



# Clinical Governance Principles for Pharmacy Services 2018

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## 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.<sup>1</sup>

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.<sup>2,3</sup>

However the objectives of the NMP are difficult to measure. While the Review of Pharmacy Remuneration and Regulation<sup>4</sup> aimed to determine how the community pharmacy sector supports the objectives of the NMP, submissions to the review noted the lack of published standard measures for assessing performance, or measuring quality in relation to the policy. Similarly, services provided specifically by pharmacists in hospitals, general practice, aged care and other practice environments lack clear measures of quality.

Some mechanisms to support quality pharmacy practice already exist, for example:

- **National Competency Standards Framework for Pharmacists in Australia**<sup>5</sup> requires pharmacists to 'understand and contribute to organisational/corporate and clinical governance' (Standard 4.7.1).
- **National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017**<sup>6</sup> makes explicit reference to PSA's Professional Practice Standards and Code of Ethics as part of the requirements for quality practice in PBS approved pharmacies.
- **Quality assurance programs** exist within the community and hospital pharmacy sectors, and recognise whether the respective quality assurance standard is being achieved within a specific certified practice.

With an estimated 230,000 medication-related admissions to hospital annually at a cost of \$1.2 billion<sup>7</sup> more must be done to monitor, evaluate and support health programs and services aiming to improve the quality use of medicines in Australia, to help ensure they are appropriate, efficient and effective. As medication experts, pharmacists play a pivotal role in helping achieve this.

**Dr Shane Jackson**  
*PSA National President*

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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 30,000 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.





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## 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.

Australia is widely regarded as having a health system which is predominantly safe and supports good clinical outcomes through the provision of high-quality care. However, unwarranted variation in care and health outcomes exist.<sup>1</sup>

Annually, an estimated 230,000 medication-related admissions to hospital occur at a cost of \$1.2 billion.<sup>2</sup> As medication experts, pharmacists play a pivotal role supporting the appropriate, efficient and effective use of medicines, the most common health intervention.

To achieve reduction in medicine misadventure and maximise health benefits to consumers, services pharmacists provide must be safe and of high clinical quality.

Clinical governance is a concept which has been recognised as a way of achieving and improving safety, quality and effectiveness in the provision of health care.

The Competency Standards for Pharmacists describe an expectation that all pharmacists understand and contribute to organisational/corporate and clinical governance.<sup>3</sup> While all pharmacy services contain a degree of quality management and governance, the formal application of clinical governance to services led by pharmacists is highly varied.

This document considers clinical governance concepts to provide pharmacists and organisations involved in the provision of pharmacy services with guiding principles for the design, implementation and ongoing evaluation of pharmacy services.

The principles can ideally be used by service designers, organisations, and individual pharmacists to help plan new pharmacy services, or reflect on opportunities to enhance aspects of clinical governance to improve the quality of patient care for existing pharmacy services.





## About this document

This document describes principles of clinical governance required to provide confidence in the safety and quality of clinical care provided to consumers by pharmacists. It recognises the approach to clinical governance described by the Australian Commission on Safety and Quality in Health Care (ACSQHC)<sup>4</sup> and contextualises this approach to pharmacist-led services through a series of principles.

The principles serve as goals for the pharmacy profession to continuously work towards, and reflect on to demonstrate and enhance the quality of care provided by pharmacists to patients and consumers throughout Australia.

**The clinical governance principles described in this document are not auditable standards, nor are they specific to a particular pharmacy service or practice setting.**

The clinical governance principles are supported by the Professional Standards for Pharmacists<sup>5</sup> which:

- articulate qualitative practice standards for the provision of specific services delivered or supervised by pharmacists
- describe a framework for clinical care to which pharmacists are accountable
- support workforce development through self-reflection.

### Using this document

It is intended that these principles will support the design, delivery, management and review of pharmacist-led services to enhance safety and quality through governance, accountability and transparency.

## Relationship and role of other documents supporting pharmacy practice

Hierarchy of guidance and regulation of pharmacy practice:



### A. Legislation – Commonwealth, state and territory

The legal framework governing pharmacy practice.

### B. Registration standards, codes and guidelines

Pharmacy Board of Australia registration standards define the requirements which must be met to be registered as a pharmacist in Australia.<sup>6</sup>

Codes and guidelines approved by the Board may be used as evidence of what constitutes appropriate professional conduct or practice for pharmacists.

### C. Codes of ethics / Codes of conduct

Articulate the values of the pharmacy profession and expected standards of ethical behaviour of pharmacists towards individuals, the community and society.<sup>7</sup>

### D. Competency standards

These describe the skills, attitudes and other attributes (including values and beliefs) attained by an individual based on knowledge and experience which together enable the individual to practise effectively as a pharmacist.<sup>3</sup>

### E. Professional practice / quality standards

Professional practice standards (or quality standards) relate to the systems, procedures and information used by pharmacists to achieve a level of conformity and uniformity in their practice.<sup>3</sup>

Quality standards may be applicable to individuals (e.g. Professional Practice Standards<sup>5</sup>; Standards of Practice for hospital pharmacists<sup>8</sup>) or to organisations (e.g. Australian Standard 85000:2017 Quality Care Pharmacy Standard<sup>9</sup>; National Safety and Quality Health Service Standards<sup>10</sup>).

### F. Professional guidelines

Guidelines are generally service specific or activity specific, and provide information on how best to deliver services consistent with expected professional standards.





# Describing clinical governance

## Definitions

This document recognises the Australian Commission on Safety and Quality in Health Care's (ACSQHC's) definition of clinical governance:

*'an integrated component of corporate governance of health service organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services. Clinical governance systems provide confidence to the community and the healthcare organisation that systems are in place to deliver safe and high-quality health care.'*<sup>10</sup>

Other definitions of clinical governance exist in Australia and internationally. All definitions of clinical governance focus on using accountability to foster and achieve safety and high-quality health care.

In the context of Australian pharmacy practice, clinical governance may be used to describe:

- governance arrangements within a community pharmacy, pharmacy department or other pharmacy business to ensure clinical accountability of pharmacists and management
- relationships between pharmacists, clinicians and a clinical governance unit and/or leaders within a hospital
- partnerships between pharmacies and commissioning bodies (such as Primary Health Networks (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).

For the purposes of this document, a **pharmacy service** is defined as; any service provided or activity undertaken within a pharmacist's scope of practice and includes health services delivered or supervised by a pharmacist<sup>5</sup>.

This could include services such as, but not limited to, dispensing prescribed medicines, assessment of minor ailments, screening/ risk assessment, pharmacist prescribing, comprehensive medication review, preparation of complex compounded products, drug information service, hospital pharmacy inpatient clinical review service, pharmacist-administered vaccinations, medicine adherence services, and absence from work certificates.

Good clinical governance is primarily achieved through system design which enhances collective responsibility and accountability of health professionals and organisations who provide health care.<sup>11</sup>

## Global evolution of clinical governance

The integration of clinical governance principles in the provision of health care varies globally. The World Health Organization formally identified the need for a coordinated approach to quality assurance activities in health care delivery systems in 1983.<sup>12</sup> 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".<sup>13</sup>

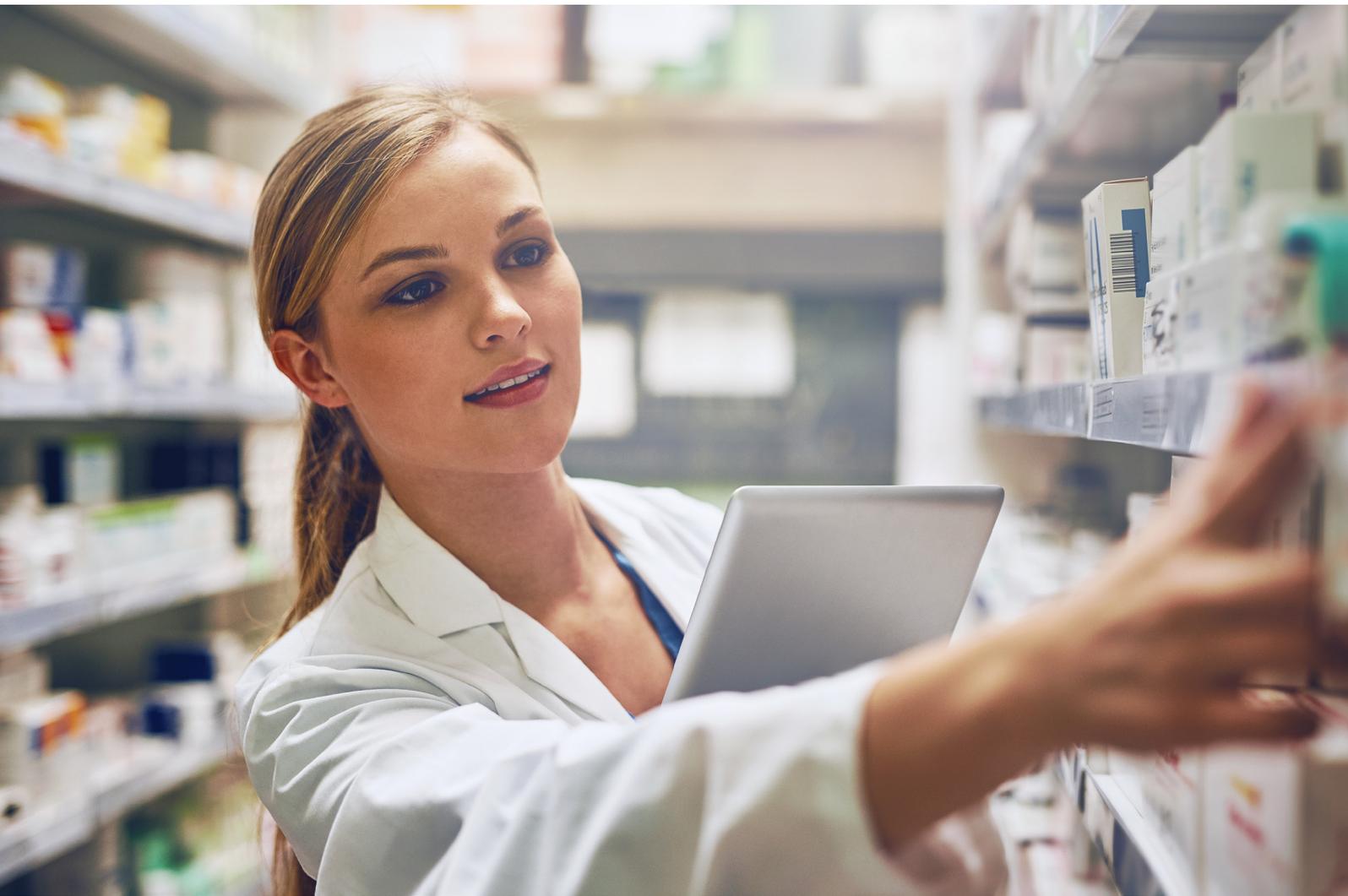
Clinical governance has been approached differently across the different health systems globally. In countries with a 'single-payer' model of care, a 'top-down' clinical governance approach has progressively applied. This involves developing systems and performance targets at an all-of-industry level, and mandating their adoption and ongoing use. Top-down approaches usually have a strong focus on accountability and standardisation.<sup>14</sup>

In other countries or health systems, a 'bottom-up' approach to clinical governance has generally adopted a more practice-based, and values-driven approach which focuses more on effective teamwork, particularly in relation to clinician input. This approach is generally accepted as having greater flexibility and support of health professionals.



Examples of leading clinical governance approaches adopted internationally include:

Country	Clinical governance framework
<b>New Zealand</b>	The New Zealand Health Quality & Safety Commission has produced a framework <sup>15</sup> for clinical governance for health providers, which supports district health boards (DHBs) and primary care organisations. Research by the New Zealand Treasury <sup>16</sup> has recognised quality improvement programs with effective clinical governance are able to achieve quantifiable savings and efficiency gains in the provision of health care.
<b>United Kingdom</b>	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: <ul style="list-style-type: none"><li>• undertaking annual clinical audits and consumer engagement to promote quality improvement over time</li><li>• participation in open disclosure of adverse events, including near misses</li><li>• consumer partnerships, including publication of patient feedback.<sup>17</sup></li></ul>
<b>Canada</b>	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.
<b>United States of America</b>	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. <sup>18</sup>

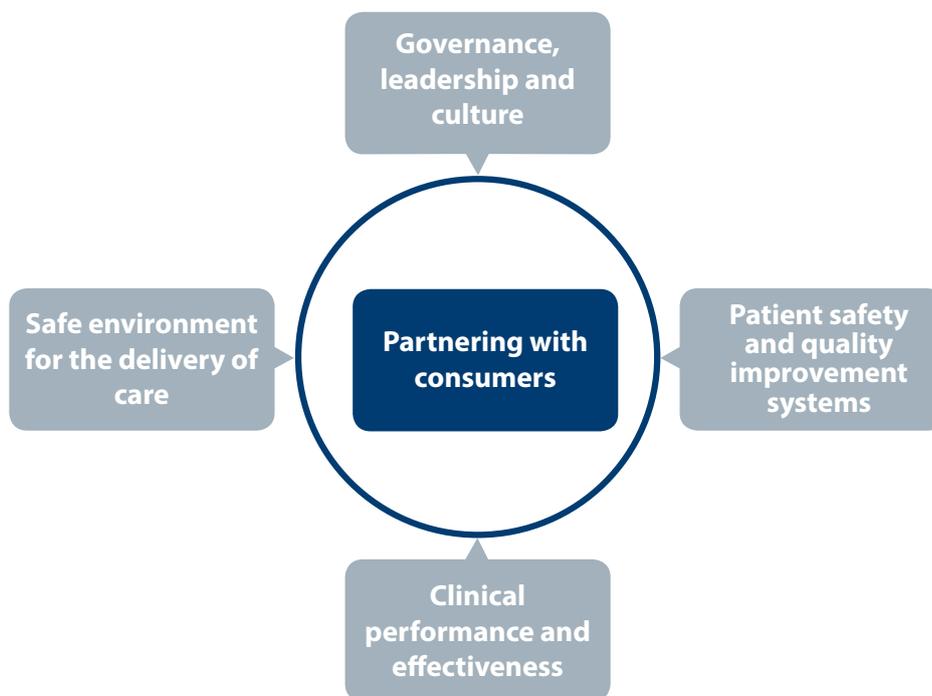


# Clinical governance in the Australian health system

## ACSQHC National Model of Clinical Governance Framework

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.

The National Model of Clinical Governance Framework published by the ACSQHC in 2017<sup>4</sup> 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** Adapted from *National Clinical Governance Framework*<sup>4</sup>

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.

Clinical governance is one component of organisational or 'corporate governance' of health care, which also includes the governance of financial, risk, human resources and legal factors.

### Clinical governance in Australia

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

Most state and territory governments have incorporated clinical governance bodies within health departments and services. These are supported through ACSQHC's initiatives such as the National Safety and Quality Health Services (NSQHS) Standards, and the National Model Clinical Governance Framework.<sup>4</sup> These initiatives provide criteria for health service organisations to develop their own clinical governance systems, but are not

prescriptive on the structures that the individual organisations develop and implement.

Governments, PHNs, health insurers and other bodies that commission health services increasingly require robust clinical governance frameworks within the services they fund. This is to provide reassurance of clinical safety, and support demonstration of cost-effectiveness of the service. Examples within Australia 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 develop responses; and build capacity within the system to identify and respond to risks and opportunities.<sup>19</sup>
- The Victorian Agency for Health Information was established 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.<sup>20</sup>



- The Australian Government’s Commonwealth Home Support Program<sup>21</sup> provides funding to service providers within a clinical governance framework. These providers 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.

Example applications of clinical governance frameworks within the Australian health system:

Health service sectors	Clinical governance framework
<b>Hospitals</b>	Implementation of an effective clinical governance framework is required to achieve accreditation under the ACSQHC National Safety and Quality Health Service Standards (NSQHS), which is mandatory for all Australian hospitals and day surgery facilities. <sup>10</sup> 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.
<b>Commissioning bodies (e.g. PHNs)</b>	Commissioning bodies are responsible for defining clinical governance needs by defining safety requirements, monitoring processes and outcomes of commissioned services. <sup>22</sup> 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. <sup>22</sup>
<b>General practice</b>	Accreditation standards for general practice <sup>23</sup> include requirements for clinical governance which are aligned with the NSQHS. These include clinical risk management, incident management and improvement systems. Accreditation is incentivised through access to Practice Incentive Payments (PIPs). <sup>24</sup>
<b>Community pharmacy</b>	The majority of community pharmacies are accredited against AS85000 Quality Care Community Pharmacy Standard which contains some elements of clinical governance, including risk management and staff management. Accreditation is an eligibility prerequisite for certain 6CPA funded medication adherence programs (e.g. staged supply). <sup>25</sup>
<b>Aboriginal Community Controlled Health Services (ACCHS)</b>	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 ACCHS. <sup>26</sup>
<b>Other health service organisations</b>	Some dental practices choose to be accredited against the NSQHS, which includes a clinical governance standard. <sup>27</sup>

The formal application of clinical governance to pharmacy practice in Australia is largely limited to practice settings which are required to meet defined standards of accreditation, such as hospital, aged care, general practices and Aboriginal and Torres Strait Islander health service environments.

While pharmacists may be practising in such settings under existing standards, this document describes principles to guide the clinical governance of **all** pharmacy services in Australia. Through describing what is generally recognised internationally as the requirements of ‘good clinical governance’ specifically in a pharmacy context, individual pharmacists, pharmacy managers and leaders can be guided to identify areas where pharmacy service development or implementation can be improved in an on-going process. 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.

The above examples demonstrate there are multiple approaches which can be taken to achieving good clinical governance. For example, accreditation programs which certify organisations against specific standards can go some or all of the way to demonstrating achievement of the principles described in this document. Similarly, use of clinical leaders, remuneration, contractual requirements, regulation, system design, or other compliance mechanisms can also be used to drive achievement of these principles.





## Why is clinical governance important for 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.<sup>28</sup> 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.<sup>28,29</sup>

Pharmacy services capture many aspects of clinical governance. However, without a deliberate process for incorporating clinical governance into the design and delivery of these, a service

cannot be certain whether potential improvements in care can be made, and where these may lie. 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.





## Relationship of pharmacy services clinical governance to stakeholders

Clinical governance is a shared responsibility that ensures everyone from frontline pharmacists and staff, to managers, owners and leaders share the common goal of delivering care that is safe and effective, of a high quality, and continually seeks to improve.

The following table provides an illustration of some of the responsibilities and benefits of clinical governance, which are usually dependent on each other. For instance, an organisational culture that supports open disclosure of errors and near-misses for the purpose of learning and improvement, enables individuals to report openly and learn from mistakes without fear of retribution.

	Responsibilities	Benefits of clinical governance
<b>Pharmacists</b>	<ul style="list-style-type: none"> <li>• Provide safe and high-quality professional practice in the care of patients and consumers</li> <li>• Contribute to planning and development activities</li> <li>• Uphold pharmacist standards, codes and guidelines applicable to their scope of practice</li> <li>• Adhere to organisational policies, procedures and systems</li> <li>• Specifically ask about and consider the individual needs of each patient/consumer</li> <li>• Identify and act on opportunities for improvement, in the provision of care and personal professional development</li> <li>• Regularly review clinical outcomes of patients, and identify opportunities to improve care</li> </ul>	<ul style="list-style-type: none"> <li>• Increased ability to demonstrate value of clinical care through measurement and monitoring</li> <li>• Increased professional satisfaction through improved clinical outcomes</li> <li>• Support to focus care on activities which provide the greatest impact on clinical outcomes</li> <li>• Enhanced safety and clinical outcome of patients under their care</li> </ul>
<b>Health service organisations (e.g. community pharmacy, hospital, independent contractors)</b>	<ul style="list-style-type: none"> <li>• Establish, oversee and manage organisational clinical governance systems</li> <li>• Ensure a safe and appropriate environment for the delivery of care</li> <li>• Appropriately delegate responsibilities to the workforce</li> <li>• Monitor clinical performance of care provided by organisations, providing feedback to clinicians on opportunities to improve care, and/or reduce safety risks</li> <li>• Actively communicate the commitment to delivery of safe, high-quality care</li> <li>• Create and support education opportunities for the workforce, particularly in areas of quality and safety</li> <li>• Allocate appropriate resources to the delivery of quality care, and regularly review services and respond to identified concerns</li> <li>• Identify, understand and minimise barriers for consumers to use the services provided</li> <li>• Collect, review and act upon consumer experience</li> </ul>	<ul style="list-style-type: none"> <li>• Improved clinical outcomes for patients and consumers being provided care by the organisation</li> <li>• Better ability to demonstrate safety, quality and efficiency outcomes of pharmacy services to funders and consumers</li> </ul>
<b>Consumers</b>	<ul style="list-style-type: none"> <li>• Being an active participant in their health care, to the extent they wish to be involved</li> <li>• Provide feedback, complaints and compliments, including sharing experiences</li> </ul>	<ul style="list-style-type: none"> <li>• Improved safety in the health care received</li> <li>• Improved clinical outcome from pharmacist-led services</li> <li>• Pharmacy care provided in a more patient-centric manner</li> <li>• Confidence pharmacy services are evidence-based with regard to safety and clinical benefits</li> </ul>
<b>Other health professionals</b>	<ul style="list-style-type: none"> <li>• Recognise and respect role of clinical governance frameworks in supporting safety and quality in pharmacy services</li> <li>• Partner with pharmacists and consumers to support the provision of patient-centred, collaborative care</li> </ul>	<ul style="list-style-type: none"> <li>• Confidence in the safety and quality of services provided by pharmacists</li> <li>• Improved understanding of safety and quality of services led by pharmacists</li> <li>• Enhanced safety and clinical outcome of patients under their shared care</li> </ul>
<b>Funding bodies</b>	<ul style="list-style-type: none"> <li>• Communicate commitment to safe, high-quality care</li> <li>• Establish minimum requirements for safety and quality of funded services</li> <li>• Monitor and respond to system-level performance indicators</li> <li>• Recognise and incentivise effective, quality care that improves clinical outcomes</li> </ul>	<ul style="list-style-type: none"> <li>• Assurance of safety, efficacy and quality of services funded</li> <li>• Greater ability to compare safety, quality, and efficiency outcomes of funded health interventions and services</li> </ul>





# Principles of Clinical Governance for Pharmacy Services

The National Clinical Governance Framework<sup>4</sup> 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		
1(a)	<b>Co-design</b>	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.
1(b)	<b>Patient-centric</b>	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.
1(c)	<b>Empowering consumers through health literacy</b>	Consumers should be empowered to participate in their care through communication measures which enhance health literacy and support informed decision-making.
1(d)	<b>Measuring and improving consumer experience</b>	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		
2(a)	<b>Commitment to safety and quality culture</b>	Pharmacy services should be supported by adequate resources and systems for the provision of safe, effective and sustainable pharmacy care, consistent with relevant evidence. Accountability for the safety and quality of pharmacy services should be jointly shared by pharmacists, funding bodies, management and consumers.
2(b)	<b>Clinical leadership</b>	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

3(a)	<b>Scope and standards</b>	Professional guidelines, standards, policies and procedures should guide quality and safety by describing the scope and provision of competent pharmacy services.
3(b)	<b>Evidence-based care</b>	Pharmacists should have access to and use appropriate evidence-based guidance, indicators, models-of-care, and data to inform clinical decisions.
3(c)	<b>Transparency</b>	The clinical benefits, risks and costs of pharmacy services should be transparent to consumers and stakeholders.
3(d)	<b>Education and training</b>	Pharmacists should be supported to maintain competence and develop professional skills to enable high performance for pharmacy services within their scope of practice.
3(e)	<b>Measurement and monitoring</b>	Clinical measures of pharmacy service effectiveness, quality and safety should be systematically measured, monitored and reviewed by pharmacists, management and funders, including through: <ul style="list-style-type: none"> <li>• undertaking clinical audits</li> <li>• participation in research projects</li> <li>• supervision and management of pharmacist and staff performance.</li> </ul>

### 4. Patient safety and quality improvement systems

4(a)	<b>Risk management</b>	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: <ul style="list-style-type: none"> <li>• policies and procedures to manage and minimise risk of patient harm</li> <li>• incident management, including near misses</li> <li>• open disclosure.</li> </ul>
4(b)	<b>Adhere to codes, guidelines and quality systems</b>	Pharmacy services should demonstrate delivery consistent with relevant industry codes, guidelines, standards and relevant policies and procedures.
4(c)	<b>Continuous quality Improvement (CQI)</b>	Services should be supported by evidence-based, ongoing, and cyclical improvement activities which support enhancements in clinical outcomes and patient safety.

### 5. Safe environment for delivery of care

5(a)	<b>Environment</b>	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.
5(b)	<b>Cultural safety</b>	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 described in 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

<b>Principles</b>	<b>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.</b>
<b>What is it?</b>	<p>Co-design describes an approach to developing services where consumers and clinicians are actively engaged in the 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.</p> <p>Co-design uses techniques such as prototyping, storyboards, process maps and process control to help craft more patient-centric services.<sup>30</sup></p> <p>In pharmacy services, characteristics of co-design can include:</p> <ul style="list-style-type: none"><li>• asking consumers to describe their health goals and needs, and necessities of pharmacy services</li><li>• consumers and clinicians (including pharmacists) collaborating to design services which spend more time on clinical activities and less time on administrative activities.</li></ul>
<b>Why is it important?</b>	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

<b>Principles</b>	<b>Service design &amp; delivery considers and supports consumer participation.</b> <b>Pharmacy services should be patient-centric and designed around the health needs and preferences of individual consumers.</b> <b>Consumers should be empowered to actively participate in decisions about their care.</b>
<b>What is it?</b>	<p>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.</p> <p>Characteristics of patient-centred care include:</p> <ul style="list-style-type: none"><li>• actively engaging consumers in the design and delivery of pharmacy services</li><li>• designing services to support ideal patient journey as primary priority rather than primarily for efficiency or structure of a pharmacy, pharmacy organisational unit (e.g. hospital) or dispensary</li><li>• identifying consumer and population needs and expectations providing care in a manner which reduces stigma of illness/condition and is non-judgemental</li><li>• 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</li><li>• 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</li><li>• respecting requirements for privacy and confidentiality</li><li>• actively engaging consumers, and their carers, in decisions about their care</li><li>• monitoring changing or evolving patient needs and adapting services in anticipation or response (e.g. mental health).</li></ul>
<b>Why is it important?</b>	The benefits of patient-centred care are well documented <sup>31</sup> 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 and clinician and patient satisfaction increases.



## 1(c) Empowering consumers through health literacy

<b>Principles</b>	<b>Consumers should be empowered to participate in their care through communication measures which enhance health literacy and informed consumer decisions.</b>
<b>What is it?</b>	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. <sup>32</sup>  Characteristics of empowering consumers through health literacy include: <ul style="list-style-type: none"><li>• providing consumers with information needed to make decisions about their care and to navigate the health system - and supporting consumers to use that information</li></ul>
<b>Why is it important?</b>	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. <sup>32</sup>

## 1(d) Measuring and improving consumer experience

<b>Principles</b>	<b>Pharmacy service providers should actively seek feedback on consumer experience as key indicators of health care quality.</b>  <b>Pharmacy service providers should learn from consumer experience measurement and use it to drive improvement in quality and safety of care.</b>
<b>What is it?</b>	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: <ul style="list-style-type: none"><li>• asking consumers about their experiences of care and empowering consumers to provide feedback that will help improve pharmacy care</li><li>• using feedback, including patient stories, to learn about and understand consumer experience, and inform ongoing improvements in service design and delivery.</li></ul>
<b>Why is it important?</b>	Consumer experience measures are now considered valid clinical quality measures in health care, making consumer engagement with feedback mechanisms essential. <sup>15</sup>





## 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 consistent with relevant evidence.

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 include:

- 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<sup>33</sup>
- recognising diversity of consumers (e.g. culture, ethnicity, sexual identity) and meeting 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.<sup>33</sup>

### 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.<sup>34</sup>



### 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

<b>Principles</b>	<b>Professional guidelines, standards, policies and procedures should guide quality and safety by describing the scope and provision of competent pharmacy services.</b>
<b>What is it?</b>	<p>Clearly defined standards and scope in health services supports consistent delivery of care at a level recognised as safe and of acceptable quality.</p> <p>The application of this clinical governance principle to pharmacy services includes:</p> <ul style="list-style-type: none"><li>• use of professional guidelines and standards to support service development</li><li>• adoption of policies, procedures and systems which are consistent with national standards, recognised practice and evidence-based guidelines and practice resources</li><li>• working constructively within clinical teams as appropriate.</li></ul>
<b>Why is it important?</b>	<p>Professional standards and guidelines articulate practice expectations to help ensure delivery of safe and effective care.</p> <p>Professional standards and guidelines can:</p> <ul style="list-style-type: none"><li>• promote consistency of care within and between practitioners and practice settings</li><li>• promote best possible health outcomes for consumers</li><li>• promote adoption of safety processes in the provision of care.</li></ul>

#### 3(b) Evidence-based care

<b>Principles</b>	<b>Pharmacists should have access to and use appropriate evidence-based guidance, indicators, models-of-care and data to inform clinical decisions.</b>
<b>What is it?</b>	<p>Evidence-based care is the deliberate, careful use of best-available evidence to make decisions in providing health care to individual patients.<sup>35</sup> It involves integration of high-quality research with patient values and clinical experience to provide the best possible health care to a consumer.</p> <p>Characteristics of evidence-based care in pharmacy services include:</p> <ul style="list-style-type: none"><li>• development of policies, protocols and approaches to pharmacy care using relevant internal data and recognised external evidence-based care guidelines and standards</li><li>• adoption of national standards of patient care</li><li>• provision of evidence-based pharmacist guidance</li><li>• identification and effective follow-up of clinical underperformance</li><li>• patient experience information being used as a valid indicator of clinical quality</li><li>• models-of-care adopted being supported by data and evidence.</li></ul>
<b>Why is it important?</b>	<p>Evidence-based care is accepted as being fundamental to any high-quality health service. Evidence-based care can:</p> <ul style="list-style-type: none"><li>• promote consistency of treatment</li><li>• promote best possible health outcomes for consumers</li><li>• improve efficiency in providing health care</li><li>• help set valid measures to evaluate quality of care provided.<sup>36</sup></li></ul>





### 3(c) Transparency

<b>Principles</b>	<b>The clinical benefits, risks and costs of pharmacy services should be transparent to consumers and stakeholders.</b>
<b>What is it?</b>	<p>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.</p> <p>Characteristics of transparency in pharmacy services include:</p> <ul style="list-style-type: none"><li>• sharing clinical priorities and vision of care with consumers</li><li>• sharing the evidence, risk and benefits of care options with consumers</li><li>• mutual respect between pharmacists and consumers which is free from concealment</li><li>• publication of clinical measures</li><li>• publicly sharing program outcomes, practice research data and research outcomes, and improvements, taking into account issues of privacy and consent</li><li>• open disclosure of incidents to consumer and relevant stakeholders</li><li>• mandatory reporting of significant/sentinel events</li><li>• provision of relevant clinical information about risks and benefits to consumers which is readily understood</li></ul>
<b>Why is it important?</b>	<p>Transparency in health services is established as leading to greater:</p> <ul style="list-style-type: none"><li>• quality</li><li>• accountability</li><li>• choice</li><li>• confidence of funders and consumers</li><li>• productivity and efficiency.<sup>37</sup></li></ul> <p>It supports more informed consumer choices and design of safer and higher-quality health services.</p>

### 3(d) Education and training

<b>Principles</b>	<b>Pharmacists should be supported to maintain competence and develop professional skills to enable high performance for pharmacy services within their scope of practice.</b>
<b>What is it?</b>	<p>Education and training within a clinical governance framework aim to ensure pharmacists and other staff have the skills and expertise to deliver safe care.</p> <p>Characteristics of an education and training framework in pharmacy services include:</p> <ul style="list-style-type: none"><li>• identification of development needs and planning to address these needs</li><li>• supporting the workforce to participate in program-specific education and training, use of practice support resources (e.g. guidelines) and credentialing processes when required</li></ul>
<b>Why is it important?</b>	<p>Effective education and training is essential to the 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.</p>





### 3(e) Measurement and monitoring

<b>Principles</b>	<p>Clinical measures of pharmacy services effectiveness, quality and safety should be systematically measured, monitored and reviewed by pharmacists, management and funders, including through:</p> <ul style="list-style-type: none"><li>• undertaking clinical audits</li><li>• participation in research projects</li><li>• supervision and management of pharmacist and staff performance.</li></ul>
<b>What is it?</b>	<p>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.</p> <p>Characteristics of effective measurement and monitoring of clinical aspects of pharmacy services include:</p> <ul style="list-style-type: none"><li>• undertaking clinical audit of objectives of pharmacy services (e.g. increase in medicine compliance following adherence services) and following-up unexpected results.<sup>15</sup></li><li>• collection of measures such as patient feedback, pharmacist and staff feedback, activity data, audits, incident and risk information and clinical indicator data</li><li>• provision of clinical data to participate in research projects</li><li>• using clinical measures as an indicator of pharmacist performance (e.g. clinical interventions and impact, achievement of benchmarks)</li><li>• measurement and evaluation is used to support quality improvements in the implementation and provision of care</li><li>• activities which validate or improve the accuracy of data recorded and analysed.</li></ul>
<b>Why is it important?</b>	<p>Measurement and monitoring are essential to understanding and demonstrating:</p> <ul style="list-style-type: none"><li>• safety of health services</li><li>• impact of health services on a person's health</li><li>• relative value of health services in achieving a desired outcome</li><li>• awareness and self-improvement by clinicians in the quality of care they provide</li><li>• to inform and measure improvement at an individual practice or industry level.</li></ul>





## 4. Patient safety and quality improvement systems

*Including: risk management, continuous quality improvement*

### 4(a) Risk management

<b>Principles</b>	<p>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:</p> <ul style="list-style-type: none"><li>• policies and procedures to manage patient safety risk and minimise risk fo patient harm</li><li>• incident management, including near misses</li><li>• open disclosure.</li></ul>
<b>What is it?</b>	<p>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 may put consumers at risk of harm and take action to prevent or control those risks.</p> <p>Characteristics of risk management relevant within a pharmacy service's clinical governance framework include:</p> <ul style="list-style-type: none"><li>• early identification and prevention of risk of harm through accurate, timely clinical documentation by all staff</li><li>• 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</li><li>• using standard operating procedures to reduce the likelihood of known clinical risks and support consistent service delivery</li><li>• reducing consumer risk through implementing policies which describe the scope and limitation of pharmacy services</li><li>• discussing incidents openly with patients, including contributing factors, likely outcomes, an apology and options to resolve.</li></ul>
<b>Why is it important?</b>	<p>Risk management can:</p> <ul style="list-style-type: none"><li>• reduce role of chance in causing harm to health</li><li>• reduce loss and costs of risks (e.g. insurance premiums)</li><li>• improve consumer and clinician experience of incident management.</li></ul>

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

<b>Principles</b>	<p>Pharmacy services should demonstrate delivery consistent with relevant industry codes, guidelines, standards and relevant policies and procedures.</p>
<b>What is it?</b>	<p>Adherence to codes, guidelines and quality systems supports clinical effectiveness and safety in describing the accepted scope and evidence supporting the service.</p> <p>Characteristics showing pharmacy services adhere to codes, guidelines and quality systems can include:</p> <ul style="list-style-type: none"><li>• demonstrating pharmacy services are delivered in accordance with professional standards</li><li>• monitoring adherence to standards, guidelines and codes as part of managing staff performance</li><li>• 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.</li></ul>
<b>Why is it important?</b>	<p>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.</p>



## 4(c) Continuous quality improvement (CQI)

<b>Principles</b>	Services should be supported by evidence-based, ongoing, and cyclical improvement activities which support enhancements in clinical outcomes and patient safety.
<b>What is it?</b>	<p>CQI describes an approach to improving processes and outcomes through ongoing structured problem solving, participation, a focus on consumers and collaboration.<sup>38</sup></p> <p>Characteristics of continuous quality improvement which support consumers' health include:</p> <ul style="list-style-type: none"><li>• 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</li><li>• conducting quality improvement education programs, quality and safety meetings (pharmacy/sector levels)</li><li>• pharmacists undertaking CPD to achieve applicable competence standards (e.g. Standard 1.6 Contribute to continuous improvement in quality and safety etc.)<sup>3</sup></li><li>• creating a culture that supports reporting, service improvement and embedding the experience of consumers to evaluate improvement activities</li><li>• application of care improvement tools in everyday care, education, quality activities and projects.</li></ul>
<b>Why is it important?</b>	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

<b>Principles</b>	<b>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.</b>
<b>What is it?</b>	<p>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 where the service is provided.</p> <p>Characteristics of the environment necessary for pharmacy services include:</p> <ul style="list-style-type: none"><li>• maintaining privacy and confidentiality for consumers (e.g. consultation room)</li><li>• providing adequate space to conduct the pharmacy service, including adequate space for consumers and carers (e.g. adequate seating)</li><li>• equipment meeting relevant international standards, Australian Standards and/or listed on the Australian Register of Therapeutic Goods (where relevant)</li><li>• ensuring consumers with mobility limitations or disability can access services.</li></ul>
<b>Why is it important?</b>	<p>Safety in the physical environment where care is delivered is essential for patient safety. Good design of health care environments has been linked to:<sup>39</sup></p> <ul style="list-style-type: none"><li>• consumer access to health services</li><li>• respecting the privacy of consumers</li><li>• improved quality and health outcome</li><li>• clinician engagement and satisfaction.</li></ul>

### 5(b) Cultural safety

<b>Principles</b>	<b>Pharmacy services should be inclusive and only provided in an environment which is culturally safe and respects the cultural diversity of consumers.</b>
<b>What is it?</b>	<p>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.<sup>40</sup></p> <p>Characteristics supporting provision of culturally appropriate pharmacy services can include:</p> <ul style="list-style-type: none"><li>• providing training for pharmacists and other staff in cultural awareness and cultural safety</li><li>• recognising and respecting the diversity of culture when communicating with consumers from a background different to one's own</li><li>• collaboration with Aboriginal Healthcare Workers and/or cultural services to better facilitate or understand cultural needs in providing pharmacy services</li><li>• understanding the influence of a patient's culture in conjunction with their medical condition(s), to improve health outcomes.</li></ul>
<b>Why is it important?</b>	<p>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.<sup>40</sup> 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.</p>



# Definitions

## Source key:

# Source definition abridged for clarity

% Source definition paraphrased for context

& Source definition scope revised for applicability to pharmacy services

	Definition	Source
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	4
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	An integrated component of corporate governance of health service organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services. Clinical governance systems provide confidence to the community and the healthcare organisation that systems are in place to deliver safe and high-quality health care	4
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	4 #
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 population's health needs, planning services around those needs and securing those services within available budgeting	41
commissioning body	an entity who procures health services	
consumer	a person who uses, or could possibly use, health services. 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.	4 %
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	38
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	40
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	4
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	4 %
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	32
incident	an occurrence which harmed, or had the potential to harm, a person (e.g. dispensing errors, confidentiality breach, exposure to infectious disease)	4 &
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)	4 %
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	any service provided or activity undertaken within a pharmacist's scope of practice Examples of pharmacy services include; dispensing prescribed medicines, assessment of minor ailments, screening/risk assessment, comprehensive medication review, undertaking clinical audits in aged care facilities, preparation of complex compounded products, drug information service, hospital clinical pharmacy service, pharmacist-administered vaccination, delivering medicine education to other health professionals, medicine adherence services, absence from work certificates etc.)	5
risk management	a structured approach to identification and lowering the likelihood or incidence of adverse health outcomes	4 &
system	the policies, processes, procedures, records and approaches used to achieve a goal	4 #
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	





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