Trials and Central Database, Embase, and Medline will all be searched. The results of these searches (abstracts only initially) will be sent to guideline writers for them to decide which articles are most relevant. Full text copies of articles of interest can then be ordered from the CARI Office. Both reports of RCTs and other study types (e.g. cohort studies, case-control studies) can be ordered.

Select Articles per Criteria

Members are to review those articles that meet the criteria for systematic review.

Review Selected Articles

Guideline Group Members will review the aggregate of studies for each clinically important outcome and formulate a grade for the quality of the evidence based on the quality of the studies, the consistency and the directness of the evidence. Members will then review the evidence across all important clinical outcomes to determine the net medical benefit to the patient and grade the overall quality of the evidence. The CARI Research Officer will be available to assist the group in this process step.

Create Selected Evidence Tables

Evidence Tables (characteristics of included studies, quality of randomized trials, results for continuous outcomes, results for dichotomous outcomes) will be drafted by the CARI Research Officer and will be included in each guideline in the Appendices section. Members will be asked to provide feedback on the Evidence Tables and to approve the finalised versions.

Critical Appraisal Summary Tables

A brief critical appraisal addressing the strength of evidence, size of effect, and relevance of effect should also be included. The Evidence Template set out below should be used for this purpose. The most crucial aspects of RCT quality are the thoroughness of the randomisation and blinding processes and the completeness of follow-up of subjects enrolled. The start of the guideline should contain the draft recommendations in a box (based on Levels I and II evidence). Suggestions for clinical practice (where good evidence is lacking) should be included under the heading 'Suggestions for Clinical Care'.

Type of Evidence (dimension)	Definition
Strength of evidence	
<i>Level</i>	The study design used, as an indicator of the degree to which bias has been eliminated by design (see evidence levels outlined above)
<i>Quality</i>	The methods used by investigators to minimise bias within a study design
<i>Statistical precision</i>	The P value or alternatively, the precision of the estimate of the effect (as indicated by the confidence interval). It reflects the degree of certainty about the existence of a true effect
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used

Source: NHMRC 2000

Write Text and Recommendation/s for the Guidelines

Drawing on the results of the critical appraisal of the evidence, Guideline Group Members will develop practice guidelines at a series of meetings. These should include the following sections:

Authorship and Group Membership

We list the names and include a short affiliation address for all Convenor/s and Members of the Guideline Group on one of the pages in the Supplement when the guidelines are published. We also include the name of the author/s of each subtopic. The rules for authorship are that authorship credit is based only on substantial contribution to: the critical appraisal and interpretation of published studies; drafting the guideline or revising it critically for important intellectual content; and final approval of the version to be published. All of these conditions must be met.

The Guideline Recommendations

The guideline/s should be clearly outlined and the supporting Evidence Level/s stated (i.e. Level I or II evidence). These should be enclosed by a textbox. Each recommendation should address benefits and harms according to the level of risk in different patient subgroups.

Suggestions for Clinical Care

This section can be used to list information that you want readers of the document to see but which does not warrant the status of an official recommendation. Examples include the intervals at which certain groups of patients should be reviewed, suggestions for patient education and support, and surgical techniques. This is the appropriate place to include data from Level III and IV evidence sources (i.e. evidence from comparative studies such as cohort studies and case-control studies). This section replaces the "Practice Tips" section that previously appeared in guidelines.

Background

The background should describe the condition to be detected, treated or prevented. Management options available for the condition should be stated along with outcomes of interventions that are both beneficial and harmful to the patient.

Search Strategy

A description of the databases that have been searched, the search terms used and the date/s of the search/es will be provided to writers by the CARI Research Officer.

What is the Evidence?

This section should list the Guideline Writers' summaries of relevant RCTs; it is not necessary to write a full systematic review. Each relevant study should be summarised as a separate

paragraph that highlights key findings (i.e. number of patients, interventions used, results of outcomes measured etc).

Summary of the Evidence

This section should summarise the information presented in the 'What is the Evidence?' section. The four Evidence Table templates provided by the CARI Research Officer should be used to present the evidence.

What do the Other Guidelines Say?

Other guidelines in circulation (e.g. K/DOQI, UK Renal Association, Canadian Society of Nephrology etc.) that pertain to the topic should be included here. If there is disagreement between these and the drafted CARI Guideline, the conflict should be discussed, and reasons for the difference provided.

Implementation and Audit

This section should include clear methods of implementing the guideline, allowing for monitoring of compliance. In doing so, it should provide outcomes that can be measured and the provision for doing so. For example, in peritoneal dialysis, one could suggest that all instances of catheter blockage, catheter leakage, and tunnel infection be recorded on a form attached to each patient's notes and in a unit database, and that the unit be asked to produce quarterly statistics on these events.

Suggestions for Future Research

If the recommendations have identified areas needing further research, the topics should be mentioned here along with suggestions of possible study designs for undertaking the research.

References

This section should contain a complete list of references for the studies included in the evidence and background section. Writers are advised to use the Vancouver reference style – see Uniform Requirements for Manuscripts Submitted to Biomedical Journals at www.icmje.org.

Appendices

Any relevant tables should be included here. Sample table templates are available for writers to use.

2nd Guideline Group Meeting

This Face to Face meeting is an opportunity to present and discuss new draft guidelines to other Group Members before presenting them at the DNT Meeting and review suggestions that other Group Members may have. It is also the time to decide who will present what at the Workshop – it is not necessary for every Group Member to present at the DNT Workshop.

Submit the Draft Guideline

Email a copy of the guideline to the CARI Office and also to the Guideline Group Convenor. Please try to follow the format of the guideline writing template to minimise editorial work. It is strongly recommended that the software *Reference Manager* be used. The CARI Office will forward the draft to 2-3 appointed members of the CARI Steering Committee for their comments. Any comments will be forwarded to the writer for their action and revision.

DNT Workshop

Amended drafts need to be sent to the CARI Office **1 month** prior to the DNT Workshop so that they can be uploaded to the CARI website for the nephrology community to read the draft guidelines in good time before the Workshop. Following the Workshop, comments received at the Workshop and via the CARI website need to be reviewed and considered by each writer, and appropriate changes made.

3rd Guideline Group Meeting

The third Face to Face meeting will be held approx. 2 months after the DNT Workshop to finalise the content of the draft guidelines before they are submitted to the CARI Guidelines Office for external peer review to occur. They will also be posted to the CARI website and the public invited to comment on them.

Peer Review

The draft guidelines submitted after the DNT Workshop will be reviewed by 3 Peer Reviewers chosen by the CARI Office. Four weeks is allowed for this step.

Review Comments and Make Appropriate Changes

Guideline Group Members are asked to work with the Group's Convenor/s to review comments received from peer reviewers and the public and determine appropriate changes to their guideline recommendations and to incorporate these changes into their guideline drafts.

Review by Steering Committee

The revised guidelines are sent to 2–3 designated members of the CARI Guidelines Steering Committee for final approval. The Steering Committee is a multidisciplinary panel constituted according to the recommendations of the NHMRC and includes a consumer representative and 2 nurse members.

Finalise and Publish the Guideline

Members are asked to review comments received from the relevant Steering Committee members and to make appropriate changes to their guidelines. The approved revised guidelines are to be emailed to the CARI Office where they will be edited and formatted. The edited guideline will be sent to the journal *Nephrology* for publication and loaded on the CARI website after print publication. Writers will be sent a copy of the edited guideline and will see a copy of the first proof pages; writers need to proofread them for typesetting and/or copyediting errors. Minor changes are allowed, but authors will be charged for excessive alterations to proofs. Corrections must be returned to the publisher by the stipulated deadline. The guideline will also appear on the *Nephrology* website after print publication.

Colour Reproduction Charges

All illustrations included in a CARI guideline will be published in black and white only. If a writer wishes to have a figure appear in colour then they must bear all costs connected with the printing of the colour illustration.

Distribution of Guidelines

Copies of the guidelines will be distributed free of charge to all renal units in Australia, to all subscribers to *Nephrology*, and to individuals who have contributed to the writing process. Additional copies will be available for purchase from the KHA for a modest fee.

Implementation, Audit and Evaluation of Selected Guidelines

A number of the guidelines will be chosen for active implementation. Support for this activity is provided by Michelle Irving, the Implementation Research Officer, who is responsible for devising and running implementation projects. She is supported in this task by an Implementation Team consisting of individuals with knowledge and experience in this area. Michelle is an experienced health promotion worker. Her telephone number is: (02) 9845 1480 and her email address is: Michelli@chw.edu.au.

Guideline Revision Cycle

It has been agreed that the Working Groups will reform once every 3 years to review the guidelines they have written and to determine whether an update is required in the light of new evidence. If the CARI Office become aware of new RCTs or meta-analyses that would substantially impact on existing guidelines, the review will be more frequent. Clearly, membership of the Working Groups may change from time to time. If a decision is made that a guideline needs to be updated or rewritten, the process outlined above will be reproduced in part or in full.