AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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Updating National Quality Use of Medicines Publications

Consultation paper

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Quality Use of Medicines and National Medicines Policy

The National Medicines Policy (NMP) underpins people's access to, and wise use of medicines.

Quality Use of Medicines (QUM) is one of the central objectives of Australia's NMP. It focuses on:

- Selecting management options wisely
- Choosing suitable medicines if a medicine is considered necessary, and
- Using medicines safely and effectively.

Medicines include prescription, non-prescription and complementary medicines.

Three National QUM publications related to medication management are currently available including[1]:

- Guiding principles for medication management in residential aged care facilities (October 2012)
- Guiding principles for medication management in the community (June 2006)
- Guiding principles to achieve continuity in medication management (July 2005).

The development of the original versions of the above guiding principles was overseen by the Australian Pharmaceutical Advisory Council, which has since been disbanded.

Due to the staggered timing of these reviews, this consultation will focus on the first two guiding principles for medication management mentioned above for residential aged care facilities and in the community.

A Project Advisory Group has been convened to provide technical and strategic advice in updating these two QUM publications.

The *Guiding principles to achieve continuity in medication management* will be the subject of a separate consultation.

[1] Publications relevant to the National Medicines Policy (NMP). Australian Government Department of Health. Available from https://www1.health.gov.au/internet/main/publishing.nsf/Content/Publications-16 Updated 08 May 2019 [Accessed 2 June 2021]

Updating National QUM publications

Background

In June 2006, the Australian Pharmaceutical Advisory Council released Guiding principles for medication management in the community. Guiding principles for medication management in residential aged care facilities were released by the Australian Government Department of Health and Ageing in October 2012. In 2021, the Australian Commission on Safety and Quality in Health Care (the Commission) was engaged by the Australian Government Department of Health to review and update these two documents.

To inform this process, a literature review and environmental scan[2] was commissioned to identify areas of importance in the quality use of medicines (QUM) and medication safety landscape for medication management within residential aged care facilities (RACFs) and the community.

The literature review and environmental scan[2] provided a summary of:

- Best practice evidence for medication management within RACFs and the community
- Review and alignment of the current evidence with existing healthcare professional practice standards, guidelines and the current guiding principles documents
- Perceived gaps, benefits or limitations of the findings.

Areas of importance highlighted in the QUM and medicines safety landscape included[2]:

- Use of digital solutions for medication management
- New models of care: embedded pharmacists in general practice and residential aged care
- The importance of deprescribing
- Polypharmacy and high risk medicines, for instance, inappropriate psychotropic use in aged care
- Transitions of care (e.g. entry to aged care from the community, transition from hospital back to home/aged care, transition of care between GPs and specialists)
- Non-medical prescribing of prescription-only medicines; including prescribing by nurses, midwives, podiatrists, optometrists, dentists

In the Australian healthcare context, updating the guiding principles for medication management needs to occur within the framework of Australia's NMP and the National Strategy for Quality Use of Medicines (NSQUM). The NSQUM incorporates individual behaviour change, organisational change and public health principles.

The NSQUM identifies the need to engage all groups whose activities influence QUM and medication safety, and to target all levels of behaviour change from awareness and knowledge of the associated issues, through to skills development and support and reinforcement for behaviours supporting medication safety.[3]

The NSQUM outlines the 'key partners' who are responsible for achieving QUM. All of these key partners need to be involved in developing and implementing interventions to improve QUM.[3]

Australia has a National Strategy for Quality Use of Medicines, the goal of which is to make the best possible use of medicines to improve the health outcomes of Australians. There are five key principles underpinning the national Quality Use of Medicines strategy:

1. the recognition of the primacy of consumers and their views
2. the notion of partnership between key participants
3. the need for consultation and collaboration and multidisciplinary activity in the design, implementation and evaluation of Quality Use of Medicines initiatives
4. support for existing Quality Use of Medicines activities and initiatives
5. the need to adopt and embrace system-based approaches.

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[2] Literature review and environmental scan: Medication management within residential aged care and the community. A report prepared by the Quality Use of Medicines and Research Centre, University of SA. April 2021.
[3] The National Strategy for Quality Use of Medicines – Executive Summary. Australian Government Department of Health and Ageing. [Accessed 4 June 2021]

A 2020 paper[4] highlighted several key considerations for updating the NMP, which is important to consider when updating the National QUM publications:

- **Person-centred focus:** the NSQUM already recognises that people are the focus of all interventions that improve medicines use. The review should include **a focus on vulnerable populations** – this includes older people (including many aged care residents); Aboriginal and Torres Strait Islander peoples, people from culturally and linguistically diverse backgrounds (including migrants and refugees), people with mental illness, disability or chronic conditions.
- **Medication safety:** monitoring risks associated with medicines is already included in the guiding principles, however, there needs to be an **increased focus on ways to prevent medication related harm** when updating the National QUM publications. Australian research has shown that more than 250,000 hospital admissions each year are due to harm from medicines and half of them could be prevented with better medication management.[4] The WHO global patient safety challenge 'Medication without harm' aims to halve preventable medication related harm by 2023. Australia's response has similar objectives including the goal to reduce avoidable medication errors, reduce adverse drug events and halve medication-related hospital admissions by 2025. These objectives align with the intent of Australia's 10th National Health Priority: Quality Use of Medicines and Medicines Safety
- **Digital health:** use of digital health solutions like My Health Record, electronic prescribing and electronic medication management has increased significantly since the current guiding principles documents were published.[4] The updated versions need to include **a greater focus on digital solutions for medication management**, including the use of telehealth.

The changing healthcare environment is also noted.[4] People are living in their homes for longer. People who would have lived in aged care when the 2012 *Guiding principles for medication management in residential aged care* were published now continue to live in their own homes with extra supports.[5] This includes those who choose to die at home and need to access palliative care services. The medication management needs of people living in residential aged care are now more complex than they were in 2012, and many people living in the community have much more complicated medication management than they did in 2006,[6] when the *Guiding principles for medication management in the community* were released.

[4] McLachlan A, et al. National Medicines Policy 2.0: a vision for the future. Australian Prescriber 2020;43(1):24-6.
[5] Pharmaceutical Society of Australia. Medicine safety: take care. Canberra: PSA, 2019.
[6] Inacio M, et al. Health Status and Health Care Trends of Individuals Accessing Australian Aged Care Programs Over a Decade: The Registry of Senior Australians (ROSA) Historical Cohort. Internal Medicine Journal 2020; accepted for publication, in press.

Proposed new guiding principles

Person-centred care

It is proposed that an additional or over-arching guiding principle on person-centred care is featured within both National QUM publications. This will ensure there is a clear focus on the need for clinicians to partner with people, involve them in their care, meet their information needs and share the decision-making about their treatment options (including whether using a medicine is the best option).

The updated guiding principles will need to take into account the changing medication management needs, preferences and expectations of both people living in residential aged care and those living in the community. This will necessitate a greater emphasis on person-centred care that is respectful of and responsive to each person's individual needs, preferences and values. People (and their carers) can be empowered by informing and educating them about the benefits and risks associated with medicines and how the risks can be avoided.

Health literacy plays an important role in improving safety and quality of medication management, as well as cultural safety in providing medication management services to Aboriginal and Torres Strait Islander peoples. A 2020 report on Consumer Health Literacy Segmentation and Activation Research Project identified and focused on four key 'vulnerable sub-populations':

- Older people (65 years and over)
- Aboriginal and Torres Strait Islander people
- Culturally and linguistically diverse (CALD) people
- People with low literacy and/or low health literacy.

Informed consent and legislative provisions governing the use of restraint in residential aged care are important issues especially in terms of inappropriate use of psychotropic medicines, highlighted within the Commission's Quality Use of Medicines and Medicines Safety discussion paper. Legislation has recently been updated, and the Aged Care Quality and Safety Commission have released new Guidance and resources to support the Aged Care Quality Standards and a toolkit on restrictive practices for aged care, amongst other resources.

The Commission's National Safety and Quality Health Service (NSQHS) Partnering with consumers Standard is about actively working with people who use the healthcare system to ensure that care is safe, high-quality and meets people's needs. This Standard's focus is on 'person-centred care' and is supported by various resources including:

- Australian Charter of Healthcare Rights
- Informed consent
- Charter guide for people with cognitive impairment
- Information for consumers
- Decision support tools
- Health literacy
- Shared decision-making
- Person-centred care.

Of note is that on 1 July 2019, a single Charter of Aged Care Rights (Charter) came into effect, replacing previous charters of care recipients' rights and responsibilities. The content of this Charter is consistent with the intent of 'person-centred care, and is for 'all people receiving Australian Government funded residential care, home care or other aged care services in the community'.

A new guiding principle in medication management within RACFs that focusses on person-centred care would require a systems approach that promotes and supports clinicians to partner with individuals (and/or the person responsible for their care). The expectation will likely be similar and reflect the intended purpose and scope within the updated *Guiding principles for medication management in the community*.

Recommendation:

1. That a new guiding principle is included in each updated set of guiding principles focused on person-centred care

Communicating with people receiving care and colleagues

Clinical communication is known to influence quality and safety outcomes. Effective communication is essential to ensuring safe, high-quality care.

Clinical communication should use a 'person-centred' and collaborative approach to facilitate the person's involvement in shared decision-making, advocacy and self-determination.[7]

In 2020, the Commission released a scoping paper on Communication for safety which aims to improve the understanding of how 'Australian health services support clinical communication, collaboration and teamwork'. Findings from this work are likely relevant to all environments where care is provided. Publically available materials are available on the Commission's Communicating for Safety resource portal.

On 30 June 2021, at the first meeting of the National QUM publications Project Advisory Group, which is responsible for providing technical and strategic advice for this Project, the importance of appropriate communication about medicines was highlighted. Project Advisory Group members agreed that clinician communication with the person receiving care, as well as communication between clinicians (including interdisciplinary collaboration), should both be highlighted within the revised National QUM publications, potentially as a new guiding principle in each.

Recommendation:

1. That a new guiding principle is included in each updated set of guiding principles focused on communicating with people receiving and the importance of communication between colleagues

[7] Iedema, R. and Manidis, M. (2013) Patient-Clinician Communication: An Overview of Relevant Research and Policy Literatures. Sydney: Australian Commission on Safety and Quality in Health Care and UTS Centre for Health Communication.

Purpose and scope

Given the purpose and scope of each of the two National QUM publications, the audience for consultation will vary. Whilst the existing 'purpose and scope' for each is outlined below, stakeholders will be asked to comment on this.

Guiding Principles for Medication Management in Residential Aged Care Facilities

The current version of the Guiding Principles for Medication Management in Residential Aged Care Facilities includes 17 guiding principles which collectively aim to promote 'safe, quality use of medicines and medication management' specifically within RACFs. They recognise the importance of partnerships as well as the need for a system-wide approach:

- that involves development of *behaviours and an environment that supports QUM*
- where medicines use and management is *linked to the RACF's continuous quality improvement and risk management programs*, and
- *supported by information and education strategies*.

Guiding Principles for Medication Management in the Community

The current version of the Guiding Principles for Medication Management in the Community includes 12 unique guiding principles. They also recognise the importance of partnerships or a multidisciplinary approach when providing care to people in the home. This set of guiding principles aims to:

- *promote the quality use of medicines and better medication management in the community*
- *assist service providers in developing or evaluating policies and procedures*
- *support those involved in assisting consumers*
- *support consumers in managing their medicine(s)*
- *guide health care professionals in developing and evaluating professional standards.*

The existing guiding principles are expected to be referred to and used by health care professionals and individual (personal) care workers, as well as health and community care service providers who support older persons managing their medicines in their home and in the community. They have also been available for use by other community-based services such as 'those supporting people with disabilities or chronic disease'.

Comments will be invited from stakeholders on the scope of each set of guiding principle:

1. Is the scope still relevant or does it need to change?
2. If the scope needs to change please describe what the scope should include.

Number of guiding principles

In updating the National QUM publications, it will be important to manage the overall number of guiding principles. The potential to consolidate some of the guiding principles within each publication will be explored.

Further information, recommendations and questions about new guiding principles as well as the potential for consolidation are provided throughout this consultation paper.

Consultation process

How you can help?

The Commission is seeking input via SurveyMonkey™ from people receiving care, consumers, carers, clinicians, service providers and other stakeholders in the aged care and community sectors to inform the review and updating of the National QUM publications:

- Guiding principles for medication management in residential aged care facilities (October 2012)
- Guiding principles for medication management in the community (June 2006).

The Commission is consulting with all stakeholders around Australia in August and September 2021.

Responses are due by 11:59pm AEST **Monday 27 September 2021.**

Several topics of importance in the medication management landscape have been identified since release of the National QUM publications. Gaining the views and perspectives of stakeholders will be a critical aspect to updating the National QUM publications to ensure they are relevant and meet your needs.

Please note: Depending upon your background as a stakeholder, you are invited to provide your views on one or both of the National QUM publications which are included within this consultation process as you see fit:

Chapter 1: Guiding principles for medication management in RACFs

SurveyMonkey Link: Guiding principles for medication management in RACFs Guiding principles for medication management in residential aged care facilities]

Chapter 2: Guiding principles for medication management in the community

SurveyMonkey Link: Guiding principles for medication management in the community [Guiding principles for medication management in the community]

You will be asked a series of key questions about:

- the on-going relevance of each existing guiding principle
- the modification, introduction of new, and where relevant, potential consolidation of guiding principles
- the format of the National QUM publications.

In addition, you will be asked whether you support (or not) the various recommendations that have been made within the consultation document.

Summary of questions

Incorporation of advice and consolidation

It will be important to consider whether each of the existing guiding principles is still relevant in practice and how the new areas of importance fit into the current guiding principles. Stakeholders are asked:

- Are all of the current guiding principles still relevant to medication management?
- Could some of the existing guiding principles on similar topics be 'grouped together'? For example in the guiding principles for medication management in residential aged care:
  - Could guiding principles 5 (Nurse initiated non-prescription medicines), 6 (Standing orders) be combined?
  - Could guiding principle 9 (Continuity of medicines supply) and 10 (Emergency stock) be combined?
  - Could guiding principle 11 (Storage of medicines) and 12 (Disposal of medicines) be combined?
  - Could guiding principles 13 (Self-administration of medicines), 14 (Administration of medicines by RACF staff), 15 (Dose administration aids) and 16 (Alteration of oral dose forms) be combined into a renamed guiding principle – Administration of medicines within the RACF?
- How will the areas of importance or increased emphasis in medication management fit into the updated guiding principles? For example:
  - Should they be new, stand-alone guiding principles?
  - Could they be incorporated into existing guiding principles?
  - Could they be incorporated as example case studies or models of care?
- Should there be greater focus on the medication management needs of Aboriginal and Torres Strait Islander peoples in the updated guiding principles?
- Should there be greater focus on other groups, for example, culturally and linguistically diverse (CALD) people, including migrants and refugees, in the updated guiding principles?

Format of the National QUM publications

The format of the National QUM publications will be revised when the guiding principles are updated.

In considering an updated format for the National QUM publications, consideration needs to be given as to what is the best way to ensure that the guiding principles documents remain up to date, accurate and relevant over time. The medication management landscape has changed significantly since publication of the current guiding principles documents, and the landscape is likely to continue to change in many important medication management areas over the coming months and years. Such recommendations, regulations and practice that are likely to experience significant change include:

- Medication management generally in residential aged care – as recommendations from the Aged Care Royal Commission are implemented, it is anticipated that there will be a number of policy and practice changes in this area
- Appropriate use of psychotropic medicines in residential aged care – as above, as Royal Commission recommendations are implemented it is anticipated there will be significant change
- Digital health – it is likely that use of digital solutions in medication management will continue to increase over time
- Changing funding rules and program rules for medication management services – the updated guiding principles will need to be flexible enough to remain accurate and up to date when funding rules for medication management services change.

Does the format of the current guiding principles documents meet the needs of stakeholders?

Would presentation of the guiding principles documents in an alternative format better suit the needs of stakeholders?

What alternative format(s) do you believe would meet your needs?

Chapter 1:

Updating the Guiding principles for medication management in residential aged care facilities (GP)

Guiding Principle (GP) 1: MEDICATION ADVISORY COMMITTEE

Current best practice is already outlined within **GP 1** regarding the need to ensure the establishment and empowerment of a multidisciplinary Medication Advisory Committee (MAC) to support the safe and effective management and QUM in RACFs. However, a 2020 study[8] in Victoria concluded that opportunities exist to improve the composition and structure, proactive identification and response to emerging issues, and systems for staff, the person receiving care and family carer training.

Given this research and recommendations relating to governance within the Final Report of the Royal Commission into Aged Care Quality and Safety, there is an opportunity to strengthen governance, composition and operation of MACs in overseeing medication management in RACFs.

GP 1 could be reconfigured to have a heightened focus on the clinical governance of medication management, which would include risk management and evaluation of the outcomes of the safe and quality use of medicines. For example, reducing the inappropriate use of psychotropic medicines and antimicrobial stewardship in aged care. The intent would be to ensure the RACF has systems in place to support clinicians in the safe and appropriate use of medicines and to reduce the risks associated with medication management in accordance with national, state and territory regulatory and legislative requirements. This would include the need for a MAC that:

- develops and endorses policies and procedures
- advises on legislation, standards and processes
- manages risk associated with medication management
- identifies education and training needs for medication management
- monitors effectiveness and performance of medication management and identify quality improvement strategies.

Below is proposed content for a revised **GP 1**:

Guiding Principle 1: CLINICAL GOVERNANCE OF MEDICATION MANAGEMENT

The RACF has systems that are used to support and promote safe and effective management of the quality use of medicines within the facility

Intent:
The safety and quality systems support clinicians in the safe and effective use of medicines and reduce medicine-related risk

Reflective question:
How does the RACF optimise appropriate clinical governance of medication management; support development and implementation of policies and procedures for medication management; identify and manage risks with medicines use; and identify education and training requirements for medication management?

Key tasks:

- Set up and implement clinical governance structures for medication management
- Develop and implement policies, procedures and guidelines for medication management
- Use a risk management system to identify, monitor, manage and review risks associated with medication management.

Strategies:

- Establish or have access to an interdisciplinary governance group with responsibility for medication management, including a formal reporting arrangement. This is usually a medication advisory committee (MAC), or a committee with a similar name and purpose
- Implement a suitable and relevant range of policies, procedures and guidelines for medication management that meet relevant national, state and territory legislative requirements
- Manage risks: Use established risk management systems to identify monitor, manage and review risks associated with medication management. Ensure the medication safety risks are recorded and use the information from measurement (for example, mandatory and other quality indicators: adverse events, incidents or patient experiences) to update risk assessments and inform quality improvement
- Identify education and training requirements: Assess the competency and training needs of the workforce in line with regulatory, legislative and organisational requirements and scope of practice, and the range of medications used
- Ensure that any digital systems used for medication management are safe, secure and fit for purpose.

[8] Picton L, Lalic S, Ryan-Attwood TE, Stewart K, et al. The role of medication advisory committees in residential aged care services. Res. Soc. Admin Pharm 2020; 16(10):1401-1408.

Separate from Commonwealth funded medication management reviews, RACFs can access pharmacists (either via a community pharmacy or as an independent service provider) to provide a QUM Service that can support the work of the MAC by:

- Advising members of the RACF's healthcare team on a range of medication management issues in order to meet the healthcare needs of the person
- Providing medication information and education to the person, carers and other healthcare providers involved in the person's care
- Assisting the RACF to undertake continuous improvement activities, including facility-level audits and feedback to staff and health care professionals
- Assisting RACFs to meet and maintain medication management requirements under the Aged Care Quality Standards
- Providing advice on:
    - legislation, standards and processes
    - information and education needs
    - clinical issues and best practice
    - policies, procedures and guidelines.

Additional support could include assisting the RACF to implement priority interventions such as:[9]

- Deprescribing scripts to assist clinician discussion with people receiving care
- Developing or revising prescribing guidelines specific to older people with multi-morbidity in RACFs
- digital systems (for example, electronic medication charts and records).

Recommendations:

1. Alter the focus of **GP 1** to **Clinical governance of medication management** and broaden the commentary and definition of 'medication management' within **GP 1** and the **Glossary**
2. Include relevant reflective questions that aim to improve the composition, structure and governance role/function of MACs including:
    a. MACs taking appropriate action within a risk management framework when reviewing RACF results and trends relating to their national mandatory quality indicators on medication management
    b. MACs proactively monitoring other relevant QUM indicators (including medication-related adverse events and/or incidents; high-risk medicines; polypharmacy) that are used to ensure safe and appropriate use of medicines within the RACF.

Guiding Principle (GP) 2: INFORMATION RESOURCES

Access to information resources is an important part of medication management and should remain in the updated versions of the guiding principles. Access to information is not only to support healthcare professionals, but also for people receiving care within RACFs, along with their carers, and will facilitate informed decision-making. The information also needs to consider those from a culturally and linguistically diverse (CALD) background as well as Aboriginal and Torres Strait Islander people.

The current version of **GP 2** outlines the information resources that are relevant to support good medication management. The literature search identified studies showing how medicines information sources can support safe medication management and the environmental scan identified current professional practice standards and guidelines relating to the information resources required for safe medication management.

Information included in the updated guiding principles should align with the relevant professional practice standards and messages in Australia's response to the WHO global patient safety challenge, which state that:

[9] Jokanovic N, Wang KN, Dooley MJ, Lalic S, et al. Prioritizing interventions to manage polypharmacy in Australian aged care facilities. Res. Soc. Admin Pharm. 2017;13:564-574.

- *there is a need to use technology to provide better medicines information to patients, so that they are better equipped to be shared decision makers in their medication management*
- *providing consumers with access to better medicines information promotes 'healthy challenge'[10] between consumers and their healthcare providers*
- *in order to provide appropriate health care, consumers and their health care providers need access to information so that they can make informed decisions about the benefits and risks of different treatments*
- *medication safety at transitions of care is improved when consumers understand their medicines and have access to their medicines information; and*
- *better communication of health information by health professionals to consumers can improve health literacy for consumers*.[11]

The Commission's Medication Safety Standard, as part of the NSQHS Standards, provides guidance on how to provide people with information about their medicines. Although this guidance has been developed primarily for use in the hospital setting, it provides useful information to guide the provision of medicines information to people in residential aged care. Action 4.11 (*Information for patients*) and Action 4.13 (*Information and decision support tools for medicines*) within the Medication Safety Standard are most relevant to the provision of medicines information and medicines information resources. Within these Actions, the intent of each is defined along with reflective questions, key tasks and strategies for improvement.

Recommendations:

1. That **GP 2** is retained
2. Adapt content within the Medication Safety Standard relevant to the provision of medicines information and medicines information resources within the residential aged care setting
3. Ensure information within **GP 2** continues to align with all relevant professional practice standards and that the resource lists are updated
4. That consideration be given to creating web-based lists of medication information resources in the updated guiding principles, so that these lists can be updated as needed to ensure people and health professionals have access to an up-to-date and centralised list of resources
5. Multimedia and multi-lingual resources are to be available to cater the needs of target groups of people. For example, people with disability and CALD communities.

Guiding Principle (GP) 3: SELECTION OF MEDICINES

The existing **GP 3** covers a number of aspects of selection of a medicine, whether it be the person's or clinician's choice or recommendation. Only those authorised to prescribe may order a medicine and the decision to prescribe is not straightforward. Whilst considered a fundamental activity, prescribing is not simply about selecting a medicine and writing a prescription or writing an order on a medication chart. It involves a decision-making process, ideally with the person receiving care (and/or their person responsible).

Appropriate prescribing and medicine selection practices that need to be highlighted within this guiding principle, along with others, include avoiding inappropriate polypharmacy, deprescribing and appropriate use of high risk medicines, for example, reducing the inappropriate use of psychotropic medicines and antimicrobial stewardship in aged care. In addition, given the medication management needs of people living in residential aged care are now more complex, other issues to consider include:

- Assessment and management of pain leading to selection and use of appropriate analgesia[12,13]
- Assessment and management of delirium

[10] *'Healthy challenge'* is meant to refer to people being equipped with information to be able to ask questions of their primary care provider about their medicines and play an active role in their medication management.
[11] Australian Commission on Safety and Quality in Health Care. Medication without harm – WHO Global Patient Safety Challenge. Australia's response. Sydney: ACSQHC, 2020.
[12] The PMG Kit for Aged Care - https://www.apsoc.org.au/PDF/Publications/PMGKit_2007.pdf
[13] Pain in residential aged care facilities: Management strategies (2nd edition): Resources - https://www.apsoc.org.au/Pain-in-RACF2-Resources

- Management of an acute exacerbation of a chronic illness
- Day to day management of an acute illness ("sick days')
- People with special or specific needs. For instance, those with a disability; with cognitive impairment; from a culturally and linguistically diverse (CALD) background; from an Aboriginal and Torres Strait Islander community
- End-of-life and palliative care prescribing of medicines.

Older people have increasingly complex medication regimens which are prevalent in RACFs and can be challenging to administer. The 2020 Pharmaceutical Society of Australia (PSA) report Medicine safety: Aged Care states that:

- 98% of people living in aged care facilities have at least one medication-related problem identified at review;
- up to 80% are prescribed potentially inappropriate medicine; and
- 17% of unplanned hospital admissions by people living in aged-care facilities are caused by an inappropriate medicine.

Research has shown that older people taking five of more medicines are at higher risk of delirium and falls, independent of medication indications.[14] Up to 91% of individuals in Australian residential aged care facilities are prescribed more than five concomitant medicines, and up to 74% of residents take more than nine medicines.[15] Studies have shown that medication regimen complexity can be simplified through use of structured tools and provide staff in RACFs the time to devote to other care activities.[16,17] Deprescribing is aimed at minimising inappropriate polypharmacy and reducing medicine complexity.

According to Dementia Australia statistics the prevalence of dementia is 52% of those people in aged care. A recent Australian study highlighted that on entering residential care, a person's general practitioner changed for 72% of people with dementia and 44% were attended by a general practitioner previously unknown to them. Polypharmacy and psychotropic medicine initiation were more common for these people than for other people in residential aged care. Better organisation of care handover and facilitation of continuity of care could potentiality improve prescribing and medicine selection practices as well as ensure quality use of medicines within RACFs.

Health professional prescribing of prescription medicines is currently allowed by appropriately credentialed or endorsed podiatrists, optometrists, dentists, nurses and midwives in Australia. In 2020, approximately 2% of registered podiatrists, 1% of registered nurses/midwives and 65% of optometrists were endorsed prescribers of medicines by their relevant board.[18] Currently, all health professional prescribers in Australia, apart from podiatrists, can prescribe certain medicines in their scope of practice subsidised by the Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (RPBS). Medicines prescribed by podiatrists are not currently subsidised on the PBS or RPBS.

There are a number of documents relating to professional practice guidelines and registration standards, scope of practice and endorsement for health professional prescribing. While the guidelines and standards are profession specific, there are several consistent themes:

- Health professional prescribers must be aware of and comply with all legal requirements for prescribing that are relevant to their profession
- They must prescribe within their scope of practice
- They must coordinate treatment with other treating clinicians
- Nurses, midwives, optometrists and podiatrists must be 'endorsed' to prescribe by their relevant health practitioner board. The endorsement process involves undergoing an approved program of study (in addition to the requirements for general registration in the profession)

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[14] Mair A, Fernandez-Llimos F, Alonso A, Harrison C, Hurding S, Kempen T, et al. Polypharmacy management by 2030: a patient safety challenge, 2nd edition. Coimbra: SIMPATHY Consortium; 2017.
[15] Hubbard RE, Peel NM, Scott IA, Martin JH et al. Polypharmacy among inpatients aged 70 years or older in Australia. Med J Aust 2015; 202(7):373-377.
[16] Sluggett JK, et al. Reducing the Burden of Complex Medication Regimens: Simplification of Medications Prescribed to Long-tErm care Residents (SIMPLER) Cluster Randomized Controlled Trial. J Am Med Dir Assocn.
[17] Chen EY, Sluggett JK, Ilomaki J, Hilmer SN et al. Development and validation of the Medication Regimen Simplification Guide for Residential Aged CarE (MRS GRACE). Clin Interv Aging 2018; 13:975-986.
[18] Graham K, et al. Barriers to and facilitators of endorsement for scheduled medicines in podiatry: a qualitative descriptive study. Journal of Foot and Ankle Research 2021;14(1):1-11.

- Nurse, midwife, optometrist and podiatrist prescribers must maintain their competence through Australian Health Practitioner Regulation Agency's (Ahpra's) continuing professional development and recency of practice requirements
- All must adhere to the principles of QUM.

In April 2021 NPS MedicineWise released the second edition of the Prescribing Competencies Framework for all health professionals permitted to prescribe. The focus is on the competencies required to prescribe medicines safely and effectively and within a person-centred prescribing process. It outlines the need to understand:

- the person, their cultural and clinical needs
- the available treatment options and their implications
- discuss and agree on a plan in partnership with the person; and
- review treatment response including adherence and/or the need to cease or modify treatment.

It also outlines the need to communicate with other health professionals to optimise the safety and effectiveness of treatment. The need to provide care and prescribe within their recognised scope of practice, as well as professional and legislative boundaries are highlighted.

The need for a skilled and competent RACF workforce should be reinforced, including the importance of education and continuing professional development. This will ensure all categories of staff participate in medication management with confidence and according to their role or scope of practice, and RACF providers will have clearer understanding of their responsibilities.

For instance, the Nursing and Midwifery Board of Australia's (NMBA) *Registered nurse standards for practice* and the *Enrolled nurse standards for practice*, which mandate registered nurses (RNs) and enrolled nurses (ENs) practice respectively, make specific reference to professional development. In addition, definition of RN delegation as well as the accountability of ENs in this relationship, are included within the *RN Standards for practice* and within the *EN standards for practice*, Standard 3 (indicators 3.3 to 3.8) and the other 9 Standards provide details of how RNs and ENs are required to work together.

Recommendations:

1. That **GP 3** be retained and strengthened with respect to appropriate prescribing, decision-making and medicine selection practices (for example, avoiding inappropriate polypharmacy; deprescribing; and appropriate use of high-risk medicines) and update resource lists
2. Move some aspects into a new guiding principle entitled **Scope of practice**, which could cover all categories within the RACF workforce
3. Include the requirement for RACFs to ensure that clinicians 'work within their scope of clinical practice and have the knowledge, skills, competence and delegated regulatory and legal authority to manage, use, and handle and administer medicines'.

Guiding Principle (GP) 4: COMPLEMENTARY, ALTERNATIVE AND SELF-SELECTED NON-PRESCRIPTION MEDICINES

Non-prescription medicines are widely available and used to treat minor ailments. A 2014 Australian report on the value of self-care with non-prescription medicines, was estimated to save the Australian healthcare system over $10 billion a year,[19] with over 80% of adults using an over-the-counter (OTC) medicine in any given month.

Types of OTC medicines include:

- Pharmacist-only medicines. For example inhalers or puffers to relieve asthma
- Pharmacy medicines. For example medicines to treat symptoms of allergy
- Medicines for general sale that can be purchased in supermarkets, health food stores and other retailers. For example, some pain relievers (analgesics) in small pack sizes and vitamins.

[19] Macquarie University Centre for the Health Economy: *The Value of OTC Medicines in Australia*, March 2014.

OTC medicines are still medicines and they can have side effects as well as benefits. Some can interact with other prescribed medicines which may impact their effectiveness, or, in combination, can cause side effects.

Use of complementary and alternative medicines (CAMs) is also common in Australia.[20] Qualitative evidence suggests that the lack of good quality information on the efficacy and safety of these medicines is an issue for both the person and health professionals. Additionally, there is limited research evidence on models of care to ensure safe medication management in this area.

However, a large number of qualitative studies have been conducted to identify people and health professionals' (mostly pharmacists) views. The evidence is fairly consistent in several aspects: people want to use CAMs; they think pharmacists should be knowledgeable about CAMs; and that pharmacists should provide information about the safety of CAMs and interactions with other medicines.[21] The qualitative research with pharmacists tended to agree with this theme[22,23] and seven main responsibilities for pharmacists relating to CAMs were identified:

- *To acknowledge and ask (patients) about the use of complementary and traditional medicines*
- *To be knowledgeable about complementary and traditional medicine products*
- *To ensure safe and appropriate use of complementary and traditional medicines*
- *To document the use of complementary and traditional medicines by consumers*
- *To report suspected adverse drug events involving complementary and traditional medicines*
- *To provide education*
- *To collaborate with other health care professionals.*[24]

Whilst there is a need to respect the right of the person to take OTCs and CAMs, their use may not be without the risk of harm. The Royal Australian College of General Practitioners (RACGP) Silver Book includes a general prescribing principle that all medicines a person is taking be considered, including non-prescription and CAMs. The National Health and Medical Research Council (NHMRC) has developed a resource for clinicians entitled *Talking with your patients about Complementary Medicine - a Resource for Clinicians*. This resource explains why it is important to talk about CAMs to people, reasons why people often do not talk to their prescriber about CAMs, and provides strategies for health professionals to talk to people about them.

The PSA Position statement on Complementary medicines, highlights the pharmacist's role in supply of these medicines. The information in this position statement is consistent with research evidence on this topic. The information in both the NHMRC guide and the PSA position statement is consistent with the information relating to use of complementary medicines within this guiding principle.

Recommendations:

1. That **GP 4** is retained
2. That **GP 4** (as well as **GP2**) resource list be updated to include reference to the NHMRC *Talking with your patients about Complementary Medicine - a Resource for Clinicians* and the PSA *Position statement on Complementary medicines*.

[20] Von Conrady DM. Patterns of complementary and alternative medicine use and health literacy in general practice patients in urban and regional Australia. Aust Fam Physician 2017; 46, 5:315–320.
[21] Braun L, et al. Perceptions, use and attitudes of pharmacy customers on complementary medicines and pharmacy practice. BMC Complementary Medicine and Therapies 2010;10:38.
[22] Tiralongo E, et al. Exploring the integration of complementary medicines into Australian pharmacy practice with a focus on different practice settings and background knowledge. Journal of Complementary and Integrative Medicine 2010;7(1).
[23] Culverhouse S, et al. Factors affecting pharmacists' recommendation of complementary medicines – a qualitative pilot study of Australian pharmacists. BMC Complementary Medicine and Therapies 2012;12:183.
[24] Ung COL, et al. Community pharmacist's responsibilities with regards to traditional medicine/complementary medicine products: a systematic literature review. Research in Social and Administrative Pharmacy 2017;13(4):686-716.

Guiding Principle (GP) 5: NURSE-INITIATED NON-PRESCRIPTION MEDICINES

The literature review did not identify any new research since 2012, however, the environmental scan identified two relevant documents relating to this topic. Whilst there was limited new evidence or guidelines relating specifically to nurse-initiation of non-prescription medicines, this remains an important aspect of medication management in residential aged care.

The Commission has developed a User guide for nursing and care staff on the National Residential Medication Chart (NRMC3) which outlines how to record administration of nurse-initiated non-prescription medicines on the chart.[25] The information contained in the user guide is consistent with the information relating to nurse initiated non-prescription medicines in the current guiding principle.

Similar guidance is also included in the 2013 Australian Nursing and Midwifery Federation Nursing Guidelines: Management of Medicines in Aged Care. These guidelines provide support and direction, for registered and enrolled nurses in the administration of medicines in aged care. In particular, within Section 7 Management of medicine regimens, point 7.7 focuses on nurse-initiated medicines.

Recommendations:

1. That **GP 5** is retained and the focus broadened to encompass the situations where initiation of both prescription and non-prescription medicines is allowed or authorised, and renamed **Nurse-initiated medicines**
2. That other existing guiding principles be incorporated under this new 'title', for instance, **GP 6 STANDING ORDERS** which are designed to allow or authorise administration of medicines in particular circumstances.

Guiding Principle (GP) 6: STANDING ORDERS

The literature search and environmental scan did not identify any new research or guidelines relating to standing orders since 2012. This topic is controversial, but remains relevant as standing orders are still used in RACFs to authorise administration of medicines in particular circumstances. They must be approved via the MAC and be applied according to the relevant state or territory legislation.

The Australian Nursing and Midwifery Federation (ANMF): Nursing Guideline: Management of Medicines in Aged Care state:

> *Standing orders, covering Schedule 4 (S4), Schedule 8 (S8) medicines and other restricted substances, may be written by a prescribing practitioner for the administration of a medicine to an individual in the case that a particular circumstance arises.*
>
> *Currently all medicines in aged care services (with the exception of nurse initiated medicines) are dispensed for individuals on the written instructions of the prescribing practitioner, including: a nurse practitioner, medical practitioner, or dental practitioner. The absence of general stocks of S4, S8, or other restricted substances in aged care services makes the use of standing orders for the administration of these medicines in aged care services, inappropriate. Where standing orders are required in special circumstances in the community, service providers should have policies and procedures in place for their use.*

There is an opportunity to collapse or incorporate into **GP 5**, which is proposed to have a broadened focus on the situations where initiation of both prescription and non-prescription medicines is allowed or authorised.

[25] It should be noted that the Commission is in the process of updating the various NRMC user guides in line with the development, implementation and trial of the electronic version of the NRMC: eNRMC.

Recommendation:

1. That existing **GP 6** be incorporated under a renamed **GP 5**, focused on situations where initiation of both prescription and non-prescription medicines is allowed or authorised.

Guiding Principle (GP) 7: MEDICATION CHARTS

Medication charts support the delivery of appropriate care for people within RACFs. They are a tool for medicines' orders and record of administration to be documented and help communicate information consistently between clinicians on the intended use of medicines for an individual. A medication chart provides a record of the prescriber's intention for treatment, an instruction for the medicine to be administered by staff of the RACF, an order for the pharmacist to dispense or supply a prescription-only medicine and a record of administration of the medicine to the person.

A major initiative to improve the safe use of medicines in Australia is the standardisation of medicines management documentation in health facilities through national medication charts. This initiative included development of the National Residential Medication Chart (NRMC) which, although not mandated, continues to be relevant for use in RACFs.

Various digital health systems aimed at improving information documentation and system-wide integration in healthcare have already been implemented in Australia. For example, the expedited rollout in 2020 of electronic prescribing across Melbourne in Victoria, which has been expanded nationally.

Apart from electronic prescribing, other digital health strategies also include active ingredient prescribing, electronic health records (including *My Health Record*), electronic medication management (including administration records), computerised clinical decision support systems and telehealth.

Currently, trials are underway on the use of an *electronic medication order chart* within RACFs. Legislation is in place to support the trial of the National Health Electronic National Residential Medication Chart (eNRMC). The Commission is developing resources to support the safe and effective implementation of the eNRMC within RACFs. The potential benefits associated with implementation of the eNRMC include:

- Reduced risk from inconsistencies between prescriber records and hardcopy medication charts, and less time spent by suppliers reconciling these differences
- Increased visibility of a person's medication record for prescribers, suppliers and RACF staff
- Timely provision of medicines
- Reduction in owing prescriptions with prescribers able to login remotely
- Allergies or interaction alerts
- Built-in reminders when a new prescription or follow-up consultation is required
- Reduced inappropriate polypharmacy.

It should be noted that the Australian Government has allocated $45.5M in the May 2021 budget in supporting RACFs to implement the eNRMC, as well as support the adoption of the *My Health Record* by June 2023. Grants to support implementation of the eNRMC system were announced in July 2021. This is in response to Recommendation 68[26] of the final report of the royal commission into aged care quality and safety.

Ideally, digital health and medication management records held within the RACF software systems and those within primary health care software systems should be interoperable, be able to synchronise automatically and/or be accessible remotely and securely.

Recommendations:

1. That **GP 7** is retained and updated to highlight the need for future implementation and use of the eNRMC and updated resources include reference to support materials for the implementation of the eNRMC
2. That consideration be given to renaming **GP 7** to focus on **Documentation of medication management**, which would encompass both hard-copy and use of digital systems.

[26] Recommendation 68: *Universal adoption by the aged care sector of digital technology and My Health Record.*

Guiding Principle (GP) 8: MEDICATION REVIEW AND MEDICATION RECONCILIATION

The Australian Government has funded medication reviews by pharmacists for over 20 years. The current program rules,[27] ratified in the 7th Community Pharmacy Agreement, fund collaborative Residential Medication Management Reviews or RMMRs (in-person or by telehealth). One RMMR can be provided at least once every 24 months. The person's general practitioner may request a subsequent review if deemed clinically necessary due to various criteria, including (but not limited to):

- *Discharge from hospital after an unplanned admission in the previous four weeks*
- *Significant change to medication regimen in the past three months*
- *Change in medical condition or abilities.*

Whilst the funding arrangements are an important aspect for RACFs to understand, along with the eligibility criteria, the focus within this guiding principle remains on the need to ensure that given their complexity, each person's medicines are reconciled, and regularly and comprehensively reviewed, and that this is a multidisciplinary and collaborative process.

Each clinician involved in a person's care has the responsibility to use their specific knowledge, skills and expertise to ensure the safe and quality use of medicines by all people in their care. If risks with medicine use are identified early it may prevent unnecessary escalation in care or hospital admission.

Action 4.05 and Action 4.06 within the NSQHS Medication Safety Standard focus on medication reconciliation, including the requirement to document the best possible medication history (BPMH). Action 4.10 focuses on medication review. In updating this guiding principle, consideration should be given to aligning with the intent of the above-mentioned Actions, along with the PSA Guidelines for comprehensive medication management reviews and the Society of Hospital Pharmacists of Australia (SHPA) Standards of practice in geriatric for pharmacy services. Published in 2020, the SHPA standards of practice, include 'medication history and reconciliation' and 'medication review' as separate components of a geriatric pharmacy service.

Similar to these and other resources, it may be worth separating the concepts of medication review and medication reconciliation activities within the *Guiding principles for medication management in residential aged care facilities* despite their close relationship in medication management. If this is supported, RACFs would need to have in place separate policies, procedures and guidelines, focussed on medication review and medication reconciliation.

Australia's response to the WHO Global patient safety challenge: Medication without harm highlights that minimising medication-related harm starts with a BPMH. A BPMH is essential for:

- Ensuring continuity of medication management
- Identifying medicine-related problems
- Identifying potential medicine-related discrepancies
- Informing the decision-making process
- Optimising the use of medicines.

Medication reconciliation requires access to a person's BPMH, including their most up-to-date medicines list. Whilst the goal of this process is stated within the current **GP 8**, this information could be further expanded either within this guiding principle and/or within respective policies, procedures and guidelines. For instance, when verifying a person's current list of medicines, especially if they are newly admitted or there have been any recent changes in their care, helpful information sources include:

- Their discharge summary from the most recent hospital admission
- A person's *My Health Record* including the Pharmacist Shared Medicines List
- General Practitioner or primary health care practitioner records
- Their personal medicines list, for instance, on the MedicineWise smartphone app.

[27] Pharmacy Programs Administrator. Program Rules. Residential Medication Management Review. PPA; July 2021.

Early evidence suggests that different models of care, including 'embedded' pharmacists, can improve medication management within RACFs. Funded trials of different models are ongoing in the Australian Capital Territory (ACT), for instance:

- The Australian Government has provided funding of $3.7 million to expand a trial to embed a part time pharmacist in all residential aged care homes within the ACT[28]
- Funding has been provided to the ACT Primary Health Network (PHN) who is partnering with the University of Canberra to conduct an expanded trial of embedding a part time pharmacist in all residential aged care homes within the ACT.

Since the current guiding principles document was published, the awareness and focus on poor medication management and inappropriate polypharmacy in aged care has increased. The Royal Australian College of General Practitioners (RACGP) Silver Book includes chapters on managing older people with polypharmacy as well as deprescribing. The practice points within these chapters, in general, align with recommendations within the WHO Global patient safety challenge: Medication without harm and Australia's response. The definition of polypharmacy in the two Australian resources refer to five or more medicines used at the same time, including prescription, over-the-counter and complementary medicines. Older people taking five or more medicines are at higher risk of delirium and falls, independent of the indication for these medicines.[29] Older people are also at higher risk of inappropriate polypharmacy due to their increased frailty and likelihood of having multiple chronic co-morbidities, each often treated with multiple medicines. Inappropriate polypharmacy can be found in instances of only a few medicines, whilst appropriate management of persons with multiple co-morbidities can involve the use of many more medicines.

In this environment, consideration should be given to:

- Increasing the focus on medication management in polypharmacy
- Recognising the need to differentiate between inappropriate and appropriate polypharmacy
- A clear understanding of what is meant by polypharmacy in aged care and what should prompt medication review, given variation in the definitions currently in use and data collection, for instance, the following medication management indicator, as part of the National Aged Care Mandatory Quality Indicator (QI) program:
    - *Percentage of care recipients prescribed 9 or more medications*
- Other more suitable measures, for instance, a person's therapeutic or drug burden.[30,31]

In addition, a recent study[32] on the high frequency of *pro re nata* (PRN) 'as needed' medicine prescribing (as well as nurse-initiated medicines) in Australian aged care services highlights the need for regular 'clinical review' to ensure ongoing safe and appropriate use. This included PRN prescribing of high-risk medicines such as opioids and antipsychotics.

Recommendation 63 within the final report of the royal commission into aged care quality and safety calls for increased access to medication review, including for their conduct to occur 'on entry to residential care'. Whilst annual review thereafter is also recommended, it is recognised that comprehensive review will be required more often based upon clinical need. For instance if there has been a significant change or deterioration in the person's condition or change to their medicines.

Pharmacists also provide extensive services involving medication management in RACFs. These include advice for use and implementation of the eNRMC, active ingredient prescribing and the provision of reports relating to the mandatory QI program (for example, antipsychotics, polypharmacy and antimicrobial stewardship).

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[28] Capital Health Network | For Consumers - Older Persons Health (chnact.org.au)
[29] Hubbard RE, O'Mahony MS, Woodhouse KW. Medication prescribing in frail older people. Eur J Clin Pharmacol 2013; 69:319–26.
[30] Kouladjian L, Gnjidic D, Chen TF, Mangoni AA, Hilmer SN. Drug Burden Index in older adults: theoretical and practical issues. Clin Interv Aging. 2014 Sep 9;9:1503-15. doi: 10.2147/CIA.S66660. PMID: 25246778; PMCID: PMC4166346.
[31] Harrison SL, O'Donnell LK, Bradley CE, Milte R et al. Associations between the Drug Burden Index, potentially inappropriate medications and quality of life in residential aged care. Drugs Aging 2018; 35:83-91.
[32] Picton L, Ilomaki J, Keen CS, Lalic L, Adams B, et al. Rates of PRN Medication Administration in Australian Residential Aged Care. JAMDA 22 (2021);117-123.

Recommendations:

1. That **GP 8** includes information on polypharmacy and deprescribing and consideration of relevant policies, procedures and guidelines on these topics and the relationship with the National Aged Care Mandatory Quality Indicator program
2. That other aspects of medication review and medication reconciliation from various resources, practice standards and guidelines be considered when updating **GP 8**, for instance, reconciliation against a best possible medication history
3. That **GP 8** be split into two discrete guiding principles entitled:
    a. **Medication review**
    b. **Medication reconciliation**

Continuity of medicines supply and emergency stock

The current *Guiding principles for medication management in residential aged care facilities* contain two principles relating to the continuity of medicines supply:

- **Guiding Principle 9:** *Continuity of medicines supply*
- **Guiding Principle 10:** *Emergency stock of medicines*

The information within the two guiding principles documents is consistent with the information identified in the literature review and environmental scan. RACFs need to have policies, procedures and guidelines in place to ensure the supply of medicines for the person is not interrupted, and adverse outcomes are avoided. This includes how to manage and respond to:

- situations where a new medicine or an urgent change to the dose of an existing medicine is prescribed (for instance, how changes to dose administration aids are managed)
- an unexpected outbreak amongst people receiving care. For example, gastroenteritis
- a person experiencing an acute symptomatic illness. For example, an infection requiring urgent treatment with an appropriate antibiotic, and according to the RACF's Antibiotic Stewardship guidelines
- an unexpected local medicines shortage.

As a result of the movement restrictions imposed during the COVID-19 pandemic, challenges to ongoing access to medicines in the Australian community were experienced. For instance, vulnerable and older people with chronic and complex conditions may not have been able to attend consultations with their health practitioner or visit their community pharmacy to have medicines prescribed and dispensed. The public's desire to stockpile and panic buy precipitated by the pandemic had the potential to result in unusually high demand for particular medicines with the added potential to cause, or potentiate, medicine shortages.

Pharmacies had difficulty sourcing brands of some medicines, with rural pharmacies particularly affected.[33] Initiatives put in place (including temporary ones) in response to this issue have included:

- as part of a telehealth consultation, prescribers permitted to send a digital image of an original prescription directly to the person's preferred pharmacy for dispensing
- a pharmacist supplying a full PBS quantity (usually 30 days) of a previously prescribed Schedule 4 medicine in the case of immediate need when a person is unable to obtain a prescription
- home delivery services that support pharmacies (or other delivery services) to provide new or existing home deliveries medicines to vulnerable people up to once per month, including to people in RACFs
- pharmacists provided temporary permission, for eligible people, to deliver medication management reviews via telehealth arrangements.

Within RACFs, strategies to ensure access to essential medicines, including end-of-life medicines, included:

- ensuring adequate supplies via anticipatory prescribing of end-of-life medicines
- if not already available, establishing an imprest or on-site medicine storage system.

[33] Bell J, et al. Access to medications during the COVID19 pandemic. Australian Journal for General Practitioners 2020;49:530-2.

Noting that the requirements relating to imprest stocks are state and territory specific, resources relevant to the management of imprest and emergency medicines in RACFs include:

- PSA Guidelines for Quality Use of Medicines (QUM) Services
- Imprest Medication Systems for RACFs developed by the Southern Metro Region Palliative Care Consortium and updated by Gippsland Region Palliative Care Consortium (April 2020)
- Victorian Government Resources relating to medicines storage and record keeping in RACFs
- NSW Health Resources on Urgent Use medications in RACFs.

The COVID-19 pandemic led to a number of changes relating to continuity of supply of medicines, for example, continued dispensing, substitution of medicines in certain circumstances where a serious shortage has been identified, and emergency supply of a small quantity of medicines in an emergency situation without a prescription.

Many of these changes required legislative changes, which were state/territory specific and a Summary of COVID-19 regulatory changes relevant to medicines can be found on the PSA website and includes:

- the state/territory specific legislation relating to each change
- the medicine(s) to which the legislative changes apply
- requirements of prescribers and pharmacists
- useful resources.

Under relevant national and state/territory legislation a pharmacist can issue a 3-day emergency supply of some prescription medicines if a person's primary care provider cannot be contacted.

Guiding Principle (GP) 9: CONTINUITY OF MEDICINES SUPPLY

The current resource list for **GP 9** refers to the Guiding principles to achieve continuity in medication management (2006), which is also undergoing review. Any modification that relates to the transitions between care environments will need to be consistent.

The Interim Residential Care Medication Administration Chart (IRCMAC) was developed as a strategy to address continuity of medicines supply and reduce omissions of critical medicines and potential for readmission to hospital. Whilst uptake has not been universal across states and territories, from August 2018 South Australia (SA) introduced an Interim Medication Administration Chart (IMAC) for people transferring from SA hospitals to RACFs and the SA Prison Health Service. In addition, in Queensland (QLD) the IMAR is used and valid for up to five days post-discharge from QLD hospitals until a long-term RACF medication chart can be updated by the person's general practitioner.

As mentioned within **GP 4** (*Medication charts*), with the changes and initiatives relating to electronic prescribing and active ingredient prescribing, along with the implementation of the eNRMC, it is anticipated that issues with the continuity of medicines supply at transitions of care will be less likely. Also noted is the Australian Government's response to Recommendation 68[26] within the final report of the royal commission into aged care quality and safety. With the expected adoption of *My Health Record* by June 2023, there will be a need for RACFs to refer to and/or update information, including about a person's medicines, within the consumer's *My Health Record*.

Recommendations:

1. That **GP 9** is retained and that the potential for combination with **GP 10** (*Emergency stock of medicines*) be considered given that both have a focus on ensuring medicines are available for administration to people in RACFs.

Guiding Principle (GP) 10: EMERGENCY STOCK OF MEDICINES

The intent of the existing **GP 10** is consistent with strategies aimed at maintaining supply and/or access to essential medicines, especially in the event of an emergency or urgent need. Governance over the list of medicines required in these circumstances is crucial, especially where inappropriate use can be of concern. For instance, appropriate governance must be in place for the use of antimicrobials and in accordance with appropriate stewardship policies, procedures and guidelines, including reference to the Aged Care Quality Standards (Personal care and clinical care), the latest Therapeutic Guidelines:

Antibiotic and other relevant resources such as Antimicrobial Stewardship in Australian Health Care and the latest chapter on Antimicrobial Stewardship in community and residential aged care.

State and territory legislative requirements also underpin who can access and use medicines that might be required as a result of urgent need.

There are other aspects within the existing guiding principle that could be included elsewhere. One example is the need to ensure appropriate storage, stock rotation etc. of an emergency stock of medicines. This information can be included within **GP 11: Storage of medicines** and relevant policies, procedures or guidelines.

Recommendations:

1. That the intent of **GP 10** be retained and consideration be given to combining with **GP 9** (*Continuity of medicines supply*) as a potential strategy for ensuring access to relevant medicines to support continuity of supply.

Storage and Disposal of Medicines

The current *Guiding principles for medication management in residential aged care facilities* contain two principles relating to the storage and disposal of medicines:

- **Guiding Principle 11:** *Storage of medicines*
- **Guiding Principle 12:** *Disposal of medicines*

The information within the two guiding principles remains relevant and ensuring the appropriate storage and disposal of medicines within RACFs is important. In addition, the Return Unwanted Medicines (RUM) project continues to be the main mechanism for safe disposal of medicines and devices (for instance inhalers; insulin pens) in Australia.

Very few additional new resources have been published relating to the safe storage and disposal since 2012. However, the NSQHS Medication Safety Standard Action 4.14, *Safe and secure storage and distribution of medicines*, provides a model for safe storage and disposal of medicines in the hospital setting, which could be adapted for use in the residential aged care setting.

Standard 3 within the PSA Professional Practice Standards, outlines the expected role of pharmacists when dispensing medicines. One of the criteria within this standard is the need to ensure that medicines are stored and disposed of safely and correctly and includes the following actions:

- 3.13.1 *Adheres to evidence-based information sources to meet storage and stability requirements of medications (e.g. cold chain, protection from light or moisture), and follows documented procedures, if required*
- 3.13.2 *Adheres to best-practice guidelines to inform decisions surrounding pre-use (source and storage), re-use and disposal of medicines*
- 3.13.3 *Disposes of medicines responsibly according to relevant legislation, considering environmental impact, sustainability principles and best-practice guidelines (e.g. return unwanted medicines (RUM) bins).*

This guidance aligns with the current guiding principles for medication management.

Given that both the storage and disposal of medicines are closely related, these two guiding principles could potentially be combined and ensure alignment with relevant state and territory legislation.

Guiding Principle (GP) 11: STORAGE OF MEDICINES

In 2020 the Commission published Principles for the safe selection and storage of medicines: Guidance on the principles and survey tool. Whilst this resource provides further information on the strategies and principles that hospitals can use to ensure safe storage and selection of medicines, RACFs could use selected aspects of the assessment survey tool as a guide to improve their medicine storage systems, including automated systems.

Recommendation:

1. That the intent of **GP 11** be retained and consideration be given to combining with **GP 12** (*Disposal of medicines*)

Guiding Principle (GP) 12: DISPOSAL OF MEDICINES

The Return Unwanted Medicines (RUM) project allows people to return unwanted medicines (including inhalers; insulin pens) to any community pharmacy within Australia for safe disposal. The Therapeutic Goods Administration (TGA) has developed consumer resources explaining why safe disposal of medicines is important and how to access the RUM program. These messages are consistent within those within this guiding principle and RACFs should have policies, procedures and guidelines in place to ensure the safe and appropriate disposal of peoples' unwanted and expired medicines (including dose administration aids and devices).

Unwanted and expired emergency imprest stock and accountable (Schedule 8) medicines held by the RACF also require mechanisms for authorised, appropriate and secure disposal. The RUM program provides advice on How to dispose of Schedule 8 (S8) medicines in an appropriate and secure manner which varies according to the relevant state or territory legislation.

Recommendation:

1. That the intent of **GP 12** be retained and consideration be given to combining with **GP 11** (*Storage of medicines*)

Administration of medicines within RACFs

The current *Guiding principles for medication management in residential aged care facilities* contain four principles relating to the administration of medicines:

- **Guiding Principle 13:** *Self-administration of medicines*
- **Guiding Principle 14:** *Administration of medicines by RACF staff*
- **Guiding Principle 15:** *Dose administration aids*
- **Guiding Principle 16:** *Alteration of oral dose forms*

The 2020 PSA report Medicine safety: Aged Care identified a number of issues related to the administration of medication in aged care including the use of dose administration aids (DAAs) and alteration of oral dose forms.

The environmental scan identified only one resource relating specifically to the administration of medicines in aged care and released in 2013 by the Australian Nursing and Midwifery Federation (ANMF): Nursing Guideline: Management of Medicines in Aged Care. The ANMF also has a series of other guidelines, policies and position statements of relevance to nurses and midwives including position statements on:

- Quality use of medicines (2019)
- Care for people living with a disability (2021)
- The use of dose administration aids (2018).

For some medicines and some chronic conditions, the risk of adverse events may increase during periods of acute illness (for example, gastroenteritis or diarrhoea).[34] People who manage their own medicines and those responsible for administering (or supervising the administration of) medicines to people in aged care, need to know how to safely manage medicines during periods of acute illness. However, current Australian standards and guidelines offer little guidance in this area. Primary care resources from Healthcare Improvement Scotland and a Position statement on "sick day rules" developed by Think Kidneys in the UK offer some insight into the medicines and chronic conditions where risk of adverse events during acute illness is highest. A UK qualitative evaluation[35] on the implementation of 'sick day guidance' provides insight on challenges in communicating the concept of

[34] Lea-Henry T, et al. Medication management on sick days. Aust Prescr. 2017;40:168-73.
[35] Martindale A, et al. Understanding the implementation of 'sick day' guidance to prevent acute kidney injury across a primary care setting in England: a qualitative evaluation. BMJ Open 2017;7:e017241.

temporary cessation of medicines and how to best manage certain medicines and conditions during acute illness including:

- which medicines should be temporarily ceased/held during acute illness to reduce the risk of adverse events
- which medicines may require dose escalation during periods of acute illness (for example, insulin, long term steroids)
- when medication use can 'return to normal' after acute illness
- how to manage medicines packed in DAAs during acute illness (for example, refer to the pharmacist to ensure appropriate identification and/or removal of the medicines to be ceased/withheld).

'Sick day' policy, procedures and guidelines should be developed and endorsed by the MAC.

Whilst there are separate recommendations that are included below within each of the next four guiding principles, it is proposed that they be collapsed and combined under a single guiding principle entitled Administration of medicines within the RACF.

Recommendation:

1. That all, or a selection, of **GP 13**, **GP 14**, **GP 15** and **GP 16** be collapsed and combined under a single guiding principle entitled **Administration of medicines within the RACF**

Guiding Principle (GP) 13: SELF-ADMINISTRATION OF MEDICINES

The ANMF Nursing Guideline: Management of Medicines in Aged Care includes guidance around self-administration of medicines by people in aged care. The recommendations within this 2013 guideline align with the current *Guiding principles for medication management in residential aged care facilities*.

Given the risk of adverse events may increase during periods of acute illness due to comorbidities or medicine use (for example, gastroenteritis or diarrhoea)[34] consideration should be given to including advice on medication management (including self-directed) during "sick days". Guidance may be needed on which medicines should be temporarily suspended, for instance diuretics, or the dose temporarily increased, for example, insulin. Factors to consider will include the type of medicine, its formulation pharmacokinetics, duration of the acute illness and comorbidities.[34]

Whilst there is no Australian-specific guidance available, reference to the Australian Prescriber article,[34] sick day management for specific chronic conditions like those by the Australian Diabetes Educator Association,[36] as well as existing international resources produced in the UK, might be useful for clinicians to guide development of a management plan for people receiving care within RACFs. The management plan may need to include situations where seeking immediate medical attention, such as transfer to hospital, is warranted.

Recommendation:

1. For consumers/residents people who are self-administering medicines include advice within policies, procedures and guidelines, for those self-administering and/or nurses, some additional guidance, on when and how to stop and restart medicines during periods of acute illness or "sick days". This may involve the need for nurses to take over the administration of all medicines.

Guiding Principle (GP) 14: ADMINISTRATION OF MEDICINES BY RACF STAFF

The ANMF Nursing Guideline: Management of Medicines in Aged Care includes guidance around administration of medicines by nurses in residential aged care facilities. The recommendations within

[36] Clinical Guiding Principles for Sick Day Management of Adults with Type 1 Diabetes or Type 2 Diabetes A Guide for Health Professionals. Canberra: Australian Diabetes Educator Association; June 2020.

this guideline align with the current *Guiding principles for medication management in residential aged care facilities*.

As mentioned above under **GP 13** (Self-administration of medicines), consideration should be given to including some additional advice on medication management for nurses on when and how to stop and restart medicines during periods of acute illness ("sick days"). This needs to include escalation to the prescribing clinician for specific instructions to be included on the medicine order.

Recommendation:

1. Include some additional advice for RACF clinicians and nurses on when and how to stop and restart medicines during periods of acute illness.

Guiding Principle (GP) 15: DOSE ADMINISTRATION AIDS

The 2020 PSA report Medicine safety: Aged care highlighted that up to 21% of DAAs in aged care have a packing error, with an average error rate of 9%. Packing errors commonly included:

- inclusion of a medicine in the dose administration aid which had been ceased
- wrong dose of medicine was packed
- packing a medicine in the DAA at an incorrect administration time
- omission of medicines that should have been packed.[37]

The report also noted that poor documentation or communication, poor handwriting on medication charts or prescriptions and lack of continuity in medicines supply (e.g. no current prescription) account for up to 25% of DAA packing errors.[37]

According to the ANMF Position statement on the Use of dose administration aids, nurses who administer medicines within RACFs are expected to take responsibility for identifying each individual medicine prior to administration. Where individual medicines cannot be clearly identified, nurses must consult the pharmacist and return a DAA for repackaging.

The two main guidelines on DAAs are the PSA Guidelines for pharmacists providing dose administration aids and the Pharmacy Board of Australia *Guidelines on dose administration aids and staged supply of dispensed medicines*.[38] These documents have been reviewed and updated since the current National QUM publications were published. The PSA and Pharmacy Board guidelines highlight that provision of DAAs is a clinical service, not just a supply function.

The above-mentioned guidelines make it clear that medication safety is paramount, and so pharmacists providing DAA services must follow robust processes of high standard to ensure safety of the person receiving care. The importance of reconciling medicines the first time, and regularly thereafter, prior to packing a person's DAA is included. This is a necessary step to ensure a complete and accurate medicines list or medication profile that takes into account all prescription, non-prescription, complementary and alternative medicines a person is taking. If necessary, it may prompt a review of the person's medicines, especially if something has changed following an admission to hospital: for instance, a RMMR or other medication review service.

In addition, Standard 15 within the PSA Professional Practice Standards states that:

> *The pharmacist provides a dose administration aid service to improve adherence and quality use of medicines, and optimise patient health outcomes.*

In general, the information contained within the PSA and Pharmacy Board guidelines for DAAs dose is in agreement with the information in the current guiding principles documents. Where recommendations in the PSA and Pharmacy Board guidelines were not included in the current guiding principles documents, in most cases they tended to be highly technical recommendations for pharmacists packing

[37] Pharmaceutical Society of Australia. Medicine safety: aged care. Canberra: PSA, 2020.
[38] Pharmacy Board of Australia. Guidelines on dose administration aids and staged supply of dispensed medicines. 2015. Available from: https://www.pharmacyboard.gov.au/codes-guidelines.aspx

DAAs (for example, recommendations for packing areas for DAAs, recommendations for record keeping when packing DAAs). Inclusion of these highly technical recommendations in the guiding principles is unlikely to be helpful to the wider audience for which the guiding principles are intended. However, several recommendations or pieces of information in the PSA guidelines which are not included in the current guiding principles should be considered for inclusion in updated versions. This includes: reconciling medicines prior to packing; consent and communication around use and continuation; and monitoring and follow up use of DAAs.

Since release of these guiding principles, automated dose-packaging systems are available to pack DAAs. However, all DAA packing systems are required to meet expected standards.[38] [39]

Continuity of supply of DAAs and other medicines can be problematic especially with 'remote' automated dose-packaging (for example, sachet) systems managed by external or corporate-style providers. This includes delays in response to a need for timely changes to the medicines within DAAs. As a result, the responsibility may shift to the local pharmacy, creating potential for error and unnecessary delays in administration of medicines.

Recommendations:

1. That **GP 15** includes greater emphasis and more information on:
    a. the need for medication reconciliation prior to DAA packing for the first time, and after changes to medicines or hospital admission
    b. the need for consent and communication around initiating and continuing use of DAAs
    c. monitoring and follow up of people using DAAs, including how to identify and manage medicines packed in a DAA during acute illness per **GP 13** (*Self-administration of medicines*); and **GP 14** (*Administration of medicines by RACF staff*)

Guiding Principle (GP) 16: ALTERATION OF ORAL DOSE FORMS

The 2020 PSA report Medicine safety: Aged care highlighted that up to one third of people in aged care in Australia have their medicines altered, most commonly by crushing tablets, and that in up to one third of these cases the medicine should not have been altered for reasons including the potential for toxicity, reduced efficacy of the medicine or changes to the stability of the medicine.[37]

A 2020 study which was published after this report, found consistent results: over 810 medication administrations were observed and dosage forms were modified in one quarter of administrations.[40] The type of modification was most commonly crushing of the tablet (72% of modifications) followed by cutting or splitting of tablets (20%). Mixing of modified dose forms in food or fluid was also common. Of the 208 cases where dose forms were modified, the dose was mixed into food (including fruit puree, custard, cereal) or fluid in 167 cases (i.e. in 80% of cases where the dose form was modified).[40] The Australian *Don't Rush to Crush* handbook[41] was used to determine whether the dose form modification was appropriate, and in 13% of cases where the dose form was modified it was done so not in adherence with the *Don't Rush to Crush* recommendations.[40] Dose form modification increased the time taken to administer medicines – the average administration time was around 40 seconds per person when no medicines were altered compared to almost two minutes per person when dose forms were modified.[40]

The current **GP 16** covers the policy and procedure aspects that need to be considered and the *Don't Rush to Crush* resource remains a key information source and is available electronically via MIMS Online™. However, **GP 16** would benefit from a greater emphasis on multidisciplinary practice that considers how to manage people with conditions that impact their functional ability to swallow, for example, dysphagia as a result of a stroke.

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[39] Guidelines for pharmacists providing dose administration aid services. Appendix 6. Canberra: Pharmaceutical Society of Australia; November 2017.
[40] Forough A, et al. Appropriateness of oral dosage form modification for aged care residents: a video recorded observational study. Int J Clin Pharm 2020;42:938-47.
[41] The Society of Hospital Pharmacists of Australia. Don't Rush to Crush. 3rd Edition. Available from: https://www.shpa.org.au/drtc3

Speech Pathology Australia Dysphagia Clinical Guideline (2012) recommends review of all people before administering a medicine and referral to their pharmacist or GP if oral dose forms of medicines need to be altered. In addition the NDIS Quality and Safeguards Commission's practice alert on Medicines associated with swallowing problems highlights medicines that can cause swallowing problems and may increase the risk of choking.

Recommendations:

1. That **GP 16** has greater emphasis and includes more information on:
    a. the need for people to be screened or assessed for swallowing safety before being given medicines
    b. timely referral to a pharmacist or the person's primary health care practitioner when it is unsafe for a them to swallow oral formulations of a medicine.
2. Consider how the content of other guiding principles may need to be amended, including **GP 8** (*Medication review and medication reconciliation*); **GP 13** (*Self-administration of medicines*); and **GP 14** (*Administration of medicines by RACF staff*).

Evaluation and quality improvement

1. Quality indicators for Aged Care

As part of the 2019–20 Budget Measure More Choices for a Longer Life – Mandatory National Quality Indicators and the Reducing the Misuse of Medicines in Residential Aged Care report, two new quality indicators relating to medication management, as well as others, were developed. From July 2021 the National Aged Care Mandatory Quality Indicator Program will be expanded to include the following:

a. Percentage of care recipients prescribed 9 or more medications
b. Percentage of care recipients who received antipsychotic medications.

The data elements required for reporting on the antipsychotic indicator includes the number of care recipients who received an antipsychotic medicine based on a seven day medication chart or administration record review. Reviews and reporting are to be conducted quarterly. The final draft of the National Aged Care Mandatory Quality Indicator Program Manual 2.0 – Part A provides information on how to measure and record data relating to these new mandatory medication management indicators.

Prior to the Australian Government decision to mandate the two above-mentioned national quality aged care indicators, the Department of Health and Human Services in Victoria had implemented a quality indicator program to help public sector aged care services collect and report on five quality indicators including one to monitor the proportion of people using '9 or more different medicines'. Resource materials accompany each indicator. For instance, apart from instructions on how to conduct the audit and collect the data, definitions of the key data elements are included as well as a risk management framework that highlights what action should be taken by the RACF. Whilst developed for public sector aged care services, the resources have also been available for use by all residential aged care providers.

2. Monitoring and managing risk associated with the use of medicines

In 2020, the Registry of Senior Australians (ROSA) published their outcome monitoring system, which defines 12 quality and safety indicators for aged care.[42] The indicators were developed for routine monitoring within existing aged care and health data collections, providing a tool which allows rapid, large-scale monitoring of the quality and safety of residential aged care in Australia. A number of the indicators that relate specifically to medication management, including:

- High sedative load
- Antipsychotic use
- Chronic opioid use
- Antibiotic use
- Medication-related adverse events.

[42] Inacio M, et al. The Registry of Senior Australians outcome monitoring system: quality and safety indicators for residential aged care. International Journal for Quality in Health Care 2020;32(8):502-10.

The four medicine classes listed above – sedatives, antipsychotics, opioids and antibiotics – fall under the classification of high-risk medicines. Their inappropriate use could result in **inappropriate polypharmacy** and/or a need for **deprescribing**. Both these issues have been highlighted within the literature review and environmental scan and within various national and international publications, reports and reviews on medication management. Deprescribing guides have recently been published by the NSW Therapeutic Advisory Group (NSW TAG) along with an associated Polypharmacy QUM indicator set, which also include Patient Reported Experience Measures (PREMs) on deprescribing and medication changes. These indicators are intended to evaluate processes involved in identification of medication-related harm in older hospitalised people and the management of inappropriate polypharmacy; however, they could be adapted for use in residential aged care.

3. Use of the existing 'evaluation' questions

The existing **Guiding Principle (GP) 17: Evaluation of Medication Management**, expects RACFs to *regularly review and evaluate each area of medication management for outcomes and take follow up action when required*. Given that this expectation is inherent within a governance and quality improvement framework, it is proposed that the series of 'evaluation' questions be adapted and adopted as 'reflective questions' within each individual guiding principle where relevant.

For example, some of the 'evaluation' questions included within the current *Guiding principles for medication management in residential aged care facilities* could be adapted as follows:

1. Is the RACF policy and procedure for safe practice in nurse-initiation of non-prescription medicines up to date and consistent with the requirements of relevant state or territory legislation and regulations?
2. What percentage of all standing orders that are reviewed for their use is compliant with the requirements of relevant state or territory legislation and regulations?
3. What percentage of residents have had a RMMR in the past 24 months?
4. What percentage of residents have had their medicines reconciled upon admission or readmission to the RACF?

Guiding Principle (GP) 17: EVALUATION OF MEDICATION MANAGEMENT

As mentioned above, **GP 17** includes a list of questions that can be used by the RACF to evaluate the application of each of the guiding principles within the RACF. These 'evaluation' questions allow within- and between-facility monitoring of implementation of the guiding principles. These questions will be reviewed separately and updated according to their ongoing relevance once the final set of guiding principles are determined.

The option to adapt and adopt these as 'reflective questions' within each individual guiding principle should be considered. If adopted in this way **GP 17** could be renamed to heighten the focus on the quality indicators, the need to implement a quality improvement framework, and moved within the hierarchy to follow a revised **GP 1**. If **GP 17** is renamed, the quality improvement focus should be enhanced to:

- include guidance for RACFs on mandatory quality indicator reporting
- advise on using available data to drive quality improvement and manage risk
- align with the intent of the proposed new **GP 1: Clinical governance of medication management**.

Recommendations:

1. That **GP 17** (*Evaluation of medication management*) be renamed, that its quality improvement focus be enhanced and aligned with the intent of a renamed **GP 1**
2. That the existing **'**evaluation' questions be adapted and incorporated as 'reflective questions' where relevant within each guiding principle.

Chapter 2:

Updating the Guiding principles for medication management in the community (GPC)

Guiding Principle (GPC) 1: INFORMATION RESOURCES

Access to information resources is an important part of medication management and should remain in the updated versions of the guiding principles. Access to relevant and up-to-date information about medicines is important for health professionals as well as people and their carers.

The current version of **GPC 1** outlines the information resources, including access to Consumer Medicines Information, that are needed to ensure safe medication management. The literature search identified studies showing how medicines information resources can support safe medication management and the environmental scan identified current professional practice standards and guidelines relating to the information resources required for safe medication management.

Information resources included in the updated guiding principles should be the most up-to-date, and align with the relevant professional practice standards[43] [44] [45] and messages in Australia's response to the WHO global patient safety challenge, which state that:

- *there is a need to use technology to provide better medicines information to patients, so that they are better equipped to be shared decision makers in their medication management*
- *providing consumers with access to better medicines information promotes 'healthy challenge'[46] between consumers and their healthcare providers*
- *in order to provide appropriate health care, consumers and their health care providers need access to information so that they can make informed decisions about the benefits and risks of different treatments*
- *medication safety at transitions of care is improved when consumers understand their medicines and have access to their medicines information; and*
- *better communication of health information by health professionals to consumers can improve health literacy for consumers.*[47]

One priority action from this report directly relates to the provision of medicines information to improve medication management: namely, to improve medication safety in polypharmacy through:

> *"Direct-to-consumer communications about primary care programs that raise awareness of self-care through promotion of:*
> - *Simplified medication regimens*
> - *Concordance with agreed medication regimen*
> - *Medicine literacy*
> - *Patient and carer engagement with safe use of their medicines."*

The Medication Safety Standard developed by the Commission as part of the NSQHS Standards, provides guidance on how to provide people with information about their medicines.

Although this guidance has been developed primarily for use in the hospital setting, it provides useful information to guide the provision of medicines information to people in the community setting. Action 4.11 (*Information for patients*) and Action 4.13 (*Information and decision support tools for medicines*) within the Medication Safety Standard are most relevant to the provision of medicines information and medicines information resources. Within these Actions, the intent of each is defined along with reflective questions, key tasks and strategies for improvement.

The Commission's work on health literacy and partnering with consumers has highlighted the importance of understanding the diversity of people, tailoring strategies for vulnerable groups, and the

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[43] Pharmacy Board of Australia. Codes, Guidelines and Policies. Available from: www.pharmacyboard.gov.au/codes-guidelines.aspx
[44] Pharmaceutical Society of Australia. Practice standards and guidance documents. Available from: www.psa.org.au/practice-support-industry/resources/
[45] The Society of Hospital Pharmacists of Australia. Standards of practice. Available from: www.shpa.org.au/standards-of-practice
[46] *'Healthy challenge'* is meant to refer to people being equipped with information to be able to ask questions of their primary care provider about their medicines and play an active role in their medication management.
[47] Australian Commission on Safety and Quality in Health Care. Medication without harm – WHO Global Patient Safety Challenge. Australia's response. Sydney: ACSQHC, 2020.

importance of developing high-quality, easy to understand, health information to support effective partnerships.

A range of contextual factors and personal characteristics have been identified that can affect the skills and abilities of people when they make decisions and take action about health and health care. These include cultural and diverse backgrounds and language, and can influence a person's health literacy.[48,49]

One recent change to the way we are to refer to medicines by their 'active ingredient' is being implemented and NPS MedicineWise have developed a consumer fact sheets in English and ten other languages to help understand this change.

Recommendations:

1. Adapt content within the Medication Safety Standard relevant to the provision of medicines information and medicines information resources within the community
2. Ensure information within **GPC 1** continues to align with all relevant professional board requirements and professional practice standards, and that the resource lists are updated
3. Consideration to be given to creating web-based lists of medication information resources in the updated guiding principles, so that these lists can be updated as needed to ensure people receiving care and health professionals have access to an up to date list of resources that also meet the community's diversity and health literacy needs

Guiding Principle (GPC) 2: SELF-ADMINISTRATION

Self-administration of medicines should continue to be a focus within this set of guiding principles. It is important for people to maintain their independence and to be encouraged to do so. It is also important to recognise that a team or multidisciplinary approach is required to ensure people in the community can continue to manage their medicines (prescription and non-prescription) in a safe and effective manner. This includes the use of over-the-counter (OTC) and complementary and alternative medicines (CAMs).

Assessment and reassessment of a person's ability to take, or continue to take their medicines should remain a focus within this guiding principle to guide the need for trialing and/or implementing support strategies, such as a dose administration aid, that will maintain their independence.

Given the focus of this guiding principle, which resonates with the concept of 'person-centred care', the content and language should be adjusted accordingly.

The risk of adverse events may increase during periods of acute illness due to comorbidities or medicine use (for example, gastroenteritis or diarrhoea).[50] Consideration should be given to including advice on medication management (including self-directed) during "sick days". Guidance may be needed on which medicines should be temporarily suspended, for instance diuretics, or the dose temporarily increased, for example, insulin. Factors to consider will include the type of medicine, its formulation pharmacokinetics, duration of the acute illness and comorbidities.[50]

Whilst there is no Australian-specific guidance available, reference to the Australian Prescriber article,[50] sick day management for specific chronic conditions like those by the Australian Diabetes Educator Association,[51] as well as existing international resources produced in the UK, might be useful for clinicians to guide development of a management plan for the person and/or their carer as well as their healthcare providers. The management plan may need to include situations where seeking immediate

[48] Australian Commission on Safety and Quality in Health Care. Health literacy: Taking action to improve safety and quality. Sydney: ACSQHC, 2014.
[49] Consumer Health Literacy Segmentation and Activation Research Project. Canberra: Consumer Health Forum; September 2020.
[50] Lea-Henry T, et al. Medication management on sick days. Aust Prescr. 2017;40:168-73.
[51] Clinical Guiding Principles for Sick Day Management of Adults with Type 1 Diabetes or Type 2 Diabetes A Guide for Health Professionals. Canberra: Australian Diabetes Educator Association; June 2020.

medical attention, such as calling the primary health care practitioner or an ambulance for transfer to hospital, is warranted.

Primary care resources from Healthcare Improvement Scotland and a Position statement on "sick day rules" developed by Think Kidneys in the UK offer some insight into the medicines and chronic conditions where risk of adverse events during acute illness is highest. A UK qualitative evaluation[52] on the implementation of 'sick day guidance' provides insight on challenges in communicating the concept of temporary cessation of medicines and how to best manage certain medicines and conditions during acute illness including:

- which medicines should be temporarily ceased/held during acute illness to reduce the risk of adverse events
- which medicines may require dose escalation during periods of acute illness (for example, insulin, long term steroids)
- when medication use can 'return to normal' after acute illness
- how to manage medicines packed in DAAs during acute illness (for example, refer to the pharmacist to ensure appropriate identification and/or removal of the medicines to be ceased/withheld).

GPC 2 refers to the *Guiding principles to achieve continuity in medication management* (2006) which is also undergoing review. Any modification that relates to the transitions between care environments will need to be consistent.

Recommendations:

1. That the language within **GPC 2** be amended to align with the concept and intent of person-centred care
2. For people (as well as clinicians) who are self-administering, include some additional advice on when and how to stop and restart medicines during periods of acute illness or "sick days". For instance, medication management on "sick days" (when and how to stop and restart medicines). This may involve the need to include practical advice for service providers or care workers and nurses who may be required to take over the administration of all medicines (either temporarily or permanently). It should be noted that **GPC 3** (*Dose administration aids*) is also impacted.

Guiding Principle (GPC) 3: DOSE ADMINISTRATION AIDS

The 2020 Pharmaceutical Society of Australia (PSA) report Medicine safety: Aged care identified a number of issues related to medication administration in the aged care setting. The report highlighted that up to 21% of DAAs in aged care have a packing error, with an average error rate of 9%. Packing errors commonly included:

- inclusion of a medicine in the dose administration aid which had been ceased
- wrong dose of medicine was packed
- packing a medicine in the DAA at an incorrect administration time
- omission of medicines that should have been packed.[53]

The report also noted that poor documentation or communication, poor handwriting on medicine charts or prescriptions and lack of continuity in medication supply (e.g. no current prescription) account for up to 25% of DAA packing errors.[53]

According to the ANMF Position statement on the Use of dose administration aids, nurses who administer medicines are expected to take responsibility for identifying each individual medicine prior to administration. Where individual medicines cannot be clearly identified, nurses must consult the person's pharmacist regarding the need for DAA repackaging.

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[52] Martindale A, et al. Understanding the implementation of 'sick day' guidance to prevent acute kidney injury across a primary care setting in England: a qualitative evaluation. BMJ Open 2017;7:e017241.
[53] Pharmaceutical Society of Australia. Medicine safety: aged care. Canberra: PSA, 2020.

The two main guidelines on DAAs are the PSA Guidelines for pharmacists providing dose administration aids and the Pharmacy Board of Australia (PBA) *Guidelines on dose administration aids and staged supply of dispensed medicines*.[54] These documents have been reviewed and updated since the current National QUM publications were published. The PSA and Pharmacy Board guidelines highlight that provision of DAAs is a clinical service, not just a supply function. The guidelines make it clear that medication safety is paramount, and so pharmacists providing DAA services must follow robust processes of high standard to ensure the safety of the person receiving care. The importance of reconciling medicines the first time, and regularly thereafter, prior to packing a person's DAA is included. This is a necessary step to ensure a complete and accurate medicines list or medication profile that takes into account all prescription, non-prescription, complementary and alternative medicines a person is taking. If necessary, it may prompt a review of the person's medicines, especially if something has changed following an admission to hospital: for instance, a HMR, MedsCheck or other medication review service.

In general, the information contained within the PSA and Pharmacy Board guidelines for DAAs is in agreement with the information in the current guiding principles documents. Where recommendations in the PSA and Pharmacy Board guidelines for DAAs were not included in the current guiding principles documents, in most cases they tended to be highly technical recommendations for pharmacists packing DAAs (e.g. recommendations for packing areas for DAAs, recommendations for record keeping when packing DAAs). Inclusion of these highly technical recommendations in the guiding principles is unlikely to be helpful to the wider audience for which the guiding principles are intended. However, several recommendations or pieces of information in the PSA guidelines which are not included in the current guiding principles should be considered for inclusion in updated versions. This includes: reconciling medicines prior to packing; consent and communication around use and continuation; and monitoring and follow up use of DAAs.

Recommendations:

1. That **GPC 3** has greater emphasis and more information on:
    a. the need for medication reconciliation prior to DAA packing for the first time, and after changes to medicines or hospital admission
    b. the need for consent and communication around initiating and continuing use of DAAs
    c. monitoring and follow up of people using DAAs.
2. That some additional advice on self-directed medication management during periods of acute illness be included. For instance, medication management on "sick days" (when and how to stop and restart medicines).

Guiding Principle (GPC) 4: ADMINISTRATION OF MEDICINES IN THE COMMUNITY

Administration of medicines in the community can involve different clinicians, health care workers and service providers who play an important role in making sure that *people who live at home receive suitable information and/or assistance* in taking their medicines safely and effectively.

Communication and coordination between the various service providers remains essential and those supporting a person to take their medicines need to understand the importance of maintaining a record of that administration or self-administration has taken place, including if a person needed to be reminded. Service providers also need to ensure that their employees, for example, disability support workers, have the necessary knowledge, skills, experience and training for the tasks they are expected and authorised (according to state and territory legislation) to perform.

It is important to highlight that those clinicians charged with the responsibility of administering a person's medicines must have the competency, and delegated responsibility and authority to do so, according to national regulation and state and territory legislation and policies, and within their scope of practice. For instance, registered nurses should be familiar with and understand their obligations when administering medicines, including how to avoid the risk of harm associated with their administration, and can keep abreast of latest news and updates by using resources developed by organisations such

[54] Pharmacy Board of Australia. Guidelines on dose administration aids and staged supply of dispensed medicines. 2015. Available from: https://www.pharmacyboard.gov.au/codes-guidelines.aspx

as NPS MedicineWise. In addition, nurses can access relevant education and other resources via the Australian College of Nursing and the Australian Nursing & Midwifery Federation.

Since publication of these guiding principles, the Health Practitioner Regulations National Law, in force in each state and territory (the National Law), is now in place. Under the National Law the Nursing and Midwifery Board of Australia (NMBA) regulates the practice of nursing and midwifery in Australia. One key role is protecting the public and the NMBA does this by developing registration standards, professional codes, guidelines and standards for practice. Enrolled nurses (ENs) are also registered by the NMBA and only those who have completed medication administration education, either as part of their undergraduate education or as postgraduate education are able to administer medicines as delegated by and under the supervision of a registered nurse.

Whilst one resource relating specifically to the administration of medicines in aged care has been identified, the ANMF Nursing Guideline: Management of Medicines in Aged Care provides a sound framework for nurses employed by service providers delivering care to older persons in the community. The ANMF also has a series of other guidelines, policies and position statements of relevance to nurses and midwives including position statements on:

- Quality use of medicines (2019)
- Care for people living with a disability (2021)
- The use of dose administration aids (2018).

There has been ongoing emphasis on improving cultural safety in health across Australia following the release of the 2018 Closing the Gap Report. Ahpra has a National Aboriginal and Torres Strait Islander Health Strategy. National professional boards, including the NMBA, are ensuring that there is an inherent understanding that cultural safety is about the person who is providing care reflecting on their own assumptions and culture in order to work in a genuine partnership with Aboriginal and Torres Strait Islander Peoples. Aboriginal Health Workers' role in medication management and in making Aboriginal communities feel safe also continues to be important, such that Aboriginal and Torres Strait Islander Health Practitioners can now be registered under the National Registration and Accreditation Scheme. The Aboriginal and Torres Strait Islander Health Practice Board is one of 15 National Boards under Ahpra, and consistent with other National Boards, has developed and released a series of registration standards. Continuing professional development resources are also available for Aboriginal and Torres Strait Islander Health Practitioners from NPS MedicineWise.

Recommendation:

1. That information and resources relevant to **GPC 4** be updated or aligned to reflect relevant state and territory legislative requirements and current practices of care providers and care environments.

Guiding Principle (GPC) 5: MEDICATION LISTS

Medicine-related problems and risk of harm to the person are minimised by maintaining a current medicines list with reasons for any changes. People should continue to be supported in maintaining an up-to-date list of all their medicines. This information should be easily accessible, such as within digital support tools like the MedicineWise smartphone app. NPS MedicineWise have an accompanying person-focused resource to explain the importance of Keeping a medicines list.

Continuity of medication management includes generating, maintaining and communicating a current list of medicines and the reasons for changes when handing over care to another clinician or service provider. This includes at transitions of care. **GPC 5** refers to the *Guiding principles to achieve continuity in medication management* (2006) which is also undergoing review. Any modification that relates to the transitions between care environments will need to be consistent.

It is critical to communicate the person's current medicines list, along with any medicine-related problems or adverse drug events that have occurred during care or as a result of a medication review according to **GPC 6** (*Medication review*). A medicine-related problem may include a person refusing or missing a dose of medicine, or withholding a medicine as a result of an acute illness.

Whilst it is important to encourage people to maintain an up-to-date record of their medicines, it is also important for clinicians to validate this information. Reference to the person's *My Health Record* is

another useful way to verify that the prescriber, pharmacist or service provider has the most up to date information about a person's medicines.

Recommendations:

1. That **GPC 5** be retained, and content information and accompanying resources updated.

Guiding Principle (GPC) 6: MEDICATION REVIEW

The Australian Government has funded comprehensive medication reviews for over 20 years. The current program rules,[55,56] ratified in the 7th Community Pharmacy Agreement,[57] fund the following medication review services in the community:

- Home Medicines Reviews or HMRs (in-person or telehealth)
- MedsCheck and Diabetes MedsCheck.

People living in a community setting and at risk of, or experiencing 'medication misadventure' are eligible to receive one HMR within 24 months. The person's general practitioner may request a subsequent review if deemed clinically necessary. Reasons for requesting additional reviews include (but are not limited to):

- *Discharge from hospital after an unplanned admission in the previous four weeks*
- *Significant change to medication regimen in the past three months*
- *Change in medical condition or abilities.*

Other models of care are also emerging where medication reviews are provided by pharmacists 'embedded' within general practices. A recent study, found that integrating pharmacists into general practices can reduce the incidence of hospital re-admissions and ED presentations in patients recently discharged from hospital.[58]

In updating this guiding principle, consideration should be given to aligning with the PSA Guidelines for comprehensive medication management reviews. This should include reference to a person's right to choose the place where the medication review is conducted, depending on their preferences, socioeconomic circumstances and cultural beliefs.

This guiding principle should address polypharmacy and deprescribing which is aimed at minimising inappropriate polypharmacy and reducing medicine complexity. Older people have increasingly complex medication regimens, and being able to manage and stay living at home can be challenging, Studies have shown that medication regimen complexity can be simplified through use of structured tools[59] and strategies.[60]

Each clinician involved in a person's care has the responsibility to use their specific knowledge, skills and expertise to ensure the safe and quality use of medicines by all people in their care. If risks with medicine use are identified early it may prevent unnecessary escalation in care or hospital admission. Whilst a comprehensive medication review (for example, HMR) by a pharmacist is ideal, there may be situations where other clinicians need to consider and review the appropriateness of a medicine, suitability of its formulation, or a change in a person's situation or condition that prompts an 'ad hoc' review of their medicines. It is possible that this would prompt referral to their primary health care practitioner or contact with the person's pharmacist for advice and/or review.

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[55] Pharmacy Programs Administrator. Program Rules. Home Medicines Reviews. PPA; 2021.
[56] Pharmacy Programs Administrator. Program Rules: MedsCheck and Diabetes MedsCheck. PPA; 2021.
[57] Australian Government. Department of Health. Seventh Community Pharmacy Agreement. https://www.pbs.gov.au/info/general/seventh-community-pharmacy-agreement: Department of Health.; 2020.
[58] Freeman C, et al. Reducing Medical Admissions and Presentations Into Hospital through Optimising Medicines (REMAIN HOME): a stepped wedge, cluster randomised controlled trial. MJA 2021; 214(5):212-217.
[59] Sluggett J, et al. Simplifying Medication Regimens for People Receiving Community-Based Home Care Services: Outcomes of a Non-Randomized Pilot and Feasibility Study. Clin Interv Aging 2020;15:797-809.
[60] Sluggett JK, et al. Protocol for a non-randomised pilot and feasibility study evaluating a multicomponent intervention to simplify medication regimens for people receiving community-based home care services. BMJ Open 2019;9:e025345.

The RACGP Silver Book, Part A, Medication management contains a series of 'consensus-based recommendations' for General Practitioners, including the need for medication review and deprescribing. The RACGP Silver Book also contains chapters on managing older people with polypharmacy and deprescribing.

Effective and collaborative communication is also essential to facilitate a person's involvement in shared decision-making and ensure safe and quality use of medicines.

Recommendations:

1. That **GPC 6** include information on risks of inappropriate polypharmacy and deprescribing
2. That other aspects of medication review from various resources, practice standards and guidelines be considered when updating **GPC 6**

Guiding Principle (GPC) 7: ALTERATION OF ORAL DOSE FORMS

The current content of **GPC 7** covers the issues that need to be considered when the person might need to have oral formulations altered to aid their administration. Reference to a key resource, *Don't Rush to Crush* needs to be included in the update.

Whilst the guiding principle does emphasise the importance of seeking advice, it would benefit from a greater emphasis on a multidisciplinary approach that considers how to manage people with conditions that impact their functional ability to swallow, for example, dysphagia as a result of a stroke. Speech Pathology Australia Dysphagia Clinical Guideline (2012) recommends review of all people before administering a medicine and referral to their pharmacist or primary health care practitioner if oral dose forms of medicines need to be altered. In addition the NDIS Quality and Safeguards Commission's practice alert on Medicines associated with swallowing problems highlights medicines that can cause swallowing problems and may increase the risk of choking.

Recommendations:

1. That **GPC 7** includes greater emphasis and more information on:
    a. the need for consumers to be assessed for swallowing safety before being given medicines
    b. referral to a pharmacist or the consumer's GP when it is unsafe for a consumer to swallow oral formulations of a medicine.
2. Consider how the content of other guiding principles may need to be amended, including; **GPC 2** (*Self-administration of medicines*); **GPC 4** (*Administration of medicines in the Community*); and **GPC 6** (*Medication review*).

Guiding Principle (GPC) 8: STORAGE OF MEDICINES

Correct storage of medicines in the community remains important and the content of **GPC 8** remains relevant. There are many ways that a person may store their medicines to ensure they maintain their stability and effectiveness as well as ensure they are out of harm's way, for instance, out of the reach of children.

NPS MedicineWise has developed a resource: Living with multiple medicines: Organising and storing medicines which contains useful information which is consistent with the content of the existing guiding principle. Clinicians, service providers and other care workers could use resources like these to highlight the important issues and encourage safe and appropriate storage of a person's medicines.

Recommendation:

1. That information and resources relevant to **GPC 8** be updated or aligned to reflect current tools, practices and legislation, and that consideration be given to combining with **GPC 9** (*Disposal of medicines*)

Guiding Principle (GPC) 9: DISPOSAL OF MEDICINES

The Return Unwanted Medicines (RUM) project continues to be the main mechanism for safe disposal of medicines and devices (including devices such as inhalers; insulin pens; dose administration aids) in Australia. It allows people to return unwanted medicines to any community pharmacy within Australia for safe disposal. The Therapeutic Goods Administration (TGA) has developed consumer resources explaining why safe disposal of medicines is important and how to access the RUM program. These messages are consistent within those within this guiding principle.

The RUM program also provides advice on How to dispose of Schedule 8 (S8) medicines (for example, strong analgesics) in an appropriate and secure manner which varies according to the relevant state or territory legislation.

A 2018 study explored the degree of medicines retention and disposal in the Australian community.[61] The conclusions highlighted the potential need for health care providers to assist in addressing any misconceptions around the QUM and medicines storage, retention and disposal. An additional concern is the significant wastage of Pharmaceutical Benefits Scheme (PBS) medicines, with the RUM collections totalling over 600,000 kilograms YTD March 2021.

Recommendation:

1. That information and resources relevant to **GPC 9** be updated or aligned to reflect current tools, practices and legislation, and that consideration be given to combining with **GPC 8** (*Storage of medicines*)

Guiding Principle (GPC) 10: NURSE-INITIATED NON-PRESCRIPTION MEDICINES

The literature review did not identify any new research specifically related to nurse-initiation of non-prescription medicine since 2006. The limited research focused on the topic of 'non-medical prescribing' by nurse practitioners where time to prescription of analgesic medicines in the emergency department was shorter for patients seen by a nurse practitioner compared to a medical doctor.[62]

However, initiation of non-prescription medicines remains an important aspect of medication management in the community and is not limited to nurses.

Similar to the *Guiding principles for medication management in residential aged care* and given that Nurse Practitioners are recognised prescribers it may be relevant to reconsider the title and scope of this guiding principle.

In the community, pharmacists are able to initiate non-prescription over-the counter (OTC) medicines and Schedule 3 Pharmacist Only Medicines, either upon direct request from a person or to treat a minor ailment.

Pharmacists are also able to initiate prescription medicines in an emergency. For instance, under relevant national and state/territory legislation a pharmacist can issue a 3-day emergency supply of some prescription medicines if a person's primary care provider cannot be contacted.

The PSA Professional Practice Standards for pharmacists outlines the 'expected standards of professional behaviour of pharmacists in Australia'. Standard 4 within these professional practice standards outlines the expected role of pharmacists when initiating or providing non-prescription medicines to people, and states that:

> *The pharmacist ensures that the provision of non-prescription medicines and therapeutic devices is consistent with quality use of medicines and appropriate to the needs of the patient.*

[61] Kelly F, et al. 'You don't throw these things out:' an exploration of medicines retention and disposal practices in Australian homes. BMC Public Health. 2018;18:1026 https://doi.org/10.1186/s12889-018-5753-6
[62] Jennings N, et al. Evaluating emergency nurse practitioner service effectiveness on achieving timely analgesia: a pragmatic randomized controlled trial. Acad Emerg Med 2015;22(6):676-84.

There are a series of actions required to meet this standard, which include the need:

- for person-centred care
- to comply with policies and procedures
- to meet storage requirements and promotion requirements (i.e. ensure that promotion of non-prescription medicines adheres to principles of QUM)
- for education and training
- for history taking, assessment, consultation and reconciliation, counselling and documentation of the medicine supplied
- for monitoring, review and follow-up of the person
- to conduct risk management and evaluation.

The actions within this PSA practice standard align with the existing **GPC 10** currently only refer to initiation of non-prescription medicines by nurses.

Given the limited scope and that other categories of health professionals are able to initiate medicines, the focus should be broadened and GPC 10 renamed to reflect situations where initiation of both prescription and non-prescription medicines is allowed or authorised.

It will be important to ensure that any medicines that are initiated in these ways are communicated to the primary health care provider and included within a person's updated medicines list. Links to **GPC 5** (*Medication lists*) and **GPC 6** (*Medication review*) should also be considered.

Recommendations:

1. That **GPC 10** is retained and the focus broadened to encompass the situations where initiation of both prescription and non-prescription medicines is allowed or authorised, and renamed **Authorised initiation of medicines**
2. That information and resources relevant to **GPC 10** be updated or aligned with state and territory drugs and poisons legislation
3. That other existing guiding principles be incorporated under this new 'title', for instance, **GPC 11** (*Standing orders*), which are designed to allow or authorise administration of medicines in particular circumstances.

Guiding Principle (GPC) 11: STANDING ORDERS

The use of standing orders is generally discouraged for administration of prescription medicines in a community setting. If used, standing orders must be in accordance with state and territory drugs and poisons legislation.

The ANMF refers to standing orders within its position statement on Registered Nurse and Midwife Prescribing.

There is an opportunity to collapse or incorporate into **GPC 10**, which is proposed to have a broadened focus on the situations where initiation of both prescription and non-prescription medicines is allowed or authorised.

Recommendations:

1. That existing **GPC 11** be incorporated under a renamed **GPC 10** focused on situations where initiation of both prescription and non-prescription medicines is allowed or authorised
2. That information and resources relevant to **GPC 11** be updated or aligned with state and territory drugs and poisons legislation

Guiding Principle (GPC) 12: RISK MANAGEMENT IN THE ADMINISTRATION AND USE OF MEDICINES IN THE COMMUNITY

The current focus of **GPC 12** is on managing 'risks and incidents associated with medicine use in the community'. **GPC 12** also highlights the need for all stakeholders to work together to ensure that there are safe systems for medication management, including systems to monitor quality use of medicines from prescribing through to the administration of medicines.

Since release of the 2006 *Guiding principles for medication management in the community*, there have been a number of Australian interventions to improve medication management in the community setting. The Pharmacy Recording of Medication Incidents and Services (PROMISe) trial developed and implemented an electronic tool for use in community pharmacy to assist with the detection and resolution of drug related problems.[63] The PROMISe trial used a purpose developed tool, the DOCUMENT system[64], used within the PSA Guidelines for pharmacists performing clinical interventions, to classify drug related problems. Until June 2021, other trials on medication management were conducted under the Community Pharmacy in Health Care Homes Trial Program. Whilst the 'home care trials' have ceased, the outcomes from the Health Care Homes Project may be useful in the review of this guiding principle and more broadly to identify useful resources.

Australia's response to the WHO global patient safety challenge outlines aims to 'improve medication safety by strengthening the systems for reducing medication errors and avoidable medication-related harm'. In 2018, the WHO defined harm as the impairment of structure or function of the body and/or any deleterious effect arising from, or associated with, plans or actions taken during the provision of primary health care. It includes disease, injury, suffering, disability and death, and may be physical, psychological or social.[65]

Australia's response goes on to describe and focus on the person's journey and important medication safety processes brought together across its three flagship areas:

- inappropriate polypharmacy
- high risk medicines (priorities: insulins, anticoagulants, opioid analgesics and antipsychotics)
- transitions of care.

It also emphasises the importance of shared and supported decision making to ensure:

- Treatment options are fully explored, including discussion of the risks, benefits and uncertainties associated with different options
- The person's values, goals and preferences are discussed
- Decisions are agreed and there is a shared understanding between the person (or medical decision maker) and their healthcare provider.

Many programs are in place to help reduce risks associated with inappropriate polypharmacy and to promote safe use of medicines. These include:

- pharmacist-led home medication review[66]
- general practitioner/primary health care practitioner-led multidisciplinary care plans[67]
- hospital outreach medication review services[68,69]

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[63] Williams M, et al. Drug-related Problems Detected in Australian Community Pharmacies: The PROMISe Trial. Annals of Pharmacotherapy 2011;45:1067-76.
[64] Williams M, et al. DOCUMENT: a system for classifying drug-related problems in community pharmacy. Int J Clin Pharm 2012;34(43-52).
[65] Cooper J, Williams H, Hibbert P, Edwards A, Butt A, Wood F, et al. Classification of patient-safety incidents in primary care. Bull World Health Organ 2018; 96:498-505. dx.doi.org/10.2471/BLT.17.199802.
[66] Jokanovic N, Tan ECK, Sudhakaran S, Kirkpatrick CM, Dooley MJ, Ryan-Attwood TE, et al. Pharmacistled medication review in community settings: an overview of systematic reviews. Res Soc Admin Pharm 2017; 13, 4:661–85.
[67] Australian Government Department of Health. Coordination of Team Care Arrangements (TCAs) MBS Item 723. Canberra: DoH.
[68] Hanna M, Larmour I, Wilson S, O'Leary K. Patient and general practitioner perspectives of the Hospital Outreach Medication Review service at Monash Health. J Pharm Prac & Res 2015; 45, 3:282–90.
[69] New hospital-initiated medication review pathways to help close safety gaps. Media release. Society of Hospital Pharmacists of Australia. November 2020.

- community pharmacy medication reconciliation services.[70]

There is evidence that some of these programs improve medication safety.[71,72]

In 2018, the PSA released Clinical Governance Principles for Pharmacy Services which cover a range of aspects within the *Guiding principles for medication management in the community*, including clinical performance and effectiveness, and, safety and quality improvement systems. In 2020, Clinical Governance was integrated into the Quality Care Pharmacy Program for pharmacies which *provides a framework to ensure pharmacy owners are accountable for and have oversight of activities and services provided in the pharmacy to maintain consistent, high quality and safe care.*

NPS MedicineWise's Prescribing Competencies Framework includes competencies that focus on the prescribers need to understand and be aware 'the risks and benefits of medicines use' when choosing suitable medicines, if a medicine is considered necessary. In addition, these competencies cover the need for prescribers to 'understand common causes of incidents and error' and to 'implement strategies to reduce the risk of these occurring'.

Whilst the content of the existing **GPC 12** is relevant it may be useful to include additional information about initiatives such as those described above and within other guiding principles relating to inappropriate polypharmacy and deprescribing.

Recommendation:

1. That information and resources relevant to **GPC 12** be updated or aligned to reflect current tools and practices, for instance, relating to inappropriate polypharmacy and deprescribing, as well as clinical governance and risk management.

[70] Pharmacy Guild of Australia Victoria. Improving medication reconciliation in community settings. Melbourne; PGA; 2017.
[71] Hanna M, Larmour I, Wilson S, O'Leary K. The impact of a hospital outreach medication review service on hospital readmission and emergency department attendances. J Pharm Prac & Res 2016; 46, 2:112–21.
[72] Mekonnen AB, McLachlan AJ, Brien JE. Effectiveness of pharmacist-led medication reconciliation programmes on clinical outcomes at hospital transitions: a systematic review and meta-analysis. BMJ Open 2016; 6:e010003.

Glossary

If appropriate, glossary definitions from external sources have been adapted to fit the context of the guiding principles for medication management in RACFs and the community.

administration of a medicine: the process of giving a dose of medicine to a person or a person taking or self-administering a medicine.

alteration of oral dose form: the altering or crushing of oral tablets or capsules before administration to people who have difficulty swallowing. The alteration is intended to assist administration and ensure that people receive necessary medicines. Alteration of oral dose forms can have potentially unsafe consequences such as increased toxicity, decreased efficacy, altered palatability, and safety or stability concerns, including creating potential hazards to health care workers.

antimicrobial stewardship: an ongoing effort by a health service organisation to reduce the risks associated with increasing antimicrobial resistance and to extend the effectiveness of antimicrobial treatments. It may incorporate several strategies, including monitoring and review of antimicrobial use.

appropriate polypharmacy: prescribing multiple medicines for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence.

assessment: a clinician's evaluation of a disease or condition based on the patient's subjective report of the symptoms and course of the illness or condition, and the clinician's objective findings. These findings include data obtained through laboratory tests, physical examination and medical history; and information reported by carers, family members and other members of the healthcare team. The assessment is an essential element of a comprehensive care plan.

audit (clinical): a systematic review of clinical care against a predetermined set of criteria.

Australian Charter of Healthcare Rights: specifies the key rights of patients when seeking or receiving healthcare services. It was updated in 2020 and reflects an increased focus on person-centred care and empowers consumers to take an active role in their healthcare.

best possible medication history (BPMH): a list of all the medicines a patient is using at presentation. The list includes the name, dose, route and frequency of the medicine, and is documented on a specific form or in a specific place. All prescribed, over-the-counter and complementary medicines should be included. This history is obtained by a trained clinician interviewing the patient (and/or their carer) and is confirmed, where appropriate, by using other sources of medicines information.

best practice: when the diagnosis, treatment or care provided is based on the best available evidence, which is used to achieve the best possible outcomes for patients.

carer: a person who provides personal care, support and assistance to another individual who needs it because they have a disability, medical condition (including a terminal or chronic illness) or mental illness, or they are frail or aged. An individual is not a carer merely because they are a spouse, de facto partner, parent, child, other relative or guardian of an individual, or live with an individual who requires care. A person is not considered a carer if they are paid, a volunteer for an organisation, or caring as part of a training or education program.

care worker: paid workers supporting people to live the community. Examples include Aboriginal Health Workers and Torres Strait Islander Health Workers, assistants in nursing, personal care assistants, community support workers, disability care workers, home and community care workers.

clinical communication: the exchange of information about a person's care that occurs between treating clinicians, patients, carers and families, and other members of a multidisciplinary team. Communication can be through several different channels, including face-to-face meetings, telephone, written notes or other documentation, and electronic means. *See also* effective clinical communication, clinical communication process.

clinical communication process: the method of exchanging information about a person's care. It involves several components, and includes the sender (the person who is communicating the information), the receiver (the person receiving the information), the message (the information that is communicated) and the channel of communication. Various channels of communication can be used, including verbal

(face to face, over the phone, through Skype), written and electronic. Sending and receipt of the information can occur at the same time, such as verbal communication between two clinicians, or at different times, such as non-verbal communication during which a clinician documents a patient's goals, assessments and comprehensive care plan in the healthcare record, which is later read by another clinician.

clinical governance: an integrated component of corporate governance of health service organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services. Clinical governance systems provide confidence to the community and the healthcare organisation that systems are in place to deliver safe and high quality health care.

clinician: a healthcare provider, trained as a health professional, including registered and nonregistered practitioners. Clinicians may provide care within a health service organisation as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health practitioners, technicians, scientists and other clinicians who provide health care, and students who provide health care under supervision.

collaboration: in the context of medication management, collaboration is a process whereby individuals and health care providers share their expertise and take responsibility for decision making. Accomplishing collaboration requires that individuals understand and appreciate what it is they, and others, want to contribute to the 'whole'.

community care or service provider: Provider of a health and community care service in the community.

complementary and alternative medicines (CAMs): CAMs include herbal, vitamin and mineral products, nutritional supplements, homeopathic medicines, traditional Chinese medicines, Ayurvedic medicines, Australian Indigenous medicines, and some aromatherapy products regulated under the Therapeutic Goods Act 1989. Other terms sometimes used to describe CAMs include 'natural medicines' and 'holistic medicines'.

consumer medicine information (CMI): brand-specific leaflets produced by a pharmaceutical company in accordance with the Therapeutic Goods Regulations to inform consumers about prescription and pharmacist-only medicines. Available from a variety of sources, for example, enclosed with the medicine package, supplied by a pharmacist as a leaflet or computer printout, provided by a doctor, nurse or hospital, or available from the pharmaceutical manufacturer.

deprescribing: the process of tapering or stopping medicines, which aims to discontinue potentially inappropriate medicines, minimise inappropriate polypharmacy and improve a person's outcomes. Also referred to as de-escalation.

discharge summary: a collection of information about events during care of a patient by a provider or organisation. The document is produced during a person's stay in hospital as either an admitted or non-admitted patient, and issued when or after the person leaves the care of the hospital.

dispensing: the (1) assessment of the medicine prescribed in the context of the person's other medication, medical history and the results of relevant clinical investigations available to the pharmacist; (2) selection and supply of the correct medicines; (3) appropriate labelling and recording; and (4) counselling of the person on the medicine(s).

diversity: the varying social, economic and geographic circumstances of consumers who use, or may use, the services of a health service organisation, as well as their cultural backgrounds, religions, beliefs, practices, languages spoken and sexualities (diversity in sexualities is currently referred to as lesbian, gay, bisexual, transgender and intersex, or LGBTI).

dose administration aid (DAA): a device or packaging system such as blister packs, bubble packs or sachets for organising doses of medicines according to the time of administration.

electronic prescribing (e-prescribing): prescriptions that are issued and dispensed in an electronic system, without the use of a paper-based document at any point.

embedded pharmacist: a pharmacist who is fully integrated within the care team and wherever medicines are used – including within primary care, residential care and other settings where medicines are prescribed, supplied and administered to people.

enrolled nurse (EN): a person who provides nursing care under the direct or indirect supervision of a registered nurse. They have completed the prescribed education preparation, and demonstrate competence to practise under the Health Practitioner Regulation National Law as an enrolled nurse in Australia. Enrolled nurses are accountable for their own practice and remain responsible to a registered nurse for the delegated care.

governance: the set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including patients and consumers). Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal, human resources) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance. Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of different participants in the organisation to achieve the organisation's objectives.

high-risk medicines: medicines that have an increased risk of causing significant patient harm or death if they are misused or used in error. High-risk medicines may vary between hospitals and other healthcare settings, depending on the types of medicines used and patients treated. Errors with these medicines are not necessarily more common than with other medicines. Because they have a low margin of safety, the consequences of errors with high-risk medicines can be more devastating.[86,87] At a minimum, the following classes of high-risk medicines should be considered:

- Medicines with a narrow therapeutic index
- Medicines that present a high risk when other system errors occur, such as administration via the wrong route.

imprest stock: a stock of medicines maintained at a pre-determined level for use in the facility, according to state or territory legislation and licencing arrangements.

inappropriate polypharmacy: prescribing of multiple medicines inappropriately, or where the intended benefit of the medicine is not realised.

informed consent: a process of communication between a patient and clinician about options for treatment, care processes or potential outcomes. This communication results in the patient's authorisation or agreement to undergo a specific intervention or participate in planned care.[89] The communication should ensure that the patient has an understanding of the care they will receive, all the available options and the expected outcomes, including success rates and side effects for each option.[90]

mandatory: required by law or mandate in regulation, policy or other directive; compulsory.

medication advisory committee (MAC): A group of advisors to the RACF who provide medication management leadership and governance, and assist in the development, promotion, monitoring, review and evaluation of medication management policies, procedures and guidelines that will have a positive impact on health and quality of life for people in their care.

medication chart: is a tool to document a record of the prescriber's clinical intention for a person's treatment, an order for the pharmacist to dispense a person's medicine, and a record of administration of the medicine to the person.

medication management: practices used to manage the provision of medicines, including:

- how medicines are selected, ordered and supplied
- how people take medicines or are assisted to take them
- how medicines use is recorded and reviewed
- how medicines are stored and disposed of safely
- how medicines use is supported, monitored and evaluated.

Medication management occurs at both individual and services levels. Medication management has also been described as a cycle, pathway or system, which is complex and involves a number of different clinicians. The person is the central focus. The system includes manufacturing, compounding, procuring, dispensing, prescribing, storing, administering, supplying and monitoring the effects of medicines. It also includes decision-making, and rules, guidelines, support tools, policies and procedures that are in place to direct the use of medicines.

medication reconciliation: a formal process of obtaining and verifying a complete and

accurate list of each person's current medicines (including prescription, over-the-counter and CAMs), and matching the medicines the person should be prescribed to those they are actually prescribed. Any discrepancies are discussed with the prescriber, and reasons for changes to therapy are documented and communicated to the next care provider (as well as the person or their carer) when care is transferred. Medication review may form part of the medication reconciliation process.

medication review: a systematic and collaborative assessment of medication management for an individual person that aims to optimise the patient's medicines and outcomes of therapy by providing a recommendation or making a change. it includes the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste. Medication review may be part of medication reconciliation.

medicines list: prepared by a clinician, a medicines list contains, at a minimum:

- All medicines a patient is taking, including over-the-counter, complementary, prescription and non-prescription medicines; for each medicine, the medicine name, form, strength and directions for use must be included
- Any medicines that should not be taken by the patient, including those causing allergies and adverse drug reactions; for each allergy or adverse drug reaction, the medicine name, the reaction type and the date on which the reaction was experienced should be included.

Ideally, a medicines list also includes the intended use (indication) for each medicine.

It is expected that the medicines list is updated and correct at the time of transfer (including clinical handover) or when services cease, and that it is tailored to the audience for whom it is intended (that is, individual or clinician).

minor ailments: conditions that are self-limiting, with symptoms easily recognised and described by the patient and falling within the scope of pharmacist's knowledge and training to treat. For example, common cold, cough, low back pain, tension headache, migraine, primary dysmenorrhoea and reflux, insect bites, nasal congestion.

My Health Record (formerly known as a personally controlled electronic health record): the secure online summary of a consumer's health information, managed by the System Operator of the national My Health Record system (the Australian Digital Health Agency). Clinicians are able to share health clinical documents to a consumer's My Health Record, according to the consumer's access controls. These may include information on medical history and treatments, diagnoses, medicines and allergies.

non-prescription medicine: medicines available without prescription. Examples are cough mixtures, simple analgesics and antacids. Some can be sold only by pharmacists ('Pharmacist Only') or in a pharmacy ('Pharmacy Only'); others can be sold through non-pharmacy outlets such as supermarkets. Also known as 'Over-the-Counter' (OTC) medicines.

Nurse Practitioner: a Registered Nurse (RN) experienced in their clinical specialty, educated at Masters Level, and who is endorsed by the Nurses and Midwives Board of Australia (NMBA) to provide patient care in an advanced and extended clinical role, including prescribing of medications.

outcome: the status of an individual, group of people or population that is wholly or partially attributable to an action, agent or circumstance.

over-the-counter (OTC) medicines: *See* non-prescription medicines.

partnership: a situation that develops when patients and consumers are treated with dignity and respect, when information is shared with them, and when participation and collaboration in healthcare processes are encouraged and supported to the extent that patients and consumers choose. Partnerships can exist in different ways in a health service organisation, including at the level of individual interactions; at the level of a service, department or program; and at the level of the organisation. They can also exist with consumers and groups in the community. Generally, partnerships at all levels are necessary to ensure that the health service organisation is responsive to patient and consumer input and needs, although the nature of the activities for these different types of partnership will depend on the context of the health service organisation.

person-centred care: an approach to the planning, delivery and evaluation of health care that is founded on mutually beneficial partnerships among clinicians and patients.

Person-centred care is respectful of, and responsive to, the preferences, needs and values of patients and consumers. Key dimensions of person-centred care include respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, involvement of carers and family, and access to care. Also known as patient-centred care or consumer-centred care.

pharmacist: a person who is registered as a pharmacist under the Ahpra, which in association with the Pharmacy Board of Australia has deemed that person to be a pharmacist. A registered pharmacist can practise in a variety of settings including community, hospital, RACF, general practice or other setting.

Pharmacist-only medicines (Schedule 3): *See* non-prescription medicines.

prescriber: a health care professional who is authorised by legislation to issue a prescription for the supply of medicines. PBS prescribers include doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS medicines under the National Health Act 1953.

primary care: clinical service provided at the entry level to the health system, and as such is usually a person's first encounter with the health system.

quality improvement: the combined efforts of the workforce and others – including consumers, patients and their families, researchers, planners and educators – to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or continually.

registered nurse (RN): a person who has completed the prescribed education preparation, demonstrates competence to practise and is registered under the Health Practitioner Regulation National Law as a registered nurse in Australia.

residential aged care facility (RACF): a special-purpose facility that provides accommodation and personal care 24 hours a day, as well as access to nursing and general health care services, and assistance towards independent living, for senior Australians who can no longer live in their own home. All government-funded aged care facilities must be approved providers and meet quality standards.

residential care: personal and/or nursing care provided to a person in a residential RACF in which the person is also provided with accommodation that includes meals, cleaning services, furniture and equipment.

restrictive practice: any practice or intervention that has the effect of restricting the rights or freedom of movement of a person with disability. Under the *National Disability Insurance Scheme (Restrictive Practices and Behaviour Support) Rules 2018* certain restrictive practices are subject to regulation. These include seclusion, chemical restraint, mechanical restraint, physical restraint and environmental restraint.

risk: the chance of something happening that will have a negative impact. Risk is measured by the consequences of an event and its likelihood.

service provider: provider of a health and/or community care service in a community setting.

shared decision making: a consultation process in which a clinician and a patient jointly participate in making a health decision, having discussed the options, and their benefits and harms, and having considered the patient's values, preferences and circumstances.

standing order: legal written instructions for the administration of medicines by an authorised person. The authorised person must have a valid and current written instruction for the specific use of the standing order. A standing order is NOT the same as a 'when required' (PRN) order.

transitions of care: situations when all or part of a patient's care is transferred between healthcare locations, providers, or levels of care within the same location, or as the person's condition and care needs change.

AUSTRALIAN COMMISSION
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