Developing and Implementing Clinical Guidelines

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1. Introduction

1.1 Purpose

This document provides guidance to assist the Agency for Clinical Innovation (ACI) networks, taskforces and institutes when developing and implementing a clinical guideline. The effort applied to the methodology/process should be aligned with the type of guideline. It is important that ACI follows the processes outlined in this document to standardise the approach to ensure that evidence based and implementable guidelines are developed. The guide also recognises that each project will have its own unique elements and a degree of flexibility in the approach is required.

When developing a new guideline, the aim is to identify best practice based on the available evidence (e.g. research, audits, patient and clinician experience) to support optimal patient outcomes. Evidence-based practice is an approach to care that encourages clinicians to use the best available evidence in combination with the individual patient’s circumstances and preferences in clinical practice (Caresearch, 2014). The approach also highlights the need to draw on knowledge from past clinical experience in addition to best external evidence. Development of a new guideline does not finish when the guideline is written, it needs to include the process for implementation and evaluation. Developing and implementing a guideline is a project and as such should follow a project management methodology (this document uses the ‘Redesign Methodology’).

1.2 Background

The ACI has access to an extensive network of clinicians with a wealth of clinical expertise. The vision of the ACI is to be valued as the leader in the health system for designing and supporting the implementation of innovative models of patient care. The concept behind the ACI Clinical Networks is recognition that the best innovations come from front line clinicians working in the NSW Health system. This document provides a framework for developing evidence based, implementable guidelines. The process described in this document should be managed by the ACI, but the ownership and creative process belongs to the networks and their members. In this way, the end result is owned by front line clinicians, creating a better and more implementable product. Clinical Guidelines produced by ACI are generally not mandated and should be considered as recommendations of best practice. For clinical guidelines to be mandated, they need to be considered through the NSW Health Policy Distribution System.

1.3 Definition

A clinical practice guideline is a set of recommendations which are based on the systematic identification and synthesis of the best available scientific evidence to make clear recommendations for the care health professionals provide (National Health and Medical Research Council, 2011). The fundamental ingredient is that guidelines are based on the best available evidence at the time as agreed by expert stakeholders. Please refer page 14 for a list of definitions for a policy directive, information bulletin, policy and procedure manual, local operating procedure or protocol and model of care.
1.4 Types of guidelines
Guidelines can be released in many different formats and should be tailored to best meet the needs of the end-user. They may be as simple as a flow chart or algorithm, or as complex as a National Health and Medical Research Council (NHMRC) guideline document.

1.5 National Health and Medical Research Council (NHMRC)
The NHMRC has a legislated role in providing high quality, evidence based health advice to the government and the community. One way it does this is through the development of high quality clinical practice and public health guidelines. NHMRC also has a role in approving clinical practice guidelines developed by external groups, and in setting standards for high quality guideline development.¹

An additional document that may be useful as a reference throughout the development of a guideline is the NHMRC “A guide to the development, evaluation and implementation of clinical practice guidelines”. Whilst the ACI recommends the use of different development tools to those recommended by the NHMRC, the document may provide additional insight into the process. The NHMRC process is very detailed and following this overall process may not be achievable depending on the type of guideline and resources available. Guidelines that may have national significance (and therefore can be endorsed by the NHMRC) will have to provide the NHMRC with a short report on the consultation process.

1.6 Clinical Program Design and Implementation (CPD&I) Team Support
A snapshot of the support and expertise available to the guideline development process from within the Clinical Program Design & Implementation (CPD&I) team is given below:

The Implementation team can provide support, offer expertise and rigour in the development and implementation of projects and guidelines.

Rural Health and Telehealth team can provide expertise in rural health and telehealth to ensure that the needs of rural and remote health services and communities are considered in both the guideline and the implementation plan.

The Centre for Health Care Redesign can provide capability building for staff across the health system in skills needed for innovation, redesign and change management, which are key to the development, implementation and evaluation of clinical guidelines.

The Health Economics and Evaluation Team (HEET) can conduct economic, financial and service utilisation impact analyses of the guideline to determine its viability and develop a business case, business proposal and/or resourcing strategy to support the guideline. Included in this is consideration of the qualitative and quantitative costs and benefits of implementing the recommendations in the guideline.

The Research Manager can assist with three tasks: deciding whether the guideline development and implementation project warrants obtaining Human Research Ethics Committee (HREC) approval; defining literature search terms and negotiating research evidence, stakeholder views and practice-based evidence to ensure they align with those outlined in the guideline development tool.

Early engagement of the CPD&I teams in the development of a guideline is encouraged. The Implementation team has templates for project initiation, project management and implementation plans that will be able to assist the guideline development and implementation process. Please contact the Implementation team for access to these templates.

1.7 Process Outline

The key steps for developing guidelines are listed below and will be described in detail throughout this document.

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2. **Phase 1 – Project Initiation**

The aim of this phase is to develop a clear understanding of what the project is and to develop a plan to respond to the issues that may arise.

### 2.1 Identify the need

There may be a number of reasons to develop a guideline including:

- Clinician/ACI Network/consumer identified issue
- Unwarranted clinical variation
- Out of date guideline or current guidelines requires updating
- New research findings
- Suboptimal clinical outcomes

It must be considered by the Steering Committee that the best way to address this issue is through a new guideline. The baseline data that identifies the requirement to develop the guideline at this stage will set the baseline for the guideline evaluation process.

### 2.2 Create the initial high level case for change

It needs to be made clear why this project should be prioritised to go forward. The rationale for action should be based on both qualitative and quantitative information. Qualitative information may include patient and clinician stories and quantitative information should define the size of the problem for example; how many patients does it affect, how many lives could be improved and how much healthcare resource could be diverted to better uses? The case for change will also need to clearly define the patient cohort in which the guideline addresses. Many different factors can contribute to the case for change, such as unwarranted clinical variation, identified priority area for the Local Health District, Specialty Health Network, the Ministry of Health, failure to implement recognised best practice, etc.

The case for change is creating the argument for change and describes what can be achieved through improving this area of practice. This work is commenced in the project initiation phase and should have been in sufficient detail to convince sponsors that further work in this area of practice is warranted. This will be high level initially becoming more detailed during the diagnostic phase.

### 2.3 Convene a project team & steering committee

The governance arrangements that are necessary will depend on the size of the project. Membership may include Network Co-Chairs or the Network Executive. Most projects will require a project team and a steering committee.

**Project Team** – this should include the relevant Network Manager, Project Officer (if applicable), Implementation Team Member (CPDI) and relevant network clinicians and managers. Furthermore, consultation throughout the development should include appropriate stakeholder groups including but not limited to representatives from rural and remote regions, Aboriginal and Torres Strait Islander people, culturally and linguistically diverse (CALD) communities and consumers/carers.
Steering Committee – this committee may be a Network Executive or another group approved by the relevant Network Executive, with knowledge of project management and subject matter expertise. The responsibility of the Steering Committee is to oversee the project to ensure valid, relevant, and rigorous guidelines are produced and to feedback to the relevant Network Executive. They will ensure that the project is on track and is meeting its aims and objectives. The committee will establish a Terms of Reference and will be guided by these throughout the development. The members should have the seniority to solve problems that the project is facing and, where necessary, escalate issues to the appropriate individual or groups.

2.4 Target Audience
Before proceeding, the purpose and target audience for each guideline will need to be clarified. This will involve a careful specification of the following:

- The clinical problems that are an issue,
- The type of care providers or consumers for whom the guidelines are intended,
- A description of consumers excluded from the scope covered by the guidelines,
- The types of settings in which the guidelines will be employed and
- The interventions to be evaluated

2.5 Project aim, objectives and scope
The project aim is a high level statement explaining what the project will achieve and it should align with the ACI’s priorities. Where possible, project aims and objectives should be developed with the project team and sponsors to obtain “buy in”. Clear project aims and objectives will:

- Ensure that everyone is working towards the same goal
- Align expectations regarding the project
- Define clearly what success looks like

The project objectives should outline the specific results and benefits to be achieved in order to reach the project aim. They should include timeframes in which the objectives are to be met (typically 12-24 months or less depending on the complexity of the guideline). The wording of the project objectives and expected outcomes should lead to the development of the evaluation measures which are critical to measuring the success of the guideline. A clear and concise definition of scope is central to the development of the guideline identifying work that falls inside and outside of the scope and assists in defining realistic project plans and managing expectations.
3. **Phase 2 – Diagnostic**

3.1 **Define the problem**

In the ‘Project Initiation’ phase an initial case for change is developed. The diagnostic phase builds on this initial ‘case for change’. The initial problem identified is likely to be a symptom of the problem – the diagnostic process will enable the root cause of the problem to be understood.

3.2 **Literature review of evidence based practice and innovation**

A literature review will identify if there are other guidelines available for all, or part of the project scope. It will also identify the evidence supporting aspects of clinical practice that will underpin the recommendations in the guideline. It is useful to contact the [NHMRC](https://www.nhmrc.gov.au), relevant peak bodies or other leading international guideline development organisations as they will be able to advise if another group has developed, or is developing a guideline for a similar issue and therefore it may be possible to adapt existing guidelines.

Critical evaluation of the relevant literature is an essential step in the development of an evidence based guideline. Critical analysis of the literature should provide information on best practice and how different healthcare providers deliver care, which can then be compared to current practice. It may also provide information on change solutions already tried and the outcomes and evaluation of the change. Analysis of current practice and innovations state wide, nationally and internationally should also be considered.

Critical analysis of the literature means the research methodology and conclusions drawn are critically appraised to ensure the recommendations are based on the best available evidence. ACI uses the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system to standardise the method used to rate a body of evidence and to make recommendations about specific clinical questions. See Appendix 3 for a summary of the GRADE system.

The findings from the literature review should be summarised and presented to the Steering Committee for consideration. Where there are gaps in the evidence, consultation should be undertaken with expert stakeholders leading to consensus based recommendations. See Appendix 4 for more information on methods for developing consensus based recommendations.
3.3 Understand the current practice to further build the case for change

After the literature review and recommendations are identified, the project team should compare current practice with key recommendations. This will further define scope and content for the guideline and help identify the format of resources that would best assist clinicians in their current practice. In order to understand how care can be improved, it is important to understand the current context of how care is provided. Diagnostic tools to identify how care is currently being provided include:

- Root Cause Analysis (RCA) reports
- Process mapping
- Patient journey mapping
- Patient/carer/staff interviews
- Staff/patient “tagalongs”
- Process observation
- Reviewing patient survey results
- Wait list analysis
- Variation analysis
- Data analysis – outcome indicators
- Adverse events – Incident & Injury Management System (IIMS)
4. Phase 3 – Solution Design

The aim of this phase is to take the prioritised issues from the diagnostic phase and develop a solution that addresses the problem.

4.1 Designing the guideline

During the diagnostic phase, the current practice and issues are identified. During the solution design phase various options are considered to meet the identified need. The recommended options will require a strong case for change.

There needs to be consideration on the format of the guideline. Web guidelines have the ability to be easily updated and the ability for online collaboration in contrast to a paper based document. The Cancer Council use a format called “Wiki Based Guidelines” which enables approved and selected experts to update guidelines. See their website for more information http://wiki.cancer.org.au/australia/Guidelines.

In some cases, if the project team intends to seek endorsement of the guideline by an agreed professional body, the guideline will need to comply with the standard format used by that body.

4.2 Circulation and endorsement

As a minimum, the following should be considered for inclusion in the guideline:

- Level of evidence or consensus (see Appendix 3)
- Applicable group (e.g. all clinicians)
- Date approved
- Date for review
- Version control
- Approval
- Responsibility for review
- Objective
- Principles
- Definitions
- Roles and responsibilities
- Scope
- Equipment (if applicable)
- Procedure
- Patient management (including pre, post)
- Disposal of equipment/waste
- Documentation
- Compliance
- References

The guideline development process should include the steps below, culminating in sign off by the ACI executive:

1. Circulate draft (with relevant supporting documents such as checklists and patient assessment forms) – seeking feedback from key stakeholders. At a minimum, 8 weeks should be given to collect feedback.
2. Review and comment by expert advisory group and amend as required
3. Seek provisional endorsement by expert advisory group
4. Review and comment by broader (targeted) group(s) such as clinical networks and relevant stakeholders. Consider also including a review by other relevant ACI networks and other NSW Health Pillars
5. Final amendments
6. Seek final endorsement by expert advisory group and/or relevant Clinical Network(s) (list under “Endorsed By” section in clinical guideline)
7. Sign off by ACI executive

See Publications Flowchart and Checklist

4.3 Evaluation Framework
Most guidelines will require an evaluation framework which the ACI HEET team can assist with developing as this will assist with the implementation approach. The approach to evaluation is usually based on a program logic and commences early in the development of a guideline. The aim of an evaluation framework is to determine the achievement of objectives and the efficiency, effectiveness, impact, and sustainability of the model. There are two main kinds of evaluation that can be undertaken:

**Formative evaluation** assesses initial and ongoing activities. It begins during project development and continues throughout the project lifecycle. This will usually relate to the evaluation of the completion of components in the implementation plan.

**Summative evaluation** assesses quality and impact of an implemented project to see if it has achieved its stated outcomes and occurs once the project has been implemented. This relates to reviewing outcomes following effective implementation of the guideline.
5. Phase 4 – Implementation

The aim of this phase of the methodology is to achieve uptake of the guideline. This will often require process redesign and behaviour change according to the recommendations in the guideline. This phase of developing a guideline is the most resource intensive phase.

Key resources in the implementation phase include:

- **ACI Implementation Team**: can provide support, offer expertise and rigour in the development and implementation of projects and guideline.
- **Understanding the process to implement a Model of Care: An ACI Framework**: This document is designed to act as a guide for ACI staff throughout the implementation process.
- **Accelerated Implementation Methodology (AIM) principles**: 10 step process proved to accelerate implementation.
- **ACI HEET Team**: conduct economic, financial and service utilisation impact analyses of the guideline to determine its viability and develop a business case, business proposal and/or resourcing strategy to support the guideline.

5.1 Develop an implementation plan

A state-wide implementation plan should be developed. An implementation plan defines the overall project objectives, timelines and individuals responsible. High level timeframes will be developed at the start of the project and will further develop as the project evolves. Completion of objectives within timeframes will help build credibility with the sponsors and those involved in the change, making them more willing and able to work with the project team. When undertaking project planning, it is important to sequence events in a logical order of progression:

- **Deliverables** – The project will consist of many activities that need to be completed. These should provide a tangible result that is measurable.
- **Milestones** – At certain points during the project there will be critical milestones. These milestones culminate from a series of deliverables, and are crucial to the change happening effectively and on time. It is important that the milestones are realistic, accountable and hence achievable.
- **Dependencies** – Careful consideration of sequencing will ensure that deliverables dependent on other tasks will be able to be completed within the desired timeframe.
- **Responsibilities** – Each deliverable identified on the implementation plan should have an owner, someone who is ultimately responsible for the completion of this task or action.

5.2 Communications plan

One of the critical steps to ensuring successful implementation of the project is communicating the right messages to key stakeholders. Communication is a tool to facilitate engagement and ownership of the project. Mapping who needs to be involved in the change and how they can be meaningfully engaged in the process will help facilitate local ownership of the change. Two way communication channels must be facilitated to ensure feedback can be received and addressed. Dissemination methods of the guideline could include:

- Establishing a Community of Interest (Site visit/Teleconference) that meets on a pre-planned basis.
• Publishing in relevant journals
• Workshops with clinicians to promote the use of the guideline
• ACI Newsletter and Network Newsletter
• Conference presentation

Developing concise and accessible tools for clinicians to access can improve utilisation of the guideline and assist with implementation. For example, ID Tag cards for clinicians can allow easy access to the key points of the guideline. Please see The Royal Children's Hospital Melbourne website for examples of ID Tags (http://www.rch.org.au/genmed/clinical_resources/Clinical_Cards_picture/).

5.3 Finalise the case for change

Create a clear and commonly held definition of both the present state and the change:

• What is the current situation (‘as is’/state of play)?
• What is changing?
• What behaviours need to change?
• Why are we changing?
• What are the consequences of not changing?
• What are the measures of success?

The resulting objectives should be clearly documented, and these will be used as a building block for the rest of the implementation plan. The evaluation framework required to support this should have already been established in the earlier phases. The case for change may need to have different language depending on the audience e.g. clinical staff or managerial staff.

5.4 Self-assessment

A self-assessment/ baseline assessment tool should be designed to assist sites and Local Health Districts and Specialty Health Networks to understand their current practice and any gaps in care provision to assist in the implementation of the new guideline.

An example of an implementation approach undertaken by ACI:

1. Communication to the Chief Executives of relevant Local Health Districts/ Specialty Health Networks to inform that the guideline is available
2. Communication to the Director Operations/ Director Clinical Governance/ Director Allied Health/ Director Nursing and Midwifery as relevant.
3. Presenting the guideline at the Director Operations/Director Clinical Governance/ Senior Executive Forum or other relevant state-wide meetings (e.g. Whole of Hospital)
4. Informing the Local Health District/ Specialty Health Network redesign leaders who may assist with creating awareness and providing support for local implementation
5. Workshop/WebEx for clinical champions, ideally locally or flexibly delivered
6. Targeted intensive support available from ACI Network Manager and/or Clinical Networks and/or Implementation Team as required.
6. Phase 5 – Sustainability

Sustainability requires buy-in from relevant clinicians and managers from the outset to ensure that the guideline meets the systems need.

6.1 Ongoing monitoring

The evaluation framework will ensure that monitoring systems are in place before implementation of the guideline. A process for ongoing monitoring can enable local services and clinicians to be assured that the guideline is working in the way that it was planned. It also enables ownership of the guideline by local clinicians and managers who are regularly informed as to how the guideline is being implemented in practice.

6.2 Revision and optimising the guideline

Once a monitoring system is in place, it will provide the tools necessary to continuously review the guideline and its impact. It also provides the project team with information they need to adapt and change implementation strategies to ensure effectiveness.

The guideline should contain a statement to the effect that it is based on the best available knowledge and evidence at a specific time. There should be regular monitoring for health outcomes and new information with a review date specified on the final guideline. The need for review should be stated explicitly, noting that a guideline should be revised at least once every three years. Preferably, the Network that developed the guideline would be the group responsible for regularly reviewing the guideline on an ongoing basis. This monitoring would ensure that planned future evaluation is undertaken and the resulting changes are communicated to relevant stakeholder groups.
### 7. Appendices

#### 7.1 Appendix 1 – Definitions

| **Policy Directive** | A policy directive is any document that contains material that must be understood by, complied with and implemented across NSW Health as a part of ongoing operations whether it be a short term or permanent direction. All policy directives must include a policy statement outlining the purpose, mandatory requirements and implementation responsibilities associated with the policy position taken by NSW Health.

The determining factor as to whether a document is issued as a policy directive is whether compliance with any part of its content is mandatory.² |
| **Information bulletin** | An information bulletin is a type of document that provides information on a change in the status of policy, legislation or other administrative arrangement.³ |
| **Policy and procedure manual** | A policy and procedure manual is a document published by NSW Health containing content derived from policy directives, guidelines, information bulletins and Government policy on a particular subject.⁴ |
| **Local operating procedure or protocol** | Local operating procedures or protocols are documents prepared by NSW Health agencies or facilities to provide specific and more detailed instructions that must be followed within that agency or facility in order to implement a NSW Health policy directive or guideline. A local operating protocol or procedure may be required to provide specific direction regarding accountabilities specific to the organisational structures within an agency, facility or site.⁵ |
| **Model of Care** | A “Model of Care” broadly defines the way health services are delivered. It outlines best practice care and services for a person, population group or patient cohort as they progress through the stages of a condition, injury or event. It aims to ensure people get the right care, at the right time, by the right team and in the right place.⁶ |
| **Implementation** | Implementation is the carrying out, execution, or putting into practice of a desired change. Implementation is the action of change and changing people’s behaviours. |
| **Sustainability** | Ensuring gains and changes are maintained beyond the life of the project. |

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7.2 Appendix 2 - Guiding Principles

The ACI Guideline Development Project Team has endorsed the NHMRC guiding principles for the development of clinical guidelines. There are nine basic principles for developing guidelines:

1. Processes for developing and evaluating clinical practice guidelines should focus on outcomes. Outcome measures can range from survival rates to quality-of-life attributes.

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. The ‘level’ of evidence refers to the study design used to minimise bias: the highest level involves a systematic review of randomised controlled clinical trials. ‘Quality’ refers to the methods used to minimise bias in the design and conduct of a study. ‘Relevance’ refers to the extent to which research findings can be applied in other settings. The ‘strength’ of evidence relates to the magnitude and reliability of the treatment effect seen in clinical studies: strong effects are more likely to be real and more likely to be clinically important. Ideally, recommendations would be based on the highest level of evidence, but this may be difficult to achieve in public health and social science interventions.

3. The method used to synthesise the available evidence should be the strongest applicable. Taking the evidence—of whatever level, quality, relevance or strength—and turning it into a clinically useful recommendation depends on the judgment, experience and good sense of the group developing the guidelines. The fact of having evidence from a high-level study does not automatically result in a good clinical recommendation.

4. The process of guideline development should be multidisciplinary and should include consumers. If guidelines are to be relevant, those who are expected to use them or to benefit from their use should play a part in their conception and development. Involving a range of generalist and specialist clinicians, allied health professionals, experts in methodology, 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 to varying local conditions. They should include evidence relevant to different target populations and geographic and clinical settings, take into account costs and constraints, and make provision for accommodating the different values and preferences of patients.

6. Guidelines should be developed with resource constraints in mind. They should incorporate an economic appraisal, which may be helpful for choosing between treatment options.

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.7

Additional factors for consideration when in the development of a guideline are that it:

1. is person and carer/family centred
2. supports integrated care
3. is innovative and considers new ways of organising and delivering care
4. sets the vision for services in the future
5. links to strategic plans and initiatives (local, national, state) supports safe, quality care for patients and carers/families
7.3 Appendix 3 – GRADE

ACI uses the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system as a means to standardise the method used to rate the quality of a body of evidence and to make recommendations about specific clinical questions.

Below is a summary of the GRADE methodology. For comprehensive information including publications, presentations and FAQs on GRADE, please see the website: http://www.gradeworkinggroup.org/

7.4 Appendix 4 – Consensus based recommendations

The way in which the guidelines are developed depends on available evidence (Appendix 3 provides information on the different levels of evidence). Where there are gaps in the evidence, consultation should be undertaken with expert stakeholders leading to consensus based recommendations. The consultation process is critical to stakeholder’s acceptance of the resulting guideline and demonstrates the transparency of the process as well as acknowledging the value of the end user to the resulting guideline.

Common techniques for developing consensus based recommendations are the Delphi method, the Nominal Group technique or a combination of these two processes. The Delphi method systematically gathers information from experts in two or more rounds of questionnaires independently. After each round, the facilitator provides an anonymous summary of opinions and reasons from the previous round to the group. This process ends when consensus is reached or a predefined number of rounds are met.

The nominal group technique is conducted in person where each person is given equal opportunity to speak and feedback is provided by the facilitator. Following on from this, options are ranked from most to least acceptable by all participants.

For more information on these techniques being used in practice, see an example of how the GRADE tool has been incorporated into developing consensus based recommendations: Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive