

Review of approaches for the development of high quality, evidence-based clinical practice guidelines for psychiatry

2 June 2023

CONTENTS

Abbreviations	6
Executive summary	8
Key considerations for alignment of RANZCP guidelines with high quality clinical practice guideline methods	9
1 Background	13
1.1 Clinical practice guidelines	13
1.2 Features of high quality clinical practice guidelines	13
1.2.1 Planning	13
1.2.2 Governance.....	13
1.2.3 Knowledge management.....	14
1.2.4 Format of the guidelines.....	14
1.2.5 Dissemination and implementation	14
1.3 Criteria for high quality evidence-based clinical practice guidelines.....	15
2 The existing suite of RANZCP clinical practice guidelines	16
2.1 Analysis of the existing suite of RANZCP clinical practice guidelines.....	16
2.1.1 Planning	16
2.1.2 Governance.....	17
2.1.3 Knowledge management.....	17
2.1.4 Format of the guidelines.....	18
2.1.5 Dissemination and implementation	18
2.1.6 Overall quality of the existing RANZCP clinical practice guidelines.....	19
2.2 Discussion regarding the existing suite of RANZCP clinical practice guidelines.....	19
3 Environmental scan of guideline development approaches used by other Medical Colleges and peak bodies	20
3.1 Methods	20
3.1.1 Guideline development approaches used by other Australian and New Zealand Medical Colleges	20
3.1.2 Guideline development approaches used by a selection of peak bodies in Australia and New Zealand.....	21
3.1.3 Guideline development approaches used by a selection of international psychiatry organisations.....	21
3.2 Results	21
3.2.1 High quality evidence-based clinical practice guidelines produced by Australian and New Zealand Medical Colleges	21
3.2.2 High quality evidence-based clinical practice guidelines produced by Australian and New Zealand peak bodies	22
3.2.3 High quality evidence-based clinical practice guidelines produced by international psychiatry organisations.....	23
3.3 Analysis of the clinical practice guidelines identified through the environmental scans	23
3.3.1 Planning	23
3.3.2 Governance.....	25

3.3.3	Knowledge management	27
3.3.4	Format of the guidelines	27
3.3.5	Dissemination, implementation and updating	28
4	Interviews with key informants	29
5	Possible options for RANZCP clinical practice guideline program	30
6	Key components of high quality, trustworthy clinical practice guidelines.....	37
6.1	Planning	39
6.1.1	Priority setting	39
6.1.2	Determine the purpose, scope and target audience	40
6.1.3	Budget and resourcing	42
6.1.4	Guideline development group composition	46
6.2	Governance	51
6.2.1	Declaration and management of conflicts of interest	51
6.2.2	Achieving consensus	53
6.2.3	Terms of reference	54
6.2.4	Public consultation.....	54
6.2.5	Internal approvals	55
6.2.6	Alternative governance arrangements to produce high quality clinical practice guidelines .	56
6.3	Knowledge management	59
6.3.1	Evidence identification	59
6.3.1.1	Defining the questions.....	59
6.3.1.2	Searching for evidence	59
6.3.1.3	Documenting the process.....	61
6.3.1.4	Identifying and selecting evidence	61
6.3.2	Evidence synthesis and assessing the risk of bias.....	62
6.3.2.1	Synthesising the evidence	62
6.3.2.2	Details to provide in a technical report	63
6.3.2.3	Appraising the methodological quality of included studies	63
6.3.3	Evidence to decision methods	64
6.3.3.1	Development of recommendations	65
6.3.3.2	Grading recommendations.....	67
6.4	Adapting/adopting existing high quality guidelines	71
6.5	Living guideline approaches	73
6.5.1	Should the RANZCP clinical practice guidelines be living guidelines?	76
6.6	Format of the guidelines	76
6.6.1	Format and publication platform.....	76
6.6.2	Online publication.....	78
6.6.3	MAGICapp	78
6.6.4	Suggestions for format of future RANZCP clinical practice guidelines	78
6.7	Dissemination and implementation.....	80
6.7.1	Dissemination	80
6.7.2	Implementation	80
6.7.3	Updating	81

8	References	83
	Appendix 1 Environmental scan	85
	Appendix 2 High quality evidence-based clinical practice guidelines endorsed by Australian and New Zealand Medical Colleges.....	91

TABLES

Table 1	Summary of key considerations for RANZCP to align with best practice principles for the development of high quality clinical practice guidelines.....	9
Table 2	High quality evidence-based clinical practice guidelines developed by Australian and New Zealand Medical Colleges	22
Table 3	High quality evidence-based clinical practice guidelines developed by Australian peak bodies.....	23
Table 4	Options with the College playing no direct role in clinical practice guideline development	34
Table 5	Options with the College continuing to play a role in clinical practice guideline development.....	35
Table 6	Example of typical items to include in a guideline budget	44
Table 7	Interpretation of the four levels of evidence used in the GRADE profile (20).....	65
Table 8	Guideline development details – included clinical practice guidelines produced by Australian and New Zealand Medical Colleges	86
Table 9	Guideline development details –included clinical practice guidelines produced by Australian peak bodies.....	89
Table 10	Australian and New Zealand College endorsed (externally produced) guidelines	91

FIGURES

Figure 1	Alternative guidance options for Path 1 - the College no longer develops or updates clinical practice guidelines	32
Figure 2	Options for Path 2 - the College continues to develop and update clinical practice guidelines	33
Figure 3	Guideline Development Process.....	37
Figure 4	How to select questions in a guideline that are suitable to be living (while other questions may remain static).....	75

Abbreviations

AADPA	Australian ADHD Professionals Association
ACRRM	Australian College of Rural and Remote Medicine
ADHD	Attention Deficit Hyperactivity Disorder
AHRQ	Agency for Healthcare Research and Quality
ANZCA	Australian and New Zealand College of Anaesthetists
ANZCP	The Australian and New Zealand College of Perfusionists
ANZJP	Australian and New Zealand Journal of Psychiatry
ACEM	Australasian College for Emergency Medicine
ACM	Australian College of Midwives
ACRRM	Australian College of Rural and Remote Medicine
ANZSGM	Australian and New Zealand Society of Geriatric Medicine
BMJ	British Medical Journal
CALD	Culturally and linguistically diverse
CBR	Consensus-based recommendations
COPE	Centre of Perinatal Excellence
CPD	Continuing professional development
CPG	Clinical Practice Guideline
CGS	Canadian Geriatrics Society
EBG	Evidence based guideline
EBR	Evidence-based recommendations
EtD	Evidence to decision
GIN	Guidelines International Network
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HTA	Health Technology Assessment
IOM	Institute of Medicine
NGT	Nominal Group Technique
NHMRC	National Health and Medical Research Council
NICE	National Institute for Health and Care Excellence
MeSH	Medical Subject Headings
PDF	Portable document format
PICO	Patient, Intervention, Comparator, Outcome
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RACS	Royal Australasian College of Surgeons
RANZCO	Royal Australian and New Zealand College of Ophthalmologists
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RANZCP	Royal Australian and New Zealand College of Psychiatrists
RANZCR	Royal Australian and New Zealand College of Radiologists
RCPA	Royal College of Pathologists of Australasia
SANDA	Stillbirth and Neonatal Death Alliance
SANDS	Stillbirth and Neonatal Death Support
SIGN	Scottish Intercollegiate Guideline Network

SR	Systematic review
TIA	Transient ischaemic attack
VMIA	Victorian Managed Insurance Authority
WHO	World Health Organization

Executive summary

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) has commissioned Health Research Consulting (hereco) to develop this report that outlines options to support high quality clinical practice guideline development for psychiatry in Australia and New Zealand. This project has been supported by the Future Development of Clinical Practice Guidelines Steering Group, initially reporting to the Practice, Policy and Partnerships Committee and later reporting directly to the RANZCP Board.

Out of scope: This project is not intended to include evaluation of the subject content of the RANZCP clinical practice guidelines published between 2014-2020.

Hereco undertook a range of research activities, and a targeted consultation with key stakeholders to develop the tailored options presented within this report on the ways to optimise the RANZCP guideline development program. Specifically, the process of developing the recommendations in this report was guided by hereco undertaking:

- a brief analysis of RANZCP's existing suite of clinical practice guidelines (see **Section 2**);
- an environmental scan of approaches used by other Australian and New Zealand Medical Colleges and peak bodies to develop high quality clinical practice guidelines (see **Section 3.1.1 Guideline development approaches used by other Australian and New Zealand Medical Colleges**);
- an environmental scan of approaches used by international psychiatry organisations to develop high quality clinical practice guidelines (see **Sections 3.1.3 Guideline development approaches used by a selection of international psychiatry organisations**); and
- interviews with several key informants nominated by the RANZCP's Clinical Practice Guideline Evaluation Steering Group (see **Section 4**).

Hereco applied its extensive guideline methodological expertise to provide suggestions on the prioritisation of activities that would be most impactful for the RANZCP to implement.

This report outlines the risks, benefits, and resource requirements associated with each guideline development option presented. Importantly, this report was informed the best practice principles recommended by national and international guideline development leadership bodies including the National Health and Medical Research Council (NHMRC), the World Health Organization (WHO), the Guidelines International Network (GIN), the **Scottish Intercollegiate Guidelines Network (SIGN)**, **Cochrane** and the **GRADE Working group**. Hereco considered the generic principles of high quality clinical practice guideline development advised by these national and international bodies, and tailored recommendations to RANZCP's unique situation. Through the research and targeted consultations, a range of recurring themes were identified in areas such as planning, governance, knowledge management, format of guidelines and dissemination and implementation. Therefore, the findings contained within this report have been structured under these key themes.

Hereco have made suggestions on areas that the College may wish to consider aligning any future guideline development activities with best practice high quality clinical practice guideline development principles. These suggestions can be found below in **Table 1**, and in orange boxes at the end of each part of **Section 6**. These suggestions have been packaged by topic and are in no particular order. However, based on the overall findings in this report, hereco have highlighted (in blue shading) six key considerations we believe would be most impactful for the guidelines developed by the College (in terms of NHMRC standards and the key informant interview themes). Given there may be resource implications with future guideline development, a staged approach to implementing the recommendations in this report is suggested. The College may wish to prioritise where it is most important to start and build from there.

Key considerations for alignment of RANZCP guidelines with high quality clinical practice guideline methods

Table 1 below presents a summary of the key considerations for alignment with high quality clinical practice guidelines (highlighted throughout **Section 6** of this report in orange break out boxes). Based on the overall findings in this report, hereco have highlighted (in blue shading) six key considerations we believe would be most impactful for the guidelines developed by the College (in terms of NHMRC standards and the key informant interview themes).

Table 1 Summary of key considerations for RANZCP to align with best practice principles for the development of high quality clinical practice guidelines

Area	Key considerations
Planning (for full details see sections 1.2.1	Planning and 6.1
Budget	<p>The College should explore external funding options (especially Government funding) to support future clinical practice guideline development.</p> <p>Avoid accepting industry funding for clinical practice guideline development.</p>
Resourcing	<p>Consider seeking methodological support for the evidence review component of clinical practice guideline development. This might be best outsourced as it is a specialised skill set.</p> <p>Consider seeking a search specialist/librarian to support the development of high quality clinical practice guidelines.</p> <p>Consider engaging the assistance of a guideline development methodologist to support the guideline development process (e.g. this methodologist supports the establishment phase, governance and processes, and transparency on the evidence to decision process).</p>
Priority setting and scoping the guideline	<p>Consider reviewing the College's guideline topic scoping process.</p> <p>Consider a more systematic, transparent, and inclusive process for guideline topic priority setting.</p> <p>Consider including all relevant stakeholders in the process of priority setting and selection of guideline topics. Consider consulting with the membership on the draft scope of the guidelines to be developed (not just consulting on the final draft guideline).</p> <p>Consider publishing the clinical questions (PICO questions) with the clinical practice guidelines.</p> <p>There should be greater clarity on the purpose of the guideline, the scope, and the intended audience. This should be published with the guideline.</p>
Multidisciplinary guideline development group	<p>Consider high level sign-off of the multidisciplinary guideline development group membership, potentially by the Board. It would be helpful to come up with a set of principles to help the Board decide whether there is true multidisciplinary representation on the guideline development group (including all stakeholders involved in the guideline topic).</p> <p>Document and publish how the guideline development committee representatives were sought, the process and criteria for selecting members and in what capacity they participated in the guideline development.</p>

Area	Key considerations
Indigenous representation	Consider reviewing the College’s current engagement with Aboriginal and Torres Strait Islander/Māori peoples in the development of clinical practice guidelines. Helpful advice can be found in the NHMRC’s Guidelines for Guidelines module on “Engaging Aboriginal and Torres Strait Islander people in guideline development”. Engagement should be based on whether the guideline topic has specific implications for Aboriginal and Torres Strait Islander/Māori Peoples.
Governance (for full details see sections 1.2.2 Governance and 6.2 Governance)	
Conflict of interest	<p>There was variation on the level of detail published about the process to deal with conflicts of interest across the suite of current RANZCP clinical practice guidelines. Consider a more consistent approach to documenting conflict of interest declarations and management across clinical practice guidelines.</p> <p>Consider ways to minimise the impact of real or perceived conflict of interest that are appropriate for the RANZCP (e.g. independent chair or establishment of a conflict of interest committee).</p>
Achieving consensus amongst the guideline development group	No information was provided about the process that the guideline development groups used to reach consensus across the suite of current RANZCP clinical practice guidelines. Guideline development consensus processes should be established prior to commencing guideline development, and this process should be communicated to the guideline development group before work commences on the guideline. The process should be published with the guideline.
Guideline development group membership	Provide greater transparency on who was involved in developing the guideline, how they were selected and in what capacity they contributed to the guidelines.
Terms of Reference	It is unclear, who is responsible for enforcing the terms of reference if the guideline development group depart from them (e.g. the scope of work on the reviewed Mood disorders guideline was substantially greater than as set out in the terms of reference).
Consultation of the clinical practice guidelines	<p>The internal processes for Fellow/members/other committees to provide feedback on clinical practice guidelines could be improved by making it easier for people to comment (e.g. provide extracted summary of recommendations and an Executive summary of the guidelines).</p> <p>Consider reviewing the effectiveness and satisfaction of the RANZCP document portal for obtaining member feedback.</p> <p>Particular College committees are important to specifically consult with, depending upon the guideline topic. Examples include the College’s Youth Mental Health Section, and the Faculty of Addiction Psychiatry and there may be others depending on the guideline topic.</p>
Internal approvals/final sign-off on the clinical practice guideline content	<p>Allow sufficient time for the internal approval process for clinical practice guidelines.</p> <p>The guideline approval timelines should not be governed by the timelines of peer-reviewed journals, rather sufficient time should be allowed for meaningful consultation of draft guidelines amongst the membership.</p>
Knowledge management (for full details see sections 1.2.3 and 6.3 Knowledge management)	
Evidence review	<p>There is limited transparency of the evidence review process and guideline development methods in any of the published RANZCP clinical practice guidelines. This should be transparently reported to align with best practice principles in clinical practice guideline development.</p> <p>There were no details of critical appraisal of included literature in any of the published RANZCP clinical practice guidelines This should be transparently reported to align with best practice principles in clinical practice guideline development.</p> <p>It is recommended that the RANZCP seek external support with risk of bias assessment of included studies as it requires a specialised skill set.</p> <p>There were no detailed PICO/Research questions available in any of the published RANZCP clinical practice guidelines. PICO/Research questions should be transparently reported to align with best practice principles in clinical practice guideline development.</p>

Area	Key considerations
Evidence to decision processes	<p>There were no details of the evidence to decision process or rationales on how evidence linked to decisions in any published RANZCP clinical practice guidelines. It is recommended that evidence to decision processes or rationales on how evidence linked to decisions are transparently reported to align with best practice principles in clinical practice guideline development.</p> <p>None of the RANZCP guidelines directly linked recommendations to supporting evidence. It is suggested that recommendations are linked to supporting evidence to align with best practice principles in clinical practice guideline development.</p>
Developing recommendations	<p>The GRADE methodology or some form of equivalent considered judgement process should be used to develop recommendations.</p> <p>When formulating recommendations, they should be actionable recommendations, using direct language, with clear links between recommendations and the evidence supporting them.</p> <p>It is helpful to decide on standardised wording to use for recommendation statements to ensure clarity and maintain consistency throughout the guideline and across the suite of RANZCP guidelines.</p> <p>The guideline development groups rationale for developing the recommendations should be transparently reported in the guideline or corresponding technical report.</p>
Grading of recommendations	<p>Some RANZCP guidelines did not provide further detail on the grades of recommendations beyond EBR or CBR. Consider implementing the GRADE approach to grading recommendations in future clinical practice guidelines.</p> <p>None of the RANZCP guidelines provided evidence to decision information (rationales) for factors that were considered or influenced the committee’s decision-making on the development of evidence-based recommendations (EBRs) or consensus-based recommendations (CBRs).</p>
Approach to knowledge management	<p>The GRADE approach to assessing the certainty of a body of evidence and developing recommendations is considered best practice by the NHMRC and internationally.</p>
Adaptation or adoption of existing high quality guidelines (for full detail see section 6.4)	
Guideline adaptation approaches	<p>Developing and updating high quality guidelines requires substantial time and resources. To reduce duplication of effort and enhance efficiency, guideline adaptation could be considered as an option for some topics.</p>
Living guideline approaches (section 6.5)	
Living guidelines	<p>A full living guideline approach to entire guidelines may be too resource intensive for the RANZCP, and not necessarily appropriate for all topics (especially as the five-year update frequency appears to be acceptable or most topics). However, the College may wish to consider whether it is appropriate to highlight specific recommendations within a guideline that could be living (that is where there is an intention to re-visit the evidence and recommendations more frequently) and agree a plan on how this will be conducted and resourced.</p>
Format of guidelines (see sections 1.2.4 and 6.6)	
Format and publication of guidelines	<p>All RANZCP clinical practice guidelines are published as a journal article in the ANZJP in narrative, review article style. While this publication format provides benefits of peer review and recognition, for some readers, the journal article format makes the guidelines difficult to navigate (no index, table of contents/indication of structure), and can render them less contemporary.</p>

Area	Key considerations
	<p>All RANZCP clinical practice guidelines are lengthy with no navigation aids which can make it difficult for the user to find the information that they are looking for. The College could consider engaging the assistance of a technical/medical writer or editor to assist with making the guidelines easier to navigate and more useable.</p> <p>Hereco found that some of the governance concerns with the existing suite of RANZCP guidelines arose because of the publication format and suggest that the College consider a more dynamic way to present its clinical practice guidelines in future. Depending upon budget and resourcing, full RANZCP clinical practice guidelines could be published in a PDF format or as a navigable webpage or separate website, with publication of a summary of the guideline in the ANZJP as a supplementary form of dissemination.</p> <p>The names of all those involved in developing clinical practice guideline should be published in the guidelines.</p>
<p>Dissemination, Implementation and Updating (for full details see sections 1.2.5 and 6.7)</p>	
Dissemination	All RANZCP clinical practice guidelines are presented in narrative, review article style making them more difficult to navigate and potentially impacting on implementation.
Implementation	<p>There are many types of companion documents that help support implementation of clinical practice guidelines. The choice and format of any companion documents should be based on the needs of the target users of the guidelines.</p> <p>It is unclear what formal mechanisms of implementation of clinical practice guidelines exist within the RANZCP (e.g. especially with the trainee or CPD programs) or what formal cross-over there is between the RANZCP clinical practice guidelines and other parts of the RANZCP education program. To streamline implementation, the RANZCP could consider formal links to these areas following publication of guidelines</p>
Updating	The updating frequency of every five years was acceptable to most key informants interviewed. The updating frequency of guidelines should be agreed at the organisational level, noting that updating frequency may be different for different topics.

1 Background

1.1 Clinical practice guidelines

Although there is no standard agreed definition of clinical practice guidelines, the former Institute of Medicine (IOM) publication “Clinical Practice Guidelines We Can Trust” defined clinical practice guidelines as “statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”. (1)

Clinical practice guidelines form a central part of evidence-based practice, support clinicians to deliver high quality care to patients, and are integral to Medical College training programs. They have “the potential to reduce inappropriate practice variation, enhance translation of research into practice, and improve healthcare quality and safety”. (1)

1.2 Features of high quality clinical practice guidelines

Clinical practice guidelines can be produced by a variety of methodologies however there are some defining features that set apart high quality clinical practice guidelines from other types of clinical guidance documents. The key features of high quality clinical practice guidelines are explored in detail in section 0. Briefly, according to the 2016 National Health and Medical Research Council (NHMRC) Standards for Guidelines(2), features of high quality clinical practice guidelines include:

1.2.1 Planning

- developed by a **multidisciplinary guideline development group** with oversight of the guideline development process. Membership should include a mix of expertise ensuring that the views of all key stakeholders are considered. Membership should include but not be limited to multidisciplinary healthcare professionals and those with lived experience (patients/carers and advocates);
- a priori establishment of **the target audience, scope of the guideline and clinical questions** (with questions ideally in PICO format. PICO stands for patient/population, intervention, comparison and outcomes);
- early identification of all the **skills required** for guideline development (including clinical expertise, methodological expertise, a medical librarian/search specialist, evidence review expertise, facilitation skills, project management and administrative skills and medical editing); and
- **address health issues of importance.**

1.2.2 Governance

- have **robust governance processes** (including transparency on the declarations and management of conflicts interest and clearly defined processes for reaching consensus);
- are transparent about **who is involved in the guideline development group**;
- include a statement on **funding sources**; and

- are externally peer-reviewed through a transparent **public consultation process**.

1.2.3 Knowledge management

- are underpinned by a **systematic review of evidence** (with reviews guided by specific research questions);
- are developed using **rigorous evidence-based methodologies** including critical appraisal of the evidence, level of evidence explicitly stated;
- consider the **body of evidence for each outcome** (including the quality of that evidence) **and other factors** that influence the process of making recommendations including benefits and harms, values and preferences, resource use and acceptability;
- make the source evidence publicly available, and being **transparent about decision-making and judgements** of the evidence by the guideline development group; and
- clearly **link each recommendation to the evidence** that supports it and assign the **strength of recommendation**.

1.2.4 Format of the guidelines

- **are clearly structured** and easy to navigate;
- make **actionable recommendations, using direct language**, with clear links between recommendations and the evidence supporting them;
- **grade the strength** of each recommendation;
- clearly articulate the **recommended course of action**, when it should be taken and by whom; and
- are **transparent** by publishing detailed information on the guideline development and evidence review processes and procedures.

1.2.5 Dissemination and implementation

- **are implementable, and easily accessible** (ideally free of charge, and available online); and
- focused on strategies to make relevant groups aware of the guidelines and to enhance their uptake.

1.3 Criteria for high quality evidence-based clinical practice guidelines

Hereco have been asked to focus this report on **high quality, evidence-based clinical practice guidelines**. The selection criteria hereco used to identify and select such guidelines are outlined in Box 1.

Box 1. Criteria for high quality evidence-based clinical practice guidelines.

A high quality evidence-based clinical practice guideline:

- makes evidence-based recommendations to be used as a clinical decision-making tool;
- is intended for national use (e.g. not developed just for use at hospital or state level); and
- has met the NHMRC definition of a 'high quality guideline'¹. Notably:
 - it is based on systematic reviews of evidence;
 - it was developed by a professional organisation or body;
 - it is publicly available; and
 - it includes a statement about declaration and management of conflicts of interest.

¹ National Health and Medical Research Council. Guidelines for Guidelines Handbook [internet]. National Health and Medical Research Council; 2016 [updated 2018 April 17; cited 2022 Sep 27]. Available from: www.nhmrc.gov.au/guidelinesforguidelines

2 The existing suite of RANZCP clinical practice guidelines

The existing suite of RANZCP clinical practice guidelines include:

- [Eating Disorders](#) (2014)
- [Mood Disorders](#) (2015) and the [Mood Disorders Update](#) (2020)
- [Schizophrenia and related disorders](#) (2016)
- [Deliberate Self-Harm](#) (2016)
- [Anxiety disorders](#) (2018)

These clinical practice guidelines are published in the College's journal, the Australian and New Zealand Journal of Psychiatry (ANZJP) and are publicly available on the RANZCP website.

The College has also developed several position statements, clinical memorandums, and resources for practice available on the [RANZCP website](#).

To date, most of the work in developing the RANZCP clinical practice guidelines has been undertaken on a pro bono basis by dedicated members of the College who are psychiatrists, together with some co-authors from other disciplines, and those with lived experience.

2.1 Analysis of the existing suite of RANZCP clinical practice guidelines

To determine the strengths and weaknesses of the RANZCP's current suite of clinical practice guidelines, a brief analysis was undertaken by hereco investigating how aligned the current suite of clinical practice guidelines are to best practice principles of clinical practice guideline development. Specifically, hereco investigated the planning, governance, knowledge management, format and dissemination of the guidelines, along with the expertise used to develop the guidelines. The results of hereco's analysis of RANZCP's current suite of clinical practice guidelines are presented below.

2.1.1 Planning

- ✓ All RANZCP clinical practice guidelines mentioned the involvement of a multidisciplinary working group/committee.
- ✓ There was high level information provided about the general scope covered by all the RANZCP clinical practice guidelines, and broad identification of the topics to be covered by the clinical practice guidelines.
- ? All RANZCP clinical practice guidelines state that they are developed in accordance with best practice as outlined by the NHMRC in their 2007 NHMRC standards and procedures for externally developed guidelines(3), however, not enough information was provided in the guidelines or technical reports on how the guidelines were developed to determine if this is correct.

- X There was no detailed information provided about the methods used for formulating the recommendations for any RANZCP clinical practice guidelines.
- X There was no a priori identification of the specific topics covered by the clinical practice guidelines, and no detailed clinical questions (PICO questions) available across the suite of RANZCP clinical practice guidelines.
- X No information was provided about how the guideline topics were prioritised.

Guideline development expertise

- ✓ Most of the RANZCP guidelines mentioned the involvement of a project team (project manager & project officer): (all guidelines except Mood disorders).
- ✓ Some guidelines mentioned the involvement of a medical writer: Schizophrenia, Anxiety, Deliberate Self-Harm.
- ✓ One guideline mentioned the use of a writing group to draft chapters (Schizophrenia).
- X No guidelines mentioned the involvement of a medical librarian/search specialist, or guideline methodologist.
- X Some guidelines mentioned that “individuals with expertise” were involved in drafting chapters, rather than a multidisciplinary team.

2.1.2 Governance

- ✓ All RANZCP clinical practice guidelines included a declaration of interest statement and named contributing authors.
- ✓ All RANZCP clinical practice guidelines included a statement that the draft clinical practice guideline underwent expert, community, and stakeholder consultation.
- ✓ All RANZCP clinical practice guidelines had a statement that the guideline was supported and funded by the RANZCP.
- X There was variation on the level of detail about the process to deal with conflicts of interest across the RANZCP clinical practice guidelines.
- X No information was provided about the process that the guideline development groups used to reach consensus.

2.1.3 Knowledge management

- ✓ Most guidelines state that they are based on reviews and syntheses of current evidence.

Evidence review

- X Limited transparency of the evidence review process and guideline development methods.
- X No details of critical appraisal of included literature were available in any of the RANZCP clinical practice guidelines.

- X No PICO/Research questions were available in any RANZCP clinical practice guidelines.

Evidence to decision methods

- X No evidence to decision information or rationales on how evidence linked to decisions was available in any published RANZCP clinical practice guidelines.

Recommendations within RANZCP clinical practice guidelines

- X None of the RANZCP guidelines directly linked recommendations to supporting evidence.
- X Some RANZCP guidelines did not provide grades of recommendations (just EBR or CBR).
- X None of the RANZCP guidelines provided evidence to decision information (rationales) for factors that were considered or influenced the committee's decision-making on the development of evidence-based recommendation recommendations (EBRs) or consensus-based recommendations (CBRs).

2.1.4 Format of the guidelines

- ✓ All RANZCP clinical practice guidelines have a summary of recommendations specifically called out into separate tables.
- ✓ Most RANZCP clinical practice guidelines have accompanying information for the public (all except Deliberate Self-Harm).
- ? All RANZCP clinical practice guidelines are published as a journal article in the ANZJP. While this publication format provides benefits of peer review and recognition, for some readers, the journal article format makes the guidelines difficult to navigate (no index, table of contents/indication of structure), and can render them less contemporary.
- X All RANZCP clinical practice guidelines are presented in narrative, review article style.
- X All RANZCP clinical practice guidelines are lengthy, ranging between 62 and 117 pages long. Although length of guideline is not a quality criterion in itself, such lengthy guidelines with no navigation aids can make it difficult for the user to find the information that they are looking for.

2.1.5 Dissemination and implementation

- ✓ All RANZCP clinical practice guidelines are publicly available on the RANZCP website.
- ✓ All guidelines have accompanying key practice points, and webinars which provide information about the guideline and continuing professional development (CPD) accreditation for health professionals.
- X All RANZCP clinical practice guidelines are presented in narrative, review article style making them more difficult to navigate and potentially impacting on implementation.
- X It is unclear what formal mechanisms of dissemination of clinical practice guidelines exist within the RANZCP (e.g. especially with the trainee or CPD programs) or what formal cross-over there is between the RANZCP clinical practice guidelines and other parts of the RANZCP.

2.1.6 Overall quality of the existing RANZCP clinical practice guidelines

The current suite of RANZCP clinical practice guidelines were judged by the criteria listed in Section 1.3 to determine if they were considered high quality. Overall, it was not possible to look at how the RANZCP clinical practice guidelines rated based on internationally endorsed guideline quality tools such as the AGREE II tool² as there was insufficient detail provided on the methods and processes used to develop the guidelines.

- ✓ Two of the RANZCP clinical practice guidelines met our criteria of a high quality, evidence-based clinical practice guideline (Section 1.3, see Box 1): Deliberate self-harm and Anxiety Disorders.
- ✗ Two guidelines did not meet our criteria due to an inadequate literature search. For example, one clinical practice guideline was not based on a comprehensive search of the literature (only PubMed was searched); another was based on existing SRs and guidelines and “informal literature reviews”.
- ? It was not possible to determine whether the remaining guideline (Mood Disorders) met our criteria as there was insufficient information in both the 2020 and 2015 versions to determine if systematic reviews of the literature were conducted. Databases were named, but there were no details of search terms, study types or other selection criteria.

2.2 Discussion regarding the existing suite of RANZCP clinical practice guidelines

The current suite of RANZCP clinical practice guidelines represent a significant body of work, effort and expertise by those guideline development groups to provide advice on matters relevant to psychiatry and the management of mental health conditions. The contributions to the guideline development process by RANZCP members are invariably pro bono contributions. We do not seek to diminish these contributions through the findings and recommendations in this report. Through our consultations with key informants suggested by the RANZCP, there are many elements of the current suite of RANZCP clinical practice guidelines that are highly valued by members. This report will highlight areas for consideration where improvements could be made to align any future RANZCP clinical practice guidelines to the highest possible guideline development standards.

² <https://www.agreetrust.org/agree-ii/>

3 Environmental scan of guideline development approaches used by other Medical Colleges and peak bodies

As part of the development of this report to advise on contemporary approaches to high quality clinical practice guideline development, hereco undertook an investigation of clinical practice guideline development approaches used by:

- other Medical Colleges in Australia and New Zealand.
- a selection of Australian peak bodies that were known to produce high quality clinical practice guidelines.
- international psychiatry organisations in the US, Canada, UK and Scotland. We also looked at the World Psychiatric Association but found that they do not produce clinical practice guidelines.

For the purposes of this report, the focus was on high quality clinical practice guidelines produced by other Medical Colleges and peak bodies (as per the criteria listed in Section 1.3).

3.1 Methods

3.1.1 Guideline development approaches used by other Australian and New Zealand Medical Colleges

Hereco conducted an environmental scan to investigate guideline development approaches used by other Medical Colleges and peak bodies in Australia and New Zealand. The focus was on high quality, evidence-based clinical practice guidelines. We analysed each guideline using the criteria detailed earlier in this report (Section 1.3), and if all criteria were met, the guideline was included.

The following Australian and New Zealand Medical College websites were reviewed for high quality, evidence-based clinical practice guidelines:

- Australian College of Midwives (ACM);
- Australian College of Nursing (ACN);
- Australian College of Physiotherapists (ACP);
- Australasian College for Emergency Medicine (ACEM);
- Australian College of Rural and Remote Medicine (ACRRM);
- Australian and New Zealand College of Anaesthetists (ANZCA);
- Royal Australian College of General Practitioners (RACGP);
- Royal Australasian College of Physicians (RACP);
- Royal Australasian College of Surgeons (RACS);
- Royal Australian and New Zealand College of Radiologists (RANZCR);
- Royal Australian and New Zealand College of Ophthalmologists (RANZCO);

- Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG); and
- Royal College of Pathologists of Australasia (RCPA).

3.1.2 Guideline development approaches used by a selection of peak bodies in Australia and New Zealand

In addition to Medical Colleges, guidelines produced by the following four peak bodies were reviewed:

- National Asthma Council;
- The Stroke Foundation (in collaboration with Cochrane Australia);
- Centre of Perinatal Excellence (COPE); and
- Cancer Council Australia.

Although, several peak bodies produce clinical practice guidelines in Australia and New Zealand, for pragmatic reasons hereco chose to focus only on these four peak bodies as we know that these organisations have produced well-regarded, high quality clinical practice guidelines.

3.1.3 Guideline development approaches used by a selection of international psychiatry organisations

To examine characteristics of guidelines produced by international psychiatry organisations, we looked at national guidelines for the UK, Canada, the US and Scotland as these guidelines are in English and potentially applicable to the Australian setting. These guidelines were developed by the following organisations:

- The Royal College of Psychiatrists (UK) co-produced with the National Institute for Health and Care Excellence (NICE).
- The Canadian Psychiatric Association.
- The American Psychiatric Association.
- The Scottish Intercollegiate Guideline Network (SIGN).

We also looked at the World Psychiatric Association and found that they do not produce clinical practice guidelines.

3.2 Results

3.2.1 High quality evidence-based clinical practice guidelines produced by Australian and New Zealand Medical Colleges

Among the 13 Australian and New Zealand Medical College websites searched, six eligible high quality, evidence-based clinical practice guidelines were identified (produced by two Colleges) (see **Table 2**). NHMRC approval indicates to users that a guideline is of high quality, is based on the best available scientific evidence, and has been developed to rigorous standards. One of the six guidelines identified as part of our environmental scan of Australian and New Zealand Medical College websites was NHMRC approved. None of the guidelines produced by Australian and New Zealand Medical Colleges that were identified through the environmental scan adopted a living guideline approach.

In some instances, rather than producing their own guidelines, some Medical Colleges contributed to the development of or endorsed clinical practice guidelines produced by other organisations. See Appendix 2 High quality evidence-based clinical practice guidelines endorsed by Australian and New Zealand Medical Colleges for a list of clinical practice guidelines endorsed by Australian and New Zealand Medical Colleges.

In addition to high quality evidence-based clinical practice guidelines, the Colleges produced various types of other guidance materials including:

- guidelines, guides or guidance (practice/clinical practice (non-evidence-based), consensus, hospital-based practice, operational, professional, quality control, reporting, safety and technical)
- practice or clinical care standards
- principles of good care
- good practice advice
- handbooks
- clinical pathways, flow charts, care algorithms, point of care tools
- position papers
- statements (position, best practice, safety and quality)
- requirements
- policy documents

Table 2 High quality evidence-based clinical practice guidelines developed by Australian and New Zealand Medical Colleges

Australian and New Zealand Medical College	Number of clinical practice guidelines produced	Clinical practice guidelines identified
RACGP	4	<ul style="list-style-type: none"> • The White Book • Guideline for the management of knee and hip osteoarthritis • Osteoporosis prevention, diagnosis and management in postmenopausal women and men over the age of 50 • Supporting smoking cessation
RANZCOG	2	<ul style="list-style-type: none"> • Intrapartum fetal surveillance • Australian endometriosis guideline
TOTAL	6	

Abbreviations: RACGP, Royal Australian College of General Practitioners; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

The detailed characteristics of the above clinical practice guidelines are available in Appendix 1 Environmental scan.

3.2.2 High quality evidence-based clinical practice guidelines produced by Australian and New Zealand peak bodies

The four clinical practice guidelines developed by specific peak bodies were also reviewed. **Table 3** below details the peak body and the clinical practice guideline they have produced. The only peak body that adopted a living guideline approach was the National Stroke Foundation.

Table 3 High quality evidence-based clinical practice guidelines developed by Australian peak bodies

Peak body	Clinical practice guidelines reviewed
National Asthma Council	<ul style="list-style-type: none">• Australian Asthma Handbook
The Stroke Foundation (in collaboration with Cochrane Australia)	<ul style="list-style-type: none">• Living Clinical Guidelines for Stroke Management
COPE	<ul style="list-style-type: none">• National Perinatal Mental Health Guideline
Cancer Council Australia	<ul style="list-style-type: none">• Clinical practice guidelines for keratinocyte cancer

The detailed characteristics of the above clinical practice guidelines are available in **Appendix 1 Environmental scan**.

3.2.3 High quality evidence-based clinical practice guidelines produced by international psychiatry organisations

The environmental scan found that the guidelines produced by international psychiatry organisations appeared to be internally funded (except for the Canadian Psychiatric Association), and the organisations had established, well-resourced guideline development processes. In line with this, all guideline developers except the Canadian Psychiatric Association used de novo systematic review for their evidence base. The Canadian Psychiatric Association used the ADAPTE approach(4) to formulate their recommendations based on existing guideline recommendations in other high quality clinical practice guidelines.

International psychiatry organisations developed their guidelines with the support of various combinations of evidence review specialists, methodologists and multidisciplinary or expert working groups, some with representation from patients and family members or carers.

The companion documents produced by international psychiatry organisations included guideline statement summaries, implementation materials, quick reference guides, posters, and patient publications.

3.3 Analysis of the clinical practice guidelines identified through the environmental scans

3.3.1 Planning

Key findings: [Who was involved?](#)

- Most guidelines reviewed were produced by some combination of a working group (expert/multidisciplinary) or chapter authors for the development of recommendations, and a research team or medical librarian for search and appraisal of the evidence.
- All guidelines produced by peak bodies had multidisciplinary groups or committees overseeing the development, with smaller expert groups overseeing topics or chapters.
- All guidelines produced by peak bodies mentioned the input of methodologists (evidence synthesis and/or guideline development) and a medical writer or editor.

Who was involved in producing the guidelines?

Most clinical practice guidelines produced by Medical Colleges were produced by some combination of a working group, and a research team or medical librarian for search and appraisal of the evidence. Some Medical Colleges mentioned use of a methodologist or and an advisory panel or organising committee to oversee the production of the guideline. Other Medical Colleges produced their guidelines internally through a policy department, special interest group or committee.

All clinical practice guidelines produced by peak bodies had multidisciplinary groups or committees overseeing the development, with smaller expert groups overseeing topics or chapters. All mentioned the input of methodologists (evidence synthesis and/or guideline development) and a medical writer or editor. All except the Asthma Handbook mentioned the input of consumers or carers.

Funding

Key findings: Funding

- All high quality clinical practice guidelines identified in the environmental scan were developed with external Government funding support (either partly or fully). Specifically, it was either Federal or State Government funding.

All of the high quality, clinical practice guidelines produced by Medical Colleges included in our environmental scan were funded by external funders (including Federal or State Governments). Other external funders included a private health insurance foundation (Medibank Better Health Foundation) and one peak body used industry funding (pharmaceutical companies) to support the development of their guidelines. All guidelines with external/industry funding had disclaimers that the funders had no influence over the recommendations.

All guidelines produced by peak bodies were funded by the Australian Government (except for the Asthma Handbook). The National Asthma Council is a not-for-profit organisation funded by both Government and the pharmaceutical industry. Development of the Australian Asthma Handbook was mostly self-funded, with the remainder by unrestricted sponsorship from industry, government, donations and its in-house marketing program.

In contrast to Australian guidelines, for three of the four international organisations examined in our environmental scan, guideline development was internally funded. However, these three organisations all have established, well-resourced guideline development programs.

The Canadian Psychiatric Association was the only international psychiatry organisation that used external funding to develop their guidelines, and also the only international organisation to use the ADAPTE approach formulate their recommendations based on existing guideline recommendations in other high quality clinical practice guidelines (rather than based on de novo systematic reviews of the literature).

3.3.2 Governance

Public consultation

Key findings: Public consultation

- The public consultation period for clinical practice guidelines produced by Medical Colleges and peak bodies was generally 1 month, with variations between 4 and 7 weeks across the guidelines.
- Medical Colleges provided varying levels of detail about process and outcome of public consultation of the guidelines.

Public consultation methods can be either open, targeted or a combination of the two. Targeted consultation methods that invite specific stakeholders to comment enable feedback to be sought in a relatively controlled manner; however, this can run the risk of important viewpoints being overlooked. Open consultation is more transparent and ensures that all stakeholders can comment on content but may produce a large volume of feedback.³

Medical Colleges provided varying levels of detail about public consultation of the included guidelines. Of those that provided information, all included some form of targeted stakeholder consultation. For two guidelines, drafts were available for open public consultation, which was promoted through the College website, and advertised through existing communication channels and social media (RACGP osteoarthritis guidelines, RANZCOG endometriosis guidelines). The duration of the consultation period was reported for two guidelines as 1 month and 6-weeks. This information was not reported for any other guidelines. For a clinical practice guideline to achieve NHMRC approval there must have been a public consultation period of a minimum of 30 days (<https://www.nhmrc.gov.au/about-us/publications/meeting-2011-nhmrc-standard-clinical-practice-guidelines>).

The public consultation period for the peak body guidelines was generally one month, with variations between four and seven weeks across the guidelines. The Australian Asthma Handbook had a targeted public consultation process, with consultees invited to provide feedback. An open public consultation process was used with the remaining guidelines. Public consultation was promoted to varying degrees via various avenues including website, newsletters, emails, social media and invitations.

³ <https://www.nhmrc.gov.au/guidelinesforguidelines/review/public-consultation>

NHMRC approval

Key findings: [NHMRC approval](#)

- One of the six guidelines produced by a Medical College had recommendations approved by the NHMRC.
- All the guidelines chosen that were produced by peak bodies were approved by NHMRC.

NHMRC approval indicates to users that a guideline is of high quality; it is based on the best available scientific evidence and has been developed to rigorous standards. Guidelines are eligible for NHMRC approval if they are developed for use throughout Australia by a recognised health organisation such as a College, peak body, professional society, special interest group or government. NHMRC will not approve guidelines developed, published or funded by industry groups, or by organisations whose main source of funding is derived from industry groups. Guidelines developers seeking NHMRC approval are advised to use the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework. GRADE is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations.

The RACGP osteoporosis guideline was the only guideline produced by a Medical College with recommendations approved by the NHMRC. All the guidelines produced by peak bodies (except Asthma Handbook) had NHMRC approval.

3.3.3 Knowledge management

Evidence base

Key findings: Evidence base

- Most of the high quality, evidence-based clinical practice guidelines produced by Australian and New Zealand Medical Colleges and peak bodies used de novo systematic reviews as the evidence base.
- One high quality guideline was developed using an adaptation approach (with a high quality guideline as a source guideline).

All high quality, evidence-based guidelines produced by Australian and New Zealand Medical Colleges and peak bodies used de novo systematic reviews as the evidence base. For RANZCOG's Endometriosis guideline a hybrid ADAPTE/de novo process was used (4), meaning they adopted or adapted suitable existing clinical practice guideline recommendations where appropriate. In instances where no recommendations existed, they developed new recommendations based on de novo systematic reviews or consensus of the guideline development committee (with consensus recommendations clearly labelled as such).

Evidence to decision methods and methods and grading strength of recommendations

Key finding: Evidence to decision methods and grading strength of recommendations

- All guidelines developed by Medical Colleges and peak bodies reporting information on evidence to decision methods used either GRADE, NHMRC methods or a mixture of the two for a guideline that was transitioning from NHMRC methods to GRADE.

All guidelines developed by Medical Colleges and peak bodies that reported information on evidence to decision methods used either GRADE, NHMRC methods or a mixture of the two for a guideline that was transitioning from NHMRC to GRADE. For evidence-based recommendations, guidelines indicated the strength of recommendations in line with the evidence to decision methods used (i.e. GRADE = high, moderate, low/very low certainty of evidence, recommendations worded as strong, weak or conditional; NHMRC = A, B, C, D). Non-evidence-based recommendations had various labels, including practice points, expert consensus, consensus-based recommendations, good practice notes and expert opinion.

3.3.4 Format of the guidelines

Key finding: Format

- All the included guidelines produced by Australian and New Zealand Medical Colleges other than RANZCP were available via the developer's website as downloadable PDFs.
- Three of the four guidelines developed by peak bodies were available in an online format.
- The Stroke guidelines were available on MAGICapp (an authoring and publication platform for guideline and evidence summaries).

All the included clinical practice guidelines produced by Australian and New Zealand Medical Colleges were available via the developer's website as downloadable PDFs. Some were able to be navigated online, and one was able to be purchased in hardcopy format (Intrapartum Fetal Surveillance guideline from RANZCOG). The types of companion documents available were standalone summaries of recommendations, algorithms, flowcharts, patient information, implementation plan and e-learning module.

Three of the four guidelines developed by peak bodies were available in an online format. The perinatal mental health guidelines were available via the COPE website as a downloadable PDF. The remaining guidelines were published online on different platforms: the Stroke guidelines via MAGICapp; the cancer guidelines via cancer wiki website; and the Australian Asthma Handbook via its own dedicated website (this guideline was the most difficult to navigate).

3.3.5 Dissemination, implementation and updating

Key finding: Dissemination

- There are a variety of guideline formats, hosting platforms and dissemination methods employed by Medical Colleges and peak bodies.

Various companion documents were available across the guidelines, such as a summary of recommendations, decision aids and other tools, fact sheets, and patient resources. The Asthma Handbook had accompanying videos for patients, and the Cancer Council guidelines included a dissemination plan.

Update frequency

Key findings: Update frequency

- For guidelines produced by Australian and New Zealand Medical Colleges, the planned frequency of update ranged between every 3-5 years.
- Peak bodies aimed to update their clinical practice guidelines every 5 years.
- Only one guideline produced by a peak body was a living guideline (where emerging evidence is continually monitored and assessed in conjunction with Cochrane Australia, and recommendations updated where appropriate as new consequential evidence emerges).

For the guidelines developed by peak bodies, COPE and Cancer Council Australia aimed to update the entire guideline every 5 years, with the Cancer Council monitoring the evidence to update specific sections if strong evidence emerged that would warrant a change in a recommendation (surveillance approach). The Asthma Handbook was a frequently updated guideline, with major or minor updates published on an ad hoc basis in response to publication of information papers by the Australian Asthma Council or guidance from other relevant organisations. The Stroke guidelines were living guidelines, where emerging evidence is continually monitored and assessed in conjunction with Cochrane Australia, and recommendations updated where appropriate as new evidence emerges.

4 Interviews with key informants

As part of the development of this report, the Clinical Practice Guideline Evaluation Steering Group requested that hereco interview several key informants as identified by the Steering Group and RANZCP. The RANZCP felt it is important that this project incorporates the voices of users and developers of the RANZCP guidelines. The key informants had knowledge of developing and/or using the RANZCP clinical practice guidelines and came from a diverse range of backgrounds including psychiatrists, RANZCP staff, and those with lived experience. The purpose of the interviews was to gain insight into the key factors that will support the development of high quality, trustworthy and implementable clinical practice guidelines by the RANZCP.

Hereco undertook the consultations independent from RANZCP involvement (to provide anonymity to the respondents), and de-identified all the information captured. The aim of the interviews was not to aggregate data to perform a formal qualitative analysis, but rather to gather information from multiple perspectives to facilitate a comprehensive consideration of all relevant issues. The information gathered in the interviews directly informed hereco's development of recommendations for suitable approaches for RANZCP for future clinical practice guideline development.

Although an understanding of past clinical practice guideline development approaches by the RANZCP was important to discuss, the focus of these interviews was forward-looking: specifically, the ways in which the RANZCP guideline development methods, processes and products could be improved.

As agreed between RANZCP and hereco, the responses of all interviewees were to be considered by hereco when formulating recommendations for future guideline development approaches but were to remain anonymous. No identifiable information was included in this report, but the insights have been used to shape the recommendations (see **Section 5** and **6**).

Hereco conducted semi-structured interviews where the key informants were asked a series of open-ended guiding questions around their views on various aspects of guideline development. Interview questions were developed to cover the aspects of guidelines development reviewed in this report, including planning, governance, knowledge management, the format of the guidelines and dissemination/implementation of high quality clinical practice guidelines. The questions were pre-approved by the RANZCP. We have highlighted our most impactful key considerations for the College in **Table 1** based on the strongest interview themes.

5 Possible options for RANZCP clinical practice guideline program

There are several factors to consider for the development of high quality clinical practice guidelines. These considerations are explored in Section 0, with some suggestions and recommendations for future RANZCP clinical practice guideline updating or development.

As part of hereco's consultation with key informants, several informants indicated that they were uncertain that the RANZCP should continue to develop or update the existing guidelines.

Key informant consultation comments

"The College should not develop clinical practice guidelines as they are time and resource intensive".

"The College are not resourced to make high quality guidelines like other international guideline development organisations".

"The College should not be producing guidelines if they can't resource them to be of high quality."

Hereco were surprised by these comments and when we explored further this was predominantly driven by the time and resources required for high quality clinical practice guideline development. Several respondents noted that the College should seek funds to enable them to develop high quality guidelines, or otherwise should consider whether they should cease developing clinical practice guidelines. The environmental scan indicated that high quality clinical practice guidelines produced by other Medical Colleges or peak bodies were all externally funded (predominantly by State or Federal Health Departments). Another alternative for funding guideline development would be to partner with other organisations with an interest in the topic.

This report explores the following two main paths that the College could take in relation to guideline development:

- Path 1: the College no longer produces or updates clinical practice guidelines, or
- Path 2: the College continues to produce and update clinical practice guidelines.

The different options for the College's activity for each these paths are outlined in **Figure 1** and **Figure 2** below. The risks, benefits, resource implications and other considerations are outlined in greater detail in **Table 4**, **Table 5** and **Section 37**.

If the College decided to no longer develop its own clinical practice guidelines, there are alternative ways it could provide clinical guidance. These include:

- endorsing high quality clinical practice guidelines produced by others,

- signposting to “useful clinical guidance” developed by others but not formally endorsing it (See an example from RANZCOG ⁴),
- referring to international guidelines and developing an accompanying statement regarding the College’s position on the existing international guidelines,
- conducting rapid evidence reviews for topical areas of concern, or
- producing position statements.

If the College chooses to endorse clinical practice guidelines produced by others, hereco are aware that there is a well-regarded existing College policy on endorsement of external guidelines. Adherence to this established endorsement process is encouraged.

⁴ <http://ranzcoг.edu.au/resources/statements-and-guidelines-directory/>

Figure 1 Alternative guidance options for Path 1 - the College no longer develops or updates clinical practice guidelines

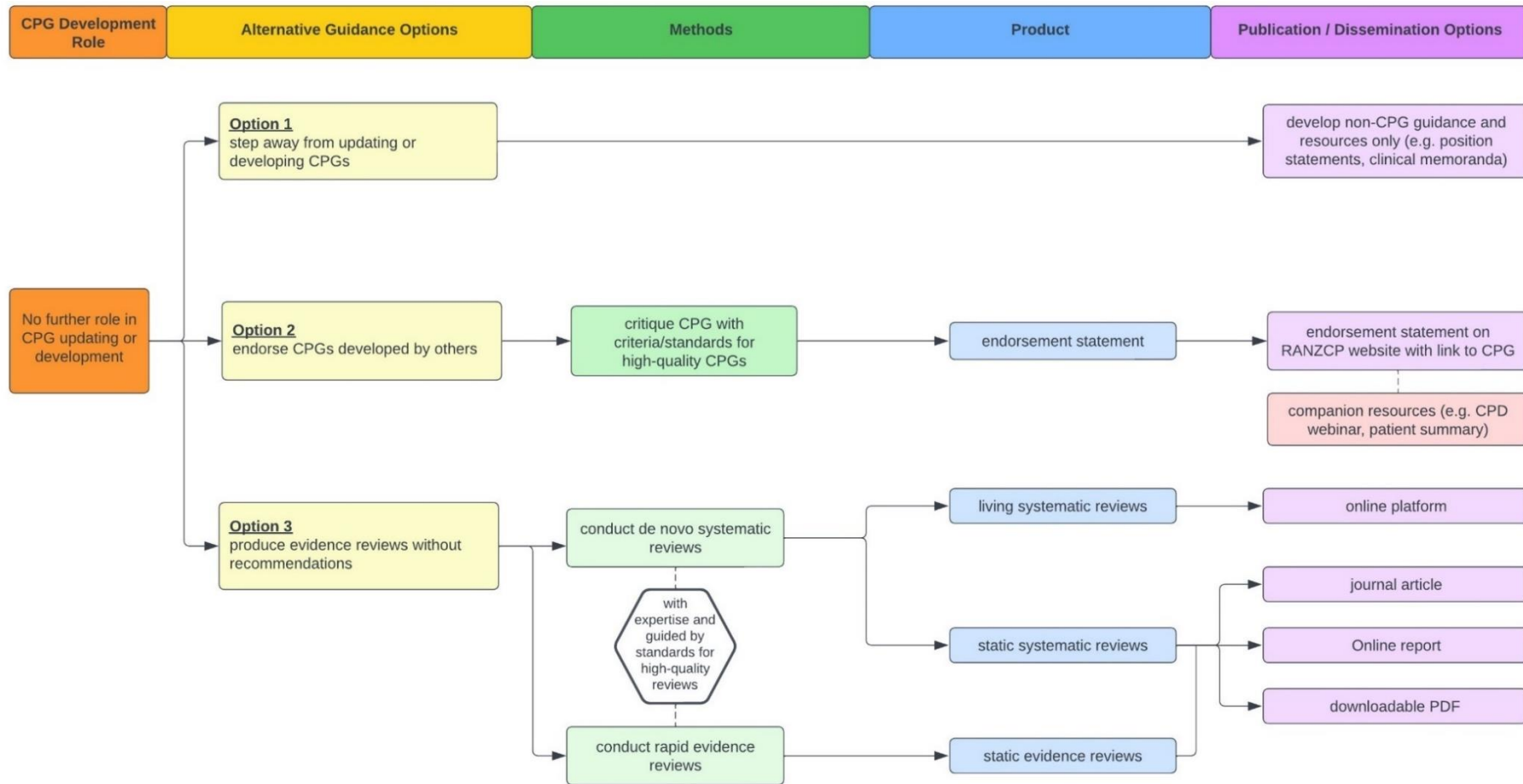


Figure 2 Options for Path 2 - the College continues to develop and update clinical practice guidelines

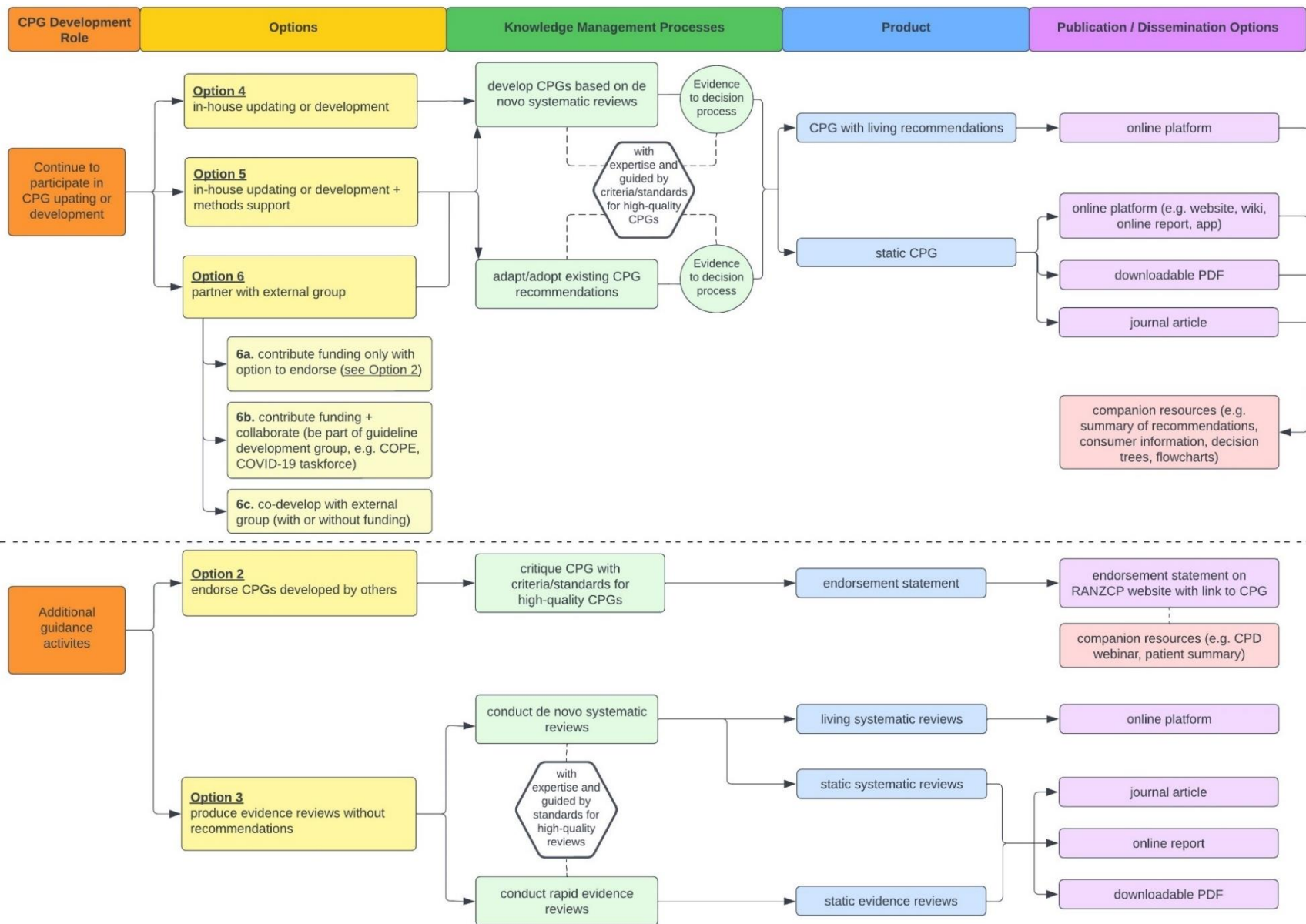


Figure 1 describes alternative guidance options for “Path 1 - the College no longer develops or updates clinical practice guidelines”. **Table 4** below explores the resourcing and governance considerations with the options presented in “Path 1, the College no longer develops or updates clinical practice guidelines”.

Table 4 Options with the College playing no direct role in clinical practice guideline development

Option 1: The College no longer develops clinical practice guidelines			
Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits</p> <p>No cost</p> <p>No risk to reputation due to content of guidelines</p> <p>Risks</p> <p>Risk to reputation if clinical practice guideline development is an expected role of the College.</p> <p>No Australian-specific guidance to guide local practice</p> <p>Resources</p> <p><u>Time</u>: nil</p> <p><u>Money</u>: nil</p>	None required.	n/a	The College continues to produce other forms of guidance (i.e. position statements, clinical memoranda).
Option 2: The College endorses existing high quality, evidence-based guidelines produced by other organisations			
Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits</p> <p>Low cost</p> <p>Risks</p> <p>No control over content or process</p> <p>Resources</p> <p><u>Time</u>: low</p> <p><u>Money</u>: \$</p> <p>The College could incorporate external guidelines into webinars, CPD program, or make plain language summaries etc.</p> <p>Example:</p> <p>Recent RANZCP endorsement of the Australian Evidence-Based Clinical Guideline for ADHD</p>	<p>Expertise or guidance to assess guidelines to make sure they are satisfied with quality and trustworthiness before endorsing (refer to RANZCP due diligence checklist)</p> <p>Example:</p>	n/a	
Option 3: The College commissions systematic reviews or rapid reviews of the evidence on a topic without generating recommendations			
Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits</p> <p>Avoids being too prescriptive</p> <p>Avoids potential politics associated with generating recommendations</p> <p>Risks</p> <p>No specific clinical guidance</p> <p>Resources</p> <p><u>Time</u>: moderate</p> <p><u>Money</u>: \$\$</p> <p>Examples:</p> <p>RANZCP Faculty of the Psychiatry of Old Age Committee commissioned the Sax Institute to develop a Evidence Check – Psychiatric service delivery for older people with mental disorders and dementia in hospitals and residential aged care</p>	<ol style="list-style-type: none"> 1. Expertise in conducting high quality systematic or rapid reviews of the literature (best to outsource). 2. An RANZCP advisory group may be required to contextualise the evidence review and own the implementation of the review. 	<ol style="list-style-type: none"> 1. Formal contract required with external evidence reviewers. 	<p>Need clinical input on specific questions to address in evidence review.</p> <p>Evidence reviews are only possible where evidence is available on the topic.</p>
ANZCA’s Acute pain management: Scientific evidence (2020)			

Figure 2 describes alternative guidance options for “Path 2 - the College continues to develop and update clinical practice guidelines”. **Table 5** Options with the College continuing to play a role in clinical practice guideline development below explores the resourcing and governance considerations with the options presented in “Path 2, the College continues to develop and update clinical practice guidelines”.

Table 5 Options with the College continuing to play a role in clinical practice guideline development

Option 4: The College continues to develop guidelines fully in-house			
Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits Lower cost (relies mostly on pro bono contributions) Most control over content and process</p> <p>Risks Potentially lower quality or less trustworthy product due to insufficient expertise in literature search or guideline development methods = risk to reputation of College</p> <p>Resources <u>Time</u>: pro bono time (amount of time depends on complexity of topic, evidence base and efficiency of process) <u>Money</u>: \$</p>	<ol style="list-style-type: none"> 1. Pro bono clinical input 2. Evidence search/guideline development expertise (in-house or pro bono) 	<p>Committee develops guideline and existing RANZCP consultation and approval processes apply</p>	<p>Case-by-case:</p> <ul style="list-style-type: none"> • is there the right expertise to ensure the requirements for a <i>high quality</i> guideline be met? • are the right processes in place to ensure the requirements of a <i>trustworthy</i> guideline are met? (Conflict of Interest process, public consultation process, governance structure)
Option 5: The College continues to develop guidelines in-house with appropriate methodological support, as needed (e.g. literature search, evidence appraisal and/or guideline development expertise outsourced)			
Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits Control over content and process More likely that a high quality, trustworthy guideline is produced</p> <p>Risks Requires internal project management expertise to manage contractors Takes longer</p> <p>Resources <u>Time</u>: pro bono time + employee/contractor/consultant time and materials (amount of time depends on complexity of topic, evidence base and efficiency of process) <u>Money</u>: \$\$-\$\$\$\$? (depends on size and scope)</p> <p>Other considerations Literature search, evidence review and guideline development expertise can help to ensure a high quality, trustworthy guideline, but governance structure also plays a role Example: RANZCOG’s 2022 National Endometriosis guideline was developed in-house with external methods support (funded by Dept of Health)</p>	<p>Systematic review methods expertise (literature search, critical appraisal, evidence synthesis)</p> <p>Guideline development expertise</p>	<p>Formal contract required with external methodological support</p>	<p>Need for funding (potentially external funding) to outsource methodological components</p>
Option 6a: The College contributes funding to an external independent group, has no role in development, but option to co-badge or endorse			
Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits Reduced control over content and process</p> <p>Risks Potentially takes longer Inability to gain consensus across organisations Lack of buy-in from membership</p> <p>Resources <u>Time</u>: pro bono time <u>Money</u>: ? Depends on the % of financial contribution to the guideline (and the scope of guideline) Example: The Clinical Practice Guideline for Perinatal Mortality</p>	<p>If endorsing: expertise or guidance to assess guidelines is required to make sure they are satisfied with quality and trustworthiness before endorsing</p>	<p>Committee required to lead the consultation on scope of guideline etc. Existing RANZCP consultation and approval processes apply</p>	<p>The College’s existing due diligence process should be applied to any potential partner organisations</p>

Option 4: The College continues to develop guidelines fully in-house

was jointly funded by The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Stillbirth and Neonatal Death Support Group Qld (SANDS Qld Inc), and SIDS and Kids Qld. RANZCOG provided comments on the guideline at public consultation and endorsed and co-badged the guideline (for further detail, see **Appendix 2** High quality evidence-based clinical practice guidelines endorsed by Australian and New Zealand Medical Colleges)

Option 6b: The College contributes funding to external independent group and collaborates (e.g. member of guideline development committee)

Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits Some control over content and process</p> <p>Risks Potentially takes longer Inability to gain consensus across organisations Lack of buy-in from membership</p> <p>Resources <u>Time:?</u> <u>Money:</u> \$-\$\$\$? Depends on scope and the % of financial contribution</p> <p>Example: The Centre of Perinatal Excellence (COPE) National Perinatal Mental Health guideline is an example of an independent arbiter of the guideline development process, with member representation on the Board and guideline development group.</p>	<p>Pro bono clinical input (member of guideline development group)</p>	<p>Fellows from RANZCP are involved in the guideline development group.</p>	

Option 6c: The College partners with a not-for-profit organisation and co-develops a clinical practice guideline

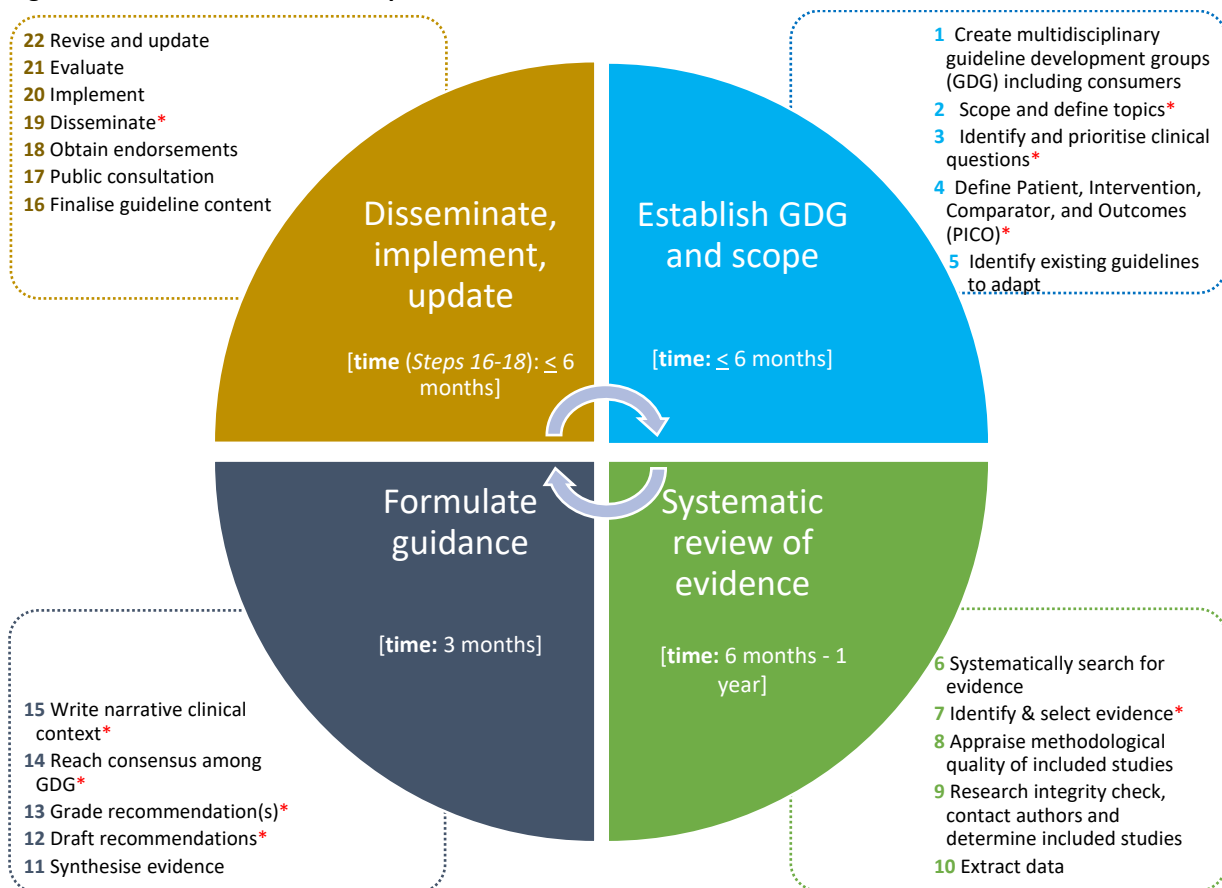
Considerations	Methods and Expertise	Governance Arrangements	Other considerations
<p>Benefits Some control over content and process</p> <p>Risks Potentially takes longer Inability to gain consensus across organisations Lack of buy-in from membership</p> <p>Resources <u>Time:?</u> <u>Money:</u> \$-\$\$\$? Depends on scope and the % of financial contribution</p>	<p>Pro bono clinical input (member of guideline development group)</p> <p>Potentially project management, evidence review and guideline development expertise required.</p>	<p>The College's existing due diligence process should be applied to any potential partner organisations</p>	

6 Key components of high quality, trustworthy clinical practice guidelines

The development of high quality clinical practice guidelines is time and resource intensive yet it does follow a relatively sequential process. **Figure 3** below summarises the steps in high quality clinical practice guideline development (adapted from Knowledge Transfer: Practice, Types and Challenges (2012)).(5)

Approximate timeframes for each part of the process are highlighted, and time points/tasks where clinical input is essential (i.e. pro bono contributions) are denoted with a *.

Figure 3 Guideline Development Process



* Time points and tasks where prioritisation of engagement from GDG is essential.

GDG: Guideline development group

In this section of the report, the key components of developing high quality trustworthy clinical practice guidelines are explored in detail.

The recommendations in this section of the report for RANZCP's consideration, have been informed by:

- national and internationally agreed best practice principles in clinical practice guideline development (1, 2, 6-12).
- the findings from our review of the existing suite of RANZCP clinical practice guidelines.
- the findings from our environmental scans of College-developed, peak body, and international guidelines.
- the findings from our consultations with key informants.

Key informant quotes have been added in italics throughout this section of the report where they highlight specific areas for consideration.

Limitations: Hereco have made suggestions and recommendations in this section of the report for RANZCP's consideration, but these suggestions are all subject to **resourcing (financial and pro bono contributions from clinical experts)**. Hereco are not aware of RANZCPs available resourcing for guideline development activities. We have therefore made some assumptions based on resourcing for other Medical Colleges of similar size when we have made recommendations.

6.1 Planning

The process of developing a guideline can be long and complex. Good organisation and planning set a guideline up for success. Thorough planning should occur before any work commences on a guideline. The planning phase is often supported by an organising team or steering committee which ideally includes **people with project management and methodological expertise**, and some subject matter experts. Guideline planning often includes:

- establishing a multidisciplinary guideline development group,
- priority setting,
- agreeing on scope and target audience of the guideline,
- sourcing and allocating funding to develop the guideline,
- establishing project governance and the guideline development methods to be used, and
- agreeing on timelines.

The NHMRC's Guidelines for Guidelines Handbook (specifically the project planning module) contains extensive advice on the suggested steps when planning to develop a new or updating an existing guideline. While it is not intended to be prescriptive, hereco finds this to be an extremely useful source of information when planning to develop a clinical practice guideline, and we have referred to it throughout Section 6 of this report. (<https://www.nhmrc.gov.au/guidelinesforguidelines/plan/project-planning>).

Additional practical resources to assist with the planning and organisation of high quality clinical practice guideline development include the GIN-McMaster guideline development checklist(9), the Guideline International Network publication "Toward International Standards for Clinical Practice Guidelines"(8) and the World Health Organization's Handbook for Guideline Development.(10)

6.1.1 Priority setting

When planning to develop a guideline, it is important to ask "is this guideline really needed"?(10) Priority setting refers to identifying, balancing and ranking priorities by all stakeholders. Guidelines should be developed in areas of greatest need to the population.(2, 9)

As part of the consultations with key informants, hereco found that respondents felt that RANZCPs clinical practice guideline priority setting process could be improved. Respondents felt they were unclear that the current suite of guidelines represented a coordinated process, but rather one that was led by the willingness of volunteer groups with an interest in the topic.

Key informant consultation comment

"We shouldn't re-invent the wheel in terms of evidence reviews and systematic reviews – I am in favour of adopting or adapting existing high quality evidence-based guidelines produced by others and contextualising them to Australia and New Zealand".

Before developing a new guideline, or updating an existing guideline, it is important to identify whether that guideline will be relevant and useful before committing to the project.(2, 9) Section 2 of the "Checklist for guideline development" as part of the McMaster checklist provides detailed considerations for priority setting when considering the need for a guideline. The advice in the McMaster checklist can also be helpful

when determining which topics to include in the guideline.(9) Given there are limited health care resources, the College could consider whether other guidelines on the same topic have already been developed and whether they address the need. **To avoid duplicating existing work, and if existing guidelines are identified, examine their applicability to the current need, their quality (using the AGREE II instrument)(6), and whether they could be adapted to the Australian and New Zealand context rather than embarking on a new guideline from scratch.**

Key informant consultation comment

“Guidelines reflect who made them. Be careful of competing interests and special interest led guideline development processes”.

The McMaster checklist advocates for a **systematic and transparent process for priority setting** for guideline topics (e.g. high prevalence and burden of disease, avoidable mortality and morbidity, variations in clinical practice or rapidly changing evidence). (9) Hereco’s consultations also found that the RANZCP guideline development process could be improved by including all relevant stakeholders at the stage of priority setting and selection of guideline topics, not just those with a special interest in the topic. This is especially important for cross-cutting topics such as addiction medicine, or conditions with greater burden of disease in particular populations.

6.1.2 Determine the purpose, scope and target audience

A clinical practice guideline should always specify its objectives, scope, and target audience. From hereco’s analysis, we found that this is an area that could be further improved for RANZCP clinical practice guidelines. We found a high level statement on scope in all existing RANZCP CPGs, but sufficient further detail was not provided. The “Guidelines for Guidelines Handbook” contains a module on scoping the guideline and the College could consider reviewing its clinical practice guideline scoping process in line with the advice in this module (<https://www.nhmrc.gov.au/guidelinesforguidelines/plan/scoping-guideline>).

As well as the scope, another important first step in developing a guideline is to **clarify the target audience**. A clear sense of the target audience informs subsequent decisions about the guideline’s scope, objectives, guideline group membership, and format and style of wording. Typically, guidelines have both primary and secondary audiences. The primary audience is the category of clinicians (and patients) for whom the guideline is intended and who are most likely to use the guideline in patient care settings. However, guideline developers often recognise a secondary audience that takes considerable interest in the recommendations. For example, a family medicine or paediatrics society may develop guidelines for its clinicians, knowing that other primary care professionals could refer to the guidelines in managing the same condition. Guideline recommendations may be used in policy processes. As explored by Eccles and colleagues, guidelines can inadvertently focus on clinicians as the target audience (meaning “physician” or “doctor”), but the topics they address may be equally relevant to a wider range of clinicians.(13) Even when the target audience is clearly clinicians, it is useful to clarify the type of clinician(s) for whom the clinical practice guideline is primarily intended. Guidelines intended for primary care clinicians may include content of less interest to specialists, and vice versa. Guidelines on a highly specialised procedure, performed only by sub-specialists, are unlikely to be used by primary care physicians and therefore need not review basic background on the health condition, can focus on narrow evidence questions, and can use specialised terminology without extensive elaboration.(13)

During hereco’s consultations there were different opinions on whether the guidelines should cover all aspects of mental health care/the patient’s journey, or whether they should specifically focus on what

psychiatrists should do (especially as the guidelines are essentially funded by the Fellows and published in a psychiatry journal). **Hereco found that some of the issues raised by key informants regarding the current suite of guidelines could be resolved if there was greater clarity on the purpose of the guideline, the scope and the intended audience.** As an aside, hereco notes if the College was to adopt an approach to the development of mental health care guidelines that encompasses all diagnostic and treatment modalities (not just those used by psychiatrists) this could form a strong rationale for government funding. This is an approach that has been successfully implemented by COPE for the development and updating of the perinatal mental health guidelines.

Hereco also suggests the College consider consulting within the College's committees or membership on the draft scope of the guideline to be developed or updated. As part of our consultations with key informants, some respondents felt that their views were not considered in the guideline development process. By consulting on the scope, this may afford the opportunity for feedback earlier in the guideline development process, rather than after the guideline has been drafted (at which point large changes may not be possible).

An example of this consultation on scope is that of the COVID-19 Taskforce's process for question development. At guideline inception, an initial consultation was conducted to identify questions of importance to stakeholders via online form to all member organisations, examination of the questions covered on the topic in existing high quality guidelines and seeking feedback from panel members during meetings. Topics arising from these three sources were compared to the agreed scope and prioritised by the Executive of the Taskforce. Specific clinical questions were then developed and prioritised by members of the respective Guideline Panel (equivalent to a Guideline Development Group), with high-priority questions then approved by the Guideline Leadership Group for evidence review and recommendation development.

As it may not be possible to cover all topics suggested, the College might consider establishing a method to prioritise the list of topics to be addressed by the guideline (e.g. prioritise topics where the evidence is most confusing or controversial, where is there current uncertainty or inconsistency in practice, or it may specify questions relating to screening, diagnosis, management/treatment).(9)

After all the issues and stakeholder feedback have been taken into consideration it is worthwhile taking a step back to review the scope.(7) Questions to ask include:

- Likely impact on patient outcomes
- Proportion of clinical population impacted
- Extent of variation in current practice
- Likelihood of new evidence emerging
- Can the guideline be developed within a reasonable timeframe?
- Are there sufficient financial and human resources to complete the guideline?
- Can some lower priority topics, questions and recommendations be removed at this stage, for later consideration?
- Does composition of the guideline development group need to be re-adjusted to address any equity issues identified in the scoping process?

Hereco's analysis of the existing suite of RANZCP clinical practice guidelines revealed that there were no detailed clinical/research questions available across the suite of guidelines. Having this information available is a critical element of high quality clinical practice guideline development as it provides methodological transparency, keeps the work focused and leads to an unbiased and effective evidence search and downstream evidence review process. Given the complexity, detailed clinical questions often appear in a separate publicly available technical report.

6.1.3 Budget and resourcing

The College has requested that hereco make specific comments about resourcing for clinical practice guideline development.

Resourcing – budget

A high quality clinical practice guideline is time and resource intensive to produce. Typically a high quality clinical practice guideline takes between 18–30 months to complete, with reported costs of up to approximately \$1 million (AUD).(14)

From the environmental scans, hereco found that all high quality clinical practice guidelines that were reviewed as part of this project were developed with external funding support (predominantly State or Federal Government funding). Section 3 of the project planning module of the NHMRC's Guidelines for Guidelines Handbook contains useful information about potential sources of funding for developing clinical practice guidelines. (<https://www.nhmrc.gov.au/guidelinesforguidelines/plan/project-planning>).

Hereco would caution against accepting industry funding as this can compromise the reputation of the guideline, can affect the trustworthiness of the guideline, and can impact implementation if the guideline is perceived as conflicted due to the funding source. For example, World Health Organization (WHO) guidelines cannot accept funding from commercial entities.(10) The funding source, the role of the sponsors and support provided for the development of the guideline should be disclosed and published.(2, 9)

There is no set formula for how to budget for a guideline; however, it is important to capture known essential costs to cover staffing and meetings, and to estimate what will be required for the more complex activities such as the evidence review.(7)

Key informant consultation comment

“Clinical practice guidelines should be the best they can be not the best we could do at the time within the limited resources we had”.

Resourcing – skills and expertise

The environmental scan found that most guidelines developed by Australian and New Zealand Medical Colleges were produced by some combination of a working group (expert/multidisciplinary) or chapter authors for development of recommendations, and a research team or medical librarian for search and appraisal of the evidence. Some Medical Colleges mentioned use of a methodologist or and an advisory panel or organising committee to oversee the production of the guideline. Other Medical Colleges produced their guidelines internally through a policy department or special interest group or committee.

RANZCP clinical practice guidelines had multidisciplinary working groups, a project manager and project officer, and sometimes a medical writer.

Key informant consultation comments

“We need a different skill set to produce clinical practice guidelines rather than project officers alone. The College’s project officers do a wonderful job but they are over-committed and guidelines take up a lot of time and specialised expertise”.

“The expertise in guideline development and evidence review needs to be external.”

“The evidence review and medical writing should be outsourced to support the guideline development group”.

Resourcing extends beyond just the financial budget, but also the skills and expertise required to produce a guideline. The NHMRC Guidelines for Guidelines module on “Project planning”⁵ provides examples of the typical items to include in a guideline budget, and the required skills. **Table 6** below has been reproduced from this module in Guidelines for Guidelines as it provides a comprehensive list of activities and staffing and may assist with accurate budgeting for clinical practice guideline development.

Hereco suggests the RANZCP guideline development process would benefit from the input of search specialist and guideline development methodologists to support the project officer staff and the guideline development group. If the College seeks to continue to develop clinical practice guidelines internally, they might need to upskill existing staff in guideline development methodologies or employ experienced staff. From our consultations with key informants, if the staffing remains in-house, their time would need to be dedicated to clinical practice guideline development rather than general project officer responsibilities which detract from the guideline development work.

⁵ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/project-planning>

Table 6 Example of typical items to include in a guideline budget⁶

Item	Details	Budget
People		
Project staff	A guideline will require a project manager to manage the guideline development group, coordinate meetings and run consultation activities. The executive or leadership team will need to commit resources to activities, promote the project, establish partnerships and collaboration opportunities.	Salaries for staff and input as required from executive or the leadership team. This is to be maintained for up to 2 years depending on the scope and complexity of the guideline
Project manager, project support officers, executive or leadership team		
Steering committee/organising committee	A small group of people to help set up the process, including setting the scope and nominating individuals for the guideline development group.	Costs may include a face to face meeting.
Guideline development group	For large guidelines you may need 6–8 meetings, with the understanding that the guideline development group will need time to prepare for meetings. Consider if training is necessary and how that can be delivered, e.g. introduction to the guideline process, how to interpret levels of evidence and to formulate recommendations based on evidence, cultural awareness training.	Costs will differ depending on the size of your committee, where they live, whether the preference for meetings is face to face or via teleconference or videoconference. Venue and travel costs will need to be accounted for. Training may involve attendance of a facilitator at a meeting. Budget for their fee for service and travel costs. Consider how much sitting fees might cost.
Stakeholder engagement	There are a variety of methods that can be used to engage stakeholders (See Engaging stakeholders).	Some methods will be more costly than others. Consider which methods will be most important for your guideline and budget appropriately.
User and/or consumer testing	Depending on the method (see Engaging stakeholders). Costs associated with setting up focus groups (including a facilitator, venue and travel costs).	NHS INVOLVE program in the UK has an example budget calculator to assist in budgeting (in GBP).
Products or activities		
Development software	There are a number of guideline development platforms, e.g. MAGICapp, GRADEpro, CancerWiki, or systematic review software, e.g. Covidence, DistillerSR that can be used. You should choose a platform that is appropriate for the size of your guideline.	Some software is freely available to use but others such as MAGICapp, or GRADEpro, Covidence or DistillerSR will need a license negotiated with the software developers.
Publishing	There may be many formats to budget for. Also consider that some hosting platforms will cost money.	Costs will vary depending on the format the guideline is published in.
Derivative products	This could include paying for any translation activities into different languages, developing decision aids or pamphlets. Also, could include development of phone apps.	Translation services should be sourced from an NAATI accredited provider.
Dissemination and implementation activities	Conferences, champions/advocate speaking appearances. Communications or media experts could also be required.	

⁶ Taken from “7. Plan your budget”, NHMRC Guidelines for Guidelines Handbook, Project Planning module <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/project-planning>

Item	Details	Budget
Sponsorship or endorsement from other bodies	Some Colleges require payment to endorse specific guidelines.	
Additional expertise (consider contracting out)		
Evidence review	<p>The evidence review process should be undertaken by qualified people with experience in this work.</p> <p>Experienced people may already be involved in the project but could otherwise be acquired through additional recruitment or by contract. The final deliverable will be the systematic review and/or a literature review being presented as a separate technical report. A statistician or librarian may also need to be sourced to assist with this work.</p> <p>You may also need to budget for licenses for software to support the systematic review process, e.g. Covidence, DistillerSR.</p>	<p>Depending on the scope of your guideline and number of questions, costs associated with the evidence review can vary considerably. More funds will need to be allocated if:</p> <ul style="list-style-type: none"> • the scope of the guideline is very broad • there are numerous questions • the available evidence may be difficult to synthesise (particularly for public health guidelines) • there are non-intervention questions e.g. diagnostic or prognostic. • there is an abundance of literature to process • access is required to institutional libraries, databases, specific journals or articles. • the questions will need to draw on modelling frameworks that require specialist expertise. <p>Given the skill required to undertake the evidence review, it is important that there is a quality assurance process in place to check the results of the review before the guideline is publicly released. This might require budgeting for extra personnel, e.g. methodologist who is independent of the process.</p>
Methodologist(s)	<p>They can help guide the guideline development group through the process in a contracted role, or perhaps as a member of the group.</p> <p>Methodologists can help draft, advise on and/or undertake the search strategy, appraise the evidence and develop evidence tables.</p>	Budget for the methodologist to attend all meetings where there is a discussion of the evidence and forming of recommendations.
Technical writing	Technical writers will be responsible for producing multiple drafts of the guideline and perhaps additional reports — public consultation report or administrative/process report.	Budget for technical writer/s to attend all meetings. You need to also factor in whether they will need to produce associated reports such as a public consultation report.
Copy-editing	Proofreading, desk-topping and editing for the draft prior to public consultation or for the final draft.	This is different to contracting a technical writer. A copy-editor will edit the full guideline in accordance with a Style manual and also check for any inconsistencies.

6.1.4 Guideline development group composition

Hereco finds the information in the NHMRC's Guidelines for Guidelines Handbook module on "Guideline development group" to be a useful source of guidance on how to establish high-functioning guideline development groups. We draw the College's attention to the advice on activities such as selecting the chair, defining the roles and responsibilities, and documenting the approach to recruitment. Some of these issues are explored below.

Forming a multidisciplinary guideline group

The form and function of the guideline development group are critical elements to the success of any clinical practice guideline development process. The guideline development group is responsible for considering the evidence, translating it into practice recommendations, and assuring that the recommendations are not biased by being based on factors other than the best available scientific evidence.(8)

As per the [2016 NHMRC Standards for Guidelines](#)⁷, membership of the guideline development group should be "*Be composed of an appropriate mix of expertise and experience, including relevant end users*". A balanced guideline development group should be comprised of the members with the following expertise:

- **Clinical expertise** (including specialists, general practitioners, allied health and nursing where applicable);
- **Patient expertise** (patient or carer representatives); and
- **Evidence review and methodological expertise.**

Nominations will ideally be sought from relevant stakeholder organisations. There should be consideration of gender balance and appropriate geographical spread of members when forming guideline development groups.(9, 15)

A proportion of the key informants interviewed by hereco thought that at times the Colleges guideline development group composition has been problematic and suggested this is an area for improvement. Some comments included:

⁷ <https://nhmrc.gov.au/about-us/publications/2016-nhmrc-standards-guidelines>

Key informant consultation comments

“Psychiatrists at the coal face should help write guidelines, not just academic research psychiatrists”.

“It is essential to have multidisciplinary representation across the continuum of care for guideline development groups, not just those with a special interest in the topic”.

“The incorporation of views of all key stakeholders could be improved in the RANZCP guidelines (particularly the view of broader mental health and general community)”.

“We need psychiatrists, but also a broader reference group of multidisciplinary care providers and those with lived experience on our guideline development committees”.

“Be careful with guideline development committee composition. Don’t draw from a narrow a pool of people, and equally, don’t make the committee too large”.

“We need to take governance of the guideline development process away from just individuals with a special interest in the topic area”.

There was some concern from key informants about **who has the final sign-off on the composition of the RANZCP’s guideline development groups. This is highlighted by hereco as an area for improvement for the College’s guideline development process.** There was a suggestion that there should be a final sign-off process on the guideline development group membership, perhaps at Board level.

When forming multidisciplinary guideline development committees, it is important to define (and publish) who is involved, in what capacity and how the members are selected.(9)

Considerations for selecting a chair

Selection of a chair/group leader that is experienced in group facilitation, maintaining constructive dynamics and identifying and resolving conflicts is important to high-functioning guideline development groups, as is the group composition. The chair does not need to be a content expert but they should have experience in evidence-based guideline development(1). If your chair is a content expert, it is important that they remain impartial during discussions and should be free from conflicts of interest.(7) The role of the chair begins before guideline development commences and they should be recruited early to assist in the initial project planning stages and to help select other members of the guideline development group.(7) Co-chairs can be used where guidelines are likely to be complex or leadership is required to be shared amongst different disciplines.(1) In this case, both co-chairs should aim to be free of conflicts of interest.

Size of guideline development group

The optimal size of the guideline development group should be considered, and that will depend on several factors such as the scope and complexity of the guideline, the time frame in which it is being developed and the budget.(7) If the group is too small it may lack sufficient expertise or may potentially be made up predominantly of those with a special interest in the topic. If the committee is too large, it may lack cohesiveness and the size can also affect group interaction.(9)

Transparency around the recruitment of representatives is an area for consideration by the College based on feedback hereco received as part of the consultation with key informants. This includes documenting the approach taken by collaborating organisations if they undertook their own recruitment process to secure representatives for the guideline development group. If there were particular representatives (such

as representatives from culturally and linguistically diverse communities) that were sought but weren't able to be secured, the approach to this and what the outcomes were should be documented.

Consumer involvement

Guidelines are designed to improve the health and wellbeing of consumers who have the right to be involved in any decision-making on health issues that affect them. Authentic consumer involvement can help make guidelines more readable and relevant, provide important information and insights missing from an evidence search and help predict the acceptability of recommendations to target groups. Open and transparent involvement of consumers in a guideline's development can also enhance its legitimacy.(7)

Individual consumers can offer valuable expertise from lived experience; however, the views of a single consumer should not be considered representative of all consumers.(7) Rather than aiming specifically to obtain a diverse range of views, selection of consumers should be based on the perspectives they can offer, and on their capacity to make a meaningful contribution to decision-making when supported to do so.

Key informant consultation comment

"Consumer perspectives are important in the guideline development process to prevent over-pathologising mental health conditions".

According to the AGREE II instrument (a tool which measures the quality of the guideline development process, not the content), high quality clinical practice guidelines should be informed by information from the target population's experiences and expectations of health care.(6)

There are various ways to ensure patient/carer perspectives inform the different stages of guideline development. For example, there might be formal consultation with consumers/carers to determine priority topics, consumers/carers might be directly involved in the guideline development group, or the drafts may be externally reviewed by consumers/carers or advocacy groups. There should be evidence and documentation in the guideline or accompanying technical report that some consumer/carer engagement process has taken place and that stakeholders views have been considered.

Key informant consultation comment

"It is important to incorporate lived experience evidence as well as RCT evidence in the guideline development process (e.g. the Alive National Centre research group, <https://alivenetwork.com.au/our-research/>)".

Section 3 of the project planning module of the NHMRC's Guidelines for Guidelines Handbook contains useful information about consumer and carer involvement and engagement in the development of clinical practice guidelines.⁸ Hereco values the practical information in this module such as the ways developers and organisations can support consumers to engage with the process in meetings and would refer the College to this module to assess what guidance is relevant based on the status of the College's existing consumer/carer engagement strategies.

Engaging Aboriginal and Torres Strait Islander peoples in clinical practice guideline development

Hereco's consultations with key informants revealed that some members thought that the consideration of issues relevant to Indigenous people as part of the guideline process could be improved.

⁸ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/consumer-involvement>

Key informant consultation comment

“It is absolutely essential to involve Indigenous representation on guideline development processes if you want the guidelines to have an impact”.

The NHMRC Guidelines for Guidelines resource has a module on *Engaging Aboriginal and Torres Strait Islander people in guideline development*⁹. This module provides a decision-making framework to help determine whether the guideline topic is a priority issue or has specific implications for Aboriginal and Torres Strait Islander peoples. This module also provides suggestions for the level of involvement Aboriginal and/or Torres Strait Islander people should have in the guideline development process. Consult with this module for further detailed information about scoping issues, determining priorities and seeking Aboriginal and Torres Strait Islander representatives for guideline development groups.

It is important to note that relevant Indigenous views may not be included in the academic literature. Groups will need to think critically when exploring data or examining results such as whether Indigenous people have been part of the data collection or design of studies, or how the data sets were informed.(7)

⁹ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/engaging-aboriginal-and-torres-strait-islander-people-guideline-development>

Key considerations: Planning

Budget

- The College could explore external funding options to enable future clinical practice guideline development endeavours.
- Avoid accepting industry funding for clinical practice guideline development.

Resourcing

- The RANZCP guideline development process would benefit from the input of search specialist and guideline development methodologists to support the project officer staff and the guideline development group.
- Consider seeking methodological support for the evidence review component of clinical practice guideline development. This might be best outsourced as it is a specialised skill set.
- Consider seeking a search specialist/librarian to support the development of high quality clinical practice guidelines.
- Consider engaging the assistance of a guideline development methodologist to support the guideline development process (e.g. this methodologist supports the establishment phase, governance and processes, and transparency on the evidence to decision process).

Priority setting and scoping the guideline

- Consider reviewing the College's guideline topic scoping process.
- Consider a more systematic, transparent, and inclusive process for guideline topic priority setting.
- Consider including all relevant stakeholders in the process of priority setting and selection of guideline topics. Consider consulting with the membership on the draft scope of the guidelines to be developed (not just consulting on the final draft guideline).
- Consider publishing the clinical questions (PICO questions) with the clinical practice guidelines.
- There should be greater clarity on the purpose of the guideline, the scope and the intended audience. This should be published with the guideline.

Multidisciplinary guideline development group

- Consider high level sign-off of the multidisciplinary guideline development group membership, potentially by the Board. It would be helpful to come up with a set of principles to help the Board decide whether there is true multidisciplinary representation on the guideline development group (including all stakeholders involved in the guideline topic).
- Document and publish how the guideline development committee representatives were sought, the process and criteria for selecting members and in what capacity they participated in the guideline development.

Indigenous representation

- Consider reviewing the College's current engagement with Aboriginal and Torres Strait Islander/Māori peoples in the development of clinical practice guidelines. Helpful advice can be found in the NHMRC's Guidelines for Guidelines module on "Engaging Aboriginal and Torres Strait Islander people in guideline development". Engagement should be based on whether the guideline topic has specific implications for Aboriginal and Torres Strait Islander/Māori Peoples.

6.2 Governance

Before commencing guideline development, the steps to be followed, how those involved will interact and how decisions will be made should be decided and documented.(16) The development of research questions and the review of evidence by the guideline development group is a complex process. The guideline group may need some additional training to work together through this process particularly to understand how decisions will be made when they might be disagreement, and how they can contribute to the process.(7)

Hereco found that there were varying degrees of satisfaction with the governance and approval processes of RANZCP clinical practice guidelines through consultations with key stakeholders.

This section of the report will explore governance matters and provide suggestions for alignment with high quality clinical practice guideline development processes and procedures.

Key informant consultation comments

“The College needs to move away from the risks posed by individual conscious or unconscious bias in the guideline development process”.

“Involve more people in the review and endorsement process (potentially at a Board level) to reduce the risk of biased advice being published”.

6.2.1 Declaration and management of conflicts of interest

The NHMRC Act 1992 defines a conflict of interest as ‘any direct or indirect pecuniary or non-pecuniary interest’. Conflicts of interest can bias guideline recommendations to disproportionately favour new, expensive and less effective treatments and products. They can also promote over-diagnosis, over-treatment and lead to the medicalisation of normal human states and behaviours.(17) The trustworthiness of clinical practice guidelines is underpinned by a robust and transparent conflict of interest declaration and management process.

Key informant consultation comments

“Guidelines reflect who made them. Be careful of competing interests and special interest group led guideline development”.

“Vested stakeholder interest needs to be managed better”.

A conflict of interest does not preclude an individual’s involvement within a guideline development group; however, to ensure the independence and integrity of decision making processes and for transparency, all relevant interests must be declared and managed appropriately.

When forming recommendations, guideline development groups consider the available evidence and interpret how it should be applied in practice. There are often limitations in this evidence so considered judgement becomes an integral part of a guideline's development. To ensure a guideline's recommendations are objective and unbiased any real or perceived conflict of interest should be declared and managed.

In 2014, NHMRC found that conflict of interest was not well managed in Australia as the NHMRC audit found that only 7% of guidelines fully declared conflict of interest management procedures. In more than 60% of guidelines conflict of interest was not mentioned at all.(14)

Hereco have reviewed the RANZCP's existing "Guideline on Declaring and Managing Conflict of Interest" and found it to have good coverage of the principles on declaring and managing conflict of interest as set out by NHMRC. Whenever starting to plan the development of a clinical practice guideline, all potential members should be required to declare their conflicts of interest in writing, prior to appointment. If not already part of the process, **the RANZCP could consider undertaking an independent assessment of the conflicts of interest declared before members are formally appointment to the guideline development committee. Hereco suggests this assessment is by the Board or some other mechanism outside of the guideline development group.**

All members of guideline development groups should complete a declaration of interest form specifically tailored to guideline development prior to appointment and the first committee meeting. This information should be collated and shared with all committee members at the first meeting. The chairperson should consider all potential conflicts of interest, and ask committee members to identify any new or changed conflicts of interest at each meeting.(7)

Ideally the conflict of interest policy should identify thresholds for conflict of interest (e.g. specify dollar values or types of financial compensation).

Managing real or perceived conflicts of interest

A substantial conflict of interest, such as ongoing financial compensation by a private company with strong links to the topic of interest, should require that individual to cease their involvement within the development of the guideline.(7) The RANZCP's existing Guideline on Declaring and Managing Conflict of Interest has an acceptable process defined for where a committee member is identified as having a real or perceived conflict of interest.

All disclosed interests should be published in some way (e.g. in the guideline itself, an administrative report or technical reports).

Minimising the impact of real or perceived conflict of interest

Hereco notes that Australia's COVID-19 Taskforce has an independent conflicts of interest committee that supports its guideline panels in managing real or perceived conflicts of interest. The conflict of interest committee assesses declarations if a potential conflict is indicated. The committee is comprised of individuals with expert knowledge of conflict of interest management. The chair of the committee makes the final decision as to whether a conflict of interest requires the development of a management plan for that individual.

Another way to minimise real or perceived conflict of interest is to appoint an independent chair of the guideline development group. The chair's primary qualification should be expertise in chairing and facilitating groups. The role of chair is critical as they are ultimately responsible for guiding your development group through the conflicts of interest policy. For this reason, it is strongly encouraged that the chair is independent, meaning they have no financial conflicts of interest and are free of non-financial interests as much as possible. The chair does not need to be an expert in the content area of your guideline; however, they should have a general understanding of the content to be able to participate in the discussion and deliberations.

Detailed information on declaration and management of conflict of interest is available on the NHMRC's Guidelines for Guidelines module on identifying and managing conflicts of interest¹⁰. There is also useful information on this topic in the McMaster checklist.(9)

Hereco encourages the College to assess their current conflict of interest processes and procedures with respect to the information provided by these two organisations.

Case study 1: Inadequate conflict of interest management in the development of clinical practice guidelines

The importance appropriate declaration and management of conflict of interest is highlighted by the example of the Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder (ADHD) (2009) developed by the Royal Australasian College of Physicians (RACP). These guidelines were developed by the RACP with funding from the Department of Health and Ageing, with the intention of seeking NHMRC approval. The RACP process was overseen by an expert working group. The RACP made the draft available prior to formal consideration by the NHMRC due to the lack of existing evidence-based guidance in this area. An independent panel of experts reviewed the scientific evidence, and an independent scientific writer drafted the content.¹ However, the NHMRC did not approve the draft guidelines as some of the references cited in the guidelines were authored by researchers who failed to disclose their receipt of sponsorship from the pharmaceutical industry. The Council of NHMRC stated that they were therefore unable to determine the integrity of some of the research underpinning the guidelines.¹ The guidelines never moved beyond the draft stage. The guidelines remained on the RACP website in draft form until the Australian ADHD Professionals Association (AADPA) released the NHMRC endorsed, Australian Evidence-Based Clinical Practice Guideline for ADHD in July 2022.¹

6.2.2 Achieving consensus

Guideline development groups may at times find it difficult to reach consensus. Differing viewpoints can lead to conflict and communication breakdown which can affect the guideline development process.(7) There are several ways to improve group participation and reduce conflict. Establishing what method will be used to reach consensus is important to do before guideline development commences. Training members can help them understand the guideline development process, and consensus processes to improve group function.

Consensus development methods

Consensus development methods help the guideline development group achieve shared decision making. According to the NHMRC Standards for Guideline Development (2) all guidelines should have clearly defined, documented processes for reaching consensus.(2, 8) Anticipated methods of consensus development should be described at the start of the guideline development process, and communicated to the group. This should include information about whether the group will adhere to a particular decision rule (e.g. for whether full consensus is required or if the majority is sufficient). Australia's COVID-19 Taskforce requires 100% consensus amongst voting members before recommendations are published.

Consensus development methods can be either explicit or implicit. Explicit methods include the Delphi method and the Nominal Group Technique.(7) Implicit methods include 'informal consensus' and 'consensus development conference' techniques.(18) There are many sources of information regarding consensus development methods and we refer RANZCP to NHMRC's Guidelines for Guidelines handbook

¹⁰ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/identifying-and-managing-conflicts-interest>

module “Guideline development group” or McMaster’s Guideline development checklist(9) for further information.

6.2.3 Terms of reference

Terms of reference define the purpose of the guideline development group, its membership and outline the working arrangements among members. They should include expectations around meeting attendance, communication, and standards of behaviour at meetings. Terms of reference should detail processes such as the schedule and format of meetings, managing conflicts of interest and confidentiality.

Hereco is unclear whether there is a standard RANZCP terms of reference document that applies to clinical practice guideline development groups. Hereco have reviewed an example of an RANZCP terms of reference for a guideline development group (Mood Disorders Clinical Practice Guideline Update 2019-2020 Steering Group) and acknowledge the detail was provided. It is unclear, who is responsible for enforcing the terms of reference if the group depart from them (e.g. the scope of work on the reviewed guideline was substantially greater than was defined in the terms of reference for the review of the 2015 mood disorders guideline).

Key considerations when developing the guideline group terms of reference are presented in the NHMRC’s Guidelines for Guidelines Handbook module “Guideline development group.”¹¹

6.2.4 Public consultation

It is essential that guidelines undergo a public consultation and peer review process prior to publication. Public consultation methods can be either open, targeted or a combination of the two. Targeted consultation methods that invite specific stakeholders to comment enable feedback to be sought in a relatively controlled manner; however, this runs the risk of important viewpoints being overlooked. Open consultation is more transparent and ensures that all stakeholders can comment on your content but may produce a large volume of feedback.¹²

For the guidelines identified through the environmental scan, the Medical Colleges provided varying levels of detail about public consultation of guidelines. Of those that provided information, all included some form of targeted stakeholder consultation. For two guidelines, drafts were available for open public consultation, which was promoted through the College website, and advertised through existing communication channels and social media (RACGP osteoarthritis guidelines, RANZCOG endometriosis guidelines). The duration of the consultation period was reported for two guidelines as 1 month and 6-weeks. This information was not reported for any other guidelines, but good practice is to publish this information with the guideline. For a clinical practice guideline to achieve NHMRC approval there must have been a public consultation period of a minimum of 30 days¹³.

From hereco’s consultations with key informants, there were mixed reports about the effectiveness of the consultation process for the RANZCP guidelines. Although structurally the right consultation processes are in place, members noted that the size of the guideline documents precluded their meaningful engagement with them. Some suggested that it might be helpful if an executive summary and summary of recommendations extracted to improve engagement with the guideline at the time of consultation. Other respondents noted that the new RANZCP portal where documents are loaded onto for review is a deterrent as it is just another platform to log onto. It was noted that respondents preferred the previous way

¹¹ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/guideline-development-group>

¹² <https://www.nhmrc.gov.au/guidelinesforguidelines/review/public-consultation>

¹³ <https://www.nhmrc.gov.au/about-us/publications/meeting-2011-nhmrc-standard-clinical-practice-guidelines>

guidelines were circulated via email as it allowed visibility of the views of others reviewing the draft guidelines (through cc'ing responses).

Key informant consultation comments

“Communication processes of the College could be improved – provide Exec Summaries and summary of recommendations of the guidelines. Be realistic. People are time poor and busy”.

“As a membership organisation, we can do better with our comms on documents that are out for consultation”.

In addition to internal consultation, guidelines should undergo a period of external consultation.(7-9) From hereco's investigation of the current suite of RANZCP guidelines, the duration and mechanisms of public consultation are in line with best practice (public consultation of at least 4-6 weeks).

Once the guideline is finalised and ready to be released it is prudent to include a summary of the public consultation process and the changes made to your guideline as a result. The summary should capture the key issues and the corresponding response and/or changes to the guideline.(7)

6.2.5 Internal approvals

Through the review of the current suite of RANZCP clinical practice guidelines, **hereco found that the guideline development methods and approvals could be more transparently reported**. High quality clinical practice guidelines produced by other organisations often have these details available in technical reports or methods reports that accompany their guidelines. Some examples of transparent reporting of evidence review and guideline development methods (in technical reports and administrative reports) include:

- The Centre of Perinatal Excellence (COPE): <https://www.cope.org.au/health-professionals/health-professionals-3/review-of-new-perinatal-mental-health-guidelines/>
- The COVID-19 Clinical Evidence Taskforce: <https://clinicalevidence.net.au/about-the-guidelines/>

The publication format of the existing suite of RANZCP guidelines in the ANZJP may have precluded this level of detail being able to be published with the existing guidelines. The issues associated with publication of the RANZCP guidelines in the ANZJP journal is explored further in the “Format of the guidelines” section of this report.

Through hereco's consultations with key informants it was noted that there should be tiered approval processes for the clinical practice guidelines. Interviewees felt that Board should be involved in approving the final guideline product, and that guidelines should not be published without adequate internal approvals. Equally, there was support for communication of any Board decisions to go back to the guideline development group and the provision of sufficient time for an opportunity for rebuttal. It was noted that on occasion the ANZJP timelines impacted on the consultation process and reduced the time available for internal processing of feedback on clinical practice guidelines and this was seen as an issue.

The consultations also revealed that College committees are important to specifically consult with, depending upon the guideline topic. These committees include the College's Youth Mental Health Section and the Faculty of Addiction Psychiatry. There may be other committees depending upon the guideline topic to be addressed. The governance around who else should be involved in the guideline should not solely rest with the guideline development group.

Hereco notes there are potential governance issues that arise when the College Fellows involved in the development of clinical practice guidelines are also involved in the ANZJP journal. This is an area for RANZCP attention.

6.2.6 Alternative governance arrangements to produce high quality clinical practice guidelines

There are several ways the College can contribute to the development of clinical practice guidelines. They can continue to produce them entirely through the College or by engaging specialist evidence review, technical writing or guideline development expertise. As clinical practice guidelines are time and resource intensive, an alternative option is to partner with other organisations interested in producing guidelines in that area. This partnership model may involve partnering with other organisations with an interest in the topic and combining resources to co-develop guidelines. A useful place to start scoping other organisations that may be thinking of producing a guideline is the NHMRC. Early conversations with NHMRC can help

Key informant consultation comments

“To properly consider the broader social determinants of mental health, the College’s Youth Mental Health Section should be involved in guideline development and approval process (they have recently developed a position statement on the mental health impacts of climate change).”

“In cases of comorbid substance use and other mental health disorders, the authors of guidelines should obtain specialist input on this e.g. consult with the Faculty of Addiction Psychiatry.”

developers decide whether to proceed with development of the guideline¹⁴.

Another alternative governance arrangement for guidelines is that of an independent arbiter producing clinical practice guidelines, as per the Centre of Perinatal Excellence (COPE) model.

¹⁴ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/project-planning>

Case Study 2: The Centre of Perinatal Excellence (COPE): governance structure and approvals process

COPE is an independent, not-for-profit company, limited by guarantee that has produced Australia's NHMRC approved perinatal mental health guideline in 2017 (and submitted an updated version of the guideline for NHMRC approval in 2023).

As detailed in their Constitution, the governance structure of COPE is that it is made up of a Board and the Company Membership, which comprises the peak professional bodies representing primary and maternity care and consumer bodies in perinatal mental healthcare in Australia. Nominated representatives from each of these bodies work with COPE to inform and shape their work (including clinical practice guideline development) and identify collaborative opportunities to improve outcomes of women, men and their families. For further information see:

<https://www.cope.org.au/about/governance/>

Case Study 3: The Australian COVID-19 Taskforce guideline: governance structure and approvals process

The Australian COVID-19 Taskforce uses a world-leading 'living evidence' approach, which combines rigorous, evidence-based methods and rapid, weekly updating. This enables the Taskforce to modify and update recommendations rapidly in response to the publication of new research evidence on COVID-19.

The guidelines use GRADE methods and are designed to meet Australian NHMRC standards.

Relevant new questions to be addressed are continually sought from stakeholders and practitioners. For prioritised questions, the evidence is actively monitored and updated. Evidence surveillance combines horizon scans and targeted searches.

An evidence team appraises and synthesises evidence and prepares evidence to decision frameworks to inform development of recommendations by multidisciplinary clinical expert panels.

A Guidelines Leadership Group oversees the development of recommendations by these expert panels and is advised by a consumer panel.

After initial approval by the Guidelines Leadership Group, all recommendations require 100% consensus by the Taskforce's 35 member organisations (member organisations are made up of representatives of all the relevant Medical Colleges and Societies in Australia).

Endorsed recommendations are published online in on the [MAGICapp platform](#) and disseminated through traditional and social media channels.

Key considerations: Governance

Conflict of interest

- There was variation on the level of detail published about the process to deal with conflicts of interest across the suite of current RANZCP clinical practice guidelines. Consider a more consistent approach to documenting conflict of interest declarations and management across clinical practice guidelines.
- Consider ways to minimise the impact of real or perceived conflict of interest that are appropriate for the RANZCP (e.g. independent chair or establishment of a conflict of interest committee).

Achieving consensus amongst the guideline development group

- No information was provided about the process that the guideline development groups used to reach consensus across the suite of current RANZCP clinical practice guidelines. Guideline development consensus processes should be established prior to commencing guideline development, and this process should be communicated to the guideline development group before work commences on the guideline. The process should be published with the guideline.

Guideline development group membership

- Provide greater transparency on who was involved in developing the guideline, how they were selected and in what capacity they contributed to the guidelines.

Terms of reference

- It is unclear, who is responsible for enforcing the terms of reference if the guideline development group depart from them (e.g. the scope of work on the reviewed Mood disorders guideline was substantially greater 10-20% of the 2015 version, as set out in the terms of reference).

Consultation of the clinical practice guidelines

- The internal processes for Fellow/members/other committees to provide feedback on clinical practice guidelines could be improved by making it easier for people to comment (e.g. provide extracted summary of recommendations and an Executive summary of the guidelines).
- Consider reviewing the effectiveness and satisfaction of the RANZCP document portal for obtaining member feedback.
- Particular College committees are important to specifically consult with, depending upon the guideline topic. Examples include the College's Youth Mental Health Section, and the Faculty of Addiction Psychiatry and there may be others depending on the guideline topic.

Internal approvals/final sign-off on the clinical practice guideline content

- Allow sufficient time for the internal approval process for clinical practice guidelines.
- The guideline approval timelines should not be governed by the timelines of the peer-reviewed journal, rather sufficient time should be allowed for meaningful consultation of draft guidelines amongst the membership.

6.3 Knowledge management

There are many existing resources with extensive information on knowledge management related to clinical practice guideline development. Rather than reproducing them in detail here, we have highlighted some important points below.

For more in-depth information on identifying the evidence, synthesising the evidence, selecting studies and data extraction we recommend referring to the “Develop” module¹⁵ of the Guidelines for guideline handbook produced by the NHMRC.

6.3.1 Evidence identification

6.3.1.1 Defining the questions

Before planning an evidence search, the clinical questions that the guideline will address need to be clearly defined, ideally in PICO format (PICO stands for patient/population, intervention, comparison and outcomes). Clearly defined questions in PICO format make sure that everyone is in agreement on scope and approach and help to guide many steps in the evidence synthesis process such as the literature search, selection criteria for including studies and data extraction. When defining the questions, consideration also needs to be given to other factors that will be used to determine if a study is included or excluded (e.g. study design, publication date, language, etc.).

It is advisable to develop a protocol detailing methods for locating, selecting, and synthesising evidence and for determining the types of evidence to include (sometimes referred to as a research protocol). This helps to ensure transparency and consistency of methods between topics if different groups are developing different sections of the guideline.

6.3.1.2 Searching for evidence

It is important to note that conducting a comprehensive search of multiple evidence sources is a complex task and according to NHMRC, developing your own searches should be avoided if you lack experience.(7)

Searching for existing clinical practice guidelines

When working within resource constraints, a pragmatic approach is to search for existing relevant clinical practice guidelines that may be suitable for adoption or adaptation. This is important as existing guidelines may address some or all the questions to be covered in the new guideline, and if found to be current and of high quality, could avoid the time and resources involved in conducting a de novo systematic review for each clinical question.

Unlike for journal articles, there is no standardised platform for clinical practice guideline publications. While some clinical practice guidelines are published in academic journals, many are not, therefore, searching for existing clinical practice guidelines requires searching a very wide range of resources. Unfortunately there is no standard set of websites that should be searched, however, in addition to bibliographic databases (such as PubMed), websites such as the [TRiP database](#) and the [Guidelines International Network \(GIN\) library](#) are a good place to start.

¹⁵ <https://www.nhmrc.gov.au/guidelinesforguidelines/develop>

Searching for systematic reviews or primary studies

If RANZCP needs to conduct its own systematic reviews, **it is recommended that systematic review methods for searching for evidence are followed (either for full or rapid systematic review, depending upon the topic and how the information will be used by RANZCP).**

There are a wide range of published and unpublished information sources that can inform the methods to conduct a systematic review of evidence (we recommend referring to the “Develop” module¹⁶ of the Guidelines for Guidelines handbook produced by the NHMRC). If a systematic review methodology is not followed for evidence searches, a rationale should be provided as to why this was not done.(9)

Hereco were asked by the RANZCP to provide advice regarding which main academic journal databases should be considered to ensure rigorous identification of key literature. We would recommend the main published sources of systematic reviews and primary studies are bibliographic databases of peer-reviewed journals such as [Embase](#), [MEDLINE](#) and [PsycInfo](#) (which is dedicated to peer-reviewed literature in behavioural science and mental health). Depending on the question, the RANZCP could also consider adding the [CINAHL](#) database which covers nursing and allied health literature. Searching Health Technology Assessment (HTA) agency websites (including NICE, CADTH etc) might also be useful to find systematic reviews (and HTAs that may cover lower level evidence).

A systematic review should be based on a comprehensive search of the literature, therefore, hereco considers that solely searching the PubMed database is inadequate. PubMed should be searched but should not be the sole source of information as the PubMed search interface is not sufficiently sophisticated to properly perform searches related to complex clinical questions, or for topics where the evidence is not likely to be found in straightforward studies of interventions. While PubMed is available to search without a subscription and has significant overlap with Medline, the cross-over between EMBASE and Medline is not extensive, meaning many European studies may be missed if only PubMed is searched. In addition, important studies related to mental health may be missed if databases such as PsycInfo are not searched.

Grey literature can also be an important source of evidence and is defined as “any literature or information that is not commercially published or searchable within standard databases”.(7) Grey literature can be particularly important when considering questions that are likely to be answered through qualitative studies, or for research on particular populations (e.g. Indigenous or culturally and linguistically diverse groups). Key sources of grey literature include clinical trials databases, government reports, disease registries, census data, theses and dissertations.

Developing search strategies and conducting searches

Developing a comprehensive search strategy is an iterative process. Once there has been a determination of where evidence might be available, an initial ‘scoping’ search can be conducted, and the results used to judge the performance of the search strategy and inform adjustments to the search terms. Both text terms and Medical Subject Headings (MeSH) terms should be used to ensure that more recent articles are captured that may not have had MeSH headings assigned to them yet. **Hereco would advise engaging an information specialist to review a search strategy** before beginning the search.

Once a comprehensive list of search terms is developed, the next step is to map them into the target databases. The search syntax of each database is different so there may need to be translation of the search strings depending upon the database. This often requires the expertise of an information specialist as a minimum.

¹⁶ <https://www.nhmrc.gov.au/guidelinesforguidelines/develop>

There is further detailed information about developing search strings in NHMRC's Guidelines for Guidelines Handbook, module "Identifying the evidence".¹⁷

Managing references

Once the searches have been conducted and references identified, a flexible system to store and sort the references is required. Citation management software provides a platform where the number of citations identified and where they were identified can be recorded. There are several programs available to manage citations¹⁸, and they all differ in cost, functionality and the ability to import and export multiple file types.

(7) **Hereco finds Endnote citation management software to be a simple and useful option.** Citation management software is important for record keeping, can help with the screening of articles and generation of citations and reference lists.

6.3.1.3 Documenting the process

Thorough documentation of the search process is required as it demonstrates transparency and enables others to reproduce the search. In particular, the following should be recorded and published in the guideline or in a technical document that accompanies the guideline:

- inclusion and exclusion criteria
- databases searched
- exact search strategy employed in each database
- filters used during the search
- exact date(s) of the search/es
- number of articles identified within each database.

6.3.1.4 Identifying and selecting evidence

After running the searches, the next step is to screen the identified articles to determine whether they meet the pre-defined inclusion criteria. Selecting studies is a multi-step process requiring methodical, sometimes subjective decisions and thorough documentation. Many of the articles picked up will be irrelevant. First the title and abstract of the identified articles are screened to eliminate any studies that are clearly irrelevant. The next step involves retrieving the full-text of the remaining articles, and then screening them for inclusion. This is often the most time consuming step of the knowledge management process, and there can be additional costs involved in sourcing full-text articles that require a paid-subscription to access. It is important to keep records and document duplicates and any reasons for exclusion (i.e. articles excluded following title/abstract screening; and articles excluded following full-text screening). A PRISMA diagram¹⁹ is a good way to present this information. Retracted studies in the screening process should be carefully marked with consideration of what impact the exclusion of these studies will have on the risk of bias assessment and final conclusions.

There are subjective judgements involved in the selection of included studies. It is important that the person reviewing the included studies has some knowledge of the topic area, or can consult with content experts, and that the final selection of studies for the review is undertaken by more than one person. This is a timepoint where clinical input to the guideline development group is required even if specialist guideline development methodologists have been engaged.

¹⁷ <https://www.nhmrc.gov.au/guidelinesforguidelines/develop/identifying-evidence>

¹⁸ Endnote, Refworks, JBI SUMARI, RevMan (Cochrane), Covidence (Cochrane), Mendeley, EPPI Reviewer 4, Zotero and Rayyan

¹⁹ <http://www.prisma-statement.org/>

6.3.2 Evidence synthesis and assessing the risk of bias

6.3.2.1 Synthesising the evidence

Clinical practice guideline recommendations can be based on various types of evidence, including, but not limited to:

- systematic reviews of the evidence (de novo or pre-existing)
- overviews of systematic reviews
- health technology assessments
- existing guideline recommendations
- rapid reviews of the evidence

The types of evidence used to develop guideline recommendations will depend upon factors including, but not limited to:

- the scope of the guideline (broad, encompassing many clinical questions versus narrowly defined),
- the type/s of question being addressed (e.g. clinical question, consumer preference considerations),
- the volume of research available to answer the question,
- the time and resources available to do the work.

Ideally, clinical practice guidelines should be informed by at least one well-conducted systematic review.

If a guideline is not informed by a comprehensive evidence synthesis or if the evidence synthesis does not convey the level of certainty about the evidence, the result can be the development of inappropriate guideline recommendations, which can have negative impacts on patient care.

Specialist expertise is required to select and apply appropriate evidence synthesis methods, including input from statisticians where appropriate.(7)

Systematic reviews

Once the body of evidence from the literature searches is assembled, a careful synthesis of the evidence is required to assist the guideline development group to make decisions about the evidence. **The RANZCP may choose to conduct a systematic review in-house, but these do take time and a specialised skill set so this task might be better outsourced if resourcing allows.**

Other types of evidence

Systematic reviews of the evidence are not always feasible to conduct or update (such as for very broad guidelines addressing a wide range of clinical questions, or where there are insufficient time and resources available). Where systematic reviews are not available or feasible, guideline developers may consider using overviews of multiple systematic reviews or may incorporate primary studies and other sources of evidence to inform their development of recommendations.(7)

In some cases, the available time and resources only allow for a rapid evidence review approach or the adoption/adaptation of an existing guideline. It is important to note that different evidence review approaches can be undertaken for different parts of the guideline. For example, the main clinical or policy questions of the guideline may be addressed by systematic reviews and additional information such as the consideration of consumer values and preferences could be addressed with other approaches to gather evidence. Wherever processes other than complete systematic reviews are used, the processes should be

as rigorous and methodologically sound as possible and minimise the risks of bias that can be introduced.(7) These processes and the rationale for using them should be transparently documented in the guideline, or a technical document accompanying the guideline.

As with all elements of research, the evidence synthesis methods should be planned and described in advance as part of a systematic review or research protocol.

6.3.2.2 Details to provide in a technical report

A detailed technical report should be prepared to support the guideline development group, including:

- all methods used for synthesis and GRADE assessment — including those pre-specified in the protocol, any subsequent amendments or additional methods and a rationale for any changes
- a description of all the included studies or reviews
- an assessment of risk of bias in the included studies or reviews
- the results of all individual studies or reviews
- the risk of bias for each study or review
- the synthesised findings, including meta-analyses and narrative or qualitative syntheses
- any outcomes pre-specified as important but for which no evidence was found
- any other identified gaps in the evidence.

This detailed technical report should be presented to the guideline development group to inform their deliberations and assist with development of recommendations. The technical report should also be made publicly available alongside the final guideline. Additionally, the results of the synthesis should be provided in summary formats. For the guideline development group, a summary ‘Evidence Profile’ can be presented for each key question. Summaries of these results can also be made available in the final guideline.

Detailed information about synthesising the evidence can be found in the NHMRC’s Guidelines for Guidelines Handbook, “Synthesising evidence” module²⁰ and in the McMaster checklist.(9)

6.3.2.3 Appraising the methodological quality of included studies

Assessing the risk of bias of studies

Several different terms are used to talk about the assessment of studies underpinning a guideline — critical appraisal, quality assessment, internal validity or risk of bias assessment. Assessing the risk of bias is a fundamental step once studies have been selected for inclusion in the review. Bias refers to factors that can systematically affect the observations and conclusions of the study and cause them to be different from the truth.(19) Risk of bias is the likelihood that features of the study design or conduct of the study will give misleading results.

Risk of bias assessment requires a degree of methodological expertise and may be conducted by the guideline development group or by experienced researchers as part of a commissioned evidence review.

²⁰ <https://www.nhmrc.gov.au/guidelinesforguidelines/develop/synthesising-evidence>

It is recommended that the RANZCP seek external support with risk of bias assessment of included studies as it requires a specialised skill set.

Once complete, the risk of bias assessment can be used to inform the synthesis of the studies' findings and integrated into the overall assessment of the certainty of the body of evidence. Further detailed information on assessing risk of bias can be found in the Cochrane Handbook(19) and the NHMRC's Guidelines for Guidelines Handbook "Assessing risk of bias module".

The details of how the risk of bias assessments were conducted and the findings of the assessments should be included in the guideline documents or associated technical reports.

6.3.3 Evidence to decision methods

Once the evidence relevant to the guideline's questions has been synthesised and conclusions have been drawn about the size and direction of the effects, the next step in developing guidance is to understand how valid and reliable that estimate is. This underpins decisions to recommend — or not — different courses of action based on this evidence. It also helps to ensure there is not a strong reliance on results that are uncertain, which can lead to inappropriate recommendations.

The existing suite of RANZCP guidelines used the 2009 NHMRC Additional Levels of Evidence and Grades for Recommendations for Developers of Guidelines as the framework for evidence review and developing recommendations. **NHMRC now recommends the use of GRADE as best practice for the development of high quality clinical practice guidelines.**

GRADE is an internationally recognised approach to rate the quality of evidence and the strength of recommendations and is also considered to be the standard in guideline development by many international organisations that develop clinical practice guidelines, such as the WHO, NICE, and Canadian Task Force on Preventive Health Care. Guideline developers seeking NHMRC approval are also advised to use GRADE.

The GRADE approach provides a structured way to consider key factors that may increase or decrease confidence in the synthesised findings of a body of evidence.(20) In other words, the GRADE approach can be used to estimate the certainty of a body of evidence. While risk of bias assessments look at individual studies, GRADE is a system for rating the quality of a body of evidence in systematic reviews and other evidence syntheses, such as health technology assessments, and guidelines.(20) GRADE also provides a transparent and structured process for carrying out the steps involved in developing recommendations.

GRADE provides a framework for specifying health care questions, choosing outcomes of interest and rating their importance, evaluating the available evidence, and bringing together the evidence with consideration of values and preferences of patients and society to arrive at recommendations.

GRADE assessment provides a structured way to consider key factors that may increase or decrease confidence in the synthesised findings of a body of evidence. These factors include:

- the risk of bias;
- the precision of the effect estimates;
- the consistency of the individual study results;
- how directly the evidence answers the question of interest; and
- the risk of publication or reporting biases.

GRADE was initially developed to address questions about the effectiveness of interventions based on randomised and observational studies. It can also be used to assess either narrative or statistical syntheses (Murad, Mustafa et al. 2017).

GRADE assesses the certainty of evidence for each outcome separately, and categorises the certainty of the evidence as high, moderate, low and very low (see **Table 7**).

Table 7 Interpretation of the four levels of evidence used in the GRADE profile (20)

Grade	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

With GRADE, the level of certainty of evidence can be downgraded — or in some circumstances upgraded, as each factor is assessed. Randomised control trials begin with a high rating, whereas observational studies begin with a low rating. For each outcome a decision is made whether to downgrade (or upgrade in the case of observational studies) the certainty of the evidence by one or two levels for each factor, leading to a final rating. Note that regardless of how many reasons there are to downgrade, the certainty of the evidence cannot fall below very low.(7)

Detailed information about how to use the GRADE approach to assess the evidence will not be reproduced here but is available in both the NHMRC Guidelines for Guidelines Handbook “Assessing the certainty of evidence” module(7) and in the GRADE Handbook(20).

In the environmental scan of guidelines produced by other Australian Medical Colleges or peak bodies, all guidelines that reported information on evidence to decision methods used either GRADE, NHMRC methods or a mixture of the two for a guideline that was transitioning from NHMRC to GRADE (see **Section 3.3.3 Knowledge management**. For evidence-based recommendations, guidelines indicated the strength of evidence in line with the evidence to decision methods used (i.e. GRADE = high, moderate, low/very low certainty of evidence; NHMRC = Level of evidence I-IV)(21).

6.3.3.1 Development of recommendations

Implementable guidelines and recommendations should be specific. There is evidence to support the use of specific, concrete statements to modify behaviour and increase recall.(7) A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.(8)

The GRADE methodology or some form of equivalent considered judgement process should be used to develop recommendations.

GRADE methodology considers several factors when developing recommendations:

- benefit and harms
- certainty of evidence

- preferences and values of patients and other key stakeholders
- resources and cost-effectiveness considerations
- feasibility
- acceptability
- equity

The benefits, harms and certainty of available evidence are generally summarised from the evidence profile. Guideline groups should also consider resources and cost-effectiveness considerations, feasibility, acceptability and equity in formulating their decisions. Consumer and clinical engagement is essential in this process. In particular, the consumer representatives will consider whether strong or varying patient preferences and values are likely to impact on the nature or implementability of the recommendations.

Importantly, there should be transparency about decision-making and judgements of the evidence by the guideline development group (e.g. be clear about other factors that influence the process of making recommendations including benefits and harms, values and preferences, resource use and acceptability).

NHMRC Standard 7 states that to make actionable recommendations guidelines will:

- Discuss the options for action.
- Clearly articulate what the recommended course of action is, when it should be taken and by whom.
- Clearly articulate what the intervention is so that it can be implemented.
- Clearly link each recommendation to the evidence that supports it.
- Grade the strength of each recommendation.

When formulating recommendations, they should be actionable recommendations, using direct language, with clear links between recommendations and the evidence supporting them. There should be clear identification of the quality of evidence and strength of recommendations as this increases the trustworthiness and improves the implementation of clinical guidelines.(8)

The guideline development groups rationale for developing the recommendations should also be transparently reported in the guideline or corresponding technical report.

Standardised wording of recommendations

It is helpful to decide on standardised wording to use for recommendation statements to ensure clarity and maintain consistency throughout the guideline, and across the suite of RANZCP guidelines.(9)

There are a variety of factors to consider when structuring recommendations. According to the NICE guideline development manual the target population (e.g., patients) and the setting should be clearly reported in recommendations when applicable and the target audience (e.g. clinicians) should also be reported in some special conditions.(11) According to the WHO guideline development handbook recommendations need to reflect the Population, Intervention, Comparator and Outcome format.(10) According to the AGREE II instrument a recommendation should provide a concrete and precise description of which option is appropriate in which situation and in what population group.(6)

Vague and non-specific statements in recommendations should be avoided. Guideline recommendations should be clearly written and behaviourally focused. It may be helpful to decide up front when the use of terms such as 'should' and 'may consider' will appear in recommendations. Commonly the use of the word 'must' in recommendations conveys the highest level of obligation, while the term 'should' conveys intermediate levels of obligation or confidence in the evidence. Use of the words 'may' and 'may consider' conveys lower levels of obligation or confidence in the evidence.

Key recommendations should be easily identifiable, and not embedded within long paragraphs.(9) Ideally recommendations should also be grouped together in a summary table, which is helpful for easily identifying the recommendations.

6.3.3.2 Grading recommendations

Based on the aforementioned factors, GRADE rates recommendations as either **strong** or **conditional**. The principle for the strength of recommendations is:

- the strength is strong when most or all individuals will be best served by the recommended course of action.
- the strength is conditional when not all individuals will be best served by the recommended course of action and there is a need to consider the individual patient's circumstances, preferences, and values.

The following criteria are used in determining the strength of recommendations:

- **Strong for:** moderate to high certainty evidence suggests that benefits in critical outcomes clearly outweigh the reported harms; a strong recommendation can be made in the absence of high-certainty evidence if patients are expected to highly desire such practice and there are no potential harms in providing it.
- **Strong against:** moderate to high certainty evidence suggests harms outweigh benefits; high certainty evidence suggests lack of benefits.
- **Conditional for:** moderate to high certainty evidence suggests equivalent benefits and harms, patients would mostly want to receive the practice, and there is no significant resources implication in doing so; low certainty evidence suggests benefits outweigh harms and there are no significant implications in patients' preferences or resources implications.
- **Conditional against:** moderate to high certainty evidence suggests equivalent benefits and harms, but there is expected large variation in patients' preference to receive this practice or important resource implications; low certainty evidence suggests harms outweigh benefits and there are no significant implications in patients' preferences or resource implications.

For some topics, a systematic review of the available evidence is conducted or is available in the literature, but there is either a lack of evidence or insufficient certainty of evidence on which to base a recommendation; unclear balance between benefits and harms, and there is expected large variation in patients' preferences. In cases where the guideline development group determines that recommendations are important, statements and advice about topics may be developed based on consensus and expert opinion (guided by any underlying or indirect evidence). These statements should be labelled as **consensus-based recommendations**.

It is recommended that a distinctive format is used to highlight the core recommendations in guidelines, to be able to quickly distinguish the strength of recommendations.

In the environmental scan, all guidelines that reported information on the evidence to decision methods used either GRADE, NHMRC methods or a mixture of the two for a guideline that was transitioning from NHMRC to GRADE. For evidence-based recommendations, guidelines indicated the strength of recommendations in line with the evidence to decision methods used (i.e. GRADE = recommendations graded as strong or conditional; NHMRC = A, B, C, D). Non-evidence-based recommendations had various labels, including practice points, expert consensus, consensus-based recommendations, good practice notes and expert opinion.

Key considerations: knowledge management

Evidence review

- There was limited transparency of the evidence review process and guideline development methods in any of the published RANZCP clinical practice guidelines. This should be transparently reported to align with best practice principles in clinical practice guideline development.
- There were no details of critical appraisal of included literature available in any of the published RANZCP clinical practice guidelines. This should be transparently reported to align with best practice principles in clinical practice guideline development.
- It is recommended that the RANZCP seek external support with risk of bias assessment of included studies as it requires a specialised skill set.
- There were no detailed PICO/Research questions available in any of the published RANZCP clinical practice guidelines. PICO/Research questions should be transparently reported to align with best practice principles in clinical practice guideline development.

Evidence to decision processes

- There were no details of the evidence to decision process or rationales on how evidence linked to decisions in any published RANZCP clinical practice guidelines. It is recommended that evidence to decision process or rationales on how evidence linked to decisions are transparently reported to align with best practice principles in clinical practice guideline development.
- None of the RANZCP guidelines directly linked recommendations to supporting evidence. It is suggested that recommendations are linked to supporting evidence to align with best practice principles in clinical practice guideline development.

Developing recommendations

- The GRADE methodology or some form of equivalent considered judgement process should be used to develop recommendations.
- When formulating recommendations, they should be actionable recommendations, using direct language, with clear links between recommendations and the evidence supporting them.
- It is helpful to decide on standardised wording to use for recommendation statements to ensure clarity and maintain consistency throughout the guideline and across the suite of RANZCP guidelines.
- The guideline development groups rationale for developing the recommendations should be transparently reported in the guideline or corresponding technical report.

Grading of recommendations

- Some RANZCP guidelines did not provide further detail on the grades of recommendations beyond EBR or CBR. Consider implementing the GRADE approach to grading recommendations in future clinical practice guidelines.
- None of the RANZCP guidelines provided evidence to decision information (rationales) for factors that were considered or influenced the guideline development group decision-making on the development of evidence-based recommendations (EBRs) or consensus-based recommendations (CBRs).

Approach to knowledge management

- The GRADE approach to assessing the certainty of a body of evidence, developing and grading recommendations is considered best practice by the NHMRC and internationally.

6.4 Adapting/adopting existing high quality guidelines

Developing and updating high quality guidelines requires substantial time and resources. To reduce duplication of effort and enhance efficiency, guideline adaptation is an option.

In hereco's experience, and that of other guideline developers, there is limited evidence to suggest that adapting a guideline saves time or money compared to developing one from scratch.(22) Despite this, guideline adaptation can still be helpful as it may minimise duplication of effort on certain guideline components like the evidence review and allows time and resources for contextualising the recommendations so that it will be effectively implemented in practice.

From hereco's consultation with key informants, there was general support from respondents for the College to consider guideline adaptation. Some comments included:

Key informant consultation comments

"We need to work smarter, not harder when it comes to leveraging off existing high quality evidence reviews and guidelines".

"We re-invent the wheel too much by not using existing evidence reviews, and this only serves to put more pressure on the volunteers producing the guidelines".

When assessing whether an existing guideline is suitable for adaptation, the quality of the guideline development process of the source guideline should be assessed, ideally through an AGREE II assessment.(6) It is rare to find one source guideline that contains recommendations covering the full scope of a proposed guideline; however, recommendations from multiple source guidelines can be considered, even when their scope is quite different.(7)

Adoption or adaptation of a whole guideline, its recommendations or other components can be considered if either:

- a suitable international source guideline is found and there is no Australian equivalent.
- an Australian source guideline needs to be made more applicable to a new setting.

If a suitable but out of date source guideline is found it may be viable to update it by repeating the same literature search and including any evidence published since the original search date. When existing guidelines are found to be unsuitable for adoption or adaptation, it is inevitably timelier and more cost effective to start a new clinical guideline from scratch. The rationale for deciding to adopt or adapt the source guideline or recommendations should be documented and provide any additional information necessary for it to be implemented.

Guideline adaptation is described in detail in the ADAPTE manual and Resource Toolkit(23), and the factors to consider when deciding whether to adopt, adapt or start developing a guideline from scratch are explored in detail in the NHMRC's "Adopt, adapt or start from scratch" module of the Guidelines for Guidelines Handbook.²¹

²¹ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/adopt-adapt-or-start-scratch>

Key considerations: Guideline adaptation

- Developing and updating high quality guidelines requires substantial time and resources. To reduce duplication of effort and enhance efficiency, guideline adaptation is an option.

6.5 Living guideline approaches

Hereco were asked to provide advice on living guideline approaches as part of this report. One of the challenges associated with traditional clinical practice guideline development is that it can be a slow process, with multiple years between a guideline and its next update. There is much global interest in having more frequently updated or “living” guidelines in healthcare as this would enable dynamic updating of recommendations once new practice-changing evidence becomes publicly available.

The COVID-19 pandemic provided a rare opportunity to test the living guidelines model as the world was presented with a novel disease, with a rapidly evolving evidence base, and there was access to generous resourcing as countries around the world were focused on minimising the impact of the pandemic. The Australian Living Evidence Consortium (ALEC) established the National Clinical Evidence Taskforce in 2020 to undertake continuous evidence surveillance to identify and rapidly synthesise emerging COVID-19 research.(24) This was a world first collaborative living guideline approach. The Taskforce provides national evidence-based guidelines for the clinical care of people with COVID-19 which are updated weekly.

Definition of a living guideline

ALEC has recently published a handbook on living guidelines “Guidance for the production and publication of living clinical guidelines”.(25) Within this handbook, a living guideline is defined as:

“An evidence-based guideline that comprises one or more living recommendations that are continually updated as new information becomes available.”

“Living guidelines identify and provide justification for which recommendations are living or static and include a rationale for the planned updating frequency.”

The handbook sets out guidance for the production and publication of living clinical practice guidelines.

Living guideline development approaches

The living guidelines handbook provides in-depth analysis of the methods and processes for developing living guidelines in healthcare.(25) The handbook provides advice for guideline developers on how to construct living guidelines by illustrating the key differences needed to develop a living guideline compared to a traditional guideline. Living guideline approaches assume that all the standard methods for the development of high quality evidence-based guidelines still apply.

How do living guideline approaches differ from traditional guideline development approaches?

The main thing that sets apart living guidelines from traditional guideline development processes (sometimes referred to as static guidelines) is that there is an **intention to re-visit the evidence and recommendations on a more frequent basis**. Living guidelines include continual literature surveillance and updating of key recommendations which is reflected in:

- increased frequency of searching
- the study identification and selection
- the incorporation of new evidence and new recommendations in the guideline, and
- publishing an update.

Living guidelines processes will not be explored in detail within this report as the living guidelines handbook covers these factors comprehensively.(25)

Criteria to make a guideline a living guideline

While there are no fixed intervals for evidence searches or frequency with which recommendations should be updated, the following are considered to be “standard” at the time of writing this report:

- An evidence search frequency once every 3 months or more frequently.
- Consideration and publication of updated recommendations once every six months.

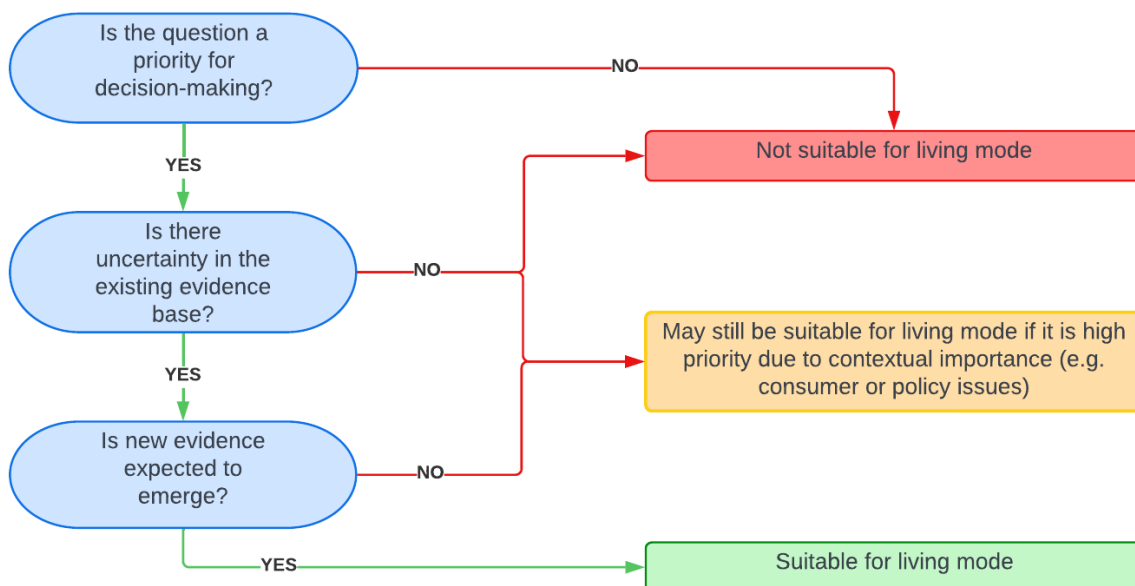
When to consider a living guideline approach

Not all guidelines or recommendations should or need to be living. There are several questions to ask when considering whether a guideline or recommendations within a guideline should be living:

- Is this a high-priority clinical area? If yes, how urgently does the topic require updated recommendations?
- Is there uncertainty or clinical controversy?
- How fast is new evidence emerging?
- What are the resources and costs involved in continual development and updating?

Figure 4 below provides a decision tree on how to decide whether specific recommendations within a guideline are suitable to be living.

Figure 4 How to select questions in a guideline that are suitable to be living (while other questions may remain static)



Source: Cheyne, S., & Navarro, D. F. (30 November 2022). ALEC Living Guidelines Handbook: "A How-to guide to the handbook" ANZ GIN Webinar Series, <https://www.youtube.com/watch?v=ExRT3UpUfiM>

6.5.1 Should the RANZCP clinical practice guidelines be living guidelines?

Where appropriate and developed to high quality guideline development standards, living guidelines are ideal as they provide up-to-date evidence-based guidance. A living guidelines model can improve efficiency, impact, and influence of clinical guidance but they are generally most appropriate for areas where evidence is changing or evolving.

Living guidelines, require a recurrent funding model and often require automated or semi-automated processes such as for literature surveillance for newly published studies and synthesis. Therefore, **not all clinical questions or topics are necessarily suited to a living guideline approach.**

From our consultations with key informants, none felt that the College should adopt a living guideline approach for its clinical practice guidelines. Most respondents were happy with a five year guideline review schedule as they feel the evidence does not evolve rapidly in many areas of psychiatry.

Key considerations: Living guideline approaches

- A full living guideline approach to entire guidelines may be too resource intensive for the RANZCP. However, the College may wish to consider whether it is appropriate to highlight specific recommendations within guidelines that would be living, that is where there is an intention to re-visit the evidence and recommendations more frequently.

6.6 Format of the guidelines

6.6.1 Format and publication platform

The current suite of RANZCP guidelines is published in the College's journal, the ANZJP in narrative, review article style. While the journal format provides an opportunity for peer review and broader widespread dissemination, it does present challenges in that the format is not flexible, it is difficult to navigate, it is static and cannot be updated readily (making the guidelines less contemporary). All RANZCP clinical practice guidelines are lengthy, ranging between 62 and 117 pages long. Although length of guideline is not a quality criterion in itself, such lengthy guidelines with no navigation aids can make it difficult for the user to find the information that they are looking for.

Feedback from hereco's consultations with key informants was mixed regarding the publication format of the current suite of RANZCP clinical practice guidelines in the ANZJP journal. Some informants felt that it was useful to publish the guidelines in the journal, they found them easy enough to find on the College website and could find the information they needed within the guidelines. The informants noted that it is important that the guidelines are published in a journal as it makes them more internationally prominent and allows for further peer review.

However, most respondents to the consultations thought that the publication format of the RANZCP clinical practice guidelines presented issues and is an area for improvement. Some comments included:

Key informant consultation comments

“The RANZCP guidelines should be online so they are more dynamic, updatable, navigable – ideally they should be on an interactive webpage with hyperlinks and indexation to quickly find the right information, with printable pages for information that is commonly used”.

“The current RANZCP clinical practice guidelines are too long, there are no summary materials, clinicians don’t have time to read them.

“They are poorly formatted, dense and difficult to navigate”.

“There was no work put into making navigation of the guidelines easier. Not a lot of work would be required to improve navigability. Indexing would help”.

“Who owns the guideline after it is published? Does the Journal dictate processes instead of the College?”.

Publication of the list of authors was also discussed as part of the key informant consultations. All informants agreed that the names of those people that are involved in developing guidance should be published in the guideline for transparency. This is in line with best practice in high quality clinical practice guideline development.(7)

NHMRC Standard 9 states that to be accessible, guidelines will be:

- easy to find.
- be free of charge to the end user.
- Be clearly structured, easy to navigate and in plain English.
- Be available online.

It is acknowledged that the publication format in the ANZJP provides peer review and broader dissemination opportunities, yet it also has the following disadvantages:

- The clinical practice guidelines remain static and cannot be updated after publication if new evidence emerges or regulatory bodies list new treatments.
- The ability to provide transparency on methodological or technical information that is required for high quality clinical practice guideline development is limited by the publication format requirements.
- There are limited formatting and guideline structure options available.
- There is a lack of clarity on who owns the guideline after publication (e.g. the journal or the College or the guideline development group).

Hereco found that some of the governance concerns with the existing RANZCP guidelines arose because of the publication format and **would suggest that the College consider a more dynamic way to present its clinical practice guidelines in future**, potentially in addition to publication in the ANZJP rather than as a replacement for this.

Hereco found also found that there are inconsistencies in the structure of the current suite of RANZCP guidelines. Variations include where and what/how much information is reported in the guideline. A potential solution to this is to have a template guideline structure with advice to authors and developers on what/how much information to provide.

6.6.2 Online publication

High quality clinical practice guidelines appear online in a variety of formats. Hereco notes that the current suite of RANZCP clinical practice guidelines is available on the RANZCP website, free of charge which is useful.

At a minimum, the WHO advises it's guideline development groups to produce a web ready portable document format (PDF)²² that are easy to download and navigate.(10) Depending on the length of the guideline and its intended audience, WHO advises that its guideline development groups consider providing full-text hypertext mark-up language (HTML) and additional materials, both electronic and printed.

6.6.3 MAGICapp

Hereco have been asked by RANZCP to comment on the publication platform 'MAGICapp' (Making GRADE the Irresistible Choice). MAGICapp is designed to develop and publish clinical practice guidelines using GRADE methodology and has built-in, standardised steps for evaluating evidence and developing recommendations consistent with the GRADE Approach. MAGICapp is a web based collaborative tool that does not require any software installation and allows publication on all devices. The current guidelines published on MAGICapp are freely available and can be viewed online without a subscription.²³

Although MAGICapp streamlines the development and review process, one of the downsides of MAGICapp is that the publication format is not as well structured as a PDF document (which is able to be edited by medical editors and graphic designers).

There is no set price for a MAGICapp subscription for guideline developers and pricing is based on organisation size and guideline development activity. Hereco has contacted MAGICapp for a quote for a subscription for RANZCP to publish their guidelines and MAGICapp indicated this would be approximately €50,000 per year.

6.6.4 Suggestions for format of future RANZCP clinical practice guidelines

Hereco suggests that depending upon budget and resourcing, that future RANZCP clinical practice guidelines are published in a PDF format or an online navigable webpage. A corresponding publication summarising the guideline can be published in a peer-reviewed journal to aid dissemination, but the journal publication version should not be the main guideline. This will enable more dynamic and contemporary guideline development and maintenance. Further detailed information on methods and evidence review can be published in separate methods and technical reports on the website, alongside the guidelines. An example of this is the Australian and New Zealand Guideline for Mild to Moderate Head Injuries in Children²⁴. This guideline is published in a PDF format, a summary webpage is available and the guideline is also published in a peer-reviewed journal for dissemination purposes.(26) The guideline methodology was also published in a peer review journal (27)

²² A web ready PDF is a smaller file size than the PDFs produced for print

²³ <https://app.magicapp.org/#/guidelines>

²⁴ <https://www.predict.org.au/head-injury-guideline/>

Key considerations: format of guidelines

- All RANZCP clinical practice guidelines are published as a journal article in the ANZJP in narrative, review article style. While this publication format provides benefits of peer review and recognition, for some readers, the journal article format makes the guidelines difficult to navigate (no index, table of contents/indication of structure), and can render them less contemporary.
- All RANZCP clinical practice guidelines are lengthy with no navigation aids which can make it difficult for the user to find the information that they are looking for. The College could consider engaging the assistance of a technical/medical writer or editor to assist with making the guidelines easier to navigate and more useable.
- Hereco found that some of the governance concerns with the existing suite of RANZCP guidelines arose because of the publication format and would suggest that the College consider a more dynamic way to present its clinical practice guidelines in future. Depending upon budget and resourcing, that future RANZCP clinical practice guidelines are published in a PDF format or an online navigable webpage.
- The names of all those involved in developing clinical practice guideline should be published in the guidelines.

6.7 Dissemination and implementation

6.7.1 Dissemination

Dissemination is the targeted distribution of information and materials about an evidence-based intervention to a specific public health or clinical practice audience. (28) Dissemination involves making guidelines accessible, advertising their availability, and distributing them widely. Effective dissemination and communication should be a carefully planned process that involves:

- considering the target audience,
- the message to get across and
- the communication strategies that will help achieve this.(7)

The best dissemination strategies involve consumers whose knowledge and lived experience are critical in the planning stages for dissemination and communication.(7) Involving consumers and other stakeholders in the dissemination planning process, as well as the guideline development phase helps to make sure that the format and language of any products is appropriate, useful and accessible. Consumers can also help you identify opportunities for promoting the guideline or identify potentially negative attention.

The most common clinical practice guideline dissemination strategy involves distribution of educational materials; however, this might not always be the best option for reaching the target audience.

The different needs of the target audiences should be considered and materials developed or adapted for each audience (while ensuring the key messages are maintained and consistent between formats).(7)

Proactive dissemination methods such as education campaigns, face to face workshops or social marketing campaigns are better than passive dissemination strategies. Evidence suggests that using a combined dissemination approach is more effective than using a single approach.(29)

It is helpful to document the approach and who will be responsible for various dissemination activities in a dissemination and communications plan.

There is further detailed information about developing a dissemination plan and considering ways to improve accessibility in the NHMRC's Guidelines for Guidelines Handbook, module "Dissemination and communication".²⁵

6.7.2 Implementation

Guidelines require investment and action to encourage adoption and operationalisation of the recommendations in practice. 'Implementation' is the process of putting recommendations into practice (NICE 2014) and requires thoughtful consideration, planning, consultation and partnership early and throughout the guideline development process.(7)

Many of the elements discussed earlier in this report are important for implementability of a guideline. These include: the scope of the guideline, ensuring trustworthiness through robust governance processes, forming actionable recommendations, public consultation prior to publishing, and the format of the guideline.(7)

²⁵ <https://www.nhmrc.gov.au/guidelinesforguidelines/implement/dissemination-and-communication>

Implementation strategies should be focused on making relevant groups aware of the guidelines to enhance their uptake. Barriers and facilitators to implementing a guideline may be revealed through public consultation.⁽⁷⁾ For example, public comments may lead to changes in the messaging of recommendations for different local contexts to tailor guidelines to specific settings. This information may also assist in prioritising some recommendations over others depending on the context, particularly if the guideline includes a large number of recommendations.

As part of hereco's consultations with key informants, it was discovered that there are no formal links between the College's guideline development process and the education/CPD areas of the College. To streamline implementation, the RANZCP could consider formal links to these areas following publication of guidelines.

Companion documents

There are many types of companion documents that help support implementation of clinical practice guidelines. The choice and format of any companion documents should be based on the needs of the target users of the guidelines. Some examples of companion documents to aid guideline implementation include:

- standalone summary of recommendations
- algorithms (e.g. RANZCOG's Intrapartum Fetal Surveillance algorithm²⁶)
- flow charts (e.g. the National Clinical Evidence (COVID-19) Taskforce flow charts²⁷)
- patient information (e.g. the Stroke Foundations' enable me patient information resource²⁸)
- implementation plan
- e-learning modules/webinars

There is further detailed information about improving implementability of guidelines in the NHMRC's Guidelines for Guidelines Handbook, module "Implementability".²⁹

6.7.3 Updating

A guideline should include an expiration date and/or describe the process that the guideline groups will use to update the recommendations.⁽⁸⁾ Guidelines become outdated at different rates depending on the availability of new evidence. NHMRC recommends that clinical guidelines are reviewed and revised no more than five years after publication. The updating schedule should be considered as the guideline is being developed and the plan and proposed methods for updating the guideline should be documented to ensure they are followed. It might be useful to consider the conditions that will determine when a partial or a full update of the guideline is required (e.g. if only certain recommendation statements need to be updated, or whether many recommendations are out of date making the entire guideline invalid, or when recommendations are necessary for newly available treatments).

²⁶ <https://ranzcof.edu.au/wp-content/uploads/2022/05/Intrapartum-Fetal-Surveillance-Clinical-Guideline-Fourth-Edition-Clinical-Algorithm.pdf>

²⁷ <https://clinicalevidence.net.au/covid-19/#clinical-flowcharts>

²⁸ <https://enableme.org.au/resources>

²⁹ <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/implementability>

Key considerations: dissemination, implementation and update frequency

- All RANZCP clinical practice guidelines are presented in narrative, review article style making them more difficult to navigate and potentially impacting on implementation.
- There are many types of companion documents that help support implementation of clinical practice guidelines. The choice and format of any companion documents should be based on the needs of the target users of the guidelines.
- It is unclear what formal mechanisms of implementation of clinical practice guidelines exist within the RANZCP (e.g. especially with the trainee or CPD programs) or what formal cross-over there is between the RANZCP clinical practice guidelines and other parts of the RANZCP education program. To streamline implementation, the RANZCP could consider formal links to these areas following publication of guidelines.
- The updating frequency of every five years was acceptable to most key informants interviewed. The updating frequency of guidelines should be agreed at the organisational level, noting that updating frequency may be different for different topics.

8 References

1. Institute of Medicine (U.S.). Committee on Standards for Developing Trustworthy Clinical Practice Guidelines., Graham R. Clinical practice guidelines we can trust. Washington, DC: National Academies Press; 2011. xxxiv, 266 p. p.
2. National Health and Medical Research Council. NHMRC Standards for Guidelines. 2016.
3. National Health and Medical Research Council. NHMRC standards and procedures for externally developed guidelines 2007.
4. Fervers B, Burgers JS, Voellinger R, Brouwers M, Browman GP, Graham ID, et al. Guideline adaptation: an approach to enhance efficiency in guideline development and improve utilisation. *BMJ Qual Saf.* 2011;20(3):228-36.
5. Misso M TH. Evidence based guideline (EBG) development: A practical guide. In: Illic D e, editor. Knowledge Transfer: Practice, Types and Challenges. New York:: Nova Publishers; 2012.
6. AGREE Next Steps Consortium. The AGREE II instrument 2017 [Available from: <http://www.agreetrust.org>].
7. National Health and Medical Research Council. Guidelines for Guidelines Handbook 2023 [Available from: www.nhmrc.gov.au/guidelinesforguidelines].
8. Qaseem A, Forland F, Macbeth F, Ollenschlager G, Phillips S, van der Wees P, et al. Guidelines International Network: toward international standards for clinical practice guidelines. *Ann Intern Med.* 2012;156(7):525-31.
9. Schunemann HJ, Wiercioch W, Etxeandia I, Falavigna M, Santesso N, Mustafa R, et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. *CMAJ.* 2014;186(3):E123-42.
10. World Health Organization (WHO). Handbook for Guideline Development - 2nd edition 2014.
11. National Institute for Health and Clinical Excellence. Developing NICE guidelines: the manual. London; 2014.
12. Scottish Intercollegiate Guidelines Network (SIGN). A guideline developer's handbook. Edinburgh; 2019.
13. Eccles MP, Grimshaw JM, Shekelle P, Schunemann HJ, Woolf S. Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning and conflicts of interest. *Implement Sci.* 2012;7:60.
14. National Health and Medical Research Council. Australian Clinical Practice Guidelines 2014 Annual Report. Canberra; 2014 July 2014.
15. Shalit A, Valley L, Nguyen R, Bohren M, Wilson A, Homer CS, et al. The representation of women on Australian clinical practice guideline panels, 2010-2020. *Med J Aust.* 2023;218(2):84-8.
16. Austin M-P HN, and the Expert Working Group. Mental Health Care in the Perinatal Period: Australian Clinical Practice Guideline. Melbourne: Centre of Perinatal Excellence; 2017.
17. Moynihan RN, Cooke GP, Doust JA, Bero L, Hill S, Glasziou PP. Expanding disease definitions in guidelines and expert panel ties to industry: a cross-sectional study of common conditions in the United States. *PLoS Med.* 2013;10(8):e1001500.
18. Fretheim A, Schunemann HJ, Oxman AD. Improving the use of research evidence in guideline development: 5. Group processes. *Health Res Policy Syst.* 2006;4:17.
19. Higgins J, D. Altman, et al.,. Chapter 8: Assessing risk of bias in included studies. J. Higgins and S. Green VuM, editor: The Cochrane Collaboration.; 2011.
20. GRADE Working Group. GRADE Handbook. Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. . H. Schünemann JB, G. Guyatt and A. Oxman., editor 2013.
21. National Health and Medical Research Council. NHMRC levels of evidence and grades for recommendations 2009

22. Burgers JS, Anzueto A, Black PN, Cruz AA, Fervers B, Graham ID, et al. Adaptation, evaluation, and updating of guidelines: article 14 in Integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. Proc Am Thorac Soc. 2012;9(5):304-10.
23. The ADAPTE Collaboration. The ADAPTE resource toolkit for Guideline Adaptation. Version 2.0. 2009.
24. National Clinical Evidence Taskforce. About the Taskforce 2022 [05 December 2022]. Available from: <https://clinicalevidence.net.au/about-the-guidelines/>.
25. Australian Living Evidence Consortium. The Living Guidelines Handbook: Guidance for the production and publication of living clinical practice guidelines [Internet]. 1.0. . 2022.
26. Babl FE, Tavender E, Ballard DW, Borland ML, Oakley E, Cotterell E, et al. Australian and New Zealand Guideline for Mild to Moderate Head Injuries in Children. Emerg Med Australas. 2021;33(2):214-31.
27. Tavender E, Ballard DW, Wilson A, Borland ML, Oakley E, Cotterell E, et al. Review article: Developing the Australian and New Zealand Guideline for Mild to Moderate Head Injuries in Children: An adoption/adaption approach. Emerg Med Australas. 2021;33(2):195-201.
28. McCormack L, Sheridan S, Lewis M, Boudewyns V, Melvin CL, Kistler C, et al. Communication and dissemination strategies to facilitate the use of health-related evidence. Evid Rep Technol Assess (Full Rep). 2013(213):1-520.
29. Grimshaw JM, Schunemann HJ, Burgers J, Cruz AA, Heffner J, Metersky M, et al. Disseminating and implementing guidelines: article 13 in Integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. Proc Am Thorac Soc. 2012;9(5):298-303.

Appendix 1 Environmental scan

For each Australian and New Zealand Medical College, the types of guidance documents produced were recorded (i.e. guidelines, clinical pathways, position statements etc.), along with the number of eligible high quality clinical practice guidelines as per the definition provided in Box 1.

For each included clinical practice guideline, the following information was recorded:

- Year published
- Edition
- Topic Area
- Developer
- Format
- Companion documents
- Funding
- Who is involved in producing the guideline
- Consultation type
- Update frequency
- Evidence base (e.g. was the guideline based on a de novo or published systematic review)
- Evidence to decision methods used (e.g. SIGN, FORM, GRADE, NHMRC Levels of evidence and grade for recommendations)
- Grading of strength of recommendations (i.e. A, B, C, D)

Below is a summary of governance and development characteristics of the included guidelines produced by Australian and New Zealand Medical Colleges (**Table 8**) and high quality guidelines produced by peak bodies (**Table 9**). The guidelines varied in the level of detail provided for each of these characteristics.

Table 8 Guideline development details – included clinical practice guidelines produced by Australian and New Zealand Medical Colleges

Guideline (year, edition) <i>Topic area</i>	Developer <i>Format</i> <i>Companion documents</i>	Funding	Who is involved in producing the guideline	Public consultation	Update frequency	Evidence base	Evidence to decision methods used	Grading of strength of recommendations
the white book (2022, 5 th edition) <i>Family violence</i>	RACGP <u>Format</u> <i>online and PDF download via developer website</i> <u>Companion documents</u> <i>Summary of recommendations, algorithm, useful tools</i>	External <u>Federal government</u> <i>Australian Government Department of Health</i>	a research team, chapter authors, advisory panel	not reported	not reported (has been updated every 6-10 years)	de novo SR	GRADE	<u>GRADE</u> (High, moderate, low, very low certainty of evidence) Evidence-based recs worded as strong or conditional Practice points (based on consensus of experts)
Endometriosis guidelines (2021, 1 st edition) <i>Endometriosis</i>	RANZCOG <u>Format</u> <i>PDF download via developer website</i> <u>Companion documents</u> <i>tools, patient information pamphlet, e-learning module</i>	External <u>Federal government</u> <i>Australian Government Department of Health</i>	organising committee, expert working group, methodologists	Open & targeted 6-week open public consultation promoted through existing communication channels, targeted correspondence, mainstream and social media.	every 3 years	published and de novo SR <i>ADAPTE process (adopted or adapted existing clinical practice guideline recommendations) or developed new recs based on de novo SRs</i>	GRADE	Evidence-based recs (High, moderate, low, very low quality of evidence) Consensus-based recs EEWG opinion
Intrapartum fetal surveillance (2019, 4 th edition) <i>Fetal surveillance</i>	RANZCOG <u>Format</u> <i>PDF download via developer website, option to purchase hard copy</i> <u>Companion document</u> <i>algorithm</i>	External <u>State government</u> <i>initial guideline funded by VMIA</i> Internal <i>update funded RANZCOG</i>	internal special interest and steering committees and external unit for literature search and critical appraisal	Targeted <u>Original guideline:</u> draft was circulated throughout Australia and New Zealand to Fellows, Diplomates, Midwives, the RACGP, the ACRRM and consumers <u>4th edition:</u> stakeholder consultation was undertaken and further amendments made following feedback.	every 4 years, unless a significant change is identified prior to this	de novo SR	NHMRC Levels of Evidence and Grades for Recommendations for Developers of Guidelines	Evidence-based recs (A, B, C, D) Consensus-based recs, Good practice notes

Guideline (year, edition) <i>Topic area</i>	Developer <i>Format</i> <i>Companion documents</i>	Funding	Who is involved in producing the guideline	Public consultation	Update frequency	Evidence base	Evidence to decision methods used	Grading of strength of recommendations
guideline for the management of knee and hip osteoarthritis (2018, 2 nd edition) <i>Osteoarthritis</i> <i>NHMRC approved</i>	RACGP <i>Format</i> <i>online and PDF download via developer website</i> <i>Companion documents</i> <i>Summary of recommendations, algorithm, implementation plan</i>	External health insurance foundation <i>Medibank Better Health Foundation</i>	an expert multidisciplinary working group, medical librarian	Open & Targeted <i>Duration:</i> 1 month, <i>Promotion:</i> RACGP website and social media channels, NHMRC Health Tracker. <i>Invitations:</i> sent to relevant federal and state government agencies, including the Australian Government Department of Health Chief Medical Officer and state chief health officers. <i>Emails:</i> consultation documents emailed to a wide range of external experts and potential users, and key internal stakeholders identified by the project team and working group. <i>Documentation:</i> de-identified public consultation summary accompanies the guideline. A list of the professional organisations, and disciplines of individual responders recorded in the administrative report.	every 5 years	de novo SR	GRADE	GRADE: strong for or against, conditional for, against or neutral. <i>Quality of evidence:</i> high, moderate, low, very low
osteoporosis prevention, diagnosis and management in postmenopausal women and men over the age of 50 (2017, 2 nd edition) <i>Osteoporosis</i>	RACGP & Osteoporosis Australia <i>Format</i> <i>online and PDF download via developer website</i> <i>Companion documents</i> <i>flowchart</i>	External Industry <i>Amgen Australia, Actavis Australia, Pfizer Australia and Servier Laboratories (Aust)</i>	multidisciplinary expert working group	Targeted & limited public (due to resource and time restrictions) <i>Stakeholder consultation:</i> consultation focused on Osteoporosis Australia stakeholders GPs (the main users of the guideline): GP subject matter experts and RACGP's Expert Committee for Quality Care <i>Public feedback:</i> Ongoing feedback on the guideline is encouraged and can be submitted via the online feedback tab.	not reported (1st and 2nd edition published 7 years apart)	de novo SR	NHMRC Levels of Evidence and Grades for Recommendations for Developers of Guidelines	A, B, C, D (Grade D used where there is expert consensus in the absence of a strong body of evidence)

Guideline (year, edition) <i>Topic area</i>	Developer <i>Format</i> <i>Companion documents</i>	Funding	Who is involved in producing the guideline	Public consultation	Update frequency	Evidence base	Evidence to decision methods used	Grading of strength of recommendations
supporting smoking cessation (2014, 2 nd edition) <i>Smoking cessation</i>	RACGP <u>Format</u> <i>online via developer website</i> <u>Companion documents</u> <i>Summary of Recommendations</i>	External <u>Federal and State government</u> <i>Australian Government Department of Health & VicHealth</i>	methodologists, expert advisory group	not reported	not reported (unclear when 1 st edition was published)	de novo SR	NHMRC classification system used for 1 st edition, for 2 nd edition GRADE used for new evidence, NHMRC translated to GRADE for areas with no new evidence	<u>GRADE</u> : Strong, weak or conditional

Abbreviations: ACRRM, Australian College of Rural and Remote Medicine; GP, general practitioner; GRADE, Grading of Recommendations, Assessment, Development and Evaluations; NHMRC, National Health and Medical Research Council; RACGP, Royal Australian College of General Practitioners; RANZCO, Royal Australian and New Zealand College of Ophthalmologists; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists; recs, recommendations; SR, systematic review; VMIA, Victorian Managed Insurance Authority.

Table 9 Guideline development details –included clinical practice guidelines produced by Australian peak bodies.

Guideline (year, edition) <i>Topic area</i>	Developer <i>Format</i> <i>Companion documents</i>	Funding	Who is involved in producing the guideline	Public consultation	Update frequency	Evidence base	Evidence to decision methods used	Grading of strength of recommendations
Australian Asthma Handbook (2022, 13 th edition, version 2.2) <i>asthma diagnosis and management in adults and children in primary care</i>	National Asthma Council <i>Format</i> <i>online (standalone, navigable website, information can be difficult to find)</i> <i>Companion documents</i> <i>Medicines guide; tools (control questionnaires, peak flow chart, spirometry); patient resources (guides, charts, videos); definitions</i>	Internal <i>majority self-funded (not-for-profit, funded by government and pharma)</i> External <i>remainder funded by unrestricted sponsorship (industry, government, donations and cause-related marketing program, Sensitive Choice.)</i>	multidisciplinary guidelines committee, working groups, other external experts consulted as needed (clinical experts; methodology consultant for evidence synthesis and formulation of recommendation s; medical writer; website developer); secretariat (project manager, project officer, communications, admin staff)	Targeted Duration: 4-weeks Stakeholder consultation: External industry stakeholder organisations invited (around 32 organisations, including: National Asthma Council Australia member bodies; peak medical bodies, including relevant Colleges and associations of health professions; other asthma-related organisations including patient advocacy organisation; pharmaceutical companies with a respiratory interest. Each submission is considered by the Secretariat and Guidelines Committee during the finalisation phase of the Handbook’s development.	Frequently updated guideline ad hoc major or minor updates in line with publication of National Asthma Council information papers, or guidance from other relevant organisations	de novo SR (“structured literature reviews”) for suitable topics Existing SRs and clinical practice guidelines for topics not selected for de novo SR	Adaptation based on GRADE	Adaptation based on GRADE Rec types: Evidence-based (no level or certainty of evidence provided) Consensus (following inconclusive literature search) Adapted from existing guidance Consensus (with reference to named sources) Consensus rec <i>Versions 1.0-1.3 used NHMRC levels of evidence and grades for recs for developers of guidelines. (2009).</i>
Living Clinical Guidelines for Stroke Management (living guidelines, last updated 2022, PICO questions reviewed annually, literature monitored monthly) <i>Management of Stroke and TIA</i> NHMRC approved	Stroke Foundation & Cochrane Australia <i>Format</i> <i>online via MAGICapp platform, ability to save current version as PDF, or to subscribe to be notified of guideline updates</i> <i>Companion documents</i> <i>Practical info</i> <i>Decision aids</i>	External Australian Government, Medical Research Future Fund.	Content steering group, project team, clinical/ content experts, expert working groups, consumer panel, systematic reviewers and guideline developers	Open Duration: 7-weeks Advertised via website, feedback collected via MAGICapp	Living guideline Updated as new evidence emerges	de novo SR (PICO questions reviewed annually, literature monitored monthly for new studies)	GRADE	GRADE Evidence-based recs (strong or weak) Practice statements/practice points (based on consensus and expert opinion, guided by any underlying or indirect evidence) <i>Under each rec where available they provide details of: research evidence, evidence to decision, rationale, practical info, decision aids, references</i>

Guideline (year, edition) <i>Topic area</i>	Developer <i>Format</i> <i>Companion documents</i>	Funding	Who is involved in producing the guideline	Public consultation	Update frequency	Evidence base	Evidence to decision methods used	Grading of strength of recommendations
Clinical practice guidelines for keratinocyte cancer (version 2, November 2019) Diagnosis and management of keratinocyte cancer (basal cell and cutaneous squamous cell carcinoma) in Australia NHMRC approved	Cancer Council Australia Format Navigable online via cancer wiki web-based guideline platform Companion documents Summary of recs Plain language summary Administrative report Dissemination plan Quick reference guide for GPs	External Government <i>Commissioned by the Australian Government Department of Health</i>	Multidisciplinary management/steering committee; multidisciplinary working party (including 2 consumer reps); subcommittees for guideline sections; project manager, senior systematic reviewer, systematic reviewer, two project officers, medical editor	Open Duration: varies, 30-days for guidelines seeking NHMRC approval, shorter for others. Submissions invited from the general public, professional societies and groups, and other relevant stakeholders. Relevant professional societies and groups, consumer groups and other relevant stakeholders are notified in advance of public consultation periods. Promotion: Notices are placed on guideline landing pages as well as the main guideline home page for individuals to be added to notification and launch lists	Every 5 years for entire guideline. However, newly published evidence is monitored. If strong evidence supporting a change in the guideline is published, the working party will consider if an update is required for a specific section	de novo SR <i>after failing to find any appropriate pre-existing guidelines</i>	NHMRC <i>NHMRC additional levels of evidence and grades for recs for developers of guidelines (2009)</i>	NHMRC (A,B,C,D) Evidence-based recs Consensus-based recs Practice Points
National Perinatal Mental Health Guideline (October 2017, 2023 update in process) Screening, prevention and treatment of mental health conditions in the perinatal period NHMRC approved	COPE Format PDF downloadable via COPE website Companion documents consumer fact sheets and email series; health professional fact sheets, clinical tools and scoring guides	External Commonwealth Government	Expert working group, harms expert committee, consumer and carer representatives, low prevalence disorder expert committee, guideline methodologists, technical writer	Open Duration: 1 month Information about consultation distributed by professional bodies that are members of COPE to College members and consumer groups. State and Territory Directors of health, perinatal consumer organisations, primary healthcare networks, peak bodies informed. Peak bodies/leaders in perinatal mental health working with Aboriginal and Torres Strait Islander and culturally and linguistically diverse (CALD) populations, approached for feedback. Promotion: Notice of public consultation actively promoted through member newsletters, blogs and social media	At least every 5 years	de novo SR	GRADE/NHMRC FORM used to inform GRADE-style recs	Evidence-Based Recs (strong or conditional) Consensus-Based Recs Practice Points

Abbreviations: CALD, Culturally and linguistically diverse; COPE, Centre of Perinatal Excellence; GP, general practitioner; GRADE, Grading of Recommendations, Assessment, Development and Evaluations; MAGICapp (Making Grade the Irresistible Choice); NHMRC, National Health and Medical Research Council; PICO, Patient Intervention Comparator Outcome; recs, recommendations; reps, representatives; SR, systematic review; TIA, transient ischemic attack.

Appendix 2 High quality evidence-based clinical practice guidelines endorsed by Australian and New Zealand Medical Colleges

To examine high quality evidence-based clinical practice guidelines developed by other organisations but endorsed by Australia and New Zealand Colleges, we looked at the guidelines endorsed by the RANZCP as well as RACGP and RANZCOG (the two Medical Colleges with the greatest number of endorsed, externally produced guidelines). We identified 15 included endorsed guidelines (see **Table 10**).

Development: The guidelines varied in the level of detail provided regarding their development. Many were developed with two or more organisations in partnership.

Endorsement: Some guidelines were endorsed by a one or two Medical Colleges, while others had broader stakeholder buy-in.

Funding: 10 guidelines were externally funded by a mixture of Government, industry and others; 4 were internally funded and 1 used a combination of internal and external funding sources.

Table 10 Australian and New Zealand College endorsed (externally produced) guidelines

Guideline	Topic Area	Developed by	Endorsed by	Funded by
Clinical practice guidelines PSA testing and early management of test-detected prostate cancer	Prostate cancer	Cancer council Australia & prostate cancer foundation of Australia	Medical Colleges RACGP, RCPA, RANZCR, ACRRM Others Urological society of Australia and NZ	Internal <i>Prostate Cancer Foundation of Australia with Cancer Council Australia contributing in-kind resources of their guideline development team.</i>
Clinical Practice Guideline for the Care of Women with Decreased Fetal Movements	Pregnancy - decreased fetal movements	Perinatal Society of Australia and New Zealand (PSANZ)	Medical Colleges RANZCOG, ACM, RACGP Others Stillbirth Foundation Australia, Australian National Council for Stillbirth and Neonatal Death Support (SANDS), National SIDS Council of Australia Ltd (SIDS and Kids), Still Aware	External <u>Community-based fundraising organisation</u> <i>Mater Foundation, Mater Health Services</i>

Guideline	Topic Area	Developed by	Endorsed by	Funded by
Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death	Pregnancy – still birth and neonatal death	The Stillbirth and Neonatal Death Alliance (SANDA) of PSANZ and in partnership with the Centre of Research Excellence in Stillbirth.	<p>Medical Colleges RANZCOG, ACM</p> <p>Others Australian and New Zealand Neonatal Network; Queensland Maternal and Perinatal Quality Council; Red Nose; Sands; Stillbirth Foundation Australia; South Australian Maternal and Perinatal Mortality Committee; Tasmanian Council of Obstetric and Paediatric Mortality and Morbidity; Women’s Healthcare Australasia; Victorian Consultative Council on Obstetric and Paediatric Morbidity and Mortality.</p>	<p>Internal <i>Support for guideline development was received from PSANZ</i></p>
Patient blood management guidelines, modules 1-5	Blood management	<p>Managed by National Blood Authority.</p> <p>Multiple Colleges and Societies (listed below) and an independent consumer advocate</p> <p><i>ACEM, ANZCA, Australian and New Zealand Intensive Care Society, Australian and New Zealand Society of Blood Transfusion, Australian Orthopaedic Association, Australian Red Cross Blood Service, College of Intensive Care Medicine of Australia and New Zealand, Haematology Society of Australia and New Zealand, RANZCOG, RACP, RACS, RCNA, Royal College of Pathologists of Australasia, Thalassaemia Australia</i></p>	<p>Medical Colleges ACEM, ANZCA, CICM, RACS, RANZCOG, RCNA, RCPA</p> <p>Others Australasian Society for Emergency Medicine, Australian and New Zealand Intensive Care Society, Australian Red Cross Lifeblood, Medical Oncology Group of Australia, Perinatal Society of Australia and New Zealand</p>	<p>Internal <i>The National Blood Authority</i></p>
The Australian guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (2nd edition)	Rheumatic fever / rheumatic heart disease	National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, RHD Australia, Menzies school of health research	<p>Medical Colleges ACRRM, RACGP, RACP</p> <p>Others Australian Indigenous Doctors’ Association, Australasian Society for Infectious Diseases, Council of Remote Area Nurses, Cardiac Society of Australia and New Zealand, Internal Medicine Society of Australia and New Zealand, National Aboriginal Community Controlled Health Organisation, National Heart Foundation of Australia, Public Health Association of Australia, Society of Obstetric Medicine of Australia and New Zealand, The Australian and New Zealand Society of Cardiac and Thoracic Surgeons</p>	<p>External Australian Government Department of Health and Ageing</p>

Guideline	Topic Area	Developed by	Endorsed by	Funded by
Clinical Practice Guideline for Perinatal Mortality	Pregnancy - perinatal mortality	The Perinatal Mortality Group of the Perinatal Society of Australia and New Zealand in collaboration with the Australian and New Zealand Stillbirth Alliance. The Mater Mothers' Research Centre, Mater Health Services, Brisbane.	Medical Colleges RANZCOG Others Perinatal Society of Australia and New Zealand; Australian and New Zealand Stillbirth Alliance; Australian College of Midwives Incorporated; SIDS and Kids; SANDS (QLD); Australian College of Neonatal Nursing (previously Australian Neonatal Nursing Association); Bonnie Babes Foundation; Stillbirth Foundation Australia.	External The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Stillbirth and Neonatal Death Support Group Qld (SANDS Qld Inc), and SIDS and Kids Qld for providing financial assistance for the first version of the guideline
Australian asthma handbook	Asthma	published by the National Asthma Council Australia.	Medical Colleges RACGP Others	Internal <i>self-funded the majority of the development costs.</i> External <i>sponsorship from the pharmaceutical companies in asthma, government program funding, donations and its cause-related marketing program, Sensitive Choice.</i>
COPD-X Concise guide	Chronic obstructive pulmonary disease	published by the Lung Foundation Australia	Medical Colleges RACGP Others Thoracic Society of Australia & New Zealand	External <i>Ongoing logistical and financial support for the development of the COPD-X Guidelines is provided by Lung Foundation Australia as part of its national COPD program. This program receives sponsorship funding from a number of industry partners.</i>
Guidelines for the assessment and management of absolute CVD risk	Cardiovascular disease	published by the Stroke Foundation.	Medical Colleges RACGP	External <i>Financial assistance provided by the Australian Government Department of Health and Ageing</i>
Clinical guideline for the diagnosis and management of work-related mental health conditions in general practice	Mental health	Monash University	Medical Colleges RACGP, ACRRM	External <i>Development of this guideline was supported by the Australian Government Department of Jobs and Small Business and Comcare, Office of Industrial Relations – Queensland Government, State Insurance Regulatory Authority (NSW), ReturntoWorkSA and WorkCover WA. The development of the final recommendations has not been influenced by the views or interests of the funding bodies</i>

Guideline	Topic Area	Developed by	Endorsed by	Funded by
Clinical practice guidelines for keratinocyte cancer	Cancer	published by the Cancer Council Australia.	Medical Colleges RACGP	Internal + volunteers <i>These new keratinocyte cancer guidelines were put together by a multidisciplinary working party group of volunteers to revise the 2008 guidelines + staff member from Cancer Council Australia overseeing and encouraging the revision of the guidelines + a medical writer and editor</i>
Australian and New Zealand Guideline for Acute Management of Mild to Moderate Head Injuries in Children	Paediatric head injury	Paediatric Research in Emergency Departments International Collaborative (PREDICT), Murdoch Children's Research Institute	Medical Colleges RACGP	External - grant <i>National Health and Medical Research Council (NHMRC) Centre of Research Excellence grants for Paediatric Emergency Medicine</i>
Australian Guidelines for the Prevention and Treatment of Acute Stress Disorder, Posttraumatic Stress Disorder and Complex PTSD	Acute stress disorder, PTSD and complex PTSD	produced by Phoenix Australia – Centre for Posttraumatic Mental Health, Department of Psychiatry, University of Melbourne	Medical Colleges RANZCP, RACGP Others The Australian Psychological Association	External <i>Commonwealth Departments of Health and Veterans' Affairs.</i>
Cholinesterase inhibitors and memantine - deprescribing (2017)	Dementia	The University of Sydney; NHMRC Partnership Centre: Dealing with Cognitive and Related Functional Decline in Older People (Cognitive Decline Partnership Centre); Bruyère Research Institute/Deprescribing Guidelines in the Elderly Project	Medical Colleges RANZCP Others Australian and New Zealand Society of Geriatric Medicine (ANZSGM); Tasmanian Health Service: Royal Hobart Hospital; Canadian Geriatrics Society (CGS); Canadian Society of Hospital Pharmacists (CSHP)	External <i>The NHMRC-ARC Dementia Research Development Fellowship; Northern Clinical School and Faculty of Medicine, University of Sydney.</i>
Dementia (2016)	Dementia	Lead by NHMRC Partnership Centre for Dealing with Cognitive and Related Functional Decline in Older People.	Medical Colleges ACRRM, RANZCP, RACGP Others Alzheimer's Australia; Australian and New Zealand Society for Geriatric Medicine; Exercise and Sports Science Australia; Occupational Therapy Australia; Speech Pathology Australia.	External <i>NHMRC Partnership Centre for Dealing with Cognitive and Related Functional Decline in Older People. The Partnership Centre receives support from the NHMRC and Funding Partners, including HammondCare, Alzheimer's Australia, Brightwater Care Group and Helping Hand Aged Care</i>

Abbreviations: ACEM, Australasian College for Emergency Medicine; ACM, Australian College of Midwives; ACRRM, Australian College of Rural & Remote Medicine; ANZCA, Australian and New Zealand College of Anaesthetists; CICM, College of Intensive Care Medicine of Australia and New Zealand; RACGP, Royal Australian College of General Practitioners; RACP, Royal Australasian College of Physicians; RACS, Royal Australasian College of Surgeons; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists; RANZCP, Royal Australian and New Zealand College of Psychiatrists; RANZCR, Royal Australian and New Zealand College of Radiologists; RCNA, Royal College of Nursing Australia; RCPA, Royal College of Pathologists of Australasia.