Clinical Practice Guidelines for the Appropriate Use of Psychotropic Medications in People Living with Dementia and in Residential Aged Care

Administrative report

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Acknowledgements
Development of this Guideline was funded by the DCRC. The members of the Guideline Development Group and Project Team have generously contributed their time to assist in the development and drafting of this Guideline and its supporting documents including; Simon Bell, Ravi Bhat, Brooke Blakeley, Sue Brennan, Malcolm Clark, Megan Corlis, Christopher Etherton-Beer, Susan Field, Julia Gilmartin-Thomas, Darshna Goordeen, Terrence Haines, Sarah Hilmer, Leanne Jack, Alison Kitson, Constance Kourbelis, Sue Kurrle, Dina Logiudice, Steve Macfarlane, Tuan Nguyen, Amy Page, Dimity Pond, Davina Porock, Tara Quirke, Mouna Sawan, Velandai Srikanth, Andrew Stafford, Michelle Steeper, Jane Thompson, Edwin Tan, Jacqueline Wesson. Carers of people living with dementia, and aged care provider organisations have contributed their experience and expertise to help ensure the Guideline is relevant to people living with dementia. External reviewers have contributed their time and expertise to provide independent feedback and review on the Guideline in particular; organisations and individuals that provided submissions and responses to the public consultation, AGREE tool appraisers and NHRMC nominated independent reviewer. Parts of this Guideline have been updated and adapted from other guidelines including:

- NHMRC Partnership Centre for Dealing with Cognitive and Related Functional Decline in Older People: Clinical Practice Guidelines and Principles of Care for People with Dementia (2016)
- American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia (2016)
- Canadian Family Physician Clinical Practice Guidelines: Deprescribing Antipsychotics for Behavioural and Psychological Symptoms of Dementia and Insomnia (2018)

Permission to update and adapt guidelines was sought from respective authors. On clinical topics where the *update and adapt* approach was taken, evidence was always evaluated by the Guideline Development Group and considered within the Australian context.

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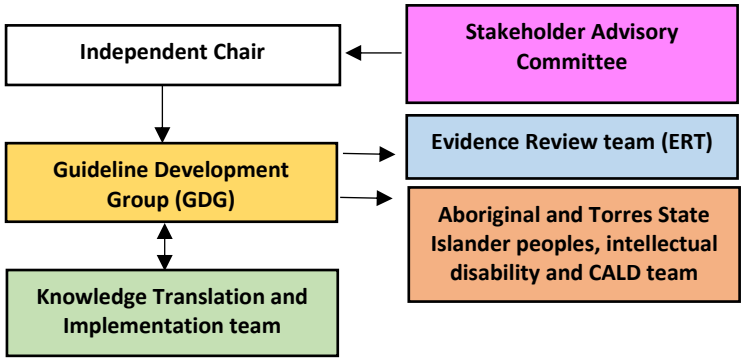
1 Funding

The guideline development was been funded by the Dementia Centre for Research Collaboration (DCRC). Additional funding support was provided by the NHMRC Boosting Dementia Research Leadership Fellowship awarded to Professor Simon Bell. The DCRC receives funding from the Australian Government and operates within the broad remit of the National Health and Medical Research Council (NHMRC) to advance the Strategic Roadmap for Dementia Research and Knowledge Translation. The DCRC's primary goals are to increase knowledge and implementation of research findings in these areas and to fund world class research. The development of this Guideline has been editorially independent from the funding body.

2 Governance

A governance structure was developed in the early stages of the project development, see Figure 1. Governance structure.

Figure 1. Governance structure



2.1 Guideline Development Group

Following the release of a request of tender, Professor Simon Bell and Professor Sarah Hilmer assembled a multidisciplinary and diverse group of clinical and research professionals. A targeted approach to Guideline Development Group (GDG) recruitment was used to ensure an appropriate mix of expertise and perspective. Individuals with expertise in dementia, medication use and aged care were invited to the GDG as well as experts in knowledge translation. The final guideline development team comprised of a methodological specialist, geriatricians, clinical pharmacologists, pharmacists, nurses, experts in knowledge translation, experts in Indigenous and migrant health, aged care provider representatives, a general practitioner (GP), a legal practitioner, a physiotherapist and, former carers and family members of people living with dementia. Dr Sue Brennan was nominated by Cochrane Australia to act as the independent and methodological chair. Please see Table 1. Guideline Development Group Members for the complete list of the GDG members and their expertise.

2.2 Membership

The role of the GDG was to contribute to the review of evidence and content development for the guideline recommendations relating to the appropriate use of psychotropic medications in people living with dementia and in residential aged care.

2.3 Expectations

It was expected that members of the GDG would:

- Adhere to the code of conduct for confidentiality
- Understand the evidence on which the guideline is based
- Participate in the scheduled introduction to GRADE methodology (system for evaluating evidence and recommendations) or demonstrate previous experience and familiarity with GRADE
- Adhere to agreed methods of communication, document generation and review
- Read and comment on documents between meetings as necessary
- Participate in the drafting of recommendations
- Comment on the draft guideline prior to publication

2.4 Roles and Responsibilities

All GDG members

- Provided advice on the scope of the guideline including the topics and clinical questions
- Read and appraised original research related to specific clinical questions as required using the GRADE methodology
- Assessed potential benefits and harms of specific medication classes
- Reached agreement on evidence to be incorporated
- Developed actionable recommendations based on review of evidence
- Assessed the acceptability and feasibility of recommendations
- Identified potential implementation issues and proposed steps to overcome them
- Ensured the guideline was worded appropriately for all end-users

2.5 Clinical and Methodology Chairpersons

- Led meetings in accordance with the set agenda
- Facilitated group processes and promoted balanced participation of GDG members
- Ensured the GDG remains focused to achieve desired meeting outcomes
- Where appropriate, described the evidence and evidence-to-decision process to assist GDG members in their decision making
- Co-ordinated the GDG and delegated tasks as required
- Worked with the Conflict of Interest Oversight Committee to manage conflicts of interest (COI) if they arose

2.5.1 Guideline Development Meetings

Each meeting had a range of multidisciplinary expertise present; however, it was considered essential that each meeting had at a minimum of one representative with lived experience (included former carers), a person who directly worked in an aged care facility and a nurse. On occasions where additional expertise was needed, additional experts were invited to the meeting to address potential gaps. The list of additional experts invited to participate can be found below. During each guideline development meeting, the GDG voted on judgements for each of the above factors. Following review and discussion of the Evidence to Decision framework, the GDG were requested to vote on the direction of the recommendation was determined (i.e. a recommendation *for* or *against* the intervention).

Table 1. Guideline Development Group Members

Independent Chair

Name	Profession or Discipline	Organisation	Role in GDG
Dr Sue Brennan	Senior Research Fellow	Cochrane Australia Monash University	Independent Chair, Methodologist
Guideline Development Group			
Name	Profession or Discipline	Organisation	Role
Prof Simon Bell	Pharmacist; NHMRC Dementia Leadership Fellow.	Monash University	Clinical Chair
Prof Sarah Hilmer	Clinical Pharmacologist; Geriatrician	University of Sydney	GDG member
Prof Sue Kurrle	Geriatrician	University of Sydney	GDG member
Prof Velandai Srikanth	Geriatrician	Monash University	GDG member
Prof Dimity Pond	General practitioner	University of Newcastle	GDG member
Adjunct Assoc Prof Susan Field	Legal Practitioner	University of New England	GDG member
Ms Tara Quirke	Dementia Advocate		GDG member
Ms Megan Corlis	Director, Aged Care and Research; Registered Nurse	Australian Nursing and Midwifery Federation	GDG member
Assoc Prof Christopher Etherton-Beer	Geriatrician and Clinical Pharmacologist	Royal Perth Hospital, University of Western Australia	GDG member
Dr Edwin Tan	Pharmacist; NHMRC-ARC Dementia Research Development Fellow	University of Sydney	GDG member, Evidence reviewer
Dr Julia Gilmartin-Thomas	Pharmacist and NHMRC-ARC Dementia Research Development Fellow	Victoria University	GDG member, Evidence reviewer
Dr Amy Page	Pharmacist; NHMRC Early Career Fellow	Monash University, University of Western Australia	GDG member, Evidence reviewer
Assoc Prof Dina Logiudice	Geriatrician	University of Melbourne	GDG member
Assoc Prof Tuan Nguyen	Pharmacist; NHMRC-ARC Dementia Research Development Fellow	University of Melbourne	GDG member
Prof Alison Kitson	Knowledge Translation; Nurse	Flinders University	GDG member
Prof Terry Haines	Physiotherapist	Monash University	GDG member
Dr Constance Kourbelis	Research Fellow	Flinders University	GDG member
Dr Andrew Stafford	Senior Lecturer	Curtin University	GDG member
Prof Davina Porock	Registered Nurse; Research Fellow	Edith Cowan University	GDG member
Additional expertise (invited to join at Guideline Development Meetings)			

Name	Profession or Discipline	Organisation	Role in GDG
Dr Jacqueline Wesson	Occupational therapist	University of Sydney	GDG member
Ms Leanne Jack	Carer		GDG member
Dr Jane Thompson	Carer		GDG member
Assoc Prof Ravi Bhat	Psychiatrist	University of Melbourne, Goulburn Valley Health.	GDG member
Assoc Prof Steve Macfarlane	Psychiatrist	HammondCare	GDG member
Assoc Prof Malcolm Clark	General Practitioner	University of Melbourne	GDG member
No team member has a COI that would preclude them from participating in the project. The independent chair from Cochrane Australia administered the financial and non-financial disclosures policy as per NHMRC requirements.			

2.6 Stakeholder Advisory Group

During the project development stage, the GDG collected a comprehensive shortlist of stakeholders to sit on the Stakeholder Advisory Group. This shortlist of stakeholders included a network of government agencies, professional groups, people living with dementia, recipients of residential aged care, carers, healthcare centres, quality improvement organisations and other end-users.

Following the award of the grant, the project team confirmed the shortlist with the GDG and invited representatives to join the committee. Table 2. Stakeholder Advisory Group Members outlines the stakeholders that agreed to sit on the committee. The Stakeholder Advisory Group was convened on three occasions.

2.6.1 Meeting 1

The first Stakeholder Advisory Group meeting was held on Monday 12 October 2020, Professor Simon Bell proposed guideline development process and project scope. Following this, the meeting was opened for discussion and feedback was specifically sought from the group regarding:

- The NHMRC guideline development process
- From the perspective from your respective organisation:
  - What resources for healthcare staff would you prioritise as most important or most useful? e.g. clinical case scenarios, fact sheets, decision aids
  - What are the most important elements for successful implementation and dissemination?

The Stakeholder Advisory Group expressed their broad endorsement of the proposed scope and context. Attendees made particular mention of the need to address the organisational and contextual barriers and enablers to appropriate psychotropic medication use. Clinical case scenarios, decision aids and fact sheets were viewed as worthwhile resources for health professionals.

2.6.2 Meeting 2

The second Stakeholder Advisory Group meeting was held via video conferencing on Monday 22 March 2021. Professor Simon Bell provided a recap and updated on the project. The finalised clinical questions and outcomes of interest were presented to the group and feedback was sought. There was discussion about the use of “responsive behaviours” to

describe behavioural and psychological symptoms associated with dementia. The group expressed the need to settle on terminology that was cognisant of people living with dementia, as well as the service providers. The term 'changed behaviour' was determined to provide this medium. Dr Constance Kourbelis provided an update on the knowledge translation component of the project. The representatives flagged the importance of consulting with prescribers and the research team took steps to address this gap. The recommendations of the Royal Commission into Aged Care Quality and Safety were discussed. Representatives expressed their respective views on relevant recommendations and the limitations and feasibility issues surrounding them.

2.6.3 Meeting 3

The third Stakeholder Advisory Group meeting was held via video conferencing on Tuesday 1 February 2022. Professor Simon Bell provided an update on the project. The draft recommendations and good practice statements for antipsychotics were presented to the group. The SAG discussed some of the barriers to implementation of the presented recommendations, particularly in areas that may have limited access to specialist services. The group expressed the need to consider these barriers when finalising the guideline recommendations as well as the strains on the aged care sector throughout the 2020-2022 COVID-19 pandemic. The group expressed broad agreement with the presented recommendations for antipsychotics.

Table 2. Stakeholder Advisory Group Members

Stakeholder Advisory Group					
Organisation		Representative	Attendance		
			Meeting 1	Meeting 2	Meeting 3
1.	Australian and New Zealand Society of Geriatric Medicine	Prof Edward Striven			
2.	Leading Age Services Australia	Ms Marlene Eggert			
3.	Royal Australian and New Zealand College of Psychiatrists	Associate Professor Steve Macfarlane			
4.	Australian College of Rural and Remote Medicine	Dr Suzanne Harrison			
5.	Australian Association of Gerontology	Associate Professor Marguerite Bramble			
6.	Dementia Australia	Dr Kaele Stokes			
7.	Aged Care Quality and Safety Commission	Dr Melanie Wroth			
8.	NPS MedicineWise	Ms Kara Joyce			
9.	Australian College of Nursing	Ms Judith Bulten MACN			
10.	Australian College of Nurse Practitioners	Ms Hazel Bucher			
11.	Australasian Society of Clinical and Experimental	A/Prof Bridin Murnion			

	Pharmacologists and Toxicologists				
12.	Pharmaceutical Society of Australia	Ms Stephanie Johnston			
13.	National Aboriginal Community Controlled Health Organisation	Ms Fran Vaugh			
14.	Therapeutic Goods Administration	Dr Nitin Bagul			
15.	The Federation of Ethnic Communities' Councils of Australia	Ms MaryAnn Geronimo			
16.	Australian Commission on Safety and Quality in Healthcare	Ms Anne Cumming Mr Steve Waller			
17.	Dementia Centre for Research Collaboration	Prof Henry Brodaty Prof Elizabeth Beattie Dr Tiffany Jessop			
18.	Good Shepherd Lodge Residential Care	Ms Barbara Cunningham Ms Annie Thompson			
19.	Montefiore Residential Care	Dr Jacki Wesson			

2.7 Technical Team

The technical team performed the systematic searching, evidence review and drafting of guideline text for the GDG to consider at meetings. Table 3 outlines the members of the technical team and their role.

Table 3. Technical team members

Name	Affiliation	Role
Prof Simon Bell	Monash University	Clinical Chair, Evidence Reviewer
Dr Sue Brennan	Monash University	Methodological Chair, Evidence Reviewer
Dr Mouna Sawan	Monash University	Accredited Consultant Pharmacist and Research Fellow, Evidence Reviewer
Ms Brooke Blakeley	Monash University	Clinical Pharmacist, Evidence Reviewer
Ms Darshna Goordeen	Monash University	Clinical Pharmacist, Evidence Reviewer
Ms Michelle Steeper	Monash University	Project Manager, Evidence Reviewer
Dr Edwin Tan	University of Sydney	Pharmacist and Research Fellow, Evidence reviewer
Dr Julia Gilmartin-Thomas	Victoria University	Pharmacist and Research Fellow, Evidence reviewer
Dr Amy Page	Monash University; University of Western Australia	Clinical Pharmacist and Research Fellow, Evidence reviewer

3 Involvement of People with Lived Experience

People with lived experience were consulted and engaged early and consistently throughout the project. Ms Tara Quirke (TQ, former carer and public contributor) was engaged from the inception of the project and is a member of the GDG. During the series of guideline development meetings, Dr Jane Thompson (JT, former carer and public contributor) and Ms Leanne Jack (LJ, former carer and public contributor) were invited to become members of the GDG and contribute their lived experiences and expertise. At each guideline development meeting at least one person with lived experience was present, with the exception of meeting 1 and 9, and contributed to discussions and voting. Written feedback on the topic covered in meeting 1 and 9 was requested from and provided by TQ, LJ and JT in their absence. Importantly, the preference and values within the evidence to decision framework was central to facilitating perspectives of those with lived experience.

The knowledge translation team engaged with Dementia Australia and their advocacy base to assist with the development of the companion guide. The advocacy base was surveyed about their information interests and needs relating to guideline topics.

4 External review

The Guideline and supporting documents underwent the following external review processes:

- An open public consultation process for 30 days (refer to Appendix 1 – Public Consultation Summary)
- NHMRC independent review (one methodological review and two expert review)
- AGREE tool appraisal by two independent reviewers (refer to Appendix 2 – Agree Tool Appraisals)

4.1 Public Consultation

The Guideline was released for public consultation on Friday 1 April 2022 – Friday 6 May 2022. The Guideline, Technical, Administrative and Dissemination reports were made publicly available through MAGICapp. All members of the Stakeholder Advisory Groups were invited to provide written feedback on the Guideline. The draft Guideline and supporting documents were also sent via email to the following professional organisations, advocacy bodies and government agencies, bodies and departments for feedback. This include all members form the Stakeholder Advisory Group.

Professional and Research Organisations

- Allied Health Professions Australia
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
- Australian Academy of Health and Medical Sciences
- Australian and New Zealand Society of Geriatric Medicine
- Australian Association of Gerontology
- Australian Centre for Evidence Based Aged Care
- Australian College of Nurse Practitioners
- Australian College of Nursing
- Australian College of Rural and Remote Medicine
- Australian Medical Association
- Leading Age Services Australia
- Pharmaceutical Society of Australia
- Royal Australian College of General Practitioners

- Royal Australian and New Zealand College of Psychiatrists

Advocacy Groups

- Carer Australia
- Consumer Health Forum
- Council of the Aged
- Dementia Australia
- National Aboriginal Community Controlled Health Organisation
- Older Persons Advocacy Network
- The Federation of Ethnic Communities' Councils of Australia

Government Agencies and Departments

- Agency for Clinical Innovation at NSW Health
- Australian Capital Territory Health Directorate
- Australian Commission on Safety and Quality in Healthcare
- Australian Government Department of Health
- Medical Services Advisory Committee
- New South Wales Health
- Northern Territory Department of Health
- Pharmaceutical Benefits Advisory Committee
- Queensland Health
- South Australia Health
- Therapeutic Goods Administration
- Victoria Department of Health
- Western Australia Health

During the public consultation period, we received twenty responses from organisations and five individual responses. The following organisations, groups and agencies provided responses to the draft guideline during the public consultation period.

Professional and Research Organisations

- Australian and New Zealand Society of Geriatric Medicine
- Australian College of Nurse Practitioners
- Australian College of Nursing
- Australian College of Rural and Remote Medicine
- Australian Medical Association
- Leading Age Services Australia
- Pharmaceutical Society of Australia
- Royal Australian College of General Practitioners
- Royal Australian and New Zealand College of Psychiatrists

Advocacy Groups

- Carer Australia
- Dementia Australia
- National Aboriginal Community Controlled Health Organisation
- Older Persons Advocacy Network
- Lived Experiences Australia
- Life Without Barriers – Behaviour Support

Government Agencies and Departments

- Agency for Clinical Innovation at NSW Health
- Australian Department of Health
- New South Wales Health
- Northern Territory Department of Health
- Therapeutic Goods Administration

Public consultation responses were reviewed and amendment to the Guideline were discussed by the Guideline Development Group. Amendments and summary of actions taken are summarised in Appendix 1. Public Consultation Summary.

5 Managing Conflicts of Interest

A COI policy and declaration of interest (DOI) form were developed by the Chair and project team. The COI policy and DOI form was developed in accordance with the NHMRC and has been adapted with permission from the Australia & New Zealand Musculoskeletal Clinical Trials Network Living Guideline for the Pharmacological Management of Rheumatoid Arthritis Committee. The COI policy and DOI form were circulated to the GDG, and any actual, perceived or potential COI were requested to be declared and returned to the project manager.

A COI oversight committee was convened to review the DOI and determine whether there were any COI within the GDG and to develop an appropriate COI management plan. The COI Oversight Committee included: Prof Simon Bell (Clinical chair), Prof Sue Brennan (Methodological chair) and A/Prof Susan Field. The DOI of all GDG members were assessed according to the criteria in Table 4. COI Assessment Matrix and the outcomes are outlined in Table 5. Declarations of interest.

5.1 COI Oversight Committee

The COI Oversight Committee met on Tuesday 10 November 2020 to review all the DOI forms. During this meeting a number of points were discussed regarding how interest should be assessed and adjudicated. When reviewing the DOI forms, the COI oversight committee were cognisant of the following points from the NHMRC's Guidelines for Guidelines Handbook (1):

- *It is inevitable that most people involved in guideline development will have an interest or stake in the process—this is typically why they were selected to participate in the first place*

- *Public perception that the personal interests of guideline development group members (such as lived experience, religious or political beliefs) may inappropriately influence decision making in guideline development. Similarly, members might be considered to be overly attached to a field of research, a particular clinical practice intervention, an ideological viewpoint or an intellectual position—this might give the impression that they cannot make objective and unbiased decisions*

- *Genuine conflicts of interest are primarily **financial** in nature*

- *Bias from personal and intellectual interests is addressed by other means*

- *A balance of different and even opposing personal and intellectual interests are precisely what you need to make sure your guideline development group can engage in healthy, informed discussion and debate on your guideline topic.*

Of note to the COI Oversight Committee were the potential interests of GDG members in the quality use of medicines (QUM), of which the guideline will focus heavily on. The QUM promotes the safe use of medicines. In certain target populations such as people living with dementia, QUM often indicates discontinuing the use of certain medicines whose risks outweigh the benefits. With this in mind, the COI oversight committee felt confident that even those who may have an industry COI (perceived, potential or actual), that it seemed unlikely that the recommendations would be promoting the motives of a pharmaceutical company or product.

The COI Oversight Committee agreed that the majority of groups had no significant COI, however further information regarding the nature of some interests were requested from relevant GDG members to ensure a rigorous and transparent process.

The COI Oversight Committee determined that there were two members with a moderate risk rating that required a COI management plan. In the management plan,

- both members were able to attend guideline development meetings, provide feedback on the evidence to decision framework and practical information
- both members were unable to vote or contribute to the decision about the directions and strength of the recommendation.

5.2 Updating COI

Before each recommendation meeting, GDG members were asked to declare any new or emerging interests which were reviewed by the COI Oversight Committee.

Table 4. COI Assessment Matrix

Assessment Matrix	
Interaction risk categories	
High	Direct financial relationship, including direct payment to individual or family member (e.g. consulting, advisory boards, paid speaker, investments or equity), payment in kind (e.g. air travel for conference other than as invited speaker), direct research support, non-academic publication (e.g. book deal)
	Direct intellectual interest (e.g. research study directly relevant to recommendations topic)
Moderate	Indirect intellectual interest, including unrelated or indirectly related academic activity or publication (e.g. research, journal article, textbook chapter) or advocacy
	Indirect financial relationship (e.g. work resulting in payment to hospital or university department, including investigator on industry-sponsored trial)
Low	Historical financial relationship; minor financial relationship (e.g. attendance at educational dinner meeting); remote financial relationship (e.g. unrelated payment or contract with hospital or university department); other minor interaction (e.g. visits from pharmaceutical representative) Personal experience
Entity risk categories	
High	Pharmaceutical or other biomedical industry, insurer
Moderate	Government, professional, consumer or advocacy bodies

Low	Academic or educational institutions or publishers

Table 5. Declarations of interest

Declaration of Interests	
Name	**Description of Interests**
Prof Sarah Hilmer (NSW)	*Financial Interests* 1. *Research Grants / Contracts* **-** Australian Commission on Safety and Quality in Healthcare Hilmer SN, Gnjidic D, Reeve E, Kalisch Ellett L, Wu H, Raymond J (2019). Use of Antipsychotic Medicines for People aged 65 years and over: A review undertaken for the Australian Commission on Safety and Quality in Health Care. Northern Sydney Local Health District, St Leonards NSW, Australia. (2019-2020 (complete), $62,400 to employer) *Organisation Interests* 1. *Relationship with organisations with financial links or affiliations with industry groups which stand to benefit from or may be affected by guideline recommendations (e.g. professional organisation)* - Chair, New South Wales Therapeutic Advisory Group (NSW TAG*) - Provide guidance to hospital drug and therapeutics committees. *NSW TAG supports quality use of medicines in NSW Hospitals, by supporting Drug and Therapeutics Committees. Support for use of medicines (including psychotropic medications) in hospitals, includes provision of tools for assessment of formulary applications, guidelines and quality indicators. There is potential for NSW TAG to use the guidelines on psychotropic medications as a basis for developing specific hospital guidance or to update relevant quality use of medicines indicators. NSW TAG is a non-governmental organisation, which receives core funding and some specific project funding from NSW Health, through the Clinical Excellence Commission, which is responsible for quality and safety in healthcare in NSW. NSW TAG also receives specific project funding for research projects (e.g. NSW Health translational research grant funding) or activities (e.g. ACSQHC co-fund development of national quality use of medicines indicators). NSW TAG does not receive funding from the pharmaceutical industry. *Intellectual Interests* 1. Other declaration of interest - co-developer of software which includes a Drug Burden Index calculator (G-MEDSS) is being considered for commercialisation by Northern Sydney Local Health District, NSW Health.
Prof Sue Kurrle (NSW)	*Financial Interest* 1. *Research Grants / Contracts* - NHMRC Cognitive Decline Partnership Centre including development of the Clinical Practice Guidelines and Principles of Care for People with Dementia (2013-2019, $12.5 million to $500,000 to employer)
Prof Velandai Srikanth (VIC)	NA
Prof Dimity Pond (NSW)	*Financial Interest* 1. *Research Grants / Contracts* - NHMRC Cognitive Decline Partnership Centre – Development of Primary Care Consensus Dementia Guidelines (2014-2019, $309,000 to Employer)

2. Research Grants / Contracts - Safer Complex systems – call for case studies, Systemic failures in nursing home care. (2020-2021, 50,000 UK pounds, Not paid to GDG member)
3. *Advisory boards*
    a. Nutricia Advisory board for production of Souvenaid, a nutritional supplement (2017, $1000 to GDG member)
    b. Brisbane North Primary Health Network Advisory Board for dementia project (2019, $1000 plus flights, accommodation to GDG member)
    c. Australian Commission on Safety and Quality in Health Care - Antipsychotics Medicine Dispensing Topic Group (November 2021 to February 2022, no payment)
    d. Dementia Training Australia, Training GPs in issues related to dementia (Webinars and other activities related to dementia including face to face meetings, rates for hourly attendance, paid to GDG member)
    e. WONCA World GP Association - Convenor, Special Interest Group in Older people and Health (2018-2022, no payment)
4. *Consulting / Honoraria* - Biogen Australia - Future of Alzheimer's disease white paper launch – speaker on panel about the importance of general practice in identifying dementia. Also chaired a working group which contributed to the development of the white paper (September - November 2021, $4608, paid to GDG member)
5. *Speakers' fees or honoraria*
    a. Mental Health Professionals Network Talk/panel on Advance Care Planning (2017, $393 to GDG member)
    b. Presbyterian Aged Care - Talk on Management of dementia for GPs (2017, $1000 to GDG member)
    c. Roche Products Pty Ltd - Primary Care Alzheimer's Disease workshop (2022, $2000, GDG member)
6. *Meeting attendance* - paid travel/receipt of meals RACGP Silver Book Advisory Committee and the RACGP "Red Book" about prevention including the section on prevention in the elderly (falls, dementia etc.) (ongoing, $150 per hour to GDG member)
7. *Private practice or professional income* - Berowra Family Medical practice - Consulting fees(1984 - present, payment is patient dependent, paid to GDG member)
8. *Unpaid consultancies and/or in-kind support* – RACGP - Publication of teaching scenario related to dementia in the RACGP "CHECK" Program (July - November 2021, no payment)

Organisational Interests

1. *Relationship with organisations with financial links or affiliations with industry groups which stand to benefit from or may be affected by guideline recommendations (e.g. professional organisation)* - Dementia Training Australia - ON advisory board for GP education and training
2. *Relationship with organisations which advocate known industry or policy positions* - Royal Australian College of General Practitioners - Provost, NSW Faculty Member, advisory group, RACGP Silver Book

Intellectual interests

	1. *PHD supervision* – supervision of a PhD student who is a GP practice nurse exploring the role of the practice nurse in dementia care Indirectly related academic activity - Employed as a casual professional by Dementia Training Australia through LaTrobe University. Webinars and other activities related to dementia including face to face meetings. Some of the teaching relates to prescribing/desprescribing
Adjunct Assoc Prof Susan Field (NSW)	NA
Ms Tara Quirke (QLD)	NA
Ms Megan Corlis (SA)	NA
Assoc Prof Christopher Etherton-Beer (WA)	*Organisational Interest* 2. *Relationship with organisations with financial links or affiliations with industry groups which stand to benefit from or may be affected by guideline recommendations (e.g. professional organisation)* - Membership of Pharmaceutical Benefits Advisory Committee (PBAC)* and Western Australia Therapeutic Advisory Group (WATAG)** *PBAC The PBAC has statutory functions and the work is all in the public domain. Its primary role is to recommend new medicines for listing on the PBS. No new medicine can be listed unless the committee makes a positive recommendation. The PBAC is an independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists and consumer representatives. When recommending a medicine for listing, the PBAC takes into account the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments. He is also Chair of the Drug Utilisation Sub Committee of the PBAC. **WATAG WATAG is in the public domain and promotes rational therapeutic drug use and provides independent advice to health professionals and health services on issues relating to the use of drugs and therapeutics in Western Australian public hospitals and the wider community. WATAG run a state-wide formulary *Intellectual interests* 3. Deprescribing research - Various ongoing projects. I don't think a material COI will arise but could be perceived.
Dr Edwin Tan (NSW)	NA
Dr Julia Gilmartin-Thomas (VIC)	NA
Dr Amy Page (VIC)	NA
Assoc Prof Dina Logiudice (VIC)	NA
Dr Tuan Nguyen (SA)	NA
Prof Alison Kitson (SA)	NA
Prof Terry Haines (VIC	*Intellectual interests*

	1. *Indirectly related academic activity* - Employment / research - Published research which identified that medications did not have a strong relationship to patient falls following discharge from hospital. Lam K, et al. The relationship between discharge medications and falls in post-hospitalised older adults: A 6-month follow-up. Australasian journal on ageing. 2019 Sep;38(3):190-8. 2. *Other declarations* – Provides expert witness testimony on the subject of falls prevention in the hospital setting for both Minter Ellison Law Firm and K&L Gates Law firm in the past 3 years.
Dr Constance Kourbelis (SA)	NA
Dr Andrew Stafford (WA)	*Financial Interests* *1. Paid authorship* a. Elsevier- Safe Use of Medications chapter in Gerontological Nursing in Australia and New Zealand (2017-2020, <$1000 to self) 1b Pharmaceutical Society of Australia Various papers (2017-2020, <$1000 to GDG member) *2. Private practice or professional income* - 6th and 7th Community Pharmacy Agreements Residential Medication Management Reviews Quality Use of Medicines (2017-ongoing, >$30 000 to GDG member) *Organisational interests* 1. *Relationship with organisations with financial links or affiliations with industry groups which stand to benefit from or may be affected by guideline recommendations (e.g. professional organisation)* - Australian Association of Consultant Pharmacy - National Advisory Group member *Intellectual interests* 1. *Directly- related academic activity - Employment/research* - Previously developed various resources to support best practice use of antipsychotics in dementia care
Dr Sue Brennan (VIC)	*Additional Information* Member of the Monash University team contracted to the NHMRC Health evidence and methods advice panel, through which we receive funding to assist NHMRC and other Australian Government agencies to develop evidence-based health advice and resources.
Prof Davina Porock (WA)	NA
Ms Lyntara Quirke(QLD)	*Organisational interests* 1. *Relationship with organisations which advocate known industry or policy positions* - Previous employee of Aged Care Quality and Safety Commission - The Aged Care Quality and Safety Commission review and assess aged care facilities and community providers in relation to meeting aged care standards (Aged Care Act 1997). Medication management (including the safe use of medications) are assessed for compliance of national best practice initiatives. Employed at Aged Care Quality and Safety Commission in August 2019. *Intellectual interests* *1. Indirectly related academic activity* – Employment/research - Previous research that strongly supports initiation or

	discontinuation of psychotropic medications in people with dementia or in residential aged care. 2. *Indirectly related employment activity* a. Self-employed – Dementia Advocate/Consultant; Engaged by residential aged care organisations to review and provide education and support to staff in pursuing non-pharmacological interventions for people living with dementia. b. Senior Environmental Design Consultant – Dementia Training Australia: Casual employee of Dementia Training Australia and assist in the development and education of staff, architects and providers of dementia specific facilities on providing therapeutic and prosthetic environments for people living with dementia. 3. *Indirectly related Committee membership and advocacy work* a. Committee member of the Creuzefeldt-Jacob (CJD) Group Support Network; b. Chair of the Bribie-Moreton Hospice Health Service Association: This group supports the local community on Bribie Island to access end of life and respite care at no charge to local community members who may need support. This is run in close collaboration with local aged care service providers.
Prof Simon Bell (VIC)	*Financial Interests* 1. *Research Grants / Contracts* - Dementia Australia Research Foundation Yulgilbar Innovation Grant - Lead investigator. An international common data model for improving medicine management for people with dementia and comorbid conditions (2019-2021, $500,000 to employer) 2. *Research Grants / Contracts* - GSK Independent Medical Education - Other investigator: New Medicine Support Service for new chronic obstructive pulmonary disease (COPD) medicines (2018, $10,000 to employer) 3. *Research Grants / Contract* - GSK partner funding for NHMRC Partnership Grant. (NHMRC Partnership Grant unsuccessful. GSK has pledged to award full cost of grant though their competitive grants process.) - Other investigator: Targeting treatable traits in primary care to prevent hospitalisations (i.e. a practice nurse-coordinated, tailored interdisciplinary intervention + telehealth to improve quality of life in COPD and prevent hospitalisations) (2020, $999,825 to pending payment to employer) 4. *Research Grants / Contracts* - University of Hong Kong (to conduct Australian arm of Global Hip Fracture Study led by University of Hong Kong. Overall study is funded Amgen). - Not an investigator on Amgen-funded Global Hip Fracture Study. Investigator: Australian arm funded by sub-contract to University of Hong Kong (2020-2021, $154,517 to pending payment to employer) 5. *Research Grants / Contracts* - Dementia Australia Research Foundation - Associate Investigator: Preventing recurrent hip fractures: are people with dementia prescribed evidence-based treatments? (2019-2020, $75,000 to employer)

	6. *Research Grants / Contracts* - Resthaven Aged Care - Lead Investigator: Pathways to potentially preventable hospitalisations among residents of aged care services (2017-2018, $50,000 to employer) 7. *Research Grants / Contracts* - Dementia Centre for Research Collaboration -Lead Investigator: Guidelines for the Appropriate Use of Psychotropic Medicines in People Living with Dementia and in Residential Aged Care (2020-2022 $300,000 to to employer) 8. *Research Grants / Contracts* - NHMRC Partnership Centre on Dealing with Cognitive and Related Functional Decline in Older People (CDPC). - Lead Investigator (Partner funding from HammondCare, Brightwater Care Group, Helping Hand Aged Care and Dementia Australia (2013-2019, $25,278,490 part of wider team and paid to employer) 9. *Research Grants / Contract* - Western Australian Nurses Memorial Charitable Trust via Brightwater Care Group - Investigator. Multidisciplinary nurse practitioner led medication regimen simplification in residential aged care (2020-2021, $15,000 to employer) 10. *Research Grants* / Contract: NHMRC Medical Research Future Fund (MRFF) Knowledge brokers for translating evidence to improve the quality use of medications (2021-2025 $1,952,566 to employer) 11. *Research Grants* / Contract: NHMRC Holistic Approach in Primary care for Preventing Memory Impairment and Dementia (HAPPI MIND) (2019-2023, $1,999,499, to employer) 12. *Research Grants* / Contract: NHMRC Leveraging electronic medical records and routine administrative data towards a population approach for monitoring dementia frequency, risk factors and management (2019-2023, $617,335, to employer) 13. *Research Grants* / Contract: NHMRC Optimising health information exchange during aged care transfers (2021-2015, $1,949,557 paid to employer) 14. *Research Grants* / Contract: NHMRC Centre for Research Excellence in Frailty and Healthy Ageing (2015-2019, $2,301,169 part of wider team, paid to employer) 15. *Research Grants* / Contract: NHMRC Ideas Grant Enabling evidence-informed policy to address Australia's opioid crisis (2021-2023, $607,538, paid to employer) 16. *Research Grants* / Contract: Hong Kong Government RGC Collaborative Research Fund COVID-19 and Novel Infectious Disease Exercise (2022-, $1,622,975 part of wider team, pending paid to employer via sub-contract to University of Hong Kong) *Organisational Interests* 1. *Relationship with organisations which advocate known industry or policy positions: Scientific Advisory Board* - Dementia Australia Research Foundation 2. Small projects, consultancies and editorial work for Society of Hospital Pharmacists of Australia (SHPA),Pharmaceutical Society of Australia (PSA) and Aged Quality and Safety Commission (all paid to employer)

	3. *Relationships of immediate family members* - Wife (Jenni Ilomaki) has undertaken consultancies for AstraZeneca - Pharmacoepidemiology consulting *Intellectual Interests* 1. *Research publications related to optimising the use of psychotropic medications in people with dementia and in residential aged care. Research publication* - Research about the prevalence, benefits and risks of psychotropic medications in people with dementia and in residential aged care. 2. *Research Fellowship* - NHMRC Dementia Leadership Fellowship- NHMRC Fellowship related to optimising medication use in people with dementia.
Additional GDG members (recruited during guideline development meetings)	
Dr Jacqueline Wesson (NSW)	NA
Dr Leanne Jack (QLD)	NA
Dr Jane Thompson (ACT)	NA
Prof Ravi Bhat (VIC)	*Financial interest* 1. *Research Grants / Contracts – NIHR/NHMRC* - COmBining memantine And cholinesterase inhibitors in Lewy body dementia treatment Trial (COBALT). 2021-2026, $1.2 million. Grant held by Assoc Prof Rosie Watson, Chief Investigator, COBALT Australian sites 2. *Advisory boards* - Department of Health, Victoria - Strengthening Public Sector Residential Aged Care Services Advisory Committee (2021, no payment) 3. *Consulting* - GV Area Mental Health Service (GVAMHS), Goulburn Valley Health. GVAMHS responsible for the Aged Psychiatric Residential Aged Care Facility in the catchment area (Gruztner House). In addition, GVAMHS is consulted by residential aged care facilities in the region for residents with severe mental health problems/ behavioural and psychological symptoms of dementia (BPSD) if the consultation with first two tiers of services resulted in no change. (Ongoing, GV Health salary) Paid by employer *Intellectual interests* 1. *PhD student* - The University of Melbourne – Diagnosis of delirium in residential aged care. Research aimed at improved diagnosis and management of delirium in residential aged care
A/Prof Steve Macfarlane (VIC)	*Financial Interests* 1. *Advisory boards* – Biogen: Alzheimer's Disease Advisory Board (September 2021, under review, paid to self) 2. *Pharmaceutical, Biotech or MedTech companies* - Anavex Life Sciences Corporation: Independent Medical Monitor for 2 studies of ANAVEX2-73 in Rett Syndrome (Q4 2020, ongoing, $2500/quarter, paid to self) 3. *Meeting attendance* – Royal Australian and New Zealand College of Psychiatrists (RANZCP): Invited speaker for 2021 Congress (May 2021, ~$1000 , paid to self) 4. *Private practice* - 2003-current, paid to self *Organisational Interests*

	1. *Relationship with organisations with financial links or affiliations with industry groups which stand to benefit from or may be affected by guideline recommendations* - RANZCP member, Past Chair of Faculty of Psychiatry of Old Age within the RANZCP. Current faculty member. 2. *Relationship with organisations which advocate known industry or policy positions* - HammondCare is an independent Christian charity with interests in health and hospitals, residential aged care, community aged care packages. They also lead the Dementia Support Australia service funded by the Australian government. I am employed 4 days per week by HammondCare *Intellectual Interests* 1. *Indirectly related academic activity* - Employment/research. Previous research that strongly supports initiation or discontinuation of psychotropic medications in people with dementia or in residential aged care 2. *Indirectly related academic activity* – Research. I have been the principal investigator on a number of Phase III clinical trials of potential disease-modifying agents in Alzheimer's disease and Parkinson's disease dementias, and I am currently the principal investigator on a number of similar Alzheimer's disease studies for Eli Lilly, Janssen, Anavex Life Sciences Corporation and Athira
Dr Malcolm Clark (VIC)	*Financial Interests* 1. *Research Grants / Contracts* - No payments for university based research projects 2. *Advisory boards* - NPS MedicineWise MedicineInsight Data Governance Committee (current, hourly rate for attendance at meetings) 3. *Digital Health companies* - Clinical advisor at Precedence Healthcare 4. *Private practice* – Work as a GP

6 Guideline Development Meeting Attendees

Table 6 reports on the members present for each guideline development and evidence review meeting.

Table 6. Members present for each guideline development and evidence review meeting.

	Meeting: Risks and benefits of antipsychotics	Meeting: Risks and benefits of antidepressants	Meeting: Discontinuation of antipsychotics	Meeting: Risks and benefits of antidepressants cont.	Meeting: Risks and benefits of benzodiazepines	Meeting: Discontinuation of antidepressants	Meeting: Discontinuation of benzodiazepines	Meeting: PRN vs. regular use of antipsychotics and benzodiazepines	Meeting: Effectiveness of interventions	Meeting – Review of draft recommendations
Dr Sue Brennan**	x	x	x	x	x	x	x			
Prof Simon Bell **	x	x	x	x	x	x	x	x	x	x
Prof Sarah Hilmer	x		x		x		x	x	x	
Prof Sue Kurrle						x			x	
Prof Velandai Srikanth		x				x	x	x		
Prof Dimity Pond	x		x		x		x	x	x	x
Adjunct Assoc Prof Susan Field	x		x		x					x
Ms Tara Quirke	x						x	x		
Ms Megan Corlis			x					x		x

Assoc Prof Christopher Etherton-Beer	x		x							
Dr Edwin Tan	x		x		x					x
Dr Julia Gilmartin-Thomas		x		x						x
Dr Amy Page	x		x		x		x		x	x
Assoc Prof Dina Logiudice	x				x			x	x	
Dr Tuan Nguyen		x		x		x	x			x
Prof Terry Haines	x				x		x		x	x
Dr Andrew Stafford		x		x					x	x
Prof Davina Porock (WA)				x		x	x	x	x	x
Dr Jacqueline Wesson		x		x		x			x	
Ms Leanne Jack	x	x	x	x	x					
Dr Jane Thompson		x		x		x	x			
A/Prof Ravi Bhat					x					
A/Prof Steve Macfarlane **	x		x			x				
A/Prof Malcolm Clark	x			x	x					
** Attendee did not contribute to voting										

MONASH University

Appendix 1 – Public Consultation Summary

#	Section of Guideline issue	Respondent Comment	GDG Response	Actions Taken
1.	Scope and Population	To improve the draft Guideline, multiple respondents suggested further clarification on whether the guideline was inclusive of people living with dementia who have mental illnesses (and with dementia or developing dementia) was needed.	The Guideline does not specifically address the management of mental illness in people living not living dementia. Evidence that related to antipsychotic, benzodiazepine and antidepressant use for the treatment of mental illness was considered out of scope of the Guideline. However, the Guideline Development Group recognises that antipsychotics, benzodiazepines and antidepressants are often used in the treatment of mental illness. Some Guideline recommendations and good practice statements about the appropriate use of psychotropic medications may still apply to people living with dementia and mental illness. Some target symptoms are associated with both changed behaviours and mental illnesses. During the formulation of some recommendations and good practice statements it was difficult to consider changed behaviours in isolation of mental illness. Therefore, when appropriate, recommendations and good practice statements were made to	Clarity on the scope of the Guideline has been added to the Introduction.

			recognise people living with dementia and mental illness.	
2.	Scope and Population	To improve the draft Guideline, multiple respondents commented that clarification on the severity dementia, stages and progression of dementia and related change behaviours was needed. The Guideline does not attempt to describe severity, stages and progression of dementia or provide specific guidance.	The Guideline has a medication class focused approach. The Guideline does not address overall management of dementia or other illnesses. The severity, stages and progression of dementia were considered in terms of the pharmacological management of specific changed behaviours (e.g. distressing psychotic symptoms and/or aggression/agitation that represents a direct threat to themselves or others in relation to antipsychotic use; severity of depressive symptoms in relation to antidepressant use). However, other recommendations and good practice statements that related to the appropriate use of antipsychotics, benzodiazepines and antidepressants applied across all stages and severities of dementia. End of life and palliative care were specified as out of scope.	Clarity on the scope of the Guideline has been added to the Introduction.
3.	Scope and Setting	Multiple respondents commented it was unclear whether *'People Living with Dementia and in Residential Aged Care'* indicates the Guideline relates to people living with dementia in the community and residential aged care settings.	The Guideline recommendations and good practice statements have been specifically formulated for: • People living with dementia in residential aged care facilities. • People living with dementia who receiving high level aged care packages/services.	The Guideline Development Group thanks respondents for their comments.
4.	Populations and sub-populations	Respondent suggested reference to Aboriginal Community Controlled	The Guideline Development Group agrees with the suggested amendment.	Amendments made:

		Health Organisation (ACCHO) Sector should be included in the Guideline.		• Information on ACCHO has been added to *Introduction, Aboriginal and Torres Strait Islander peoples* section.
5.	Scope and Interventions	Multiple respondents recommended that the Guideline consider of other psychotropic medication classes including (opioids, mood stabilisers, anticonvulsants, and anti-dementia drugs) or specific psychotropic medications (e.g. clozapine, risperidone).	The focus on antipsychotics, benzodiazepines and antidepressants was informed by stakeholder consultation. This focus was also informed by the prevalence of these medications in people living with dementia in Australian residential aged care. The Guideline Development Group agrees that there would be value in specific recommendations and good practice statements related to other psychotropic medication classes (e.g. including opioids, mood stabilisers, anticonvulsants and anti-dementia medications. Making specific recommendations about these other medication classes were beyond the scope of the present Guideline. However, the general principles contained in the Guideline also apply to the use of these other psychotropic medication classes.	The Guideline Development Group thanks the respondents for their comments.
6.	The Guideline	Respondent commented that carers are absent from the good practice statements and Conditional Recommendations.	The Guideline Development Group agrees that carers provide major contributions to medication management for people living with dementia.	The Guideline Development Group has formulated an additional good practice statement to acknowledge the role of carers in medication management. Amendments include: • Addition of a Good Practice Statement 13 that recognises

				carers and their contributions towards the care of people living with dementia. • Addition of a *Carers* section to the Introduction.
7.	The Guideline	Respondents commented on a lack of inclusion of people with lived experience in the development of the Guideline, in particular people living with dementia and people living with mental illness.	Perspectives of people living with dementia were included throughout the guideline development process in the following ways: • The Guideline Development Group included a consumer investigator. • Carers and family members of people living with dementia were included in the development of the Guideline recommendations and good practice statements. • Dementia Australia, which represents over 450,000 Australians living with dementia and is Australia's leading dementia advocacy body participated in the Stakeholder Advisory Committee and were involved at various stages of guideline development. • The public consultation process provided an opportunity for people with lived experience to contribute to the Guideline. • People living with mental illness were not considered within Guideline scope.	The Guideline Development Group thanks the respondents for their comments. We have highlighted the contribution of carers and people living with dementia. The *Involvement of People with Lived Experience* section in the Administrative Report also provides further information.
8.	The Guideline	Multiple respondents commented that differences and distinction within rural and remote areas have not	The Guideline Development Group considered feasibility, equity and resources as part of the GRADE	Acknowledgement of the differences and distinctions within rural and remote

		been given appropriate consideration and are likely to impact the feasibility and implementation of many recommendations and good practice statements. Mention of the role of telehealth to improve accessibility should also be considered.	Evidence to Decision framework. The Australian College Rural and Remote Medicine participated on the Stakeholder Advisory Committee. The Guideline Development Group included members with rural practice and policy experience. We also conducted focus groups with five aged care provider organisations alongside the guideline development process. This included aged care provider organisations that operate aged care facilities in regional and rural areas. The Guideline Development Group sought to outline best practice. The Guideline Development Group believed all Australians deserve best practice regardless of whether they reside in metropolitan, rural or remote areas. However, the Guideline Development Group acknowledged that aged care services operate with different resourcing and within different local contexts. For this reason, implementation may require different models of care (e.g. telehealth). The Guideline Development Group acknowledged that accessing specialist care can be challenging, particularly in some regional and rural areas. However, believed it is still important to strive for new and innovative models of care that facilitate specialist care for all.	areas has been highlighted throughout the Guideline. Amendments include: • Addition of *Rural and Remote Areas* section in Introduction.

9.	The Guideline	Respondent suggested including reference to My Health Record and clinical information systems in aged care.	The Guideline Development Group agrees that My Health Record and Clinical information systems have a key role in the documentation, particularly as the digital capability of My Health Record increases.	Acknowledgement of My Health Record and clinical information systems has been highlighted in the Guideline. Amendments include: • Reference to My Health Record in Good Practice Statement 44 and 48*9* • Addition of My Health Record and clinical information systems in aged care services section in the *Introduction.*
10.	Consent/ The Guideline	Respondent suggested that the Guideline should include processes around complaints and concerns relating to restrictive practices and independent review as being part of best practice.	The Guideline Development Group recognises the importance of empowering care recipients (and/or carers/substitute decision maker) to report or challenge the use of restrictive practices.	Further information and resources about the processes of lodging complaints has been highlighted in the Guideline. Amendments include: • Addition of *Lodging complaints about medication management* section in the *Introduction.* • Addition of Good Practice Statement 12 about complaints processes.
11.	Scope/The Guideline	Multiple respondents commented on the absence of advice about non-pharmacological strategies.	The Guideline addresses the use of antipsychotics, benzodiazepines and antidepressants. The Guideline does not address overall management of dementia or other illnesses. The Guideline needs to be read in conjunction with other resources. This includes Australia's Clinical Practice Guidelines and Principles of Care for	Further information and resources about non-pharmacological strategies have been highlighted in the Guideline. Amendments include: • Addition of *Non-Pharmacological Strategies* section in the *Introduction.*

			People Living with Dementia (2016) and resources on management of changed behaviours commissioned by the Dementia Centre for Research Collaboration. Non-pharmacological strategies were considered out of scope for this Guideline.	
12.	About this Guideline	Multiple respondents commented on various points relating to: • GRADE and strength of recommendations. • Wording and terminology used in recommendations and Good Practice Statements. • Clinical context, clinical judgement and best practice. • Scope of evidence used to inform the recommendations. • Alignment with other professional guidelines.	The Guideline Development Group agree that there would be value in providing more detail about the methodological terminology and methodological approach.	Additional information has been added to the *About this Guideline* section to address use and interpretation of the Guideline.
13.	Evidence to Decision Framework - Feasibility section	Multiple respondents commented on potential barriers to implementation and feasibility of Recommendations and Good Practice Statements. Some respondents mentioned that expansion of Medicare Benefits Schedule (MBS) items and improved education and training would likely enable the implementation of the Guideline.	We conducted focus groups with five aged care provider organisations alongside the guideline development process to help ensure that the recommendations and good practice statements were formulated with implementability in mind. During the development of each clinical topic, considerations for the feasibility and implementation of the Guideline were included within the *Feasibility* sections in the Evidence to Decision Framework. Recommendations and good practice statements have been developed to outline and establish best practice for	The Guideline Development Group thanks the respondents for their comments.

			the appropriate use of psychotropic medications. It is recognised that the implementation of many of the Guideline recommendations and good practice statements will be dependent on adequate resources.	
14.	Recommendation and good practice statements on antipsychotics	Multiple respondents noted that recommendations, good practice statements and best practice should also consider contextual factors and clinical judgement for appropriate use of antipsychotics medications.	Evidence-based practice involves research evidence, resident preferences and values, and clinician judgment and experience. The importance of informed and shared decision-making has been embedded into the Guideline. Recommendations and good practice statements have been formulated to provide flexibility in relation to individual resident and provider contexts (e.g. slower dose tapering may be needed when discontinuing psychotropic medications that have been used on a longer-term basis). We have also advocated for specialist review when assessing the possible need for continuation beyond standard recommended maximum treatment duration.	The Guideline Development Group thanks the respondents for their comments.
15.	The Guideline	Respondent suggested including reference to the importance of Advance Care Planning and Advance Care Directives for people living with dementia.	The Guideline Development Group agrees and recognises that Advance Care Planning and Advance Care Directives have an important role to play in the care of people living with dementia.	Further information about Advance Care Planning and Advance Care Directives has been added to the Guideline. Amendments include: • Addition of Good Practice Statement 14 that recognises the relevance and importance of

				Advance Care Planning and Advance Care Directives.
16.	Conditional Recommendation 1	Respondents noted that the statement required further contextualisation and clarity on wording.	The Guideline Development Group agrees with the respondents suggested comment.	Amendment to the statement is underlined: • <u>For people living with dementia and changed behaviours,</u> the Guideline Development Group recommends against the use of first-generation antipsychotics as the risk of harms outweigh the potential benefits.
17.	Conditional Recommendation 2	Respondents noted that the statement required further contextualisation and clarity around wording.	The Guideline Development Group has decided to retain the current wording, as it is correct for this context.	The Guideline Development Group thanks the respondents for their comments.
18.	Conditional Recommendation 4	Respondents suggested addition of the following: • Discontinuation requires individualised and gradual/slow tapering plan. • Regular monitoring of the person's mental state for symptoms and signs of relapse or any discontinuation effects.	The Guideline Development Group recognises the importance of regular monitoring, and slow and individualised tapering plan, however decided to retain the current wording as these points are explained in Good Practice Statements 10 and 23	The Guideline Development Group thanks the respondents for their comments.
19.	Conditional Recommendation 5 and Conditional Recommendation 13	Respondents commented: • Clarification is required for the terms 'acute anxiety', 'acute bereavement' and 'emotional shock', which are not diagnostic labels. General terms have the potential to become a justification for benzodiazepines in a variety of situations.	The Guideline Development Group supports the suggestion to remove indications, which do not represent a diagnostic label.	Amendments to recommendation 5 and 13 have been made to only include: • <u>Conditions such as significant alcohol withdrawal, acute seizures and end-of-life care in the last days of life.</u>

		• Specific symptoms for which the medication can be used for the individual resident and any other circumstances governing its use should be documented.		
20.	Conditional Recommendation 6	Respondents suggested addition of the following: • Discontinuation requires individualised and gradual/slow tapering plan.	The Guideline Development Group recognises the importance of regular monitoring, and slow and individualised tapering plan, however decided to retain the current wording as these points are explained in Good Practice Statements 10, 29 and 30, which accompany the recommendation.	The Guideline Development Group thanks the respondents for their comments.
21.	Conditional recommendation 7	Respondent suggested re-wording of recommendation to improve clarity that the statement relates to the treatment of agitation alone.	The Guideline Development Group agrees with the respondents comment and have amended accordingly.	Amendments to the statement are underlined: • <u>For people living with dementia and agitation, the Guideline Development Group recommends against routine use of antidepressants for the treatment of agitation, on the basis of evidence of adverse events and limited effectiveness</u>. If a person living with dementia is experiencing agitation and has not responded to adequate non-pharmacological strategies and a medication is considered, a trial of selective serotonin re-uptake inhibitors (SSRIs) may be safer than antipsychotics depending on the individual's harm-benefit profile. Citalopram has the strongest

				evidence for agitation in people living with dementia.
22.	Conditional recommendation 8 and 9	Respondents commented: • Caution against recommendations to not use antidepressants. • Lack of mention of the need to ensure intervention when someone has suicidal ideation and importance of early intervention and optimal mental health outcomes. • Lack of mention of the need to ensure intervention when the person has clinically significant depression. • Include situations where it might be reasonable to trial antidepressants, as there might be a range of reasons for not responding to a previous trial of an antidepressant. • Widening the recommendation for using antidepressants to those with a moderate depressive disorder, who have not previously responded to an antidepressant.	The Guideline Development Group recognises the importance of clinical context. The Guideline Development Group has sought to provide greater clarity in the statements. The Guideline Development Group does not agree with widening the recommendation for using antidepressants to those with a moderate major depressive disorder, who have not previously responded to an antidepressant.	Amendments to the statement are underlined: Addition of Conditional Recommendation 8: • For people living with dementia who develop clinically significant depressive symptoms, the Guideline Development Groups recommends assessment by a a psychiatrist, geriatrician **and/or** older person's mental health as early as possible. Amendments to the following statements are underlined: • For people living with dementia who <u>newly</u> develop depressive symptoms or mild-to-moderate major depressive disorder, the Guideline Development Group recommends against routine initiation of antidepressants. For people living with dementia who develop moderate major depressive disorder AND who have previously responded to an antidepressant, consider prescribing an antidepressant when an adequate trial of non-

				pharmacological strategies alone has been unsuccessful. For people living with dementia who develop severe major depressive disorder or depressive disorder <u>with suicidal ideation and/or risk of self-harm</u>, consider prescribing an antidepressant alongside non-pharmacological strategies. Assessment by a psychiatrist is recommended for people living with dementia who develop severe major depressive disorder or depressive disorder with <u>suicidal ideation and/or risk of self-harm</u>
23.	Conditional recommendation 11	Respondents commented: • Suggest taking 'severe' depression out of first sentence • Adding to second sentence as: *'history **of** **<u>episode/s</u>** of severe major depressive disorder…consider continuing treatment…This review should be undertaken by, or in consultation with, a psychiatrist'* • Suggest that for recurrent depressive episodes, antidepressant therapy be continued more than six months and ideally longer than a year • Where a specialist psychiatrist is not available, allowances must be made for the specialist GPs and Rural Generalists providing	The Guideline Development Group agrees with the respondents comment and have amended accordingly	Amendments to the statement are underlined: • For people living with dementia using an antidepressant <u>for mild-to-moderate major depressive disorder,</u> the Guideline Development Group recommends a regular review of the harms and benefits of continuation, in consultation with the person living with dementia and/or their substitute decision-maker, and to discuss the option of discontinuation. For people living with dementia <u>with a first-time episode of severe major depressive disorder who respond to treatment, the antidepressant</u>

		regular care to manage patients to keep them safe and well.		should be continued for six months after symptoms have resolved then a trial of discontinuation should be considered. For people living with dementia who develop severe major depressive disorder, who have had a history of one or more episode/s of severe major depressive disorder or depressive disorder with suicidal ideation and/or risk of self-harm, consider continuing treatment and reviewing regularly for harms. This review should be undertaken by, or in consultation, with a psychiatrist, geriatrician **and/or** older person's mental health.
24.	Conditional Recommendation 12	Respondents suggested: • Addition of 'or other appropriate indications' to statement.	The Guideline Development Group agrees with the respondents suggested comment.	Amendments to the statement are underlined: • For people living with dementia using an antidepressant for agitation, without evidence of concomitant major depressive disorder or another appropriate indication, the Guideline Development Group recommends that discontinuation be considered.
25.	Good Practice Statement 2	Respondent commented: • Good practice statements would be improved if it outlined the specific roles and responsibilities and align them with existing professional standards and resources.	The Guideline Development Group agrees with this suggestion in principle. However, the good practice statements have been worded to provide a degree of flexibility to health care professionals and aged care provider organisations to implement the statements within their	Amendments to the statement are underlined: • Prescribers, pharmacists, aged care providers, nursing and aged care staff all have responsibilities in facilitating the active involvement of

			local context. This was deemed important due to variability in access to resources across Australia, including in rural and remote areas.	people living with dementia in decision-making in relation to use of psychotropic medications. Each professional group should be familiar with and adhere to their own professional practice standards for safe and effective medication management.
26.	Good Practice Statement 3	Respondent commented: • Powerful and effective wording about decision-making under the heading of Substitute Decision-Maker and Supported Decision-Making should be reflected in the Good Practice Statement 3 • Suggest addition of: It should not be assumed that people living with dementia cannot make decisions regarding their own treatment. • Suggest addition of: Supported decision-making can involve a person that the person living with dementia trusts.	The Guideline Development Group agrees with the suggestion *'it should not be assumed that people living with dementia cannot make decisions regarding their own treatment'* and *'Supported decision-making can involve a person that the person living with dementia trusts*'. The Guideline Development Group will retain the remaining wording as is.	Amendments to the statement are underlined: • The ability of people living with dementia to make decisions regarding medications often declines but may fluctuate over time. However, it should not be assumed that people living with dementia cannot make decisions regarding their own treatment. Supported decision-making involves a trusted person assisting a person living with dementia to decide. It may also be necessary to involve a substitute decision-maker to make decisions on behalf of the person living with dementia. Substitute decision-making is legislated by Australian states and territories. In some Australian jurisdictions there are occasions when a substitute decision-maker cannot make health decisions on behalf of the person living with dementia and health decisions

				must be referred to the relevant Tribunal. •
27.	Good Practice Statement 4	Respondent suggested: • Addition of: non-pharmacological strategies should also be used with a view to reducing and eliminating the medications if possible**.**	The Guideline Development Group agrees with the respondents suggested comment and will amend the accordingly.	Amendments to the statement are underlined: • Psychotropic medications should not be considered as an alternative to non-pharmacological strategies. If a psychotropic medication is used, non-pharmacological strategies should continue alongside pharmacological treatment. <u>Non-pharmacological strategies may assist to minimise the dose and duration of psychotropic medication use..</u>
28.	Good Practice Statement 5 and Good Practice Statement 6	Respondents commented: • Suggest replacing 'periodically' with 'regularly'. • Suggest including that the discussion occurs in the preferred language of the person living with dementia and/or alternate communication methods may be needed. • In relation to 'comprehensive discussions', consideration of the resourcing challenges in RACF may be needed as this may be unrealistic to achieve in aged care facilities currently. • Suggest indicating that the prescriber has primary	The Guideline Development Group have chosen to use the wording 'prior to prescribing' rather than indicate that it is the 'primary responsibility of the prescriber' for the comprehensive discussion about harms and benefits and to obtain informed consent. While we envisage that these responsibilities will often fall within the domain of the prescriber, we have provided a degree of flexibility in the wording to allow for implementation in different contexts and with different workforce models. .	Amendments to the statement are underlined: • Prior to prescribing a psychotropic medication, there should be a comprehensive discussion with the person living with dementia, support person and/or their substitute decision-maker about possible individual benefits and harms. This discussion should include treatment preferences and be documented in the medical record, behaviour support plan and nursing progress notes where applicable. <u>This discussion should consider health literacy and occur</u>

		responsibility for the comprehensive discussion about benefits and harms as this discussion is fundamental to obtaining informed consent from the consumer or the substitute decision maker.		in the preferred language of the person living with dementia where possible. Treatment preferences should be regularly reassessed.
29.	Good Practice Statement 7 and Good Practice Statement 8	Respondents commented: • Outline a commitment to set a short-term review date, then ongoing. Stating 'anticipated' could unnecessarily extended timeframes.	The Guideline Development Group agrees with suggestions for Good Practice Statement 8.	Amendments to the statement are underlined: • When initiating a psychotropic medication, the date for review should be planned and discussed with the person living with dementia and/or their substitute decision-maker, nurse and aged care staff. The date for review should be documented in the medical record, behaviour support plan and nursing progress notes where applicable.
30.	Good Practice Statement 9	Respondent commented: • Reword point about swallowing medication to improve clarity of prompt. • Add transition of care as a prompt for review.	The Guideline Development Group agrees with suggestions and have made amendments accordingly.	The Good Practice Statement has been amended to include: • Person having difficulty or refusing to swallow medications, particularly when no alternative dose forms exist. • Transition of care.
31.	Good Practice Statement 10	Respondent commented: • Suggest inclusion that all tapering plans should be developed with pharmacist involvement. Due to the	The Guideline Development Group agree with the importance of developing individualised tapering plans and the value of analysing previous attempts at discontinuation. We agree that tapering	Amendments to the statement are underlined: • An analysis of previous unsuccessful attempts at discontinuation should be

		formulation of some medicines (e.g. sustained or extended release tablets), halving or breaking tablets is not appropriate. Pharmacists can guide best way to reduce dose for particular medicines. • Add that analysis of previous unsuccessful attempt at discontinuation should be undertaken to establish, if possible, factors that may influence a successful reduction or discontinuation.	plans should be developed with relevant members of the health care team. We envisage that this will often fall within the domain of the pharmacist, however, we have provided a degree of flexibility in the wording to allow for implementation in different contexts and with different workforce models.	undertaken to establish, if possible, factors that may influence a successful reduction or discontinuation. • An individualised tapering plan should be developed in conjunction with the person living with dementia and/or their substitute decision-maker and relevant members of the healthcare team.
32.	Good Practice Statement 19	Respondents commented: • A week 12 review of antipsychotics by a psychiatrist/geriatrician will have significant resource implications that cannot be met • Add that analysis of previous unsuccessful attempt at discontinuation should be undertaken to establish, if possible, factors that may influence a successful reduction or discontinuation would improve the good practice statements.	The Guideline Development Group recognises that aged care facilities operate in different contexts and can have limited access to specialist medical services. However, the Guideline Development Group believe specialist review is important in the care of people living with dementia. All recommendations and good practice statements have been developed to outline and establish best practice for the appropriate use of psychotropic medications. We anticipate that the recommendations and good practice statements may be used for advocating for greater resource allocation and innovative workforce models.	Amendments to the statement are underlined: Total initial antipsychotic treatment duration for changed behaviours should not exceed 12 weeks. The planned treatment end date should be recorded in the medical record, behaviour support plan, pharmacy dispensing history and nursing progress notes. Exceptions for continuation beyond 12 weeks include as of part of a period of dose tapering as part of planned treatment reduction or discontinuation. Continuation beyond 12 weeks should not occur without either: • review by a psychiatrist or geriatrician; • a formal documented discussion between the prescriber and a

				psychiatrist or geriatrician in which both practitioners agree; or • a documented clinical review involving the prescriber and at least one other medical practitioner in which both practitioners agree. • Amendments about unsuccessful discontinuation analysis has been added to good practice statement 10.
33.	Good Practice Statement 22	Respondents commented: • If psychotropic doses are reduced/discontinued, this would usually be done slowly following review by, or in consultation with, a psychiatrist. • There are significant potential risks in reducing or withdrawing psychotropic medications in people with severe mental illness, such as risk of relapse of mental illness, distress, suicidal ideation and physical aggression.	The Guideline Development Group recognises the key role that psychiatrists have in the care for people living with dementia who have mental illness/psychiatric comorbidities.	Amendments to the statement are underlined: • For people living with psychiatric comorbidities (e.g. schizophrenia, bipolar disorder) who develop dementia, antipsychotic maintenance treatment may be continued according to the person's treatment plan that has been developed in consultation with a psychiatrist. Regular review of the harms and benefits should be undertaken by, or in consultation, with a psychiatrist.
34.	Good Practice Statement 23	Respondents commented: • Statement should include mention to regular monitoring of the patient's mental state for symptoms and signs of relapse or any discontinuation effects should occur.	The Guideline Development Group agrees with suggested addition and have amended accordingly.	Amendments to the statement are underlined: • Regular monitoring should occur for discontinuation symptoms or reoccurrence of symptoms.

35.	Good Practice Statement 24	Respondents commented: • Statement should include the situations where symptoms recur within the tapering process, not just after discontinuation. • Statement should include that psychotic symptoms should also be qualified because sometimes the nature of the psychotic symptom is more important/distressing than its frequency.	The Guideline Development Group agrees with the addition of the word qualified and with the need to cover situations where significant reduction of symptoms does not occur. The Guideline Development Group will retain the remaining wording as is.	Amendments to the statement are underlined: • Any recurrence of distressing psychotic symptoms or aggression/agitation following antipsychotic discontinuation should be quantified and <u>qualified,</u> documented in the medical record, behaviour support plan and nursing progress notes. If treatment of these recurrent symptoms is not possible with adequate non-pharmacological strategies, restarting of the antipsychotic or trialling a different medication may be considered. <u>If there is not a significant reduction in symptoms advice should be sought from a psychiatrist, geriatrician, outreach team or behavioural management advisory service.</u>
36.	Good Practice Statement 29	Respondents commented: • Statement should indicate that 25%-50% dose reduction is only suggested and tapering plans for long term users may need to be slower.	The Guideline Development Group agrees with suggested clarification of wording.	Good Practice Statement 29 has been reworded to improve clarity.
37.	Good Practice Statement 31 and Good Practice Statement 36	Respondents commented: • Detail should be added to understand the adverse events associated with SSRI medications and take action to monitor and record, perhaps	The Guideline Development Group agrees with the respondent's suggestion.	Amendments to the statement are underlined: • If an antidepressant is indicated for a person living with dementia and major depressive disorder, selective serotonin re-uptake inhibitors (SSRIs) generally have

		linked with good practice statement 36.		the most favourable safety profile in older people, however, are also associated with adverse events such as sleep disturbance, falls, bleeding risk and hyponatremia (see GPS 36).
38.	Good Practice Statement 33	Respondents commented: • Caution is required over the statements to avoid medications with cholinergic qualities (multiple antidepressants). Blanket statements such as these do not allow for the flexibility required for a patient centred approach.	The Guideline Development Group acknowledges that where possible, antidepressants with anticholinergic properties should be avoided.	Amendments to the statement are underlined: • For people living with dementia, avoid antidepressants with strong anticholinergic properties (e.g. tricyclic antidepressants) where possible due to the risk of adverse events including cognitive impairment.
39.	Good Practice Statement 41	Respondents commented: • an explicit instruction that the prescriber of any pro re nata (PRN) psychotropics to obtain consent from the person living with dementia or their substitute decision maker before prescribing, or as soon as possible afterwards (in situations where it would not be safe to delay prescription for the purposes of first obtaining consent).	The Guideline Development Group agrees with the respondent's suggestion and have amended accordingly.	Amendments to the statement are underlined: Those who prescribe or administer PRN antipsychotics or benzodiazepines should act in accordance with the laws for informed consent in their jurisdiction and understand the conditions under which the medication can be used. Consent should be obtained from the person living with dementia or their substitute decision maker before prescribing PRN antipsychotics or benzodiazepines. If it would be unsafe to delay prescription then consent should be obtained as soon as possible afterwards.

40.	The Guideline	NHMRC Independent Reviewer: • While the wording of the recommendations is written in plain English it is not consistent throughout the Guideline. For example, conditional recommendation 1 is worded as 'First-generation antipsychotics are not recommended for people living with dementia and changed behaviours.' Conditional recommendation 2 is then worded as 'For people living with dementia and changed behaviours, the Guideline Development Group recommends against routine use of second-generation antipsychotics as the risk of harms outweigh the potential benefits.' Most of the guidelines presented in this document follow the format of conditional recommendation 2. It is suggested that recommendations are edited to read consistently (or as close to consistent as possible) with the wording of conditional recommendation 2.	The Guideline Development Group recognises the reviewers comment and will amend wording accordingly.	Conditional recommendations 1-14 have been amended to follow a consistent format recommended by the reviewer. Conditional recommendation 1 has been amended to 'For people living with dementia and changed behaviours, the Guideline Development Group recommends against the use of first-generation antipsychotics.' We have retained the wording of conditional recommendation 15 because we believe the recommendation is clearer the way is it currently phrased.
41.	The Guideline	NHMRC Independent Reviewer: • Note that the AGREE II assessments were being conducted during public consultation period.	NA	Two independent appraisers have completed the AGREE tool. The appraisal can be found in *Administrative Report, Appendix 2.*

42.	The Guideline	NHMRC Independent Reviewer: • The methods for the public consultation process have not been provided in the administrative report.	NA	The Guideline Development Group thanks the reviewer for their comments. The further information about public consultation has been provided in the *Administrative Report, Public Consultation* Section. A Public Consultation Summary has been added to the *Administrative Report, Appendix 1*.
43.	The Guideline	NHMRC Independent Reviewer: • Total funding from each source has not been provided.	The Guideline Development Group will amend the statement accordingly.	Our funding statement has been amended to include: **'**Development of this Guideline was funded by the Dementia Centre for Research Collaboration (DCRC). Additional funding support was provided by the NHMRC Boosting Dementia Research Leadership Fellowship awarded to Professor Simon Bell.'
44.	The Guideline	NHMRC Independent Reviewer: • Please see comment D.2 regarding consistent language.	The Guideline Development Group recognises the respondents comment and will amend wording accordingly.	Conditional Recommendations 1-14 have been amended to follow a consistent format recommended by the reviewer. Conditional Recommendation 1 has been amended to 'For people living with dementia and changed behaviours, the Guideline Development Group recommends against the use of first-generation antipsychotics.' We have retained the wording of Conditional Recommendation 15 because we

				believe the recommendation is clearer the way is it currently phrased.
45.	The Guideline	NHMRC Independent Reviewer: • The authors stated that there were no major clinical trials underway that would impact the strength or direction of the Guideline recommendations. While this is perfectly acceptable, it is suggested to include a statement that indicates as such in at least the technical document, when reporting the number of records identified from the searching of databases (e.g., following the 'search results' subheading in the 'results' subheading.	The Guideline Development Group agrees with suggested clarification of wording and have amended accordingly.	We have added the following sentence in each of the Results sections the in Technical Report Part 2. *'No major clinical trials were identified that may impact the strength or direction of the Guideline recommendations.'*
46.	The Guideline	A summary of recommendations is not available as a separate document, however it does appear as its own section within the guideline document itself as part of the executive summary.	The Guideline Development Group notes this comment and will provide a summary of recommendations document.	A separate document of the recommendations has been added to the Guideline.
47.	The Guideline	NHMRC Independent Reviewer • The Guideline Development Group has used available systematic reviews and where necessary updated these by further searches to include more recent studies. It is striking that for several topics there is little recent research, which may reflect the difficulties of undertaking suitable studies and	The focus on antipsychotics, benzodiazepines and antidepressants was informed by stakeholder consultation and are considered the three most commonly used medication classes in this context. The Guideline Development Group agrees that it would be worth differentiating between possible benefits and harms of benzodiazepines vs. Z-	Amendments made: • Further information about the medication focus has been added to the *About this Guideline* section, including a statement of the medication classes that were included in the systematic search for evidence.

		also of attracting funding to do such research. It might have been useful to consider the role of the Z-drugs (zopiclone and zolpidem) as alternatives to benzodiazepines in the treatment of insomnia.	drugs. However, this would be a separate clinical question and is beyond the scope of the present Guideline. During the evidence review, the systematic search was not inclusive of Z-drugs and given the evidence on people living with dementia and psychotropic medication is limited, the Guideline Development Group is unable to make evidence-based statements about Z-drugs.	
48.	The Guideline	NHMRC Independent Reviewer • Various Australian and international sources are cited, and there don't seem to be any major inconsistencies. There is however no mention of the UK NICE guidance, for example that on antipsychotic prescribing Antipsychotics | Prescribing information | Dementia | CKS | NICE. There are some differences here, e.g. NICE suggests no more than 6 weeks treatment, in contrast to up to 12 weeks in these guidelines. Also haloperidol appears (slightly surprisingly, perhaps) alongside risperidone in the NICE guidance.	During the early Guideline development process, the project team assessed multiple Guidelines that may have been be suitable to adapt, (refer to Technical Report Part 1 section Guideline Methodology), this included the National Institute for Health and Care Excellence (NICE) - Dementia: assessment, management and support for people living with dementia and their carers (UK, 2018). The Guideline Development Group were aware of the NICE guidance. However, the Guideline Development Group opted for consistency with other Australian recommendations. Our recommendation is consistent with the 2016 Clinical Practice Guidelines and Principles of Care for People Living with Dementia. Our 12-week recommendation is also consistent with 2021 Australian Therapeutic Guidelines that	The Guideline Development Group thanks the reviewer for their comments.

			recommends avoiding continuing an antipsychotic for longer than 12 weeks to treat agitation, aggression or psychosis in dementia. Our recommendation is consistent with the Australian Pharmaceutical Benefits Scheme (PBS) criteria for up to 12 weeks of initial treatment with risperidone. While we have recommended that total initial duration should not exceed 12 weeks, we have also recommended that treatment effectiveness and dose should be reviewed every 1-2 weeks. We have also recommended that all residents of aged care facilities living with dementia who use antipsychotics for changed behaviours should have an adverse event monitoring protocol.	
49.	The Guideline	NHMRC Independent Reviewer: • The guidelines largely make sense and the emphasis on stopping treatment alongside starting it is welcome. The guidelines require quite a lot of consultations and reviews, which probably would have resource implications, but that may be beyond the scope of the current exercise.	The Guideline Development Group notes the reviewers comment and agrees that implementation of the Guideline will require a multidisciplinary approach. Throughout the guideline development process, we conducted focus groups with 5 aged care provider organisations to obtain feedback about topics including the processes and resources required for implementation. We have considered the resource implications for each clinical question using the GRADE Evidence toDecision framework.	The Guideline Development Group thanks the reviewer for their comments.

			We believe that consultation and review are important elements in the appropriate use of psychotropic medications in people living with dementia. We will produce a series of resources to assist with guideline implementation (e.g. 1-page fact sheets, companion guide, curated inventory of existing resources). We also note that recent workforce developments (e.g. funding for embedded onsite pharmacists from January 2023) may assist with guideline implementation.	
50.	The Guideline	NHMRC Independent Reviewer: • My only comment relates to 'depression' below. Why not say 'moderate to severe or moderate and severe depression'? Also, this sentence implies that you only prescribe if it's moderate depression and have previously responded to an antidepressant. I'm not clear where that evidence is coming from. If someone has moderate/severe depression and hasn't responded to non-pharmacological treatment, it's reasonable to consider a trial with all the caveats and safety monitoring for ADRs in place. • 'For people living with dementia who develop moderate major depressive disorder AND who have previously responded to an	The Guideline Development Group have amended some of the wording of this recommendation to improve clarity of the recommendation. The Guideline Development Group does not agree with widening the recommendation for using antidepressants to those with moderate depressive disorder, who have not previously responded to an antidepressant.	Amendments to the wording of statement to improve the clarity include the following additions and amendments: Amendments to the statements are underlined: Addition of Conditional Recommendation 8: • <u>For people living with dementia who develop clinically significant depressive symptoms, the Guideline Development Groups recommends assessment by a a psychiatrist, geriatrician and/or older person's mental health as early as possible.</u> Amendments to the following statements are underlined:

		antidepressant, consider prescribing an antidepressant when an adequate trial of non-pharmacological strategies alone has been unsuccessful'.		• For people living with dementia who newly develop depressive symptoms or mild-to-moderate major depressive disorder, the Guideline Development Group recommends against routine initiation of antidepressants. For people living with dementia who develop moderate major depressive disorder AND who have previously responded to an antidepressant, consider prescribing an antidepressant when an adequate trial of non-pharmacological strategies alone has been unsuccessful. For people living with dementia who develop severe major depressive disorder or depressive disorder with suicidal ideation and/or risk of self-harm, consider prescribing an antidepressant alongside non-pharmacological strategies. Assessment by a psychiatrist is recommended for people living with dementia who develop severe major depressive disorder or depressive disorder with suicidal ideation and/or risk of self-harm

MONASH University

Appendix 2 – AGREE Tool Appraisals

AGREE Tool Appraiser 1								
AGREE II tool								
	1 Strongly Disagree	2	3	4	5	6	7 Strongly agree	Comments
Domain 1								
Item 1							X	The objectives are clearly described. Expected benefit or outcome is not specifically stated in the main document. However, this is specifically stated for each individual question in the Technical report Part 2.
Item 2							X	Clearly describes what is in and out of scope. The target population is clearly defined as is the healthcare settings and contexts. Target medications are well specified.
Item 3							X	Both the target population groups and the target audience are clearly described
Domain 2								
Item 4						X		A specific development group was established. All relevant details, except geographic location, were provided for each member. Geographic location could be determined for many of the members based on their institution location. Members were of appropriate backgrounds and skill sets and the group was chaired by a methodology expert. The roles and responsibilities of the group were clearly defined in the administrative report.
Item 5							X	A Stakeholder Advisory Group was established with excellent representation from relevant peak bodies representing clinical, consumer, aged care providers and relevant government quality improvement agencies. The involvement of people with lived experience is also noted. These groups and their level of involvement are clearly defined in the administrative report.

Item 6							X	The target audience is well defined and a detailed implementation and dissemination plan has been provided.
Domain 3								
Item 7							X	All electronic databases and websites used in the search are listed. All terms are listed and the full search strategy provided in the technical report - part 1. Search dates are provided in technical report part-2 for each question and database. Sufficient detail is provided for replication.
Item 8						X		Each clinical question was framed using the PICO process. Study design hierarchy was pre-specified and inclusion/exclusion criteria were clearly documented both overall and for each question. The justification for the inclusion/exclusion criteria was not always clear
Item 9							X	Studies were independently assessed for methodological quality using well established risk of bias tools. The evidence for each clinical question was reviewed and discussed by the Guideline Development group. The GRADE Evidence to Decision (EtD) framework was used to guide formulation of the guidelines based on the evidence.
Item 10					X			A voting system was used following review and discussion of the EtD framework to determine the direction of the recommendation using the GRADE definitions. Methods for resolving disagreement or gaining consensus rather than majority for contentious issues were not specified.
Item 11							X	For each question a range of considerations were presented including benefits vs harms, acceptability, equity, preferences and values etc.
Item 12							X	Each recommendation is preceded by a section describing the deliberations of the Guideline Development Group. Each recommendation is clearly linked to the evidence, including tables of results, quality assessments of the evidence and how these influenced the recommendations.
Item 13					X			Recommendations were released for public consultation. However, I cannot find any specific evidence of mention of

								the external review process – of which this assessment is part. This may be added following completion of the reviews.
Item 14					X			A statement on updating the guidelines is provided with time frames. Specific methods for performing updates is lacking.
Domain 4								
Item 15							X	All recommendations are specific, clearly presented and include key criteria such as the population, the recommended action and its purpose. Special considerations where these do not apply and timeframes (where appropriate) are clearly described.
Item 16						X		Alternative options are not specified directly but via links to related recommendations
Item 17							X	Key recommendations are clearly defined and easy to access/find. Recommendations are well supported by good practice statements.
Domain 5								
Item 18							X	Barriers and sensitivities were identified by the Stakeholder Group and through focus groups with aged care providers and carers of residents throughout the guideline development process. Barriers and facilitators were also identified and described for each clinical question as were values and preferences of consumers, resources, equity, acceptability and feasibility. Discussion by the guideline Development Group on each of these aspects was used to inform recommendations and strategies
Item 19					X			A dissemination plan has been made available for public consultation. Key messages directed towards target audiences will be developed. A range of supporting resources will be developed including summaries, digital resources and lay resources for consumers. It appears that these have not yet been produced. However, dissemination activities have been planned in detail with associated timelines
Item 20						X		Resources and other considerations are listed for each clinical question and were considered by the development

								group as part of the Evidence to Decision Framework. Where available costing data were drawn from the literature for direct and indirect costs. Scenarios related to both increased and decreased costs were presented and costings of alternative treatments considered. May have benefited from having a health economist involved.
Item 21					X			Success and measurement indicators are outlined to measure the success of the dissemination process. There are no specified processes for ongoing audit or monitoring of process measures or person level outcomes as an indicator of guideline adherence. However, there are some recommendations within the Good Practice Statements related to implementing systems to monitor adverse events
Domain 6								
Item 22						X		The name of the funding body is explicitly stated. There is not specific wording that the funding body did not influence the content of the guideline. However, given the nature of the funding body this is unlikely
Item 23							X	A robust COI process was in place and clearly communicated in the administrative report
Overall guideline assessment								
	1 Lowest possible quality	2	3	4	5	6	7 highest possible quality	
Rate the overall quality of this guideline							X	
I would recommendation this guideline for use	**Yes**		Yes, with modifications		No			Overall this is a thorough, robust and important piece of work, undertaken in a complex area of clinical practice. The main limitation is that dissemination resources have not yet been developed and there does not appear to be a system for ongoing monitoring of adherence to the guidelines. However, these aspects do not impact on the quality of the

				guidelines themselves and I expect the resources will be developed as per the dissemination plan.

AGREE Tool Appraiser 2								
AGREE II tool								
	1 Strongly Disagree	2	3	4	5	6	7 Strongly agree	Comments
Domain 1								
Item 1						X		p15, first para. Clear statement; not specific regarding expected health benefits.
Item 2						X		The detailed clinical questions are clearly provided in the Technical Report, part 1. The overarching question(s) is less explicit in the introduction to the guideline.
Item 3							X	Introduction. Clear statement.
Domain 2								
Item 4						X		Provided in administrative report. Appropriate membership for guideline topic and scope. Methodology expert included; policy makers, disciplinary experts included. The disciplinary/content expertise of a small number of members is not provided.
Item 5							X	Views and preferences of target population included via: * membership of GDG (carers with lived experience) * literature search of values, preferences, equity informed the evidence review/evidence-to-decision framework
Item 6					X			Clearly defined, if somewhat brief (Sec5).
Domain 3								
Item 7							X	Explicitly and comprehensively provided in the two Technical reports.
Item 8							X	Explicitly and comprehensively provided in the Technical Reports.
Item 9						X		The GRADE framework has been used to describe the certainty of evidence for each clinical question. The specific

								context -- examining harms as much or more than benefits, but reporting the strengths and limitations of the body of evidence together -- makes some of the discussion surrounding the body of evidence challenging to interpret.
Item 10						X		The description the recommendation development process is clear. The GRADE process was used. The specifics of the voting and specific process of the Good Practice Statements are less clear.
Item 11							X	Clear attention to benefits, side effects and risks throughout. Clear reporting (in a complex area); recommendations reflect benefits and harms.
Item 12						X		GRADE process used; evidence-to-decision is explicitly provided.
Item 13				X				This is not currently described, but this activity *is* an external review. I have interpreted this as separate from public consultation. Need to decide whether to include this item.
Item 14						X		Statement of intention in introduction. Use of technology to facilitate update (Magic App). Brief details on methodology.
Domain 4								
Item 15						X		The recommendations are as specific as the context permits. One or two recommendations could possibly be more specific (or the reasons they could not be more specific could be clearer) e.g. discontinuation.
Item 16						X		Non-pharmacological options (as a specific example) are considered.
Item 17							X	
Domain 5								
Item 18							X	Resources, acceptability and feasibility were explicitly considered for each clinical question. The dissemination plan also considers some of these factors.
Item 19						X		Dissemination plan.
Item 20						X		Resource implications for each set of recommendations are explicitly considered.

Item 21			X					As far as I can determine, there is nothing in the guideline currently that provides explicit advice regarding monitoring/audit criteria. This information is also not in the dissemination plan. That said, the recommendations are worded in a way that permits the development of monitoring/audit criteria and the dissemination plan identifies recommendations most likely to have an impact on public health.
Domain 6								
Item 22				X				The process and details regarding conflicts of interest are explicitly provided in the Administrative report. The funding body is clearly identified in multiple places. I am unable to find an explicit statement that the funding body did not influence the content of the guideline. (Given the role and function of the funding body, the risk associated with this omission are very small).
Item 23							X	This is explicitly and comprehensively provided in the Administrative Report.
Overall guideline assessment								
	1 Lowest possible quality	2	3	4	5	6	7 highest possible quality	
Rate the overall quality of this guideline						X		
I would recommendation this guideline for use	**Yes**		Yes, with modifications		No			The guideline is clearly communicated, the GDG and stakeholder advisory group are broad in terms of expertise and inclusion and the methods employed are rigorous and comprehensive. The context for the guideline is highly complex which presents challenges for evidence evaluation and communication. The guideline meets and communicates these challenges very well.

References

1. National Health and Medical Research Council. 2016 NHMRC Standards for Guidelines. Canberra: Commonwealth of Australia; 2016. [Available from: https://www.nhmrc.gov.au/guidelinesforguidelines/standards].