



THE UNIVERSITY OF
SYDNEY

Evidence-Based Clinical Practice Guideline for Deprescribing Opioid Analgesics

Administrative Report

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The full guideline and supporting documents are available at:
www.opioiddeprescribingguideline.com.au

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Background

Healthcare professionals across a range of disciplines acknowledge that opioid deprescribing is a complex and challenging practice, with continued prescribing the default behaviour.¹ Evidence-based opioid deprescribing guidelines have been identified as a valuable resource for healthcare professionals to support clinical decision-making and reduce suboptimal opioid use.¹ There are currently no evidence-based guidelines internationally that specifically focus on the deprescribing of opioids. The Evidence-Based Clinical Practice Guideline for Deprescribing Opioid Analgesics has been developed to provide recommendations on when and how to deprescribe opioids, for adults prescribed opioids for pain in primary care settings.

This guideline was registered on the Australian Clinical Practice Guideline Register on the 29th of August 2019. It has been developed according to the National Health and Medical Research Council's Standard for Clinical Practice Guidelines, Guideline Development and Conflicts of Interest: Identifying and Managing Conflicts of Interest of Prospective Members and Members of the NHMRC Committees and Working Groups Developing Guidelines, and Section 14A of the National Health and Medical Research Council Act 1992. This Administrative Report details the information required by the NHMRC in accordance with the requirements of the NHMRC Standards for Clinical Practice Guidelines 2011.

Funding

The development, publication and dissemination of the guideline were funded through a Research Training Program Scholarship Stipend (valued at \$38,464.92 per annum, 76.7% of total funding) and a supplementary scholarship from the University of Sydney (valued at \$10,000 per annum, 20% of total funding) awarded to PhD Candidate Aili V Langford. The research team were awarded a 2019 Sydney Pharmacy School, Faculty of Medicine and Health, University of Sydney Research Support Grant (valued at \$5000, 3.3% of total funding). Individual guideline development group members received funding from the NHMRC during guideline development, however these grants did not directly fund guideline development activities. Professor CWC Lin is funded by an NHMRC Investigator Grant (1193939). Associate Professor D Gnjdic is funded by the NHMRC Dementia Leadership Fellowship (1136849). Dr E Reeve is funded by an NHMRC Dementia Research Development Fellowship (1105777) and Investigator Grant (1195460). The funding bodies were not involved in guideline development and as such the views and/or interests of the funding bodies have not influenced the guideline recommendations.

Governance

Organisation

The University of Sydney is the organisation responsible for developing and publishing the guideline.

Core Guideline Group

The Core Guideline Group consisted of Guideline Development Group (GDG) members AV Langford, CR Schneider, CWC Lin and D Gnjjidic. The GDG co-chairs were D Gnjjidic and CR Schneider. AV Langford was the first author of the guideline and its accompanying documents. The core guideline group led the GDG and were responsible for inviting members to the GDG, assessing and managing conflicts of interest, ensuring guideline progression in accordance with planned timelines, liaising with external stakeholders and leading projects related to guideline development such as stakeholder perspective research.

Process and criteria for selecting GDG members

We recruited GDG members who were either content experts, end-users, methodology experts, implementation experts or consumers. We sought to include healthcare professionals who are involved in the prescription or monitoring/management of prescriptions of opioids (end-users). At a minimum, we intended for our GDG to have at least one member from the following groups: GPs (family physicians, primary care physicians), pain specialists, addiction specialists, pharmacists and registered nurses. To recruit potential content experts, end-users and methodology experts, we contacted local and international experts in relevant fields. All potential members were invited via an email which briefly explained the aim of the guideline and the process of guideline development. If a potential member declined, they were asked to suggest another person in their place. If they expressed an interest in participating, they were provided with more information (via email or in-person) and were asked to complete the conflict of interest (COI) form. The consumer representative was remunerated for her time. Other GDG members received no reimbursement for their involvement in guideline development.

GDG Members

The GDG was composed of 17 members who were:

- Healthcare professionals (general practitioners, pain specialists, addiction specialists, registered nurses, pharmacists, physiotherapists) with experience in caring for persons taking opioids and research expertise in the field of deprescribing in Australia and internationally.
- Methodologists with expertise in the areas of deprescribing guideline development, conducting systematic reviews and the GRADE approach.
- Implementation experts.
- Organisational representative.
- Consumer representative.

All members of the GDG along with their affiliations and expertise are listed in [Table 1](#). Other individuals involved in the development of the guideline who were not a formal member of the GDG are listed in [Table 2](#), along with their affiliation(s), profession and role in guideline development.

Table 1: Guideline Development Group members, affiliations and expertise

Name	Organisational affiliation(s)	Profession/discipline/expertise
Ms Aili V Langford	Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, NSW, Australia	Pharmacist PhD candidate
Associate Professor Danijela Gnjidic	Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, NSW, Australia	Deprescribing Expert Pharmacologist
Dr Carl R Schneider	Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, NSW, Australia	Registered Nurse Pharmacist
Professor Chung-Wei Christine Lin	Institute of Musculoskeletal Health, School of Public Health, The University of Sydney, NSW, Australia	Physiotherapist Methodologist
Professor Lisa Bero	University of Colorado Anschutz Medical Center, Schools of Medicine and Public Health, Colorado, USA	Methodologist Systematic Review Expert
Professor Fiona M Blyth	School of Public Health, Faculty of Medicine and Health, The University of Sydney, NSW, Australia	Public Health Physician Pain Epidemiologist
Professor Jason N Doctor	Sol Price School of Public Policy, University of Southern California, California, USA	Behavioural Scientist Implementation Expert
Dr Simon Holliday	School of Medicine and Public Health, University of Newcastle, NSW, Australia; HealthHub Taree	General Practitioner Addiction Physician
Professor Yun-Hee Jeon	Sydney Nursing School, Faculty of Medicine and Health, University of Sydney, NSW, Australia	Registered Nurse Nurse Gerontologist Methodologist
Dr Joanna C Moullin	School of Population Health, Faculty of Health Sciences, Curtin University, WA, Australia	Implementation Scientist Pharmacist
Associate Professor Bridin Murnion	Discipline of Addiction Medicine, Faculty of Medicine and Health,	Clinical Pharmacologist Addiction Medicine

	The University of Sydney, NSW, Australia	Pain Medicine
Associate Professor Suzanne Nielsen	Monash Addiction Research Centre, Faculty of Medicine, Nursing and Health Sciences, Monash University, VIC, Australia	Content Expert Pharmacist
Ms Rawa Osman	NPS MedicineWise, NSW, Australia	Organisational Representative Pharmacist
Dr Jonathan Penm	Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, NSW, Australia	Pharmacist Content Expert
Dr Emily Reeve	Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University (Parkville Campus), VIC, Australia	Pharmacist Deprescribing Expert Deprescribing Guidelines Expert
Dr Sharon Reid	Royal Australian College of General Practitioners; Specialty of Addiction Medicine, Central Clinical School, Faculty of Medicine and Health, University of Sydney, NSW, Australia; Drug Health Services, Sydney Local Health District, NSW, Australia.	General Practitioner Senior Lecturer, Specialty of Addiction Medicine Medical Officer, Drug Health Services, Sydney Local Health District
Dr Janney Wale	Independent consumer representative	Community Engagement

Table 2: Non-Guideline Development Group members and role in guideline development

Name	Organisational affiliation(s)	Profession/discipline <i>Role in guideline development</i>
Ms Benita Suckling	Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, NSW, Australia; Metro North Health, Queensland Health, QLD, Australia	Pharmacist MPhil Candidate <i>Reviewer for overview of systematic review (title/abstract screening, full text screening and eligibility assessment)</i>

Dr Jack Collins	Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, NSW, Australia	Pharmacist Post-doctoral Research Associate <i>Reviewer for overview of systematic reviews (Risk of Bias Assessment, GRADE Assessment)</i>
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We also wish to thank Yulia Ulyannikova, Academic Librarian at The University of Sydney, Australia, for assistance in developing the search strategy for the overview of systematic reviews, and Melanie Hamilton, MPhil Candidate at the Institute for Musculoskeletal Health at the University of Sydney and her research team for their contributions to Appendix 1 of the Guideline: ‘Opioid deprescribing in patients with chronic non-cancer pain: A systematic review of international guidelines’.²

GDG Roles and Responsibilities

The GDG was responsible for overseeing development of the guideline. This included:

- Refining the guideline scope and key clinical questions.
- Reviewing the research-evidence and certainty of evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.
- Making consensus statements and practice points where there was insufficient research evidence to formulate a recommendation.
- Reviewing the evidence and draft recommendations.
- Reviewing the first draft of the guideline.
- Reviewing the draft guideline following feedback from the public consultation.
- Reviewing the draft guideline following feedback from methodological review.
- Finalising the draft guideline for submission to NHMRC for consideration of approval.

[Table 3](#) specifies the roles and contributions of GDG members to specific guideline tasks and sections.

Table 3: Roles and responsibilities of GDG members

Activity	Most responsible person†	Support people±
Stakeholder perspective research	AV Langford	D Gnjidic CWC Lin CR Schneider L Bero FM Blyth J Penm
Overview of systematic reviews	AV Langford	D Gnjidic CWC Lin CR Schneider

		B Suckling J Collins
Dissemination and implementation plan	AV Langford	J Moullin CR Schneider D Gnjidic CWC Lin
Guideline sections		
Plain English Summary	AV Langford	D Gnjidic CWC Lin CR Schneider J Wale
Executive Summary	AV Langford	D Gnjidic CWC Lin CR Schneider
Background	AV Langford	D Gnjidic CWC Lin CR Schneider
Scope	AV Langford	D Gnjidic CWC Lin CR Schneider
Guiding Principles	AV Langford	D Gnjidic CWC Lin CR Schneider E Reeve
Methods	AV Langford	D Gnjidic CWC Lin CR Schneider L Bero
Recommendations	AV Langford	All members of GDG
Areas of major debate	AV Langford	All members of GDG
Summary of findings	AV Langford	All members of GDG
Stakeholder values and preferences	AV Langford	D Gnjidic CWC Lin CR Schneider L Bero FM Blyth J Penm

Resource requirements	AV Langford	D Gnjidic CWC Lin CR Schneider
Clinical considerations	AV Langford	All members of GDG
Ethical and legal considerations	AV Langford	D Gnjidic CWC Lin CR Schneider
Opioid related harm minimisation strategies	AV Langford	S Nielsen B Murnion
Population considerations	AV Langford	D Gnjidic CWC Lin CR Schneider
Other Guidelines and Resources on Opioid Deprescribing	AV Langford	D Gnjidic CWC Lin CR Schneider
Gaps in knowledge and future research	AV Langford	CR Schneider D Gnjidic CWC Lin
Plans for updating guidelines	AV Langford	CR Schneider D Gnjidic CWC Lin
Conclusion	AV Langford	CR Schneider D Gnjidic CWC Lin

Note: All GDG members were provided the opportunity to review/comment on all sections of the guideline.

†Person responsible for leading task and/or drafting section

±People responsible for reviewing and revising the first draft of the section/assisted with completion of the task prior to sending to whole GDG

Declaration and management of conflicting interests

All GDG members were required to declare any potential or perceived COIs. Where possible, potential COIs were reviewed prior to inviting members (for example, recent publications reviewed for COIs). After the invitation to join the GDG was accepted, each GDG member was asked to complete the COI form. Each member completed the International Committee of Medical Journal Editors (ICMJE) Disclosure of Interest Form. The purpose of disclosure of interests was to provide information on financial, business/professional and intellectual competing interests related to the topic addressed.

GDG members were asked at all meetings and prior to the public consultation period if they had any new interests to declare, and their forms were updated accordingly. All COIs and

management plans were disclosed at the first GDG meeting to provide all members an opportunity to voice any concerns about interests relating to other GDG members. Members were asked to inform the core GDG if at any point between meetings, a new conflict arose. Disclosures were required in relation to relationships/activities/interests in the three years preceding and any anticipated relationships/activities/interests in the twelve months following appointment to the GDG. If a COI was declared, it was documented and if required, a management plan was discussed between the core guideline group and the group member. Completed disclosure forms and management plans were kept electronically by AV Langford. Individual guideline members' COIs and management plans are listed in [Table 4](#) and non-GDG members' COIs are listed in [Table 5](#).

Table 4: Disclosure of potential conflicts of interest of GDG members

Name	Declared Conflict of Interest	Management Plan
Ms Aili V Langford	Nil.	Not applicable.
Associate Professor Danijela Gnjidic	Nil	Not applicable.
Dr Carl R Schneider	Nil	Not applicable.
Professor Chung-Wei Christine Lin	Nil	Not applicable.
Professor Lisa Bero	L Bero is a panel member of the guideline development group for the WHO guideline entitled 'A Guideline on balanced national policies for ensuring access to and preventing unsafe use of controlled medicines'.	Conflict of interest assessed by core GDG, no action required.
Professor Fiona M Blyth	Nil.	Not applicable.
Professor Jason N Doctor	JN Doctor served as a consultant and received payments for work conducted on behalf of Precision Health Economics a consulting group in 2017.	Conflict of interest assessed by core GDG, no action required.
Dr Simon Holliday	Nil.	Not applicable.
Professor Yun-Hee Jeon	Nil.	Not applicable.
Dr Joanna C Moullin	Nil.	Not applicable.
Associate Professor Bridin	Nil.	Not applicable.

Murnion

Associate Professor Suzanne Nielsen	S Nielsen was a named investigator on united educational grants from Indivior (exploring new treatments for opioid dependence) and Seqirus (to understanding monitoring harms from prescription opioids as reported in ambulance attendance and emergency department data). S Nielsen's institution has received honoraria from Indivior for delivering training on identifying and treating codeine dependence.	Conflict of interest assessed by core GDG, no action required.
Ms Rawa Osman	NPS MedicineWise receives funding from the Department of Health. NPS MedicineWise launched a national program on 'Opioids, chronic pain and the bigger picture'.	Conflict of interest assessed by core GDG, no action required.
Dr Jonathan Penm	Nil.	Not applicable.
Dr Emily Reeve	Nil.	Not applicable.
Dr Sharon Reid	Nil.	Not applicable.
Dr Janney Wale	Nil.	Not applicable.

Table 5: Disclosure of potential conflicts of interest of non-GDG members involved in guideline development

Name	Declared Conflict of Interest	Management Plan
Ms Benita Suckling	Nil.	Not applicable.
Dr Jack Collins	Nil.	Not applicable.

Consumer involvement in the GDG

An initial stage of guideline development involved stakeholder perspective research with consumers.³ A purposive sample of people taking one or more opioids for the management of pain was recruited. Participants with both acute and chronic pain conditions were sought.

Study advertisements were distributed through PainAustralia, community pharmacies and Facebook. An interview guide was developed from a review of the literature and discussion with experienced healthcare professionals and researchers. Interview questions related to the management of opioids, interactions with healthcare professionals and resources to support the development of opioid deprescribing guidelines. Findings from this study informed the guideline scope, key clinical questions and recommendations through incorporation into the evidence-to-decision framework.

We sought to recruit a consumer with lived experience of pain who currently/previouslly uses/used opioid(s) for the management of pain. The position for consumer representative on the guideline was advertised through The Consumers Health Forum. The core guideline group reviewed expressions of interest and applications to join the GDG. As a GDG member, they attended each GDG meeting and provided input throughout the entire development process. A targeted approach was utilised during the public consultation process to obtain feedback from key consumer representative organisations. Individual consumers were also able to provide feedback during public consultation.

GDG interactions and processes

We conducted five GDG meetings over video-conference in May, August and November 2020 and two in April 2021. Meeting minutes were circulated to the GDG following each meeting. The initial meeting was conducted to introduce members and discuss the scope and content of the prospective guideline and to propose key clinical questions and finalise the evidence synthesis approach. The second and third meetings were conducted to discuss the evidence synthesis, the certainty of evidence and the evidence-to-decision framework. At the second and third meetings, recommendations were drafted. The final two meetings in April 2021 were conducted to refine the draft recommendations and establish consensus on the strength and wording of draft recommendations. Refinement of recommendations and revision of the draft guideline occurred via email correspondence and video-conference meetings between the core guideline group and individual GDG members.

Development of recommendations

Recommendations were drafted by the core GDG team, through reviewing the summary of the evidence, stakeholder perspective research and populated EtD framework. After drafting, the recommendations were refined through group discussion with all GDG members via teleconference, followed by discussion with individual group members and email until unanimous consensus was reached. The recommendations contained within this guideline are classed as one of the following:

- i) Recommendation for
- ii) Recommendation against
- iii) Conditional Recommendation for

- iv) Conditional Recommendation against, OR
- v) Consensus Recommendation.

The terminology “we recommend” is used for recommendations, and “we suggest” is used for conditional and consensus-based recommendations.⁴ For each recommendation, a supporting discussion is included to provide details about the certainty of evidence that informed the recommendation and the GDG’s rationale when developing the recommendation.

Development of evidence-based recommendations

GDG members used GRADE⁵ to review the evidence base and assign a strength to each recommendation. The body of evidence for each question was assessed first by the project team and given a preliminary certainty of evidence (High, Moderate, Low or Very Low) rating following the GRADE criteria.⁵ The GDG reviewed the evidence and adjusted the rating. The GDG also confirmed the wording of each recommendation and assigned a strength to the recommendation. The strength assigned to each recommendation reflects the GDGs confidence in the evidence, as well as the desirable and undesirable consequences of implementing each recommendation, as determined by the EtD framework.

Development of consensus-based recommendations

Where the evidence synthesis produced no direct evidence relating to the key clinical questions, the GDG devised a consensus-based recommendation based on their clinical, consumer, policy and content expertise. This was done in accordance with NHMRC guidance which states that “recommendations formulated in the absence of quality evidence (where a systematic review of the evidence was conducted as part of the search strategy) are clearly labelled as such. The preferred term for this type of recommendation is a consensus-based recommendation.”⁶

Development of practice points

Where the GDG felt that additional advice on a topic outside the scope of the search strategy was warranted, practice points were devised. Practice points are additional considerations and practical information to support recommendations, based on expert opinion rather than being derived directly from a systematic review of evidence.

Method to achieve group consensus

At each GDG meeting, the discussion was facilitated by the co-chairs (D Gnjidic and CR Schneider) and first author (AV Langford), who ensured that all members had the opportunity to contribute. After all five GDG meetings, modifications to recommendations based on group feedback were made by the core guideline group and the full summary of draft recommendations was disseminated electronically to the GDG. Each member of the GDG provided comments on the draft recommendations and where necessary, individual meetings

with GDG members and the core guideline group were conducted. Following amendments to the recommendations based on GDG members feedback, the full draft guideline (containing the draft recommendations) was circulated via email to the entire GDG for comment and recommendation approval. At the initial guideline meeting, the GDG set a consensus threshold value of 80%. This meant that if 80% of the GDG members agreed on the recommendation, it would be suitable for inclusion in the guideline. However, no formal voting was required as each group member approved the recommendations and practice points prior to a formal voting process. Points of contention during recommendation generation have been discussed and documented in the guideline under the section entitled 'Areas of major debate'.

Independent review

The draft guideline underwent review by three independent reviewers to assess the guideline using the AGREE-II instrument prior to submission to the NHMRC. Changes were made to the guideline in response to these assessments where appropriate. We would like to acknowledge and thank the following AGREE-II reviewers:

- Dr Joy Dai-Keller, Lecturer, College of Medicine and Public Health, Flinders University Research affiliate and casual academic, School of Pharmacy, University of Sydney
- Dr Wade Thompson, Assistant Professor, Department of Anesthesiology, Pharmacology, and Therapeutics, Faculty of Medicine, University of British Columbia
- Dr Barbara Farrell, Senior Scientist, Bruyere Research Institute and Assistant Professor, Department of Family Medicine, University of Ottawa, Ontario, Canada

Public consultation

The Therapeutic Goods Administration (TGA) Opioid Regulatory Communications Committee was consulted to develop the public consultation strategy. We approached representatives from professional organisations that represent specialties that commonly prescribe opioids (e.g., general practitioners, pain medicine physicians, physical medicine and rehabilitation physicians), delivery systems within which opioid prescribing occurs (e.g., hospitals), and representation from community organisations with interests in pain management and opioid prescribing. We asked each organisation to review the full draft guideline and provide written comments. The dates of the public consultation were from the 2nd February to the 3rd April 2022 (inclusive). The Draft Guideline, Summary of Recommendations, Technical Report, Administrative Report and Dissemination and Implementation Plan were publicly available via this website: www.opioiddeprescribingguideline.com. In accordance with NHMRC requirements, the public consultation draft was sent to government agencies, including the Therapeutic Goods Administration (TGA), Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC), and to the Director-General, Chief Executive or Secretary of each Australian health department (state, territory and commonwealth). In addition, the following Australian organisations were specifically targeted

to provide comment on the draft guideline:

- Allied Health Professions Australia (AHPA)
- Arthritis Australia
- Australasian College for Emergency Medicine (ACEM)
- Australian and New Zealand College of Anaesthetists (ANZCA) and Faculty of Pain Medicine
- Australian Association of Consultant Pharmacy (AACP)
- Australian Commission on Safety and Quality in Health Care - The Medication Safety Oversight Committee and the Health Services Medication Expert Advisory Group
- Australian Deprescribing Network (ADeN)
- Australian Dental Association (ADA)
- Australian Medical Association (AMA)
- Australian Pain Society (APS)
- Australian Physiotherapy Association (APA)
- Australasian Pharmaceutical Science Association (APSA)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Chronic Pain Australia
- Consumers Health Forum (CHF)
- Dementia Australia
- Federation of Ethnic Communities Councils of Australia (FECCA)
- Musculoskeletal Australia
- National Aboriginal Community Controlled Health Organisation (NACCHO)
- National Prescribing Service MedicineWise (NPS)
- NSW Agency for Clinical Innovation (ACI)
- Painaustralia
- Palliative Care Australia (PCA)
- Pharmaceutical Benefits Advisory Committee (PBAC)
- Pharmaceutical Society of Australia (PSA)
- Pharmacy Guild of Australia
- Primary Healthcare Networks (PHNs)
- Royal Australasian College of Physicians (RACP)
- Royal Australian & New Zealand College of Psychiatrists (RANZCP)
- Royal Australian College of General Practitioners (RACGP)
- Rural Doctors Association of Australia (RDAA)
- Scriptwise
- Society of Hospital Pharmacists of Australia (SHPA)
- State and Federal Departments of Health
- The Australian College of Nurse Practitioners (ACNP)
- The Australian College of Rural and Remote Medicine (ACRRM)

Once feedback was received, the core guideline group reviewed comments and revised the guideline accordingly with input from the wider GDG. Public consultation feedback and subsequent changes to the guideline have been detailed in the Public Consultation Submission Summary Report.

Organisations endorsing the guideline will be listed in the final published Administrative Report. Organisations who will be approached to consider endorsement of the final published guideline once the recommendations are NHMRC approved include:

- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Australian College of Nurse Practitioners (ACNP) & Drug & Alcohol Nurses of Australasia (DANA) (joint response)
- Australian Commission on Safety and Quality in Health Care - Clinical Pharmacy Unit
- Australian Deprescribing Network (ADeN)
- Australian Pain Management Association (AMPA)
- Australian Pain Society (APS)
- Australian Physiotherapy Association (APA) - Pain Special Interest Group
- Chronic Pain Australia
- Dementia Australia
- Faculty of Pain Medicine (FPM), Australian and New Zealand College of Anaesthetists (ANZCA)
- National Aboriginal Community Controlled Health Organisation (NACCHO)
- Painaustralia
- Palliative Care Australia (PCA)
- Pharmaceutical Society of Australia (PSA)
- Royal Australasian College of Physicians (RACP) – AFPHM and AChAM
- Seqirus
- Society of Hospital Pharmacists (SHPA)
- The Agency for Clinical Innovation (ACI)
- The Australian Psychological Society (APS)
- The Royal Australian & New Zealand College of Psychiatrists (RANZCP)
- The Royal Australian College of General Practitioners (RACGP)

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