20 September 2018

Ms Rosemary Carlin
Coroner
Coroners Court of Victoria
65 Kavanagh Street
Southbank VIC 3006

Email: *cpuresponses@coronerscourt.vic.gov.au*

Dear Coroner Carlin,

RE: Investigation into the death of Ian J Gilbert

The Pharmaceutical Society of Australia (PSA) received on 22 June 2018 a copy of your Finding with inquest into the death of Ian J Gilbert (Court reference: COR 2015 000742). I wish to extend my sympathy to the family and friends of the deceased.

In accordance with section 72(3) of the *Coroners Act 2008* (Vic), I hereby provide written responses to the two recommendations made to the PSA (Recommendations 4 and 5, presented on p. 31 of the report).

For each of the recommendations, several PSA interventions are listed and summarised, specifically as follows:

- Recommendation 4 – Interventions 1 – 6
- Recommendation 5 – Interventions 7 – 9.

Details of each intervention are provided over the page. For each completed intervention, the title header is highlighted in blue shading. For those interventions which are in progress or planned, the title header is highlighted by orange shading.

Recommendation 4. *That the Pharmacy Board of Australia and the Pharmaceutical Society of Australia consult with each other and any other professional body they deem relevant, as to what, if any, further guidance and support should be provided to pharmacists to enable and empower them to discharge their duty of care to patients in situations where they have a concern as to the safety and appropriateness of prescribed medication.*

Intervention 1	**Meeting with the Pharmacy Board of Australia**
How documented	PSA met with the Pharmacy Board of Australia on 15 August 2018 to discuss how both bodies can work together to better support pharmacists with professional practice issues and activities relevant to this case. Attendees were: • Dr Shane Jackson, National President, PSA • Graham Catt, Chief Executive Officer, PSA • Belinda Wood, General Manager – Policy & Advocacy • William Kelly, Chair, Pharmacy Board of Australia Issues canvassed and proposed/agreed actions included the following: • Each organisation to work with relevant respective stakeholders (e.g. medical bodies, consumer organisations) to promote a respectful and collaborative approach to patient safety, including timely and appropriate intervention by health practitioners, and clear communication to patients and carers. • Establish, in consultation with relevant stakeholders, principles for interprofessional collaboration and communication with a view to seeking endorsement and implementation by pharmacy and medical organisations. • Consider strategies to engage with practitioners in a way that maximises the opportunity to influence practice. • Identify relevant current resources on assertiveness training for pharmacists. • Develop guidance for pharmacists on how to communicate and follow up on a clinical intervention.
How operationalised	The key outcome was the Interprofessional collaboration summit hosted by PSA (see **Intervention 2**). Other flow-on activities include Interventions 3, 4, 7, 8 and 9.
Procedures for ongoing review	PSA staff and officials have engaged in discussions on several occasions since this meeting to follow up on the proposed actions. PSA and the Pharmacy Board are also committed to having regular discussions about professional practice issues that are in the interests of patient safety and public protection.
URL link or electronic copy	None

Intervention 2	Interprofessional collaboration summit
How documented	In consultation with the Pharmacy Board of Australia, PSA hosted an interprofessional collaboration summit on 21 August 2018. Objectives of the summit: • Consensus agreement on collaboration principles for pharmacists and doctors to ensure safe prescribing and supply of medicines to consumers. • Identify organisational leadership strategies to support adoption of collaboration principles by relevant professions. Attendees were from: • Australian Health Practitioner Regulation Agency • Australian Medical Association • Consumers Health Forum of Australia • Pharmaceutical Society of Australia • Pharmacy Board of Australia • The Pharmacy Guild of Australia • The Royal Australian College of General Practitioners • The Society of Hospital Pharmacists of Australia The Royal Australasian College of Physicians was also invited but did not attend. Discussion topics included: • Factors impacting on safe prescribing and supply • Draft collaboration principles • Potential strategies to influence practice (practitioner behaviour) – enablers, hurdles • Potential strategies to increase doctor/pharmacist collaboration
How operationalised	Follow up work on draft collaboration principles being progressed (see **Intervention 3**).
Procedures for ongoing review	Ongoing communication with summit participants regarding other associated activities.
URL link or electronic copy	**Attachment 1**: *PSA summit to unite pharmacists and doctors for patient safety* (Media release, 17 Aug 2018) PSA Twitter *post* PSA Facebook *post*

Intervention 3	Collaboration principles
How documented	Following discussions at the interprofessional collaboration summit (**Intervention 2**), a set of collaboration principles for ensuring consumer safety and confidence in prescribing and supply of medicines was developed. The current draft is as follows. Effective, patient-centred collaboration requires: 1. acknowledgement that patient safety and quality use of medicines is paramount 2. respect for the professional obligations and expertise of doctors and pharmacists 3. shared accountability between doctors, pharmacists and consumers for patient safety and care, whilst respecting professional autonomy 4. meaningful involvement of consumers in medication management 5. an obligation for doctors and pharmacists to use appropriate and effective communication channels 6. action by doctors and pharmacists to be prioritised based on assessment of patient risk/urgency.
How operationalised	Professional associations involved in the summit have agreed to review the draft collaboration principles and seek organisational support for endorsement.
Procedures for ongoing review	Summit participants are considering what further action can be taken to promote and support effective collaboration between doctors and pharmacists to ensure patient safety and quality use of medicines.
URL link or electronic copy	None

Intervention 4	Prescriber collaboration
How documented	An article to be published in the October 2018 issue of PSA's professional journal, *Australian Pharmacist.* The key points covered in the article are: • Background information on the Coroner's case • The pharmacist / prescriber relationship – best practice vs. what can happen in practice • How to 'rebalance' the relationship – being well informed and prepared, improving professional relationships, engaging throughout patient care, not underestimating own professional input • Information about the summit (**Intervention 2**) • Guidance on how a pharmacist can respond to a potentially inappropriate prescription

	• New Zealand collaboration model: *Vision 2020 – Partnership for care.* A document prepared by the New Zealand Medical Association and the Pharmaceutical Society of New Zealand. Outlines six vision areas – to work together in integrated and collaborative health practice to improve patient care and health outcomes: a. The patient's healthcare journey b. Health professional roles c. A shared working environment d. Services e. Professional competence and ethics f. Payment arrangements for services
How operationalised	Publication as a feature story in PSA's professional journal *Australian Pharmacist*
Procedures for ongoing review	None
URL link or electronic copy	**Attachment 2**: *Balancing acts* (Feature story on prescriber collaboration to be published in *Australian Pharmacist* October 2018 issue) **Attachment 3**: *Vision 2020: Partnership for care* (Pharmaceutical Society of New Zealand and New Zealand Medical Association, 31 Oct 2014)

Several other pieces of work in progress when this recommendation was received by PSA are also relevant. Interventions 5 and 6 (outlined below) are being conducted as part of PSA's core business as the Australian Government appointed Health Peak and Advisory Body.

Intervention 5	**Pharmacists in 2023**
How documented	Through the release of a discussion paper, PSA is consulting with pharmacists, consumers, governments and other health professions on what the future of pharmacists will look like in five years' time. PSA believes that pharmacists need to be: embedded wherever medicines are used; equipped to enhance community access to health services; and enabled to be recognised and appropriately remunerated.
How operationalised	Public consultation on the discussion paper is currently in progress.
Procedures for ongoing review	Feedback from the consultation will inform PSA's next steps in the development of the role of pharmacists in the primary care arena.
URL link or electronic copy	**Attachment 4**: *Pharmacists in 2023 – a discussion paper* (consultation paper)

Intervention 6	Clinical governance principles for pharmacy services
How documented	With support from the Australian Government Department of Health, PSA is reviewing the potential role and applicability of clinical governance to pharmacist practice and the provision of pharmacy services. PSA has developed a draft document entitled *Clinical governance principles for pharmacy services* through adaptation and application of clinical governance principles described by the Australian Commission on Safety and Quality in Health Care. The principles (numbered) and components (bullet points) for pharmacy services currently drafted are: 1. Partnering with consumers • Co-design • Patient-centric • Empowering consumers through health literacy • Measuring and improving consumer experience 2. Governance, leadership and culture • Commitment to safety and quality culture • Clinical leadership 3. Clinical performance and effectiveness • Scope and standards • Evidence-based care • Transparency • Education and training • Measurement and monitoring 4. Patient safety and quality improvement systems • Risk management • Adhere to codes, guidelines and quality systems • Continuous quality improvement 5. Safe environment for delivery of care • Environment • Cultural safety
How operationalised	Public consultation is currently in progress on the proposed set of clinical governance principles that PSA believes would help ensure services delivered by pharmacists meet expectations for the delivery of health care which is patient-centred and focussed on quality health outcomes. The intent is that the set of clinical governance principles would be applicable to any current pharmacy service (e.g. dispensing, assessment of minor ailments, screening and risk assessment, pharmacist vaccination) or future pharmacy services.

Procedures for ongoing review	PSA is currently exploring options for next steps.
URL link or electronic copy	**Attachment 5**: *Clinical governance principles for pharmacy services* (consultation draft)

Therapeutic Advice and Information Service

Although not an intervention that can be progressed by PSA, we note that the National Prescribing Service operated the Therapeutic Advice and Information Service for ten years between 2000 and 2010. This was a national drug information service for general practitioners, pharmacists and other community-based health professionals.

It operated as a telephone service with an email and online enquiry facility and managed approximately 6000 enquiries about medicines per year. The callers were mostly community pharmacists (38%) and general practitioners (33%). The service was provided through a consortium of six hospital-based drug information centres and typical enquiries related to: adverse reactions, clinically significant drug interactions, optimising therapeutic effects, and medicine use in pregnancy and lactation.

The service was highly valued by health professionals but ceased operation as the model was considered to be unsustainable. (See article in: *Australian Prescriber*, 1 Oct 2010, Vol. 33, pp. 147-9. At: *https://www.nps.org.au/australian-prescriber/articles/goodbye-tais-and-thanks-for-all-the-information*)

Recommendation 5. *That the Pharmaceutical Society of Australia review its Standard and guidelines for pharmacists performing clinical interventions and consider the circumstances in which a pharmacist might be encouraged to provide a copy of a Clinical Intervention Form to the patient and/or prescriber and/or another person.*

Intervention 7	**Standard and guidelines for pharmacists performing clinical interventions**
How documented	Review of the 2011 PSA document particularly in the context of how undertaking clinical interventions and associated documentation can be improved to prevent misadventure and negative outcomes. Additional information will be included on how pharmacists can best communicate (both verbally and through written communication) with a prescriber about a clinical intervention and when they do not believe the prescribed medicine and/or directions are safe or appropriate. While there is a section in the current standard and guidelines, this information will be strengthened and also emphasise that pharmacists are autonomous health professionals, and have the right to refuse supply of medicines if they believe it is unsafe or inappropriate. In addition, further guidance will be included on how pharmacists can best communicate with consumers about a clinical intervention and support the consumer to ensure they receive safe and effective treatment. A small section in the current standard and guidelines summarises communication with consumers,

	however this will be expanded to cover what information pharmacists should provide to consumers, and actions that should be taken and recommended to ensure consumers are able to access treatment that is appropriate and safe. The process and intention of the clinical intervention documentation will also be reviewed. Currently the documentation for clinical interventions focuses on providing a record of the intervention for pharmacists, however this will be expanded to include the documentation as a communication tool with both prescribers and consumers.
How operationalised	Revision and update of the PSA 2011 *Standard and guidelines for pharmacists performing clinical interventions* will begin in September 2018. The standard and guidelines will be revised by an experienced pharmacist and reviewed by PSA staff prior to finalising the guidelines. The revised publication will be endorsed by the PSA Board and disseminated to the profession via: • Media release – issued to pharmacy and health media • Advice to the Pharmacy Board of Australia regarding publication of the updated version with a request to disseminate the information to all registered pharmacists • Electronic direct mail to PSA pharmacist members • PSA social media platforms such as Twitter and Facebook.
Procedures for ongoing review	Every three years
URL link or electronic copy	None

Intervention 8	**Dispensing practice guidelines**
How documented	Review and update of the 2017 PSA document to focus on the sections covering communication with prescribers, recording and documentation, and patient counselling will occur. The communication with prescribers section will be expanded to emphasise that a pharmacist is an autonomous health professional and has an obligation to ensure that any medicine dispensed to a patient is safe. Information will be provided on how pharmacists should communicate with prescribers in the case that an agreement is not reached, and what pharmacists should do to ensure the patient receives correct treatment. The recording and documentation section will provide greater clarity on the relevance of recording clinical interventions where required as part of the dispensing process and how this documentation can be used to communicate with prescribers and consumers to ensure safe medicines use. Information on patient counselling will be expanded to cover communication with consumers when a pharmacist believes that the prescribed medicine and/or the directions are inappropriate and the prescriber is not in agreement, and what information should be provided verbally and in writing to the consumer. Details

	will also be provided on what pharmacists should do to ensure the consumer obtains the correct treatment.
How operationalised	Revision and update of the PSA 2017 *Dispensing practice guidelines* will begin in September 2018. The guidelines will be revised by an experienced pharmacist and reviewed by PSA staff prior to finalising the guidelines. The revised publication will be endorsed by the PSA Board and disseminated to the profession via: • Media release – issued to pharmacy and health media • Advice to the Pharmacy Board of Australia regarding publication of the updated version with a request to disseminate the information to all registered pharmacists • Electronic direct mail to PSA pharmacist members • PSA social media platforms such as Twitter and Facebook.
Procedures for ongoing review	Every three years
URL link or electronic copy	Current version of the guidelines is available at: *https://www.psa.org.au/wp-content/uploads/2018/09/Dispensing-Practice-Guidelines-2017-pdf-8.3MB.pdf*

Intervention 9	**Continuing education activities**
How documented	Education modules focussing on case studies will be developed to demonstrate how additional information included in the clinical interventions and dispensing practice guidelines can be applied in practice. The case studies will look at situations that pharmacists may encounter where the pharmacist believes the prescribed medicine and/or dose is not safe or appropriate for a patient but the prescriber disagrees. Pharmacists will work through the case studies and be guided through how they need to communicate with the prescriber and patient, what documentation is needed and its function, and how pharmacists should assist the consumer to ensure they get appropriate treatment. The education will also cover implications for certain actions and what needs to be considered when encountering a situation like this in practice, as well as strategies to minimise negative consequences (e.g. negatively impacting on the relationship with the prescriber or patient).
How operationalised	Online modules will be written and developed by pharmacists commencing in September 2018. PSA will seek continuing professional development accreditation for these modules. They will be available on the PSA website and promoted to pharmacists through email.
Procedures for ongoing review	Continuing education activities will be available for up to two years unless there is a significant change in practice that will require the modules to be updated to remain relevant.
URL link or electronic copy	None

PSA is committed to improving the practice of pharmacists as well as interprofessional communication and collaboration between pharmacists and prescribers. I am confident that the body of work outlined will provide proactive guidance and practice support to pharmacists, particularly around performing clinical interventions, and dispensing and counselling on medicines. PSA will continue to work with the entire profession to improve the role and contribution of pharmacists to medication safety and patient-centred care.

Yours sincerely,

Graham Catt
Chief Executive Officer

Attachments:

1. *PSA summit to unite pharmacists and doctors for patient safety* (Pharmaceutical Society of Australia, Media release, 17 Aug 2018)
2. *Balancing acts* (Feature story to be published in Oct 2018 issue of *Australian Pharmacist*)
3. *Vision 2020: Partnership for care* (Pharmaceutical Society of New Zealand and New Zealand Medical Association, 31 Oct 2014)
4. *Pharmacists in 2023 – a discussion paper* (Pharmaceutical Society of Australia, Consultation paper, Jul 2018)
5. *Clinical governance principles for pharmacy services* (Pharmaceutical Society of Australia, Consultation draft, Sep 2018)

Attachment 1

Pharmaceutical Society of Australia

MEDIA RELEASE

www.psa.org.au

August 17, 2018

PSA summit to unite pharmacists and doctors for patient safety

The Pharmaceutical Society of Australia will host an inter-professional collaboration summit to explore how doctors and pharmacists can work together more effectively to support patient care through the safe use of medicines.

Prompted by a recent Coroner's report into the death of a Melbourne man following complications of methotrexate toxicity, the summit will bring together leaders from key pharmacy, medical and consumer organisations at Pharmacy House in Canberra on 21 August 2018,

In handing down her findings, Coroner Rosemary Carlin said the patient's unnecessary death resulted from key failings of the pharmacist and prescribing doctor to work collaboratively to effectively resolve a prescribing error. In particular, the coroner noted "*Doctors and pharmacists should trust and respect each other, whilst retaining their independence. In dismissing her concerns, it appears that Dr Lim did not afford [the pharmacist] the respect she deserved. In dispensing the methotrexate despite her concerns, it appears that [the pharmacist] afforded [the GP] too much respect, or at least lost sight of her role as an independent safeguard against inappropriate prescribing.*"

PSA National President Dr Shane Jackson said the Coroner's report highlights the need for a more collaborative relationship between pharmacists and doctors that recognises their respective roles and responsibilities while also acknowledging their independence.

"The summit will seek to develop a set of principles to support respectful and collaborative practice between pharmacists and doctors," Dr Jackson said.

"It is time to work together on key principles that underpin the collaborative relationship between pharmacists and doctors, particularly regarding the safe use of medicines, for the benefit of our patients"

"We have invited other professional bodies to join the summit so together, we can empower pharmacists and doctors to meet their duty of care in regards to patient safety."

-ENDS-

Media contact:

Jarryd Luke
Communications Officer
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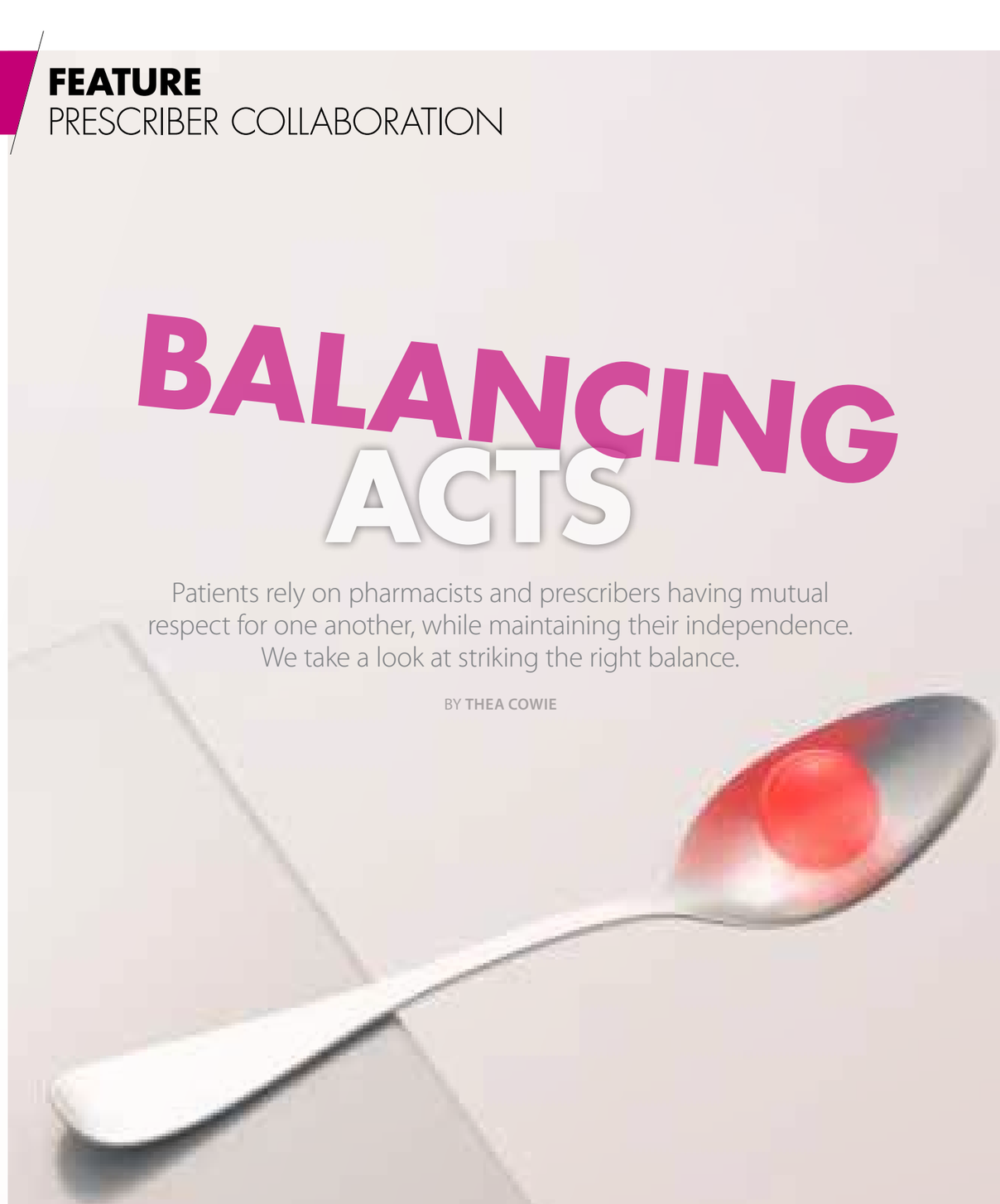
Attachment 2

BALANCING ACTS

Patients rely on pharmacists and prescribers having mutual respect for one another, while maintaining their independence. We take a look at striking the right balance.

BY **THEA COWIE**



Ian John Gilbert, 77, had a psoriasis flare-up. He visited his GP, got a script filled and headed home for some relief.

Days later he died a 'needless and entirely preventable' death from 'complications of methotrexate toxicity', according to findings by the Victorian Coroner, Rosemary Carlin.

'The dispensing pharmacist immediately recognised that the daily dose prescribed by the GP was potentially dangerous and called him to convey her extreme concern,' stated the Coroner's report released in June.

'The GP assured her that he had checked the dose and it was correct. Though she was not at all reassured, the pharmacist felt obliged to dispense the medication in accordance with the prescription and did so.'

The Coroner went on to make a number of recommendations regarding ways to prevent inappropriate dispensing.

'Doctors and pharmacists should trust and respect each other, whilst retaining their independence. In dismissing her concerns, it appears that the GP did not afford the pharmacist the respect she deserved,' the Coroner stated.

'In dispensing methotrexate despite her concerns, it appears that the pharmacist afforded the doctor too much respect, or at least lost sight of her role as an independent safeguard against inappropriate prescribing.'

The pharmacist/prescriber relationship

Best practice

So what should the pharmacist/prescriber relationship look like? Well, Pharmaceutical Defence Limited Professional Officer, Gary West, said: 'long standing convention has evolved that a pharmacist's role is to be an independent check on the safety and appropriateness of doctors prescribing'.

'A pharmacist who does not act appropriately when a potential problem is detected may be called to account by a pharmacy regulator for unprofessional conduct.'

He pointed to *Pharmacy Board of Australia Dispensing guidelines,*[1] which provide clear direction regarding pharmacists' responsibilities.

'In dispensing a prescription, a pharmacist has to exercise an independent judgement to ensure the medicine is safe and appropriate for the patient, as well as that it conforms to the prescriber's intentions,' the guidelines state.

'Where clarification is required, the patient or their agent should be consulted and if necessary, the prescriber contacted.'

Additional guidance on the prescriber/pharmacist relationship can be found in the *PSA Code of Ethics for Pharmacists*,[2] including Integrity Principle 2 which states: 'A pharmacist only practises under conditions which uphold the professional independence, judgement and integrity of themselves and others'.

The *National Competency Standards*[3] stress that pharmacists must use their expertise to minimise medication misadventure.

In practice

There are many reasons that pharmacist/prescriber relationships can stray from the ideal, acknowledged PDL Professional Officer John Guy.

'As was alluded to in the Coroner's report, this relationship can break down if the prescriber is unwilling to engage effectively with a pharmacist who may have a concern,' he said. 'In some instances pharmacists are lacking in confidence when interacting with doctors.'

Added PDL's Mr West: 'Impediments to appropriate communication between pharmacists and prescribers may include workload pressures and interruption to practice, misunderstanding the intention of each health practitioner, poor communication skills and lack of mutual respect.'

Another common occurrence was for familiarity to compromise independence, noted PSA Victorian Branch Committee member, Jarrod McMaugh.

'The more a pharmacist works with a particular doctor, especially if you have any kind of relationship outside of work, then you can get to the point where you think "oh I've known this doctor forever, they know what they're doing"', explained the Managing Partner at Capital Chemist Coburg North. »

Rebalancing the relationship

Be well informed and prepared

PSA Senior Pharmacist Carolyn Allen said that when it came to improving collaboration with prescribers it was important that pharmacists were well informed and well prepared.

'If you're concerned about a prescription, obtain as much relevant medicines and medical history and information as you can from the patient and research respected and approved references,' Ms Allen said.

'Check three or more standard Australian reference sources, and discuss with other pharmacists if you need to.'

Then when you phone the prescriber you'll be able to confidently explain that you're concerned that the prescription is not consistent with the references.

'Do not relay this discussion through a practice nurse or secretary, but ask to talk directly with the prescriber,' said Ms Allen.

'Be ready to offer an alternative solution that is consistent with the references. Aim to be clear and concise in your discussion.'

Improve professional relationships

PDL's Mr West said collaboration could also be improved through good relationships with prescribers.

'Make an effort to build a relationship with local prescribers by demonstrating your willingness to work collaboratively with them to improve the care of your mutual patients,' he said.

'Prescribers will recognise the value of pharmacists if their interactions with a pharmacist are professional, appropriate and patient-centred.'

Mr Guy added that it could also help to ask prescribers if there were more appropriate times or ways of communicating with the prescriber, for example, email.

'That can demonstrate consideration for the prescriber and their patients,' Mr Guy said. »

'Our role is to protect patients from medications and prescriber error.

– Jarrod McMaugh, PSA

KICKSTARTING THE CONVERSATION

In August, PSA hosted a summit bringing together key stakeholders to discuss the question of how doctors and pharmacists can work together more effectively to support patient care through the safe use of medicine.

Representatives of numerous medical and pharmacy organisations were in attendance, along with the Consumers Health Forum, AHPRA and the Medical and Pharmacy Boards of Australia.

The focus of the summit was developing principles of collaboration that the relevant organisations can commit to, with patient-centred care and patient safety the priority.

PSA is now working with those organisations to agree on those principles, and developing ways of embedding these principles in to the practice of health professionals.

PSA National President Dr Shane Jackson said part of this was an understanding and acknowledgement of the key role of pharmacists as medicines experts.

'A focus only on competition doesn't help our patients access healthcare or reach their treatment goals,' he said.

'I look forward to not having to defend pharmacists' role as accessible primary healthcare providers who can do much more than what they currently are. Collaboration is vital, but we need other organisations and individuals to come to the party to ensure collaboration is mutual.'

DEALING WITH POTENTIALLY INAPPROPRIATE PRESCRIBING BEHAVIOUR

A script comes across the counter and your instincts say something is not quite right.

Trust them, said PSA Victorian Branch Committee member, Jarrod McMaugh. And then gather the evidence to back them up. Here's a guide to dealing with potentially inappropriate prescribing behaviour.

1. DO YOUR RESEARCH.
Have a solution and backups.

PSA Senior Pharmacist Carolyn Allen advised obtaining as much relevant information from the patient as possible, researching multiple respected and approved Australian references, and if needed, speaking with other pharmacists.

Come up with a few potential solutions. As Mr McMaugh observed: 'If you put it on the prescriber to come up with a solution to something that they didn't even know was a problem until you rang, then the conversation may not be productive,' he said.

3. CONTACT THE PRESCRIBER.
Be clear and concise.

Prepare notes if you're feeling some trepidation.

'You will feel so much better calling the prescriber with notes sitting in front of you saying "here's the problem, here's what supports it, here's my suggested solution and backups"', Mr McMaugh said.

4. **IF THE PRESCRIBER INSISTS.**

If the prescriber insists that you dispense, but you still feel it's inappropriate, PDL recommends:

- Delaying supply until further information can be gathered
- Seeking advice from sources such as drug information centres
- Contacting other practitioners including specialists that the patient may have seen previously for the condition
- Considering whether it is vital that the medicine be supplied immediately, based on the indication and the severity of the condition.

PDL Professional Officer John Guy said further guidance could be found in a recent PDL Practice Alert.[4]

5. SPEAK WITH THE PATIENT.
Document actions.

PDL recommended that pharmacists 'provide patients with a clear understanding of your concerns reinforced by documents, such as CMIs and even extracts from references'. Then record all actions and the reasoning associated with them.

Mr McMaugh suggested: 'I'd be saying "I've spoken to the prescriber. I'm not happy to supply this. I feel that it's not safe. I think you should have this conversation with the prescriber again, or get a second opinion, and I'm going to annotate the prescription". Then document everything in your own records as well'.

Engage throughout patient care

Any interaction you have with a patient can be an opportunity to ensure appropriate prescribing, Mr McMaugh said.

'There's always an opportunity for us to identify issues with the way people are using their medication,' said Mr McMaugh.

'It could come up in a Chronic Pain Meds Check, a regular Meds Check or any other interaction we have with the patient.'

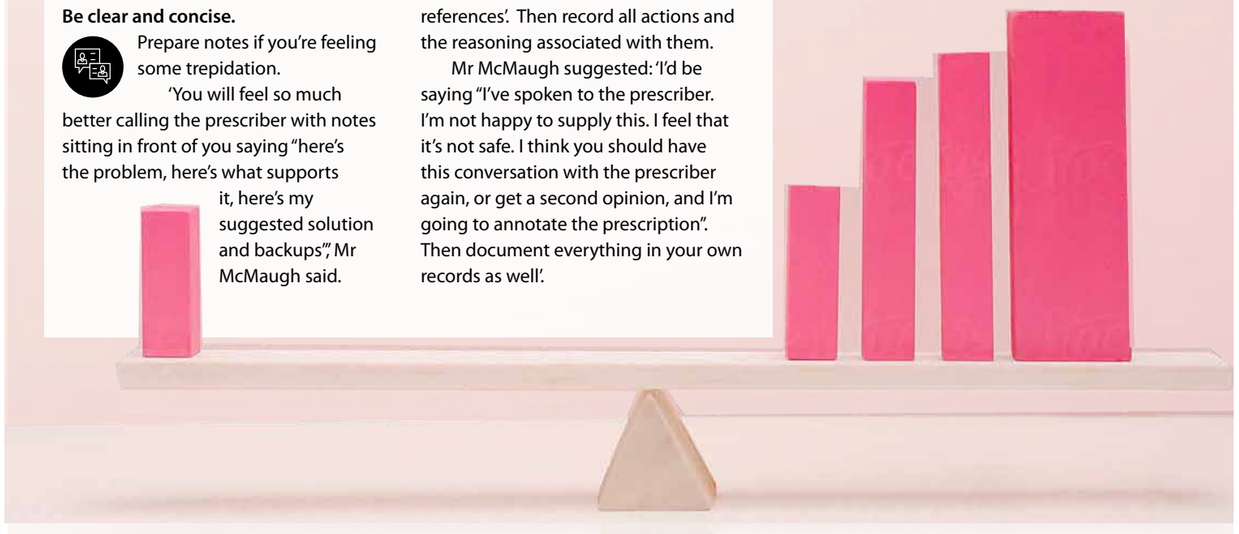
These interactions present both an opportunity and a responsibility.

'If we're finding an issue then that should always generate a conversation with the patient and the prescriber,' Mr McMaugh said. 'Our role is to protect patients from medications and prescriber error. That sounds a bit abrupt but really, when you really boil it down, that's exactly what we're here to do'.

Don't underestimate

Pharmacists deal with medicines so regularly that they can become complacent about just how dangerous they can be. 'But the reality is,' Mr McMaugh said, 'people can die if we don't do our job properly.'

And as the Victorian Coroner's findings stressed: 'pharmacists should not underestimate their own importance'.



Partnership for Care: NZ model for collaboration

Collaboration between doctors and pharmacists has been enshrined in New Zealand in a vision statement that stresses the importance of the professions working together.

PSA Strategic Policy Manager Bob Buckham worked for the Pharmaceutical Society of New Zealand as it and the New Zealand Medical Association drafted the 2014 document.

'The vision statement sought to state what the key roles for doctors are, what the key roles for pharmacists are, and how the two roles fit together for providing care' he said.

'One of the key benefits was having recognition of what the pharmacist knows and does – that pharmacists do have this specialised knowledge and role in medicines management and optimisation.'

Entitled *Vision 2020: Partnership for Care*,[5] the document sets out six vision areas: The Patient's Healthcare Journey, Health Professional Roles, A Shared Working Environment, Services, Professional Competence and Ethics, and Payment Arrangements for Services.

Building on this document, the organisations have established the Integrated Health Care Framework for Pharmacists and Doctors.[6]

It outlines what should be considered to help ensure any new service or model of practice is developed in an integrated and patient-centred way.

'So rather than just submitting an application for a new service or medication rescheduling cold – with the medical organisations not knowing anything about it and then arguing 'pharmacists shouldn't be doing that' – the framework helps ensure roles, purpose and boundaries of practice are determined beforehand to avoid all of that public back-and-forth,' Mr Buckham said.

REFERENCES

1. Pharmacy Board of Australia. Guidelines for dispensing of medicines. 2015. At: www.pharmacybaoard.gov.au/documents/default.aspx?record=WD15%2F17694&dbid=AP&chksum=whuWgDvj9dwviuEOS%2BHzOg%3D%3D
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4. Pharmaceutical Society of New Zealand and New Zealand Medical Association. Vision 2020: Partnership for Care. 2014. At: www.nzma.org.nz/__data/assets/pdf_file/0004/37669/Partnership-for-care-2020-Pharmacists-and-Doctors-working-together-2014-Vision-Printer.pdf
5. Pharmaceutical Society of New Zealand and New Zealand Medical Association. Integrated Health Care Framework. 2017. www.psnz.org.nz/Folder?Action=View%20File&Folder_id=96&File=IntegratedHealthCareFramework_Final.pdf
6. Pharmaceutical Defence Limited. PDL Practice Alert 5 July 2018: Medication Misadventure – Methotrexate. 2018. At: www.pdl.org.au/

Attachment 3

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

NZMA
New Zealand Medical Association

VISION 2020

PARTNERSHIP FOR CARE

Pharmacists and Doctors working together.

New Zealand pharmacists and doctors working together in an integrated and collaborative health practice environment can significantly improve patient care and health outcomes.

This vision identifies a desired future state of collaboration and partnership that is based on strong and supported clinical relationships, optimised for the benefit of the patient and the health system. It outlines the major goals and enablers that will shape and guide the actions that both professions need to take to reach that vision.

Partnership for Care has been prepared by doctors and pharmacists from the New Zealand Medical Association (NZMA) and the Pharmaceutical Society of New Zealand Inc. (PSNZ). It offers a vision of an enhanced patient medication journey and informs the development of health interventions, their delivery and accessibility.

6 VISION AREAS

1 *The Patient's Healthcare Journey*

Doctors and pharmacists will pursue a whole-of-system approach for high quality, coordinated services for patients that focus on patient centred care and population health.

The patient's healthcare journey will be a seamless continuum of care provided by health professionals that involves diagnosis, prescribing and dispensing of medicines, medicine therapy optimisation, monitoring and patient adherence support for prescribed medicines.

2 *Healthcare Professional Roles*

Pharmacists and doctors will have shared responsibility and specific roles in patient care.

- Doctors providing diagnosis and having primary patient care responsibilities.
- Pharmacists having specialist skills in medicines management and optimisation, being fully utilised.
- Both jointly educating patients about medicines' side effects and what to do if these occur.
- Both actively monitor and review and contribute to patient care plans.

Through Alliances, doctors and pharmacists will also work collaboratively with nurses and other healthcare professionals as integral members of the healthcare team, providing an integrated care solution for patients.

3 *A Shared Working Environment*

Pharmacists and doctors will prioritise and enable sharing in joint working environments. This will include having:

- Electronic shared care records, which aid communication for the integrated patient care journey.
- Medicines reconciliation that supports every transfer of care.
- Co-location and consolidation of care services with shared support systems and infrastructure.
- Peer review within the pharmacist-doctor partnership and combined continuing professional development opportunities.

4 *Services*

Services provided by doctors and pharmacists will be consistent with, and contribute to, the development and achievement of Government's stated health sector strategies.

New initiatives will be identified and developed jointly, recognising respective roles and expertise, and informed by the best available evidence.

Service design will be underpinned by the Triple Aim for quality improvement:

- Improved quality, safety and experience of care.
- Improved health and equity for all populations.
- Best value for public health system resources.

5 *Professional Competence and Ethics*

Both professions will have obligations to maintain competence to practice and to continue their professional development. Shared learning and mutual recognition of professional learning as part of the Annual Practising Certificate recertification programmes of Continuing Education/Continuing Medical Education points will be in place. Both professions will support the stated codes and policy positions of the ethics of each and will seek alignment.

6 *Payment Arrangements for Services*

More flexible approaches to managing patients' health care needs will be permitted by flexible funding arrangements in primary care. Greater scope for collaboration and coordination of services will happen by encouraging and enabling alternative funding streams for more comprehensive approaches to servicing the particular needs of the enrolled population and that support other integration enablers such as co-location, management systems.

Designated doctors and pharmacists for Rest homes will be part of funded rest home care.

GOALS AND OBJECTIVES
ACTIONING

This 2020 Partnership for Care provides the overarching strategic vision for both professions to develop their goals and objectives for actioning to achieve 2015–2020. Each professional organisation – PSNZ and NZMA – will develop and share key goals and objectives.

Attachment 4

Pharmaceutical Society of Australia

PHARMACISTS IN 2023:

A Discussion Paper

2018

PSA Australia's peak body for pharmacists

PSA5487

Published by Pharmaceutical Society of Australia

Design & layout: Vanessa Bleakley

PSA acknowledges the contribution of Associate Professor Mark Naunton in the preparation of this Discussion Paper

www.psa.org.au

Foreword

I see a future where the pharmacy profession meets community health needs whilst focussing on ensuring pharmacists are utilised to their **full scope of practice**, they are supported to **develop as practitioners**, we have a **quality framework** for service delivery by pharmacists and we are recognised and appropriately remunerated for our significant skills, expertise and training as healthcare professionals.

Initially, I had envisaged a 10 – year plan for the profession, but overwhelming feedback from PSA members and the wider profession noted that more urgent change is needed for pharmacists to be able to retain their best and brightest in the profession and to be truly regarded as medicines experts. Based on that feedback we have shortened our timeframe for impact, we need to have delivered significant change for the pharmacy profession by 2023.

Change is inevitable if we are to realise the objective of having pharmacists seen as medicines experts across healthcare and as responsible and accountable for medicines safety and effectiveness. The discussion paper, built upon the views of pharmacists and consumers, highlights the need for pharmacists to transition to a consultation-based, patient-centric and collaborative model of care, whereby pharmacists take responsibility and accountability for medicines management. These opportunities that PSA is suggesting for the future require feedback from the profession to be able to guide PSAs next steps in the development of the role of pharmacists in community pharmacy, and in the broader primary care arena.

PSA's vision has pharmacists delivering services tailored to consumer need, delivered at the right time, by the pharmacist with the right skill set in the right setting. We should see services form a continuum from dispensing through to comprehensive medication review, delivered in an individualised manner based on patient need and focussed on the quality use of medicines.

The ultimate objective of PSA in releasing the *Pharmacists in 2023* discussion paper is to have an empowered pharmacy workforce across healthcare, from hospital to community pharmacy and in the broader primary care sector. This will require pharmacists to be enabled through appropriate funding mechanisms and quality assurance programs, to be equipped through suitable training and recognition programs and to be embedded wherever medicines are used.

We seek the views of our members, the pharmacy profession, consumers and key stakeholders in providing input into this discussion paper so that we can realise the true potential for pharmacists in the future. I look forward to consulting with a broad range of people and organisations in delivering our action plan for *Pharmacists in 2023* by the end of 2018.

I invite everyone interested in shaping the role of pharmacists in 2023 to be part of this important discussion.

Dr Shane Jackson

National President
Pharmaceutical Society of Australia

Contents

Introduction

The Australian health system is widely regarded as being world class, characterised by effectiveness, efficiency and universality. And as the global healthcare environment evolves, so must the Australian health system. The rapid pace of change has resulted in major health system reform that is likely to continue over the coming years to improve patient access, enhance primary care, capitalise on technological advances, ensure a future-ready workforce, and deliver cost-effective health outcomes.

Several reports over the past decade have identified potential roles for pharmacists in this changing healthcare environment, calling on the profession and its representative organisations to implement change. Community pharmacy for example has reached a tipping point, whereby incremental changes in enhancing the role of the community pharmacist in medication management can result in greater responsibility and accountability for improved medication outcomes in the Australian healthcare system.

Since the 6th Community Pharmacy Agreement was signed, the Report on Pharmacy Regulation and Remuneration ('The King Review') and the Productivity Commission Report released in August 2017 have all shone a light on the potential future role of the pharmacist in the healthcare system. Recommendations by the Productivity Commission supporting pharmacists working in patient-centred and collaborative care roles with other health professionals offers the potential for serious gains in the healthcare system.

While a number of these reports and others have identified the need to better utilise the knowledge and skills of pharmacists, and offer various descriptions of roles, activities or services that pharmacists could provide, none have articulated HOW this can be achieved and what needs to change to enable it to happen.

PSA's 2017 work in developing our Early Career Pharmacist (ECP) White Paper[1] identified 10 key recommendations for the profession to action. These provided a strong direction in the need for roles and models of practice that recognise and utilise the full knowledge, expertise and skill of pharmacists training and scope of practice.

Pharmacists have more knowledge and training about medications, and their safe and optimal use, than any other health professional group. Pharmacists have been found to have greater basic pharmacology knowledge and clinical application of that knowledge

than general practitioners.[2] Yet, Australia is still missing out on the opportunity to maximise the safe, effective and optimal use of medicines and improved health outcomes by focussing pharmacist activities largely in the context of dispensing.

PSA believes the expertise of pharmacists as the only health professionals whose training is specifically focussed on the optimal and safe use of medications should be better utilised, better recognised, and enabled through remuneration of evidence-based services and models of care.

In 2017, PSA announced the commencement of developing a '10 Year Action Plan' for the pharmacy profession. Combined with international evidence and experience and information collated through engagement over the past year with consumers (both consumers and patients), health professional groups, Government ministers, advisors, and agencies, and pharmacists working across all practice settings, PSA has identified the direction required for the profession to head.

In the process of collating this evidence and insight, it became patently clear that the timeframe for the 10 Year Action Plan was too long. The imperative for change was too immediate. For pharmacists to transition practice to the consultation-based, consumer-centric and collaborative models of care required by consumers and the healthcare system, and desired by pharmacists a more immediate plan is needed. The next five years is therefore critical for shaping professional practice to meet future health needs.

Pharmacists in 2023 seeks to identify and unlock opportunities that realise the full potential of pharmacist practice as part of the wider health care team to address the health needs of all Australians.

ECP Whitepaper Key Recommendations

The pharmacy profession has a collective responsibility to:

1. Take decisive action to ensure a robust and sustainable community pharmacy sector.
2. Negotiate to raise the Pharmacy Industry Award rates
3. Advocate for, and pursue alternative remuneration models for pharmacy services.
4. Identify and propose new roles and models of practice for pharmacists – with supported pathways to enable progression in these areas.
5. Work with researchers, policy makers and practitioners to ensure that evidence is translated to the delivery of evidence-based services by frontline pharmacists.
6. Ensure productive collaboration between pharmacy organisations to shape the profession in a positive way.
7. Engage with consumers and other health professionals through an awareness campaign which promotes the full extent of a pharmacist's scope, skill and expertise.
8. Recognise all practising pharmacists as clinical pharmacists, regardless of practice setting.
9. Explore the development and recognition of specialties within pharmacy practice.
10. Develop Quality Indicators for individual pharmacist practice.

Imperative for change

Consumers

To inform understanding of potential future patient-centric services and models of practice, PSA partnered with the Consumers Health Forum of Australia (CHF) to conduct a forum with consumer advocates and a survey of over 1000 people from the broader Australian population about their views.[3]

The survey provided a population-level examination of the barriers to the potential use of pharmacist services, while the forum provided an in-depth exploration of what informed consumer advocates see as the key role of pharmacists.

The results of this work found that consumers recognise that there is a wider range of roles that pharmacists can and should play in the health sector. They value pharmacist's expertise around medications and feel that greater use of and access to this specialty would be appropriate and useful. The extent to which consumers value the accessibility of their pharmacists was a key theme, and that pharmacists can offer continuity of care in a way that other health professionals cannot. This is because pharmacists are considered approachable, knowledgeable, are highly trusted and are more accessible than other health professionals who offer appointment-based services.

A perceived variation in access and delivery of services from pharmacists was reported by consumers, including recognition that there is clinical specialisation within the profession but they are unaware how they can access this either in the community or hospital settings.

Consumers explained that they want greater availability of pharmacists, and described a spectrum of services that could be provided that relate to the accessibility of pharmacists and their medicines expertise. Some of the suggestions included access to tests and vaccinations, help in managing medications and common self-limited conditions, and they want pharmacists to be collaborating with other healthcare professionals.

Governments and the Health-System

Australia's National Medicines Policy (NMP) aims "to improve positive health outcomes for all Australians through their access to and wise use of medicines". The NMP has objectives that are based on active and respectful partnerships between governments, health professionals and providers, the medicines industry, media and consumers. The NMP places an emphasis on quality health outcomes, focusing on people's needs and highlighting the skills, experience and knowledge of the individuals in this medicines 'partnership'.

The four central objectives of the NMP are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry

Further focus on the Quality Use of Medicines (QUM) is provided by the 'National Strategy for Quality Use of Medicines' published in 2002 with a goal to "make the best possible use of medicines to improve health outcomes for all Australians". The strategy describes QUM as involving: selecting management options wisely, choosing suitable medicines if a medicine is considered necessary, and using medicines safely and effectively.

However, current evidence demonstrates that significant gaps exist in the quality use of medicines in Australia. Medication safety is a significant problem with an estimated 230,000 medication-related hospital admissions happening in Australia each year.[4] This costs the Australian healthcare system approximately $1.2 billion annually. However this is likely to be an underestimation as these figures do not include visits to general practitioners or community pharmacists for medication related problems, therefore the overall cost of medication misadventure is likely to be much greater.

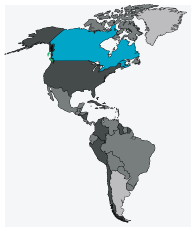
Internationally, a number of jurisdictions have recognised the contribution pharmacists can make to quality use of medicines and have implemented system changes to enhance the role of pharmacists in the healthcare system. Along with robust, supportive evidence, this has facilitated practice change to enable pharmacists to move from a predominantly supply-focussed role to a role that has more responsibility and accountability for medication management that helps address health needs.

United Kingdom

The United Kingdom Government has taken interest in enhancing the role of pharmacists over recent times and particularly since publication of the Nuffield Report in 1984[5]. In 2004, the 'Agenda for Change' grading and pay system for National Health Service (NHS) staff had pharmacist roles compared against the NHS Knowledge and Skills Framework. More recent reforms have sought more integrated services that are efficient and provide better outcomes for consumers.

New Zealand

Closer to home, the New Zealand Government's medicines strategy specifically identifies the unique role pharmacists have in the quality use of medicines.[6] Enhancing the collaboration between pharmacists and other health professionals aims to ensure the right people receive the right care and the right time. Concerns however have been expressed about the funding system that underpins this expectation.



Canada - From Then to Now

While it has taken twelve years, these graphics demonstrate that system change is possible. Canadian pharmacists now have the opportunity to provide expended services within scope. [Adapted from the Canadian Pharmacists Association Blueprint for Pharmacy.]

2005 | PHARMACISTS' SCOPE OF PRACTICE IN CANADA

	BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	NWT	YT	NU
Initiate drug therapy independently	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Prescribe for minor ailments/conditions	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Make therapeutic substitution	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Change drug dosage/formulation	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Renew/extend prescriptions	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Administer a drug by injection	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Order and interpret lab tests	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
Regulated Pharmacy Technicians	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘

2017 |

	BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	NWT	YT	NU
Initiate drug therapy independently	✘	✔	L	L	✘	✘	L	L	✘	✘	✘	✘	✘
Prescribe for minor ailments/conditions	✘	✔	✔	✔	✘	✔	✔	✘	✔	✔	✘	✘	✘
Make therapeutic substitution	✔	✔	✔	✘	✘	✘	✔	✔	✔	✔	✘	✘	✘
Change drug dosage/formulation	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✘	✘	✘
Renew/extend prescriptions	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✘	✘
Administer a drug by injection	✔	✔	✔	✔	✔	L	✔	✔	✔	✔	✘	✘	✘
Order and interpret lab tests	✘	✔	P	L	✘	✔	P	P	P	✘	✘	✘	✘
Regulated Pharmacy Technicians	✔	✔	✔	L	✔	✘	✔	✔	✔	✔	✘	✘	✘

✔ Implemented in pharmacies L Implemented with limitations P Pending implementation regulations or policy for implementation ✘ Not implemented

Pharmacists

Over the past twelve months, PSA has undertaken an extensive consultation process to discuss the future roles and practice of the profession. Face-to-face workshops in Queensland, New South Wales and Victorian state conferences and a profession-wide online survey has gathered the wide-ranging issues, concerns and ideas on present and future practice from over 500 pharmacists from all practice settings.

Feedback from pharmacists has said that they want to provide more effective care through use of their knowledge and advice. In everyday practice they see examples of consumer health needs that aren't being addressed within the current health system. However they have explained how their capacity to intervene is restricted by time, workload pressures, program rules, insufficient remuneration and funding mechanisms that confine practice – in terms of who pharmacists can provide a service to and where that service can be provided. This includes the administrative burden of some pharmacy programs.

Some of the system-level issues affecting consumers pharmacists feel obliged to manage and resolve, without this being recognised within existing remuneration programs. These have included coordinating prescription requests, particularly for residents of aged care facilities, medication reconciliation at transitions of care – especially at hospital discharge and admission, and attempts to support consumers with difficulties in paying for their medications.

Pharmacists have said that they want more professional satisfaction and opportunities to develop their careers. This involves greater recognition of the general and specialised professional care and advice they provide and can offer the care of consumers and to support the inter-professional healthcare team. This feedback has been received from pharmacists working in most practice settings.

Pharmacists working in primary-care and aged-care settings have said that opportunities for greater provision of more advanced/complex care need to be enabled, and to be delivered where this care is needed. They also seek greater recognition of advanced practice and clinical specialisation in community pharmacy and other primary care settings, and greater ability to contribute to support patients with chronic disease.

Feedback from hospital pharmacists has highlighted a lack of flexibility in some hospital systems, and have called for more opportunities to expand practice experience. Hospital pharmacists have described barriers in accessing pathways of clinical specialisation, while others seek opportunities for a more generalised or 'clinically rounded' advancement of practice. Some comments have also expressed how the advanced clinical knowledge and expertise of many hospital pharmacists is restricted to acute hospital care only.

A very clear message in our feedback from pharmacists is that they want greater integrity and accountability across the profession. They are concerned with the negative perceptions of the profession, and want high quality professional practice to be recognised within and outside of the profession. They have also called for more robust evidence to support and improve the quality of pharmacist services, including capture of meaningful outcomes data that supports the economic and health value of pharmacist care.

As highlighted in PSA's ECP White Paper, remuneration of pharmacists and pharmacist services featured strongly as a concern. Many pharmacists commented on how existing funding mechanisms focus on supply and transactional activities, when quality outcomes should have priority. They want funding mechanisms that recognise and enable collaborative practice activities and services – both within the profession across care settings, but also to support the care pharmacists provide to link in with others in a patient's care team. Feedback also expressed concern regarding recognition and remuneration for pharmacists advancing in their practice, utilising their skills in managing more complex conditions.

The imperative to change is that Australia is missing out on the opportunity to maximise the safe and effective use of medicines and improve patient outcomes by confining pharmacists to supply-related activities. This mould must be broken – utilisation of pharmacists across the healthcare system, but especially in community pharmacy to their full scope of practice has the opportunity for serious gains in our healthcare system. The expertise of these highly trained health professionals can be better utilised by:

- **Embedding** pharmacists wherever medicines are used;
- **Equipping** pharmacists to enhance community access to health services; and
- **Enabling** pharmacists to be recognised and appropriately remunerated.

The PSA's Strategic Intent

The Pharmaceutical Society of Australia is the only Government-recognised peak body for all pharmacists practicing in all settings across Australia. PSA's vision is to improve Australia's health through excellence in pharmacist care, and it's purpose is to lead and support evidence-based healthcare service delivery by pharmacists. PSA's mission is achieved by ensuring pharmacists have the opportunity to have rewarding careers, providing lifelong professional support for pharmacists and the pharmacy profession, and advocating for their appropriate recognition and remuneration.

Upon these foundations, the PSA Board met in early 2018 to discuss how the pharmacy profession is evolving and to outline a strategic intent to guide the organisation's activities. The result is the PSA Strategic Intent:

"By 2023, pharmacists within the health system will be more highly valued and their role optimised. They will be practicing to full scope, operate as normative members of the health team and the rewards and recognition for pharmacists will be more appropriate to this role."

With full disclosure of our intentions, PSA believes that to ensure the pharmacist profession meets community health needs, pharmacists must be supported to practice to full scope, develop as practitioners and all activities are underscored by a quality framework for service delivery.

Pharmacists practising to full scope of practice

PSA believes pharmacists as the medicines experts should have the opportunity to practise to their full scope of practice. This means pharmacists should have the opportunity to improve health outcomes through medicines management in the Australian healthcare system. If we are truly to address the significant issue we have with medicines management in this country then pharmacists must be able to do more. The roles of pharmacists should not be inhibited by only thinking of what pharmacists are currently doing – the challenge for the profession as a whole, is to articulate what pharmacists practising to full scope of practice means. Simply, for PSA, this means increased responsibility, and accountability for medicines management.

Pharmacist development

We must also ensure the pharmacists are supported to be the best healthcare practitioners they can be. They must be recognised as medicines experts, they should be rewarded and remunerated for their significant expertise, skills and training and we must have a framework that allows for career development and recognition. Pharmacists need to be supported to develop the capability for the opportunities that will allow a capable workforce to deliver the services that are not only needed now, but will be needed in the future.

Standards of practice

This is what PSA considers 'raising the bar' because with responsibility for medicines management, so comes accountability and a focus on continuous quality improvement. Our patients expect the services we provide to them to be delivered to a high quality. The outcomes from the services delivered by pharmacists should be tangible, measurable, and should impact on medicines use and health outcomes. And, PSA believes pharmacists who are practising to a high professional standard need to be recognised for this.

Question 1:

Should any of these objectives be considered more important for patient care than others?

Question 2:

What immediate gaps need to be filled to realise these objectives?

Pharmacists in 2023 Discussion Paper: Consultation

Change is inevitable if pharmacists are to realise their full potential, and this document echoes call for pharmacists to be supported to transition to a consultation-based, patient-centric and collaborative model of care, whereby pharmacists take responsibility and accountability for medicines management. The opportunities proposed for the future require feedback from the broader healthcare profession, consumers and policy makers to be able to guide PSAs next steps in the development of the role of pharmacists in all care settings.

In contrast to previous 'vision papers' or future-focussed consultations, *Pharmacists in 2023* seeks your comments on implementation. Challenging the established sole focus of pharmacists' role as medicine dispensers, this Discussion Paper encourages feedback that thinks 'beyond dispensing' and to how the pharmacist role might look wherever the health need exists. This is both within, and outside of, established practice settings to comment on changes that will benefit Australia's healthcare future.

Based on the feedback from pharmacists, consumers and assessing international developments, PSA sees the profession focusing its activities in key areas, with the next 2-3 years focussed where pharmacists can make the greatest contribution. This will be through addressing gaps in the current health system and supporting Government health policy objectives through the following areas; medication supply, medication management programs, public health and prevention, collaborative care teams, prescribing and supporting disadvantaged groups.

Pharmacists in 2023 seeks to go beyond outlining services, to uncover the barriers and identify the system changes required to better utilise pharmacists in delivering health outcomes.

Pharmacists in 2023 aims to ensure that system changes and funding mechanisms make a genuine difference to the health of the Australian population, as well as ensuring that pharmacists are more closely incorporated into the broader primary and secondary health care environments; AND supporting consumers as they move between these.

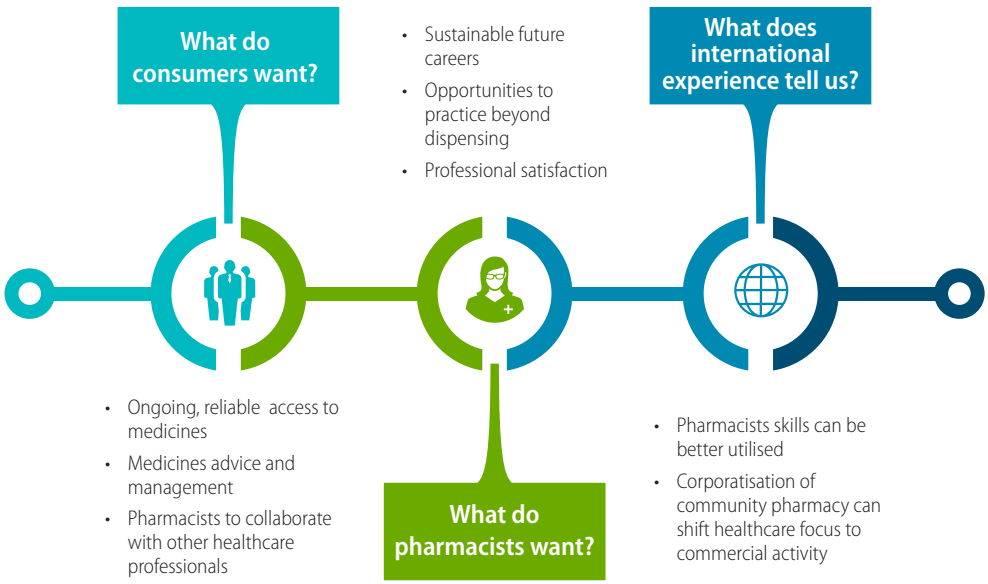
This document positions pharmacists as critical contributors to Australia's changing healthcare environment. Whilst community pharmacy is the most common setting in which pharmacists work and through which services are delivered, there are many other environments in which pharmacists can - and do – make a contribution to consumers' health.

PSA invites submissions to the questions posed in this Discussion Paper by **Friday 7 September 2018**. Submissions can be lodged electronically via email to **pharmacistsin2023@psa.org.au** or directly to:

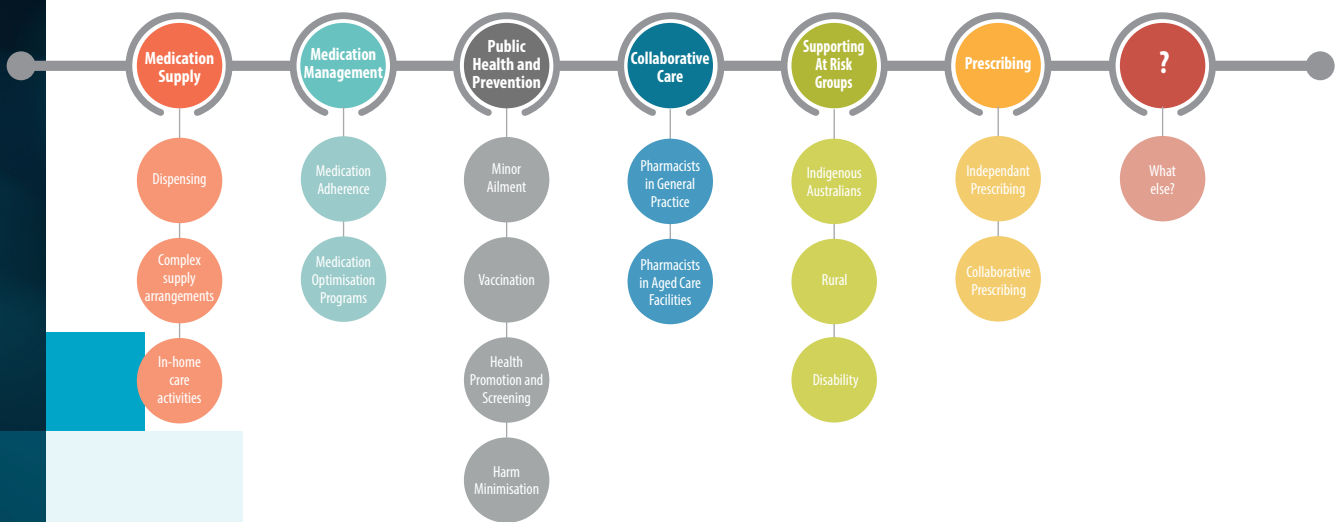
Pharmacists in 2023
PO Box 42
Deakin West ACT 2600.

Embedding

Improving patient outcomes can be achieved by embedding Pharmacists wherever medicines are used.



The following graphic represents several activities within the pharmacist scope of practice based on feedback from pharmacists, consumers and assessing international developments. Embedding pharmacists wherever medicines are used speaks to four areas - Medication Supply, Medication Management, Collaborative Care Teams, and Supporting At-Risk Groups



Medication Supply

PSA's vision has pharmacists delivering services tailored to consumer need, delivered at the right time, by the pharmacist with the right skill set in the right setting. There should be a continuum of services and care related to the access to and optimal use of medications. This can start from provision of non-prescription medications, dispensing prescription medications, through to reviewing understanding and adherence to treatments, reviewing the effectiveness of treatment and chronic medication management and review. These are all delivered in an individualised manner based on patient need and focussed on the quality, safe and effective use of medicines.

Apart from a defined group of relatively low-risk products, consumer access to medications occurs under the oversight of pharmacists through pharmacies. The long-established role of community pharmacists has been based on the supply model primarily focussing on preparing, dispensing, and supply of medicines which can include complex supply arrangements involving preparation of injectable medicines and compounded products.

More effective use of the pharmacy workforce and technology to redesign the dispensing process has created efficiencies in the technical process of medicines supply, and has allowed more time for the pharmacist to provide face-to-face patient-centred care.

Medication Management

Supporting the management of medications to optimise their use and effectiveness is fundamental to the education, training and professional practice of pharmacists. This occurs from assessing need and advising on self-management and/or non-prescription medication treatment, to identifying the need for medical diagnosis and prescription medication treatment, supporting consumers to understand the purpose and use of their medications, through to evaluating and optimising medication treatment including advising on deprescribing when required. In more integrated care settings, pharmacists support prescribing and utilisation of medication use at a population level and are part of interprofessional teams responsible for ongoing chronic care management.

Pharmacists also support consumers' navigation of the health system through coordinating supply of repeat prescriptions (particularly in aged residential care facilities), and liaising with prescribers on the consumer's behalf.

Pharmacists have commented that caps placed on funded medication management programs are a barrier to equitable access for consumers who may benefit from these programs. They have expressed concern about the quality of some medication management services and that more accountability at an individual service delivery level is needed. Also, existing program rules affect referral into these programs and where they may be delivered.

Question 3:

What processes, tools or mechanisms would support the delivery and outcomes of medication management programs by pharmacists to integrate with others in a person's healthcare team?

Question 4:

How can remuneration mechanisms better reflect the range complexity of care required for some medication management services?

Question 5:

If medication management services were outcomes-focussed in their funding, what must be considered in designing an appropriate funding mechanism?

Question 6:

What could be incorporated into the design of the program to ensure accountability and an appropriate level of quality?

Collaborative Care Teams

A collaborative care team is where the patient and their healthcare providers work together to achieve the optimal health outcomes. It could refer to situations where the team is located in the same practice setting and interact closely, or it could refer to providers who work independently but are providing care to the same patient. It also refers to making sure that linkages with existing care providers such as community pharmacists are better integrated with other care environments such as general practice through the use of digital technologies.

When establishing models for pharmacists to be integrated better into health care teams, pharmacists have moved from a transaction-based, commoditised dispensing model of practice to a relationship-based, patient-centric and collaborative model.

Health reforms internationally have seen pharmacists integrate better into care teams including Canada, UK, Scotland, and USA. Internationally pharmacists have been increasingly integrated into general practice and aged care facilities.

Studies from Canada have found that doctors, pharmacists, other staff, and patients felt that the inclusion of a pharmacist into the primary care practice improved the quality of patient care, was a valuable resource, and empowered patients to better manage their medications.

Pharmacists are already being integrated into general practice, aged care facilities and into Aboriginal health services and disability services. An announcement in the 2018-19 Federal Budget saw the expansion of the Workplace Incentive Program to include non-dispensing pharmacists. This program provides a funding model to incentivise general practices to utilise pharmacists as part of a collaborative care team.

A model posed by PSA for pharmacists in general practice focusses activities in three areas, with the majority of pharmacist time spent on the first two areas as outlined below.

Education and Training	Clinical Governance	Patient-level Activities
• Develop and lead education and training processes related to quality use of medicines within the practice	• Deliver evaluation audits on best practice management for chronic disease - e.g. CVD, diabetes	• Identifying, resolving, preventing, and monitoring medication use and safety problems
• Delivering education sessions (including new evidence, guidelines and therapies) to doctors and practice staff.	• Develop and lead clinical governance activities centred around the quality use of medicines	• Reducing poly-pharmacy and optimising medication regimens using evidence-based guidelines, recommending cost-effective therapies where appropriate
• Responding to medicine information queries including; questions relating to medication formulas, medication availability and specific medication concerns from GPs (e.g. switching anticoagulants, antidepressants, opioid equivalence).	• Collaboratively lead and develop systems, processes and communication strategies for each practice that will reduce the risk of medicine misadventure through all transitions of care and enhance the quality use of medicines	• Facilitating uptake of chronic disease medication management consultations by the patients' nominated community pharmacy, as well as 6CPA funded programs such as dose administration aids, MedsCheck, and Home Medication Review
• Significant focus should also occur on the use of high-cost medications for example hepatitis C medications	• Promote and enhance the uptake of electronic and self-directed care. Ensuring uptake of My Health Record and electronic medicines lists	
	• Act as a point of contact for local community pharmacies	
	• Improving the quality prescribing of high cost therapies including biologics	

Question 7:

How can pharmacists be more involved in Collaborative Care teams?

Question 8:

How can services and models of care be delivered in locations that best suit the needs of the consumer? Eg. Home-based care, Aboriginal and Torres Strait Islander health and rural and remote settings?

Question 9:

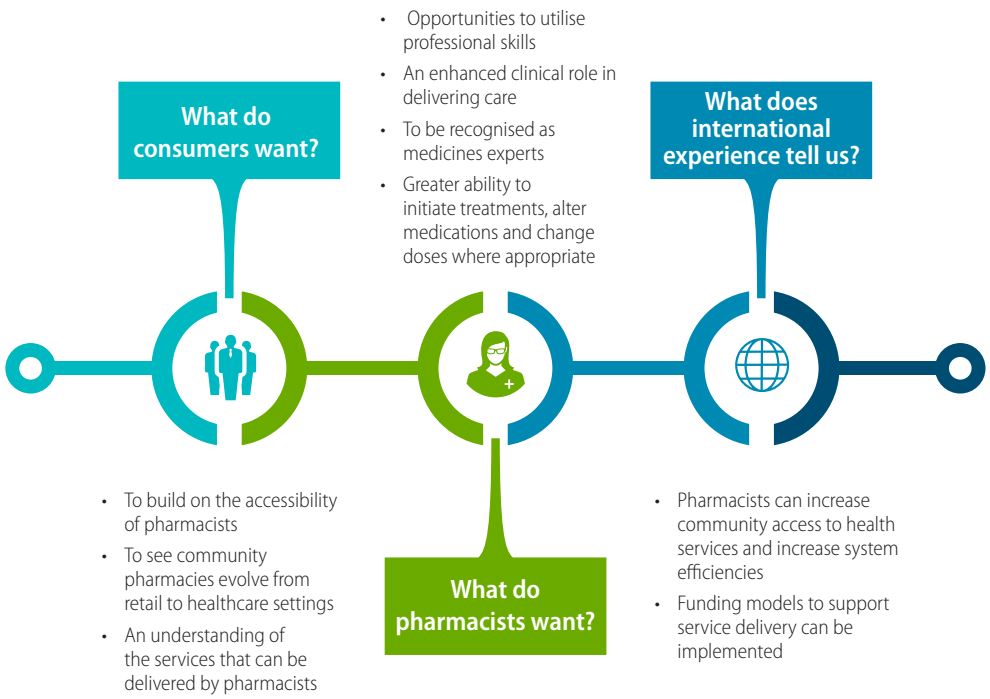
What are the barriers to implementation and how can these be overcome?

The full integration of pharmacists into a more collaborative, patient-centred model of care, is a long-term objective, particularly when supporting at-risk groups within our community such as Indigenous Australians, Rural and Remote communities and Disability Services.

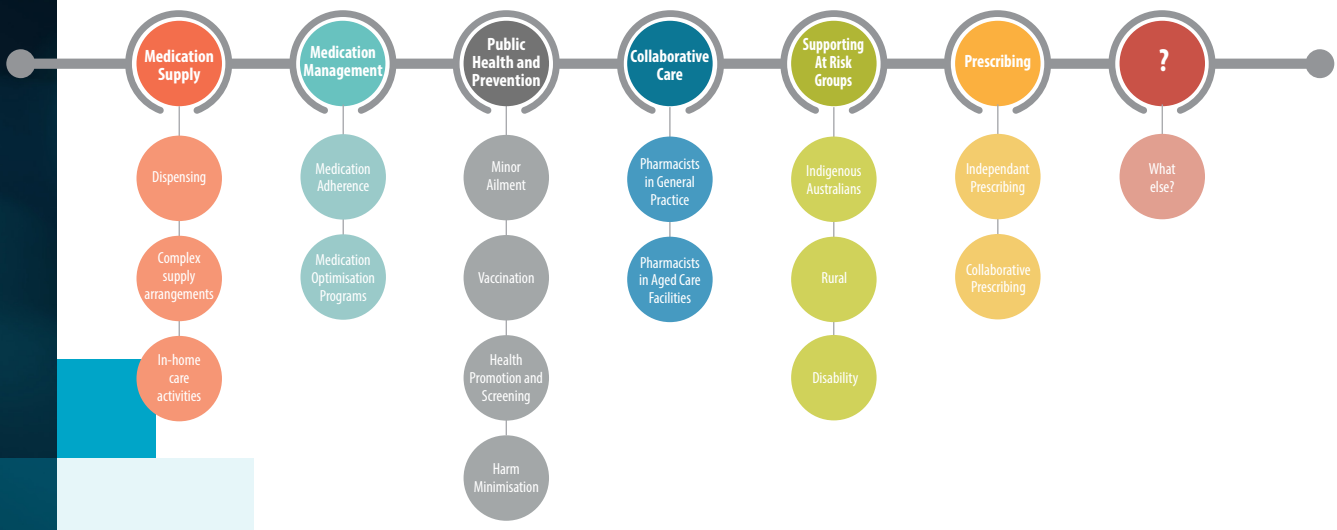
Likely requiring different funding streams and significant changes within the health system as a whole, the vision of having a pharmacist available wherever of medicine is used is a central tenet of the future of pharmacist practice in Australia.

Equipping

Improving patient outcomes can be achieved by equipping pharmacists to enhance community access to health services.



Equipping pharmacists to enhance access to health services speaks to two areas within a pharmacists' scope of practice – Public Health and Prevention, and Prescribing.



Public Health and Prevention

Pharmacists have played a key role in managing patients' health concerns by using their clinical training to 'assess then treat or refer' based on the patient's needs. This contribution supports public health and prevention, timely access to care and reduces the burden on general practice and hospitals. Minor ailments and referral schemes (MAS) have been implemented in other countries including England, Canada, and Scotland with New Zealand also focussing on developing a MAS. The MAS was introduced in Scotland in 2006 and allowed specific groups of people to access treatment of self-limiting illness such as fungal infections, allergies, diarrhoea, ear aches, sore throats, and headaches. The MAS in Scotland is currently undergoing an expansion with pharmacists undergoing additional training to assess and refer patients and provide an expanded number of medications for conditions such as shingles, impetigo, female urinary tract infections, exacerbations of COPD, as well as bridging oral contraception.

Patients often do not wait long in a pharmacy to be seen by a pharmacist and the consultations for minor ailments are often short (<5 mins)[7]. The MAS in the UK was commissioned locally by primary care trusts in some parts of England and encourages people to use their community pharmacy as a first point of contact for self-limiting conditions (e.g. head lice, cough and colds, hay fever). A review of pharmacy-based MAS showed that the number of consultations and prescribing for minor ailments at general practices can decline following the introduction of a MAS.[8]

There is broad support to design and implement a Minor Ailment Scheme in Australia. In some parts of Australia community pharmacies are an ideal place to deliver a MAS with appropriately trained staff and extended opening hours, and potentially lower travel costs for some people due to the wide network of community pharmacies available in Australia. The development and implementation of a MAS in Australia is an example of utilising the existing network of Community Pharmacies in Australia to improve the accessibility of care within Australia that meets consumer needs.

Question 10:

How would pharmacists be remunerated for the time spent with patients based on the complexity of the issues identified and outcomes achieved?

Question 11:

What are the barriers to implementation and how can these be overcome?

Vaccination

Pharmacist-delivered vaccination in the community setting has been available in many countries such as the United Kingdom, the US, Canada, and, more recently, New Zealand[9]. Australia has recently benefited from the introduction of pharmacist-provided vaccination in all states and territories for several vaccines (e.g. influenza, MMR, dTpa/DTPa), though the types of vaccines that can be provided varies across state and territory jurisdictions. Further expansion of pharmacist-administered vaccinations will further increase the overall protection of the Australian population against communicable diseases. A limitation for expansion includes remuneration as currently vaccinations delivered by pharmacists attract out of pocket costs from patients.

Question 12:

How can pharmacists could be more involved in vaccination services?

Health Promotion and Screening

The unique accessibility of pharmacists creates the opportunity to deliver health promotion education and services to individuals or groups of consumers as part of a coordinated program including smoking cessation and weight management programs. Pharmacists also provide health screening and monitoring services for consumers including cholesterol, blood pressure, blood glucose and sleep apnoea.

Consumers have commented that they will often ask their pharmacist for advice before going to their GP. This can be to confirm whether the complaint is serious enough to warrant a medical diagnosis and management, or whether the pharmacist can advise on self-management or non-prescription treatment. Consumers have also explained that they see their pharmacist more than their GP, particularly when collecting prescription repeat supplies.

The accessibility and knowledge of pharmacists in providing health advice freely and without appointment is often well recognised. However criticism has been expressed towards pharmacists in incentivising the sale of a product to compensate for their time and advice.

Improved use of technology

Consumers are interested to see an improvement in the use of technology used by pharmacists. Consumers are supportive of pharmacists having greater access to electronic health records as this will provide them with more accurate and reliable information. Consumers recognised that if pharmacists have access to information beyond medications prescribed, such as diagnoses, through a system like My Health Record, then they could make better recommendations.

The care and treatment provided by pharmacists, and recommendations to optimise medication use could be incorporated into electronic shared care records. Similarly, assessment made and provision of non-prescription medicines in community pharmacy form part of an individual's management.

Question 13:

How can we increase recognition of pharmacist-provided care?

Question 14:

How should health promotion and screening programs be designed to eliminate concerns about fragmentation, and ensure that the care that a pharmacist provides can be captured and recognised by others providing care to an individual?

Question 15:

What kinds of programs or remuneration mechanisms could recognise this valued role of the pharmacist and address the perception of "incentive to sell"?

Improved use of technology

Consumers are interested to see an improvement in the use of technology used by pharmacists. Consumers are supportive of pharmacists having greater access to electronic health records as this will provide them with more accurate and reliable information..

The care and treatment provided by pharmacists, and recommendations to optimise medication use could be incorporated into electronic shared care records. Similarly, assessment made and provision of non-prescription medicines in community pharmacy form part of an individual's management.

Question 16:

How can pharmacist activities and provision of care be captured in an electronic shared care record? What value would this provide the consumer, wider health care team, and the health system?

Pharmacist specialisation

A key finding from member feedback was the need for pharmacists to develop specialist knowledge to help patients with specific needs. Specific areas identified by consumer feedback included pain management. A number of pharmacists in the community have developed clinical interest areas and provide services related to these including wound management, sleep apnoea, asthma and COPD services, and mental health support and advice to name a few.

In the hospital setting it is common for pharmacists to develop specialised knowledge in areas of specialty practice (e.g cardiology, paediatrics, oncology).This specialised knowledge may develop organically through considerable experience and in managing the full complexity of care required in the secondary care setting.

Formal education and qualifications can also provide applied clinical knowledge at more advanced levels than that required to attain professional registration, and such qualifications are often taken up by pharmacists in all care settings and areas of practice.

While the National Competency Standards Framework for Pharmacists reflects the continuum of advanced practice, no formal training pathway exists for the profession that leads to defined vocational registration as occurs in the medical profession. Furthermore, outside of the profession, consumers and other health professionals have expressed the desire to know which pharmacists have specialised knowledge and how to identify them.

Question 17:

Separate to the existing process for advanced practice credentialing, would formal recognition of pharmacist specialisation in defined areas of clinical practice (to a defined standard) be beneficial for future practice? (For example, mental health, oncology, cardiology, paediatrics etc and/or pharmacist-practice specialties such as medicines information, pharmaceutical compounding)

Question 18:

Assuming a robust process for defining standards of clinical practice for such specialisation, what benefits would formal pharmacist specialisation provide?

Question 19:

Should some roles, services or activities be restricted to defined levels of practice or specialisation?

Pharmacist Prescribing

Equipping pharmacists with the ability to prescribe is often a difficult subject to discuss, mainly based on preconceptions and misinformation. However, a range of non-medical health professionals already have prescribing privileges, including dentists, optometrists, nurse practitioners, midwives and podiatrists.

Within recent years pharmacists have been able to supply a limited range of emergency contraceptives, anti-infectives (ocular chloramphenicol, famciclovir, fluconazole) and proton pump inhibitors (PPIs) under specific conditions due to the recent down-scheduling of these medications to the Schedule 3 category. Pharmacists have also been able to provide continued dispensing for statins and oral contraceptives in most states and territories in Australia since 2013 where there is an immediate need and it is not practicable to obtain a prescription from the patient's doctor. New Zealand have recently had their legislation altered to allow appropriately qualified pharmacists to prescribe.

If we accept that pharmacists are medicines experts who currently make clinical diagnoses (within their scope of practice) and make medication recommendations for over-the-counter medicines, then prescribing could be considered simply a continuation of their medicines management role.

The last 25 years has seen the introduction of non-medical prescribing with the United Kingdom particularly leading the world. Non-medical prescribers and doctors have reported that patients accessing non-medical prescribers receive higher quality of care and can improve teamwork and in cases reduce doctors' workload. A comprehensive review has shown that non-medical prescribers (including pharmacists) with varying levels of undergraduate, postgraduate, and specific on-the-job training related to the disease or condition are as effective as usual care medical prescribers, in a range of settings.[10]

The literature regarding pharmacist prescribing in Australia has focused on exploring pharmacist's readiness to prescribe as well as evaluating the opinions of pharmacists, GPs, and patients.[9-15] Improving access to medications has been documented as the primary reason for supporting this role expansion of pharmacists.[9-14] Current support from GPs in Australia favours a dependent (collaborative) prescribing approach with an independent prescribing model largely regarded as inappropriate, although these are findings from a very small sample of GPs (n=22) in 2008.[15] Several pilot studies have examined pharmacist prescribing in various settings, including hospital emergency departments, a preadmission clinic, and outpatient clinics in Australia.[19-21]

In Australia, developments are currently occurring investigating the roles of pharmacists in prescribing, from collaborative prescribing to independent models. Generally, supplementary or collaborative prescribing is defined as

> *"a voluntary partnership between the independent prescriber (e.g. medical practitioner) and a supplementary prescriber to implement an agreed patient specific management plan, with the patients consent"*

Independent prescribing is defined as

> *"Prescribing by a practitioner who is responsible and accountable for the assessment of patients with diagnosed and undiagnosed conditions and for the decisions about the clinical management required, including prescribing"*

This is likely to be more challenging for pharmacists and is likely to require postgraduate training in diagnosis. It is expected that this will take a significant time from a change management perspective for the health professions including pharmacy to accept.

Question 20:

Do you believe that pharmacists have the current skills to be able to prescribe in a collaborative role. How could this be developed in the future?

Question 21:

Should independent prescribing be a key focus for the pharmacist profession?

Question 22:

Should the decision to initiate a prescription medicine always be separated from the supply of that medicine? How can this be implemented in practice?

Question 23:

What are the barriers to implementation and how can these be overcome?

Enabling

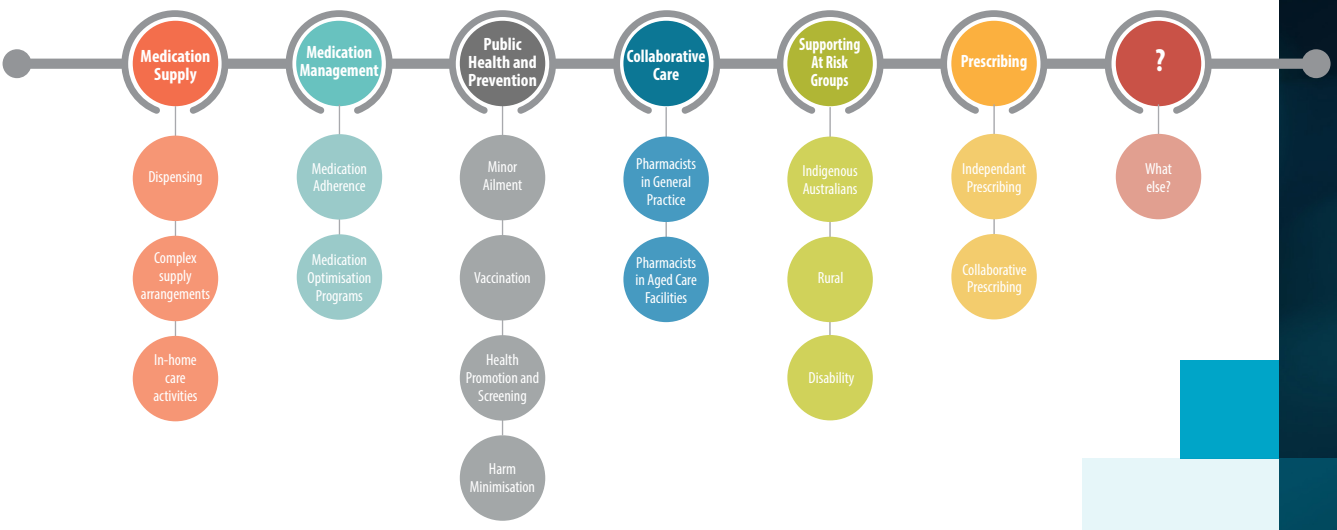
Improving patient outcomes can be achieved by enabling system changes so that the role of pharmacists recognised, they are fully utilised and appropriately remunerated.

- To be recognised for their skills, expertise and specialisation
- To be appropriately remunerated for the health services they deliver

- A health system that is simple to navigate, accessible, affordable and 'joined up'
- Increased access to digital health initiatives
- Continuity of their care and collaboration between healthcare providers To deliver high quality healthcare

- System change is possible
- Patient care can be enhanced through optimising the role of pharmacists
- Financial inventive and commercial imperatives influence practice

Enabling system changes speaks to the entire pharmacist scope of practice, but specifically calls on the final element – what else?



Question 24:
Are there other areas of pharmacist involvement that may improve medicines management and patient care that have not been identified?

Question 25:
Should any of these areas be considered higher priority for implementation than others?

Consumers recognise that there is a much wider role that pharmacists can and should play in the health sector. Consumers value pharmacist's expertise around medicines and feel greater access and use of them is appropriate. Like previous consultations, consumers feel pharmacists can offer good continuity of care because of their extended opening hours and ease of accessibility. Consumers are highly supportive of this model and are broadly not in favour of a move to more formal appointment-based services that they generally receive now without an appointment. Reconciling this with the need for the profession to transition to a consultation-based setting will need balancing with consumer expectations on the accessibility of pharmacists within community pharmacy.

A major theme that emerged from consumers is that community pharmacies do not currently feel like a health setting and they felt that a favoured model of care was a health destination style setting. Consumers strongly stressed the need for private consultation areas in pharmacies. Consumers also expressed the desire for increased access to pharmacists (rather than pharmacy assistants). Consumers voiced their concerns around stigma and discrimination particularly in the areas of pain, illicit drug users and HIV/AIDS and suggested training may be needed to counteract the stigma and judgement face by some patients.

Question 26:
What system changes or incentives can encourage innovation in pharmacist care?

Question 27:
Can a funding model be proposed that shifts the retail/medication supply focus to a clinical decision making and chronic disease management?

Question 28:
What value do funders and policy makers place on services as opposed to the medicines provision function? Can a funding model remunerate pharmacists for time spent and health outcomes as a result of intervention?

Question 29:
Should the Community Pharmacy Agreement (CPA) transform to a framework that supports future models of pharmacist care? How?

Question 30:
Outside the CPA, what other remuneration options exist and how could they be adopted?

The pharmacist workforce in Australia is well regarded for its professionalism and medicines expertise. The challenge to seeing pharmacists working to their full potential is to address the structural and funding barriers that currently result in minimal participation in key Australian health initiatives.

Question 31:
What are the major system enables to ensure pharmacists can deliver the services and activities that contribute to safe and effective use of medicines?

Question 32:
How do we ensure and measure quality and standards of practice of pharmacist-delivered services, and 'raise the bar' in delivery of care?

Question 33:
Are the standards of practice active/living documents that are fore of mind on a daily basis?

Question 34:
What needs to be considered in preparing the pharmacist workforce for new roles?

In order to deliver on consumer needs and unlock opportunities for pharmacists in 2023, we need to enable changes within the Australian health system - this is the key objective for Pharmacists in 2023.

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Pharmaceutical Society of Australia

Attachment 5

Pharmaceutical Society of Australia

Clinical governance principles for pharmacy services

Consultation Draft

AUGUST
2018

PSA Australia's peak body for pharmacists

Foreword

Quality use of medicines is one of the central objectives of Australia's National Medicines Policy (NMP), the overall aim of which is to improve health outcomes through access to and the appropriate use of medicines.[1]

The NMP, and particularly the quality use of medicines arm of the policy, holds a preeminent position as a pillar of professional pharmacy practice. With greater knowledge and training on medicines and medication management, pharmacists hold a fundamental role in ensuring safe and optimal use of medicines.[2,3]

However the objectives of the NMP are difficult to measure. While the Review of Pharmacy Remuneration and Regulation[4] aimed to determine how the pharmacy sector supports the objectives of the NMP, PSA's submissions to the review noted the lack of published standard measures for assessing performance or measuring quality in relation to the policy.

PSA contends that a framework for quality practice already exists, for example, the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017*[5] makes explicit reference to PSA's Professional Practice Standards and Code of Ethics as part of the requirements for quality practice. However, with an estimated 230,000 medication-related admissions to hospital annually at a cost of $1.2billion,[6] more must be done to monitor and evaluate programs and services aiming to improve the quality use of medicines, to help ensure they are appropriate, efficient and effective.

This document proposes that the principles of clinical governance described by the Australian Commission on Safety and Quality in Health Care (ACSQHC) should be adapted and applied to the services and programs delivered by pharmacists. This would assist recognition of and accountability to high-quality care, and support continuous improvement of pharmacist services that aim to improve health outcomes through the quality use of medicines. The design, delivery and management of pharmacist services under these principles would also help address governance, accountability and transparency concerns expressed in evaluations of community pharmacy agreements and the Review of Pharmacy Remuneration and Regulation.

PSA believes that providing care under these principles of clinical governance would help ensure pharmacist services meet expectations for contemporary delivery of health care by being patient-centered, and focused on quality health outcomes.

We are seeking your views on the proposed principles of clinical governance, and how they should apply to the services and care provided by pharmacists. Your responses to the consultation questions in Appendix 4 will help to clarify and refine the definition, description and applicability of the proposed principles to pharmacy practice.

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About PSA

The Pharmaceutical Society of Australia (PSA) is recognised by the Australian Government as the peak national professional pharmacy organisation. It represents Australia's 29,000 pharmacists working in all sectors and locations.

PSA's core functions relevant to pharmacists include:

- providing high-quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice
- representing pharmacists' role as frontline healthcare professionals.

PSA is also a registered training organisation, and offers qualifications including certificate- and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

Contents

Introduction

Clinical Governance

Clinical governance has been recognised as a key mechanism of achieving and improving safety, quality and effectiveness in the provision of health care.

The definition and model of clinical governance and quality systems varies widely across jurisdictions and health care organisations, within Australia and internationally.

The National Competency Standards Framework for Pharmacists in Australia[1] defines clinical governance as:

> *A framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.*

While the Australian Commission for Quality and Safety in Health Care (ACQSHC) define clinical governance as:

> *'the set of relationships and responsibilities established by a health service organisation between its state or territory department of health, governing body, executive, workforce, patients, consumers and other stakeholders to ensure good clinical outcomes.*[2]

OR

Clinical governance describes the set of relationships and responsibilities established within a health service organisation which is accountable for the delivery of safe, effective and high-quality health services.[2]

In the context of pharmacy practice, this may include:

- governance arrangements within a community pharmacy, pharmacy department or other pharmacy business to ensure clinical accountability of pharmacists and management
- relationship between pharmacists, clinicians and a clinical governance unit within a hospital
- partnerships between community pharmacy and commissioning bodies such as PHNs
- clinical accountability within a general practice environment where pharmacists contribute to quality use of medicines
- professional responsibilities of accredited pharmacists in undertaking medication reviews
- accountabilities of pharmacists working in shared care arrangements (e.g. within a mental health team)

Why is clinical governance important?

This is primarily achieved through system design which enhances collective responsibility and accountability of health professionals and organisations who provide health care.[3]

The clinical governance framework builds on the Professional Standards for Pharmacists[4] by:

- drawing out key themes which are essential for service provision
- describing principles to describe how these standards and themes should be implemented in pharmacy practice
- applying these themes in a way that promotes accountability and evidence to support safe and effective clinical care.

Global trends in clinical governance

The integration of clinical governance principles in the provision of health care globally is varied. The World Health Organisation formally identified the need for a coordinated approach to quality assurance activities in health care delivery systems in 1983.[5] However, it was not until the 1990s the term 'clinical governance' was first introduced in relation to the United Kingdom National Health Service (NHS) and defined as '*a system through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish*".[6]

Different approaches to clinical governance have been taken within different health systems globally. In countries with a 'single-payer' model of care, a 'top-down' clinical governance approach has progressively applied. This approach involves developing systems and performance targets at an all–of-industry level and requiring their adoption and ongoing use. Top-down approaches usually have a strong focus on accountability and standardisation.[7]

Conversely, a 'bottom-up' approach to clinical governance generally adopts a more practice-based, values-driven approach which focuses more on effective teamwork, particularly in relation to clinician input. This approach is recognised as having a greater flexibility and support of health professionals.

Examples of leading clinical governance approaches adopted internationally include:

Country	Clinical governance framework
New Zealand	The Health Quality & Safety Commission New Zealand has produced a framework[8] for clinical governance for health providers, which supports district health boards (DHBs) and primary care organisations. Research by the New Zealand Treasury[9] has recognised quality improvement programs with effective clinical governance programs are able to achieve quantifiable savings and efficiency gains in the provision of health care.
United Kingdom	All NHS services must participate in the national clinical governance framework, which predominately uses a 'top-down' approach. For community pharmacies, demonstration of a range of clinical governance measures is required to receive quality payments. In addition to typical components of quality management systems such as risk-management, these clinical governance measures include: • undertaking annual clinical audits and consumer engagement to promote quality improvement over time • participation in open disclosure of adverse events, including near misses • consumer partnerships, including publication of patient feedback.[10]"
Canada	The Canadian Patient Safety Institute (CPSI) works with governments, health organisations and health providers to support improvement in safety and quality. This is primarily achieved through provision of guidelines, resources and active engagement with the health sector.
United States of America	As primary funders of health care in the USA, health maintenance organisations (HMOs) have a strong interest in effective clinical governance. California-based HMO Kaiser Permanente has been recognised as a leader in adopting effective, integrated, clinician-led clinical governance systems which have improved the effectiveness and efficiency of health-care provided to their consumers. Fundamental to its success has been a whole-of-system approach to care and wellness. This approach allows for macro-level monitoring of the impact of all health care provided on health outcomes and designing care around the most effective and safest strategies for their health consumers.[11]

Importance of clinical governance to pharmacy services

The delivery of pharmacy services by pharmacists is widely recognised as supporting the safe and effective use of medicines within the Australian community.[12] However, it has been historically difficult to quantify the extent to which each service achieves these outcomes.

Evaluations of funded pharmacy programs have raised concerns these professional services do not exist within a clinical governance framework that is capable of demonstrating the clinical value, safety and cost-effectiveness of specific services.[12,13]

The implementation of an effective clinical governance model can help ensure this can be achieved, as more effective pharmaceutical care can be delivered through:

- identifying models of care or service delivery which promote individual and organisational accountability for health care outcomes
- capturing and evaluating clinical data that compares professional service provision against achievement of defined health outcomes or indicators
- structuring funding models that incentivise achievement of specific quality indicators or health outcomes
- focussing on improvement in outcomes rather than process.

Clinical governance in the Australian health system

Role of the Australian Commission for Safety and Quality in Health Care (ACSQHC)

The ACSQHC is established to lead improvements in the safety and quality of health care in Australia. It is jointly funded by the Commonwealth Government and state/territory governments.

National Model of Clinical Governance Framework

As part of this role, the ACSQHC developed the National Model of Clinical Governance Framework[2] in 2017. It describes the roles and responsibilities of consumers, clinicians, health service organisations and managers in supporting safe, high-quality care through an effective clinical governance framework.

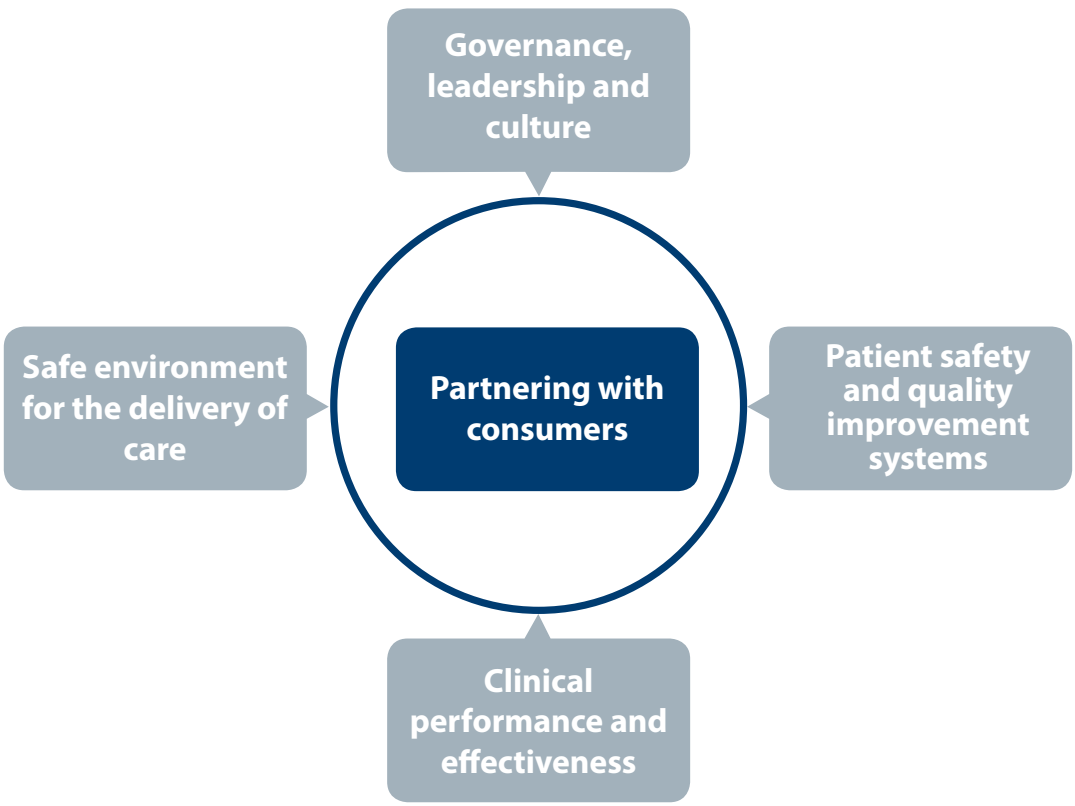

Figure 1. Components of clinical governance, reproduced from National Framework for Clinical Governance

Adapted from National Clinical Governance Framework[2]

This model is consistent with components generally accepted around the world as being fundamental to effective clinical governance systems. Importantly in this structure, consumer partnership is considered central to every component of the framework.

Implementation of clinical governance in Australia

The emergence of clinical governance in Australia has been progressive over recent decades.

Most state and territory health governments have incorporated clinical governance bodies within health departments and services, supported through the ACSQHC's initiatives, such as the National Safety and Quality Health Services (NSQHS) Standards and the National Model Clinical Governance Framework.[2] These initiatives provide criteria for health service organisations to develop clinical governance systems, but are not prescriptive on the structures individual organisations develop and implement.

Governments, PHNs, health insurers and other bodies commissioning health services increasingly require robust clinical governance frameworks within funded services to provide reassurance to clinical safety and demonstration of cost-effectiveness of the service. Examples include:

- The NSW Clinical Excellence Commission provides system wide clinical governance leadership, including: supporting the implementation and ongoing development of local quality systems; develop policy and strategy relating to improvements of clinical quality and safety; review adverse clinical incidents and develops responses; and build capacity within the system to identify and respond to risks and opportunities.[14]
- Victoria has established a Health Information Agency to analyse and share information across the system to ensure everyone has an accurate picture of where the concerns are in relation to clinical safety, and recognise areas of strong performance.[15]
- The Australian Government's Commonwealth Home Support Program[16] provides funding to service providers within a clinical governance framework, which must adhere to Home Care Standards developed by the Australian Aged Care Quality Agency and report on financial, quality and consumer outcomes through an online portal which provides a national overview of service activity benefits and value.
- Specific clinical governance structures and oversight of nurse practitioners exists in some states and territories to support safety and quality in prescribing of scheduled medicines.

The application of clinical governance frameworks to the Australian health system is described below:

Australian health service sectors	Clinical governance framework
Hospitals	Implementation of an effective clinical governance framework is required to achieve accreditation under the National Safety and Quality Health Standards (NSQHS), which is mandatory for all Australian hospitals and day surgery facilities.[2] Public hospitals are often supported additionally by clinical governance commissions (e.g. NSW Clinical Excellence Commission) which provides support in strategies and systems which can be used to improve the safety and quality of care provided.
Commissioning bodies (e.g. PHNs)	Commissioning bodies are responsible defining clinical governance needs by defining safety requirements, monitoring processes and outcomes of commissioned services.[17] These bodies also have a role in supporting clinical governance of health providers through system improvement, workforce development and influencing the update of quality improvement activities.[17]
General practice	Accreditation standards for general practice[18] include requirements for clinical governance which are drawn from ACSQHC Health Service Standards. These include clinical risk management, incident management and improvement systems. Accreditation is incentivised through access to Practice Incentive Payments (PIPs).[19]
Community pharmacy	The majority of community pharmacies are accredited against AS85000 Quality Care Pharmacy Standard which contains some elements of clinical governance, including risk management and staff management. Accreditation is an eligibility prerequisite for some 6CPA funded medication adherence programs (e.g. staged supply).[20]
Aboriginal Community Controlled Health Services (ACCHS)	ACCHS operate at a regional level and have adopted clinical governance models which involve active collaboration with the community, other clinicians and provide targeted feedback on practice to clinicians. Peer-to-peer education exercises and comparison of outcomes is considered a strong driver of safety and improvement in ACCHSs.[21]
Other health service organisations	Some dental practices choose to be accredited against the NSQHS, which includes a clinical governance standard.[22]

The formal application of clinical governance principles to pharmacy practice in Australia is largely limited to hospital, aged care and Aboriginal and Torres Strait Islander health service environments.

This document describes principles to guide the clinical governance of all pharmacy services in Australia. The principles help identify clinical governance gaps in pharmacy service development or implementation. Adequately responding to identified clinical governance gaps is needed for a service to be as safe, effective and efficient as it can be in supporting the health of consumers.

Principles of Clinical Governance for Pharmacy Services

The National Clinical Governance Framework[2] components are generally accepted to be essential to effective clinical governance and have therefore been adopted in this document. From these components, clinical governance principles necessary for provision of safe and effective pharmacy care have been developed and customised.

Summary of principles

Principles fundamental to good clinical governance in pharmacy services include:

1. Partnering with consumers	
Co-design	Consumers are actively engaged in the planning and design of the services and care they receive. Health consumers, their carers and pharmacists should be partners in the co-design of pharmacy services.
Patient-centric	Service design & delivery considers and supports consumer participation. Pharmacy services should be patient-centric and designed around the health needs and preferences of individual consumers. Consumers should be empowered to actively participate in decisions about their care.
Empowering consumers through health literacy	Consumers should be empowered to participate in their care through communication measures which enhance health literacy and informed consumer decisions.
Measuring and improving consumer experience	Pharmacy service providers should actively seek feedback on consumer experience as key indicators of health care quality. Pharmacy service providers should learn from consumer experience measurement and use it to drive improvement in quality and safety of care.

2. Governance, leadership and culture	
Commitment to safety and quality culture	Pharmacy services should be supported by adequate resources and systems for the provision of safe, effective and sustainable pharmacy care. Accountability for the safety and quality of pharmacy services should be jointly shared by pharmacists, funding bodies, management and consumers.
Clinical leadership	Pharmacists, managers and funders should champion and model quality & safety values in behaviours and decisions. Clinical leaders within the practice setting and wider profession should engage with pharmacists and related staff on safety and quality. Safety and quality performance of pharmacy services should be actively monitored and reviewed.

3. Clinical performance and effectiveness	
Scope and standards	Professional guidelines, standards, policies and procedures should guide quality and safety by describing the scope and provision of competent pharmacy services.
Evidence-based care	Pharmacists should have access to and use evidence-based guidelines, indicators, models-of-care, and data to inform clinical decisions.
Transparency	The clinical benefits, risks and costs of pharmacy services should be transparent to consumers and stakeholders.
Education and training	Pharmacists should be supported to maintain competence and develop professional skills to enable high performance for pharmacy services within their scope of practice.
Measurement and monitoring	Clinical measures of pharmacy services effectiveness, quality and safety should be systematically measured, monitored and reviewed by pharmacists, management and funders, including through: • undertaking clinical audits • participation in research projects • supervision and management of pharmacist and staff performance.

4. Patient safety and quality improvement systems	
Risk management	Safety and quality in pharmacy services should be supported by risk management systems which have actively engaged pharmacists in their design. These systems should include: • policies and procedures to manage patient safety risk • incident management, including near misses • open disclosure.
Adhere to codes, guidelines and quality systems	Pharmacy services should demonstrate delivery consistent with relevant industry codes, guidelines, standards and relevant policies and procedures.
Continuous quality improvement	Services should be supported by evidence-based cyclical improvement activities which support enhancements in clinical outcomes and patient safety.

5. Safe environment for delivery of care	
Environment	Pharmacy services should only be conducted where equipment is fit-for-purpose and the environment supports safe and high-quality care that meets consumer needs.
Cultural safety	Pharmacy services should be inclusive and only provided in an environment which is culturally safe and respects the cultural diversity of consumers.

These principles and components of clinical governance are describedin more detail in subsequent pages.

1. Partnering with consumers

Including: **patient involvement**

Involves: **shared decision making, consumer experience, communication (open, transparent, effective, health literacy), co-design**

1(a) Co-design

Principles	**Consumers are actively engaged in the planning and design of the services and care they receive.** **Health consumers, their carers and pharmacists should be partners in the co-design of pharmacy services.**
What is it?	Co-design describes an approach to developing services where consumers and clinicians are actively engaged in defining and design of care. Through this active engagement, co-design focuses strongly on design, delivery and outcomes of services centred around the patient experience. Co-design uses techniques such as prototyping, storyboards, process maps and process control to help craft more patient-centric services.[23] In pharmacy services, characteristics of co-design can include: • asking consumers to describe goals, needs and unmet needs of pharmacy services • consumers and clinicians (including pharmacists) collaborating to design services which spend more time on clinical activities and less time on administrative activities.
Why is it important?	In health care, co-design is considered an approach to designing better experiences for consumers, carers and clinicians which can result in patient-centric rather than process-centric health care, and better meets the needs of consumers.

1(b) Patient-centric

Principles	**Service design & delivery considers and supports consumer participation.** **Pharmacy services should be patient-centric and designed around the health needs and preferences of individual consumers.** **Consumers should be empowered to actively participate in decisions about their care.**
What is it?	Patient-centred care describes an approach to design and delivery of pharmacy services in which the service is genuinely built around the needs and preferences of consumers. Characteristics of patient-centred care include: • actively engaging consumers in the design and delivery of pharmacy services • designing services to support ideal patient journey as primary priority rather than primarily for efficiency or structure of a business unit (e.g. hospital) or dispensary • identifying consumer and population needs and expectations • healthcare providers asking about and respecting consumer beliefs and values about their health, including cultural values particularly with respect to Aboriginal and Torres Strait Islander people • services and models of care recognising the uniqueness of an individual's health needs and personal illness experience due to culture, beliefs and previous experiences • respecting requirements for privacy and confidentiality • actively engaging consumers, and their carers, in decisions about their care • monitoring changing or evolving patient needs and adapting services in anticipation or response.
Why is it important?	The benefits of patient-centred care are well documented[24] in demonstrating that where health care is well-designed around patient needs and preferences: • the quality and safety of health care increases • cost of care decreases • clinician and patient satisfaction increases.

1(c) Empowering consumers through health literacy

Principles	**Consumers should be empowered to participate in their care through communication measures which enhance health literacy and informed consumer decisions.**
What is it?	Health literacy describes the skill, knowledge, motivation and capacity of an individual to be able to make informed and effective decisions and actions in regard to their health.[25] Characteristics of empowering consumers through health literacy include: • providing consumers with information needed to make decisions about their care and to navigate the health system - and supporting consumers to use that information
Why is it important?	Strategies implemented to enhance these personal attributes can empower more active and effective engagement with health, improve safety and quality of care, improve equity and reduce health disadvantages.[25]

1(d) Measuring and improving consumer experience

Principles	**Pharmacy service providers should actively seek feedback on consumer experience as key indicators of health care quality.** **Pharmacy service providers should learn from consumer experience measurement and use it to drive improvement in quality and safety of care.**
What is it?	Consumers, as partners in pharmacy care, are able to provide authentic and time-critical feedback on measures of safety and quality. This feedback can avoid near-misses becoming safety incidents and help inform system improvement which reduces risks and improves service quality. Characteristics of measuring and improving consumer experience include: • asking consumers about their experiences of care and empowering consumers to provide feedback that will help improve pharmacy care • using feedback, including patient stories, to learn about and understand consumer experience and inform ongoing improvements in service design and delivery
Why is it important?	Consumer experience measures are now considered a valid clinical quality measures in health care,[8] making consumer engagement with feedback mechanisms essential.

2. Governance, leadership and culture

Including: clinical leadership, clinician involvement

Involves: integration, leadership, accountability, teamwork, culture

2(a) Commitment to safety and quality culture

Principles	**Pharmacy services should be supported by adequate resources and systems for the provision of safe, effective and sustainable pharmacy care.** **Accountability for the safety and quality of pharmacy services should be jointly shared by pharmacists, funding bodies, management and consumers.**
What is it?	A safety and quality culture describes characteristics of a health provider that does not accept behaviours or actions which put patients at risk and acknowledges the place of the patient and staff experience in their significant contribution to quality, safe care. Characteristics of this commitment to a culture of safety and quality in pharmacy services includes: • developing and implementing policies and procedures that clearly describe roles and responsibilities • providing appropriate resources for safe care, including providing adequate staffing and equipment • providing care which is financially sustainable, consistent and provides continuity of care for the consumer • leadership, teamwork and communication which promotes learning, justice and evidence-based patient-centred care[26] • recognising diversity of consumers (e.g. culture, ethnicity, sexual identity etc.) and meets consumer's individual needs for culturally safe, high-quality care
Why is it important?	To improve patient safety and quality, successful, strong leadership is vital. By creating a culture of mutual respect and trust, incidents are more consistently and accurately documented, which allows for more effective evaluation of required resourcing and improvement measures.[26]

2(b) Clinical leadership

Principles	**Pharmacists, managers and funders should champion and model quality & safety values in behaviours and decisions.** **Clinical leaders within the practice setting and wider profession should engage with pharmacists and related staff on safety and quality.** **Safety and quality performance of pharmacy services should be actively monitored and reviewed.**
What is it?	Clinical leadership describes both: • leading processes which improve the delivery of safe and high-quality health care • attributes needed to lead a health care team. Characteristics of clinical leadership in pharmacy services includes: • maintaining appropriate clinical expertise to inform program design and monitoring, including defining clinical outcomes and their measurement • facilitating access to clinical expertise required to deliver evidence-based care • leaders committed to managing clinical risks and preventing clinical incidents • active communication of patient safety issues • creating an environment in which there is transparent responsibility and accountability for maintaining standards, allowing excellence in clinical care to flourish • clarity of responsibility and delegation of authority • clinicians fully engaged in the design, monitoring and development of service delivery systems • identifying consumer needs with medical practitioners and broader inter-professional care team and working collaboratively to make a positive contribution to care
Why is it important?	Sustainable patient safety and system improvement is considered to be dependent on strong clinical leadership.[27]

3. Clinical performance and effectiveness

Including: **clinical effectiveness, clinical audit, use of information, staff management, education and training for clinical competence**

Involves: **access to evidence, clinician training/support, self-review, accountability, sharing of data/ monitoring feedback from consumers/carers**

3(a) Scope and standards

Principles	**Professional guidelines, standards, policies and procedures should guide quality and safety by describing the scope and provision of competent pharmacy services.**
What is it?	Clearly defined standards and scope in health services supports consistent delivery of care at a level recognised as safe and of acceptable quality. The application of this clinical governance principle to pharmacy services includes: • use of professional guidelines and standards to support service development • adoption of policies, procedures and systems which are consistent with national standards, recognised practice and evidence-based guidelines and practice resources • working constructively within clinical teams as appropriate
Why is it important?	Professional standards and guidelines articulate practice expectations to help ensure delivery of safe and effective care. Professional standards and guidelines can: • promote consistency of care within and between practitioners and practice settings • promote best possible health outcomes for consumers • promote adoption of safety processes in the provision of care

3(b) Evidence-based care

Principles	**Pharmacists should have access to and use evidence-based guidelines, indicators, models of care and data to inform clinical decisions.**
What is it?	Evidence-based care is the deliberate, careful use of best-available evidence to make decisions in providing health care to individual patients.28 It involves integration of high-quality research with patient values and clinical experience to provide the best possible health care to a consumer. Characteristics of evidence-based care in pharmacy services includes: • development of policies, protocols and approaches to pharmacy care using relevant internal data and recognised external evidence-based care guidelines and standards • adoption of national standards of patient care • pharmacists being provided access to evidence-based guidelines • identification and effective follow-up of clinical underperformance • patient experience information being used as a valid indicator of clinical quality • models-of-care adopted being supported by data and evidence
Why is it important?	Evidence-based care is accepted as being fundamental to any high-quality health service. Evidence-based care can: • Promote consistency of treatment • Promote best possible health outcomes for consumers • Improve efficiency in providing health care • Help set valid measures to evaluate quality of care provided.[29]

3(c) Transparency

Principles	**The clinical benefits, risks and costs of pharmacy services should be transparent to consumers and stakeholders.**
What is it?	Transparency involves the sharing of health service information such as safety incidents, consumer feedback, quality measures, or de-identified clinical data with relevant stakeholders, including consumers. Characteristics of transparency in pharmacy services includes: • sharing clinical priorities and vision of care with consumers • mutual respect between pharmacists and consumers which is free from concealment • publication of clinical measures • sharing program outcomes, practice research data and research outcomes and improvements publicly taking into account issues of privacy and consent • open disclosure of incidents to consumer and relevant stakeholders • mandatory reporting of significant/sentinel events • provision of relevant clinical information about risks and benefits to consumers which is readily understood
Why is it important?	Transparency in health services is established as leading to greater: • quality • accountability • choice • confidence of funders and consumers and • productivity and efficiency.[30] It supports more informed consumer choices and design of safer and higher-quality health services.

3(d) Education and training

Principles	**Pharmacists should be supported to maintain competence and develop professional skills to enable high performance for pharmacy services within their scope of practice.**
What is it?	Education and training within in a clinical governance framework aims to ensure pharmacists and other staff have the skills and expertise to deliver safe care. Characteristics of an education and training framework in pharmacy services includes: • identification of development needs and planning to address these needs • supporting the workforce to participate in program-specific education and training, use of practice support resources (e.g. guidelines) and credentialing processes when required
Why is it important?	Effective education and training is essential to delivery of competent, consistent, safe health care. It can also increase confidence of practitioners and more actively engage the workforce in the care they provide.

3(e) Measurement and monitoring

Principles	**Clinical measures of pharmacy services effectiveness, quality and safety should be systematically measured, monitored and reviewed by pharmacists, management and funders, including through:** • **undertaking clinical audits** • **participation in research projects** • **supervision and management of pharmacist and staff performance**
What is it?	Evaluation of pharmacy services and continuous improvement is only possible with continuous measurement and monitoring; an approach which requires relevant data to be continually collected and reviewed. Characteristics of effective measurement and monitoring of clinical aspects of pharmacy services include: • undertaking clinical audit of objectives of pharmacy services (e.g. increase in medicine compliance following adherence services) and following-up unexpected results.[31] • collection of measures such as patient feedback, pharmacist and staff feedback, activity data, audits, incident and risk information and clinical indicator data • provision of clinical data to participate in research projects • using clinical measures as an indicator of pharmacist performance (e.g. clinical interventions and impact, achievement of benchmarks) • measurement and evaluation is used to support quality improvements in the implementation and provision of care • activities which validate or improve the accuracy of data recorded and analysed
Why is it important?	Measurement and monitoring are essential to understanding and demonstrating: • safety of health services • impact of health services on a person's health • relative value of health services in achieving a desired outcome • awareness and self-improvement by clinicians in the quality of care they provide • to inform and measure improvement at an individual practice or industry level

4. Patient safety and quality improvement systems

Including: risk management, continuous quality improvement

4(a) Risk management

Principles	**Safety and quality in pharmacy services should be supported by risk management systems which have actively engaged pharmacists in their design. These systems should include:** • **policies and procedures to manage patient safety risk** • **incident management, including near misses** • **open disclosure**
What is it?	Risk management in clinical governance refers to lowering the likelihood or incidence of adverse health outcomes through use of strategies which quantify, assess and reduce risk. This is achieved by systems which identify practices that put consumers at risk of harm and take action to prevent or control those risks. Characteristics of risk management relevant within a pharmacy service's clinical governance framework include: • early identification and prevention of risk of harm through accurate, timely clinical documentation by all staff • pharmacists contributing to development and review of procedures for services they deliver (e.g. through staff engagement in a pharmacy or working groups for larger programs) to improve safety of service • using standard operating procedures to reduce the likelihood of known clinical risks and support consistent service delivery • reducing consumer risk through implementing policies which describe the scope and limitation of pharmacy services. • discussing incidents openly with patients, including contributing factors, likely outcomes, an apology and options to resolve.
Why is it important?	Risk management can: • reduce role of chance in causing harm to health • reduce loss and costs of risks (e.g. insurance premiums) • improve consumer and clinician experience of incident management

4(b) Adhere to codes, guidelines and quality systems

Principles	**Pharmacy services should demonstrate delivery consistent with relevant industry codes, guidelines, standards and relevant policies and procedures.**
What is it?	Adherence to codes, guidelines and quality systems supports clinical effectiveness and safety in describing the accepted scope and evidence supporting the service. Characteristics showing pharmacy services adhere to codes, guidelines and quality systems can include: • demonstrating pharmacy services are delivered in accordance with professional standards • monitoring adherence to standards, guidelines and codes as part of managing staff performance • demonstrating sound reasoning when making clinical judgements that a guideline or code is ambiguous or insufficient to optimise a patient outcome, and taking necessary actions to support that patient's health
Why is it important?	Demonstrating consistency with relevant codes, guidelines, standards and legal obligations promotes accountability and provides confidence to consumers, commissioning bodies and the public in quality of health services.

4(c) Continuous quality improvement

Principles	**Services should be supported by evidence-based cyclical improvement activities which support enhancements in clinical outcomes and patient safety.**
What is it?	CQI describes an approach to improving processes and outcomes through structured problem solving, participation, a focus on consumers and collaboration.[32] Characteristics of continuous quality improvement which support consumers' health include: • monitoring of practice variance identified through tools such as clinical audit (including consumer feedback and evaluation), continuous data measurement and clinical indicators to inform improvement activities • conducting quality improvement education program, quality and safety meetings (pharmacy/sector levels) • pharmacists undertaking CPD to achieve applicable competence standards (e.g. Standard 1.6 Contribute to continuous improvement in quality and safety etc.)[1] • creating a culture that supports reporting, service improvement and embeds the experience of consumers to evaluate improvement activities • application of care improvement tools in everyday care, education, quality activities and projects
Why is it important?	Continuous quality improvement is accepted as a fundamental approach to maintaining and improving safety and quality in health care services. Formalising CQI into a clinical governance framework helps focus improvement activities towards changes which directly improve health outcomes and patient experience.

5. Safe environment for delivery of care

Including: **premises, infrastructure, equipment**

Involves: **physical safety, privacy, dignity**

5(a) Environment

Principles	**Pharmacy services should only be conduced where equipment is fit-for-purpose and the environment supports safe and high-quality care that meets consumer needs.**
What is it?	The environment in which pharmacy services are provided has a significant impact on the quality and safety of the service. The environment includes the building, fittings, fixtures, services and equipment present in the location the service is provided. Characteristics of the environment necessary for pharmacy services include: • maintaining privacy and confidentiality for consumers (e.g. consultation room) • providing adequate space to conduct the pharmacy service, including adequate space for consumers and carers (e.g. adequate seating) • equipment meeting relevant international standards, Australian Standards and/or listed on ATRG (where relevant) • ensuing consumers with mobility limitations or disability can access services
Why is it important?	Safety in the physical environment where care is delivered is essential for patient safety. Good design of health care environments has been linked to:[33] • consumer access to health services • improved quality and health outcome • clinician engagement and satisfaction

5(b) Cultural safety

Principles	**Pharmacy services should be inclusive and only provided in an environment which is culturally safe and respects the cultural diversity of consumers**
What is it?	Cultural safety is a commitment that the health system will not compromise the legitimate cultural rights, values and expectations of all consumers, such as recognising those of Aboriginal and Torres Strait Islander people. It is a recognition, appreciation and response to the impact of cultural diversity on the utilisation and provision of effective clinical care.[34] Characteristics supporting provision of culturally appropriate pharmacy services can include: • providing training for pharmacists and other staff in cultural awareness and cultural safety • recognising and respecting the diversity of culture when communicating with consumers from a background different to one's own • collaboration with Aboriginal Healthcare Workers and/or cultural services to better facilitate or understand cultural needs in providing pharmacy services • understanding the influence of a patient's culture in conjunction with their medical condition(s), to improve health outcomes
Why is it important?	Consumers from different cultural backgrounds often have specific and unique health needs, which may be reflected through disparity in health indicators and burden of disease.[34] For example, Aboriginal and Torres Strait Islander people are disproportionately affected by chronic health conditions. Health professionals need to be both clinically competent and culturally responsive to positively affect health and wellbeing.

Definitions

accountability	systems by which a party takes responsibility for its activities and actions
adverse event	incident which results in, or could have resulted in, harm to a patient or consumer[2]
clinical audit	review of health care provided against predetermined criteria, often for determining performance against benchmarks and targets and driving improvement
clinical data	health related information related to a person's health and health care
clinical governance	[definition under consultation: refer Question 1]
clinical leadership	application of skills and attributes needed to inspire, motivate and lead improvement in safety and quality of health care
clinician	a health professional providing health care to a consumer, including pharmacists.
co-design	an approach to design of pharmacy services which actively involves all relevant stakeholders – including consumers, pharmacists, managers and staff
commissioning	the process of procuring health services. It involves deep understanding of a populations health needs, planning services around those needs and securing those services within available budgeting.[35]
commissioning body	an entity who procures health services
consumer	a person who uses, or could possibly use, health services.[2] For the purpose of this document, the term may also include carer(s) and/or relatives involved in the care of a person receiving care.
consumer experience	the totality of a consumer's interaction with health care, usually in the context of care provided by a health service organisation. It reflects a consumer's perception of competence, culture, integration and communication.
continuous quality improvement	an approach to improving processes and outcomes through structured problem solving, participation, a focus on consumers and collaboration[32]
culture	1. the ideas, values and behaviours demonstrated by leaders, managers and staff in an organisation 2. the ideas, customs and social behaviours of a particular group of people
cultural safety	a commitment that the health system will not compromise the legitimate cultural rights, values and expectations of a person's cultural identity, such as Aboriginal and Torres Strait Islander identity[34]
environment	the physical surroundings in which health care is delivered, including the building, fixtures, fittings and services. Environment can also include other patients, consumers, visitors and the workforce.[2]
funder	person or entity paying for a health service (e.g. consumer, government body etc.)
governance	the relationships and responsibilities between management, staff and relevant stakeholders which control and influence the provision of products and services within an organisation
health literacy	attributes of an individual, such as skill, knowledge, motivation and capacity, to be able to make informed and effective decisions and actions in regard to their health[25]
incident	an occurrence which harmed, or had the potential to harm, a person (e.g. dispensing errors, confidentiality breach, exposure to infectious disease)
indicator	a quantifiable characteristic of health, usually used as measure of performance in health care
near miss	an incident which may have caused harm, but was avoided before harm occurred (e.g. dispensing error identified prior to medicine being supplied to a consumer)
open disclosure	transparent communication with consumers about incidents which occur in the provision of pharmacy care. Open disclosure includes pharmacists and the organisation they work for being accountable for the incident to the patient and providing appropriate support in responding to the incident.
patient	see 'consumer'
patient-centric	an approach to design and delivery of pharmacy services in which the service is genuinely built around the needs and preferences of consumers
pharmacy service	a health service within the scope of pharmacy practice (e.g. dispensing, assessment of minor ailments, screening/risk assessment, pharmacist-administered vaccination, medicine adherence services, absence from work certificates etc.)
risk management	a structured approach to identification and lowering the likelihood or incidence of adverse health outcomes
system	the policies, procedures, records and approaches used to achieve a goal
transparency	In the context of this document, transparency involves the sharing of health service information such as safety incidents, consumer feedback, quality measures, or de-identified clinical data with relevant stakeholders, including consumers, without concealment

Appendices

Appendix 1: Environmental scan: Definitions for clinical governance

The following table is provided as background to the draft Clinical Governance Principles on definitions of *clinical governance* adopted by relevant organisations:

Organisation/ country	Definition	Themes
Australian Commission for Quality and Safety in Health Care[2]	Clinical governance is the set of relationships and responsibilities established by a health service organisation between its state or territory department of health (for the public sector), governing body, executive, clinicians, patients, consumers and other stakeholders to ensure good clinical outcomes. It ensures that the community and health service organisations can be confident that systems are in place to deliver safe and high-quality health care, and continuously improve services. Clinical governance is 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 health services that are safe, effective, integrated, high quality and continuously improving.	Relationships and responsibilities to ensure good care. Continuous improvement Integrated systems Accountability to patients and community.
New Zealand[8]	Clinical governance is an organisation-wide approach to the continuous quality improvement of clinical services. It is larger in scope than any single quality improvement initiative, committee or service. It involves the systematic joining-up of all patient safety and quality improvement initiatives within a health organisation. In practice, it requires clinicians to be engaged in both the clinical and management structure of their health organisation to contribute to the mission, goals and values of that organisation. It is also about managers engaging more with clinicians and enabling them to be involved.	'organisation-wide approach' Continuous improvement Integrated systems Clinician engagement
RACGP (Australia)[36]	A framework through which clinicians and health service managers are jointly accountable for patient safety and quality care.	Accountability Framework
Pharmacy Services Negotiating Committee (UK NHS)[10]	Clinical governance is a system through which healthcare providers are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish.	Accountability Continuous improvement Environment supports quality care

Appendix 2: Environmental scan: Clinical governance principles

The following principles of clinical governance were identified during environmental scanning. They are included as an appendix to the document to stimulate discussion and ideas during public consultation:

Australia: Safer Care Victoria Delivering high-quality healthcare - Victorian clinical governance framework (2017)[37]

Clinical governance is not about compliance. High-performing health services achieve great outcomes by taking actions that go beyond compliance.

Clinical governance principles	
Excellent consumer experience	• Commitment to providing a positive consumer experience every time
Clear accountability and ownership	• Accountability and ownership displayed by all staff • Compliance with legislative and departmental policy requirements
Partnering with consumers	• Consumer engagement and input is actively sought and facilitated
Effective planning and resource allocation	• Staff have access to regular training and educational resources to maintain and enhance their required skill set
Strong clinical engagement and leadership	• Ownership of care processes and outcomes is promoted and practised by all staff • Health service staff actively participate and contribute their expertise and experience
Empowered staff and consumers	• Organisational culture and systems are designed to facilitate the pursuit of safe care by all staff • Care delivery is centred on consumers
Proactively collecting and sharing critical information	• The status quo is challenged and additional information sought when clarity is required • Robust data is effectively understood and informs decision making and improvement strategies
Openness, transparency and accuracy	• Health service reporting, reviews and decision making are underpinned by transparency and accuracy
Continuous improvement of care	• Rigorous measurement of performance and progress is benchmarked and used to manage risk and drive improvement in the quality of care

New Zealand: Health Quality & Safety Commission Clinical Governance Guidance for Health and Disability Providers (2017)[8]

What are the key principles of clinical governance?

The key principles for clinical governance to be effective are:

- consumer-/patient-centred care
- open and transparent culture
- all staff actively participate (and partner) in clinical governance
- continuous quality improvement focus.

To fully realise the building and sustaining of high-quality services focused on consumers/patients, their needs and their experience of care in an environment that fosters trust and openness requires an organisation-wide commitment. That commitment needs to engage all staff (Ministerial Task Group on Clinical Leadership 2009).

Australia: RACGP Principles for Clinical Governance[36]

Clinical governance is a 'system through which organisations are responsible for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'.

The elements of clinical governance commonly include:

- education – basic and ongoing
- clinical audit
- clinical effectiveness – evidence based practice
- risk management – clinical and general
- research and development
- openness.

Canada: Canadian Patient Safety Institute[38]

Drivers of effective governance for quality & patient safety:

- Skills and Role
- Knowledge
- Measurement
- Information
- Relationships
- Quality and Safety Plan
- Quality and Patient Safety Culture
- Effective Governance

Appendix 3: Example application of clinical governance principles to existing services

To aid understanding, the following table provides an illustration of how existing pharmacy services might compare against the clinical governance principles. Level of achievement of the principles is subjectively indicated by the likert-type gradient scale below.

As this is purely subjective and generalised across wide variation of services without a formal assessment, this should not be taken to represent an accurate or comprehensive, evidence-based evaluation. It should not be considered to represent the opinion of PSA or the Department of Health.

Principle not being achieved **Principle fully achieved**

Clinical governance principle		Status	Comment
1. Partnering with consumers			
Co-design	Consumers are actively engaged in the planning and design of the services and care they receive. Health consumers, their carers and pharmacists should be partners in the co-design of pharmacy services.		Consumers increasingly inform service-design at system-level for new services. Mechanisms to inform delivery at individual practice level needed. Informal feedback likely considered by some managers in service design.
Patient-centric	Service design & delivery considers and supports consumer participation. Pharmacy services should be patient-centric and designed around the health needs and preferences of individual consumers. Consumers should be empowered to actively participate in decisions about their care.		Mechanisms to engage consumers identifying individual needs and preferences of some services needed. Use of medication management apps (e.g. prescription reminder, online order) increasing consumer-focus of services. MyHealthRecord has potential to empower consumer involvement in service and decisions
Empowering consumers through health literacy	Consumers should be empowered to participate in their care through communication measures which enhance health literacy and informed consumer decisions.		Health literacy is being increasingly considered in development of new services, but absent in some. Improved readability of consumer medicines information needed. Greater implementation of standards that focus on health literacy required to achieve principle (e.g. ACSQHC standards, guidelines and tools).
Measuring and improving consumer experience	Pharmacy service providers should actively seek feedback on consumer experience as key indicators of health care quality. Pharmacy service providers should learn from consumer experience measurement and use it to drive improvement in quality and safety of care.		Some tools exist, (e.g. patient experience surveys, business support tools, banner group online feedback tools) however there is an opportunity for greater consistency and sample sizes in use of these tools. Need greater recognition of how consumer/patient experience can inform improvements in pharmacy services, and mechanisms to support this. Often perceived as a customer business metric, not a clinical measure.
2. Governance, leadership and culture			
Commitment to safety and quality culture	Pharmacy services should be supported by adequate resources and systems for the provision of safe, effective and sustainable pharmacy care. Accountability for the safety and quality of pharmacy services should be jointly shared by pharmacists, funding bodies, management and consumers.		Personnel resources generally adequate for pharmacist care, although this is difficult to quantify and be accountable to. Anecdotal reports of reduced remuneration for dispensed medicines leading to increased and possibly unsafe workloads
Clinical leadership	Pharmacists, managers and funders should champion and model quality & safety values in behaviours and decisions. Clinical leaders within the practice setting and wider profession should engage with pharmacists and related staff on safety and quality. Safety and quality performance of pharmacy services should be actively monitored and reviewed.		Community pharmacy services often occurs in isolated practice environments. Variable access to clinical leadership focussing on safety and quality at a pharmacy-level. Funding mechanisms which support and champion clinical leadership and culture needed.

Clinical governance principle		Status	Comment
3. Clinical performance and effectiveness			
Scope and standards	Professional guidelines, standards, policies and procedures should guide quality and safety by describing the scope and provision of competent pharmacy services.		Extensive guidelines and resources available from professional bodies, regulators and accreditation programs.
Evidence-based care	Pharmacists should have access to and use evidence-based guidelines, indicators and data to inform clinical decisions.		Nationally standardised indicators and/or data related to clinical performance and effectiveness of pharmacy services not currently available or measured. MyHealthRecord provides opportunity to support evidence-based care through access to clinical information.
Transparency	The clinical benefits, risks and costs of pharmacy services should be transparent to consumers and stakeholders.		Some data collection which demonstrate value (eg. outcomes of clinical interventions) are not quantified or reviewed with respect to informing quality improvement. Costs of services could be more transparent for consumers.
Education and training	Pharmacists should be supported to maintain competence and develop professional skills to enable high performance for pharmacy services within their scope of practice.		Requirement for annual CPD plans for pharmacists exists, with strong commitment to clinical knowledge. Opportunity to enhance communication skills and knowledge particularly regarding health literacy and communication with culturally and linguistically diverse people.
Measurement and monitoring	Clinical measures of pharmacy services effectiveness, quality and safety should be systematically measured, monitored and reviewed by pharmacists, management and funders, including through: • undertaking clinical audits • participation in research projects • supervision and management of pharmacist and staff performance.		The opportunity to learn from clinical audits and participation in research of 'fundamental' services could be explored (e.g. for dispensing, over-the-counter advice and management). Development of nationally standardised evidence-based quality indicators (e.g. barcode scan rates) or clinical indicators (e.g. clinical intervention significance) that monitor effectiveness of safety or quality needed. Measurement of performance in safety and effectiveness of services and activities to inform quality improvement exists in some pharmacies, but support needed to enable this to be expected practice for all services. Such as near miss/error reporting review and management with dispensing.
4. Patient safety and quality improvement systems			
Risk management	Safety and quality in pharmacy services should be supported by risk management systems which have actively engaged pharmacists in their design. These systems should include: • policies and procedures to manage patient safety risk • incident management, including near misses • open disclosure.		Systems for recording clinical incidents exist at a practice level, however incident recording systems inconsistently applied, such as capture & review of dispensing near misses or errors. Currently a paucity of system-level incident data. No central reporting and review of incidents. Open disclosure encouraged by professional indemnity insurers.
Adhere to codes, guidelines and quality systems	Pharmacy services should demonstrate delivery consistent with relevant industry codes, guidelines, standards and relevant policies and procedures.		Professional codes, standards, guidelines exist, but there is no mechanism for assessing and providing recognition to practitioners demonstrating a high-level and consistent adherence to codes, standards and guidelines. Some accreditation programs available which verify procedures exist and that staff have been trained.
Continuous quality improvement	Services should be supported by evidence-based cyclical improvement activities which support enhancements in clinical outcomes and patient safety.		Nationally standardised set of measures or indicators needed in order to implement a formal CQI activity. Informal responses to incidents do occur and can improve local practices.

Clinical governance principle		Status	Comment
5. Safe environment for delivery of care			
Environment	Pharmacy services should only be conducted where equipment is fit-for-purpose and the environment supports safe and high-quality care that meets consumer needs.		The minimum requirements for pharmacy premises are articulated by state government and pharmacy authorities. Profession increasingly aware of the need for confidential counselling areas or rooms, but these are not universally available or used appropriately. Seating availability in some pharmacies inadequate for consumer needs.
Cultural safety	Pharmacy services should be inclusive and only provided in an environment which is culturally safe and respects the cultural diversity of consumers.		Difficult to quantify. Anecdotal reports suggest some Aboriginal and Torres Strait Islander people often do not see community pharmacies as culturally safe. Low uptake of PBS translation services. Supporting uptake of cultural competence training and measuring consumer/patient experience would improve identification and recognition of cultural needs of individuals and groups.

Appendix 4: Public consultation questions

Definition of clinical governance

Many definitions of clinical governance were reviewed through the development of this 'Clinical Governance Principles for Pharmacy Services' consultation draft. PSA proposes to adopt either the definition of clinical governance from the Competency Standards, or alternatively, using the definition adopted by the ACSQHC in a full or abridged form:

Competency Standards Framework for Pharmacists in Australia[1] defines clinical governance as:

> *A framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.*

OR

Full ACSQHC definition:

> '*the set of relationships and responsibilities established by a health service organisation between its state or territory department of health, governing body, executive, workforce, patients, consumers and other stakeholders to ensure good clinical outcomes.* [2]

OR

Abridged ACSQHC definition:

> Clinical governance describes the set of relationships and responsibilities established within a health service organisation which is accountable for the delivery of safe, effective and high-quality health services.[2]

1. Which proposed definition of clinical governance do you support for use in this document? If none are supported, what is a more appropriate definition for use in this document?

Clinical governance principles

The document describes clinical governance principles relevant to the provision of pharmacy services, which are summarised on page 8–9.

2. Do these principles appropriately describe the approach to clinical governance which should be adopted in all pharmacy services? If not, what changes do you suggest to achieve this?

In responding to Question 2, you may wish to provide comment on these principles:

- Gaps or duplication which you identify within the clinical governance principles;
- Principles which do not consider to be appropriate for application to pharmacy services

3. Would adoption of these clinical governance principles provide you with greater confidence in the quality and safety of pharmacy services you provide, access or commission?

Descriptors of clinical governance principles

4. For each element of clinical governance principles, please provide feedback on any gaps, duplication or improvements you have identified (see below tables).

Partnering with consumers	Yes/ No/ Partially	Comments
Are all aspects of this principle adequately described in the document?		
Is the application of the principle to pharmacy practice clear and easy to understand?		

Governance, leadership and culture	Yes/ No/ Partially	Comments
Are all aspects of this principle adequately described in the document?		
Is the application of the principle to pharmacy practice clear and easy to understand?		

Clinical performance and effectiveness	Yes/ No/ Partially	Comments
Are all aspects of this principle adequately described in the document?		
Is the application of the principle to pharmacy practice clear and easy to understand?		

Patient safety and quality improvement systems	Yes/ No/ Partially	Comments
Are all aspects of this principle adequately described in the document?		
Is the application of the principle to pharmacy practice clear and easy to understand?		

Environment	Yes/ No/ Partially	Comments
Are all aspects of this principle adequately described in the document?		
Is the application of the principle to pharmacy practice clear and easy to understand?		

Application to pharmacy practice

Specificity

This document has been developed with the intent that the clinical governance principles can be applicable to any pharmacy service. This includes services described in the Professional Practice Standards (e.g. dispensing, assessment of minor ailments, screening/risk assessment, pharmacist vaccination etc.), other pharmacy services being provided, as well as being applicable to future pharmacy services.

5. **Are the clinical governance principles applicable to the provision of existing and potential pharmacy services?**

   Are they too specific, or not able to be applied to a specific pharmacy service(s)?

   If so, how could this be addressed?

'Principle 3(e) Monitoring and measurement' relates to both the act of collecting, categorising and quantifying information (measurement), and the active review or evaluation of that information (monitoring):

Clinical measures of pharmacy services effectiveness, quality and safety should be systematically measured, monitored and reviewed by pharmacists, management and funders, including through:

- undertaking clinical audits
- participation in research projects
- supervision and management of pharmacist and staff performance

6. **Does Clinical Governance Principle 3(e) adequately cover both 'measurement' and 'monitoring'? If not, which of the following is preferable:**

   (a) rename the principles 'monitoring'

   (b) rename the principle 'monitoring' and create a new principle for 'measurement'

   (c) make a change not described above? (please describe)

Suitability

The Clinical Governance Principles for Pharmacy Services have been developed with the goal of guiding an approach for clinical governance in the development of and delivery of pharmacy services. This may include clinical governance from an individual pharmacy level through to large scale programs offered nationally.

7. **Are these principles appropriate for all pharmacy services? If not, how could the principles be amended?**

Clinical governance is a concept not routinely used in the provision of pharmacy services outside of hospitals. It is intended that this document is understood by a wide audience, including pharmacists, managers and pharmacy staff.

8. **What suggestions could make this document easier for pharmacists, managers and pharmacy staff to understand and apply? How could this be achieved?**

Other

9. **Do you have any other comments regarding the Clinical Governance Principles for Pharmacy Services?**

Submission of feedback

Feedback is welcomed in any format it is provided, although electronic submission of feedback using the template provided is preferred.

Please provide feedback to **policygrp@psa.org.au** by close of business on Friday 28 September 2018.

More information

If you wish to discuss this project in more detail, please contact;

- **policygrp@psa.org.au**
- (02) 6283 4777

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