Getting It Right

Guiding Principles for Medicines Stewardship Programs

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DISCLOSURE
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EXECUTIVE SUMMARY

Stewardship implies careful and responsible supervision of an important resource.
These Guiding Principles for Medicines Stewardship Programs will assist health service organisations to develop and implement medicines stewardship programs. The goals of medicines stewardship are to ensure the safe and Quality Use of Medicines (QUM) that meet an individual's needs, while minimising harm to the individual and society, with an aim to improve overall health outcomes for the whole population.

QUM underpins all medicines stewardship programs. These programs require good governance and leadership, a culture of safety and quality improvement and appropriate resourcing. Without these the programs are unlikely to be successful or sustainable.
All programs should be multidisciplinary, collaborative and tailored to the local context. The implementation of medicines stewardship programs requires the use of proven behavioural change methodologies and a planned communication strategy. All such programs should evaluate the impact and effectiveness of the implemented strategies.

The most well-recognised medicines stewardship program involves antimicrobials. More recently health service organisations have developed analgesic (often focusing on opioids) or anticoagulant stewardship programs.

These Guiding Principles and accompanying toolkit seek to:

- describe the essential elements required to establish medicines stewardship programs
- assist health service organisations to develop sustainable stewardship programs
- advocate for broad-based capacity building.

These principles can be adapted for individual health service organisations to deliver consistent, safe, high-quality, equitable care and outcomes from the use of medicines.

Part A:

Guiding principles for the health service organisations

1. The principles of QUM should underpin the medicines stewardship program.
2. Medicines stewardship should be integrated into existing medicine governance systems and frameworks supported by executive and clinical leadership.
3. A culture of safety and quality improvement should be embedded within the healthcare organisation to support medicines stewardship.
4. Medicines stewardship programs should be appropriately resourced to optimise effectiveness, build capability and capacity, and ensure the sustainability of improvement strategies.

Part B:

Principles for the medicines stewardship program

1. Medicines stewardship programs should be led by a team that draws on a range of multidisciplinary skills, expertise and knowledge.
2. Medicines stewardship programs should be developed and tailored to the local context and stakeholders.
3. Medicines stewardship programs should include a multifaceted strategy that uses proven methodologies in behavioural change and clinical practice improvement.
4. Medicines stewardship programs should include a communication strategy that focuses on timely, effective and appropriate communication tailored to the intended audience.
5. Medicines stewardship programs should evaluate, monitor and report on the impact and effectiveness of implemented quality improvement strategies.

These Guiding Principles should be considered in conjunction with other available resources for medicines stewardship. They should also be read in conjunction with the Getting it Right: Medicines Stewardship Toolkit.

OVERVIEW

PURPOSE

These Guiding Principles will assist health service organisations to develop and implement medicines stewardship programs. The goals of medicines stewardship are to ensure the safe and Quality Use of Medicines (QUM) that meet an individual's needs, while minimising harm to the individual and society, with an aim to improve overall health outcomes for the whole population.

These Guiding Principles and accompanying toolkit seek to:

- describe the essential elements required to establish medicines stewardship programs
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BACKGROUND

Various stewardship programs and initiatives have been implemented in Australia and internationally. The World Health Report 2000 recognises stewardship as a function of the health system akin to governance. The report identifies several components for appropriate health system stewardship.[1] Importantly, stewardship includes multiple health system levels, from consumer interactions to jurisdictional and national medicines policy. At each of these levels, stewardship programs should:

- define vision and direction
- maintain the strategic direction of policy development and implementation
- exert positive influence through regulatory approaches, by collecting and using data, detecting and correcting undesirable trends and promoting evidence-based improvements
- guide the behaviour of a wide range of stakeholders from healthcare financiers to healthcare providers, establishing effective accountability mechanisms.[1-4]

Beyond the formal health system, stewardship should ensure that government policy and legislation promote people's health, using a One Health approach. For example, the antimicrobial stewardship program in health care uses the One Health approach, encompassing food production, the environment and other classes of antimicrobials such as antifungals and antivirals. It aligns with agricultural policy, environmental policy and veterinary practice.

Medicines stewardship

There is no single definition for medicines stewardship, however there are definitions that address therapeutic areas such as antimicrobial agents, anticoagulants and analgesics.[5,6] Commonalities include strategies and interventions involving the appropriate procurement and storage of medicines, the interaction of multidisciplinary teams, guideline-based prescribing/deprescribing, documentation to support communication, dispensing and administration of a medicine, audit and feedback, as well as the safe and appropriate disposal of unused medicines. The goals of medicines stewardship are focused on the protection and optimisation of individual and population health, supporting a One Health approach, and the best use of finite health resources for maximum utility. This includes selecting treatment options wisely, including non-medicine or non-pharmacological alternatives.

Medicines stewardship programs require a broad perspective that involves finding solutions (or interventions) that can be implemented sustainably across the medication management pathway[7] and the transitions of care. Following a Council of Australian Therapeutic Advisory Groups (CATAG) review of local, national and international programs,[8-13] the following common elements of medicines stewardship programs have been identified:

- A focus on QUM.
- Implementation of governance and accountability responsibilities.
- Multidisciplinary expertise and collaboration.
- Implementation of a quality improvement culture.
- Use of evidence-based improvement methods and change management.
- A program of monitoring outcomes and reporting.
- Ensuring clear communication of programs and outcomes to relevant stakeholders and the wider healthcare community.
- Consideration of resourcing and capacity building to ensure sustainability of the program.

The objectives of medicines stewardship could be framed in terms of equity, coverage, access, quality, safety, effectiveness and patient-centred care.

A range of sub-specialty stewardship programs may be appropriate in a sub-specialist referral setting, often related to therapeutic-specific

areas.[14] For example, antimicrobial, opioid or anticoagulant stewardship programs. However, in more generalist settings, it may be more appropriate to implement a medicines stewardship service that addresses a number of different therapeutic areas.

SCOPE

These Guiding Principles apply to health service organisations and individuals, whether they are local, district/network, regional or state/territory organisations involved in the development, enhancement or implementation of medicines stewardship programs. For those organisations that are developing or have developed a program, these Guiding Principles provide a framework against which to review the process and guide changes if necessary.

The Guiding Principles are equally relevant to community, private health care or private hospital health care settings with an interest in medicines stewardship programs. However, further consultation is required to investigate their applicability in these settings. Many of the considerations within these Guiding Principles are specific to the public hospital setting and the main focus of these principles is to provide best-practice guidance within this setting.

This resource is applicable to all involved in delivering medicines stewardship programs in health services. These include:

- Drugs and Therapeutic Committee (DTC) chairs and members
- Local Health Network (also known as Local Health Districts, Health Service Networks, Local Hospital and Health Networks) leads for corporate and clinical governance
- National Safety and Quality Health Service Standards implementation leads
- Local, area and state/territory quality and safety committees
- Healthcare professionals who are involved in the medication management pathway
- Consumer and community representatives.

Medicines use for consumers in public health service organisations includes inpatient and outpatient settings, hospital-in-the-home settings and at transitions of care, including discharge.

GUIDING PRINCIPLES

PART A.
Guiding principles for health service organisations

GUIDING PRINCIPLE 1A

The principles of QUM should underpin the medicines stewardship program.

QUM within Australia's National Medicines Policy,[15] applies equally to decisions about medicine use by individuals and decisions that affect the health of the population. Any medicines stewardship program should focus on:

- judicious use (selecting management options wisely, including the use of non-pharmacological measures either instead of, or in addition to an indicated medicine
- appropriate use (choosing suitable medicines if a medicine is considered necessary)
- safe use (using medicines safely and effectively to get the best possible results)
- efficacious use to achieve the goals of therapy by delivering beneficial changes in actual health outcomes.

QUM supports equitable access to medicines and other healthcare-related services. When formulating medicines stewardship programs, the drivers of inequity of access to health care and/or medicines and its relevance to the local context should be considered.

Cost-effectiveness of medicines may also need consideration within the context of the most appropriate treatment option and QUM.

The National Strategy for QUM recognises both the central role consumers play in attaining QUM and the wisdom of their experience.[16] Medicines stewardship programs should partner with consumers in the program's design and activities. This principle is supported by the National Safety and Quality Health Service Standards (NSQHS), Partnering with Consumers Standard.

Medicines stewardship programs should also consider consumer diversity and tailor efforts to meet diverse consumer needs. As required by the Antimicrobial Stewardship Clinical Care Standard,[5] information about a person's condition and treatment options should be provided in a way that the individual, their carer and/or family can understand so that they can participate in shared decision-making.

| GUIDING PRINCIPLE 2A |

Medicines stewardship should be integrated into existing medicine governance systems and frameworks supported by executive and clinical leadership.

The Australian Commission on Safety and Quality in Health Care (the Commission) states, "Clinical governance is an integrated component of the 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, high quality and continuously improving."[17]

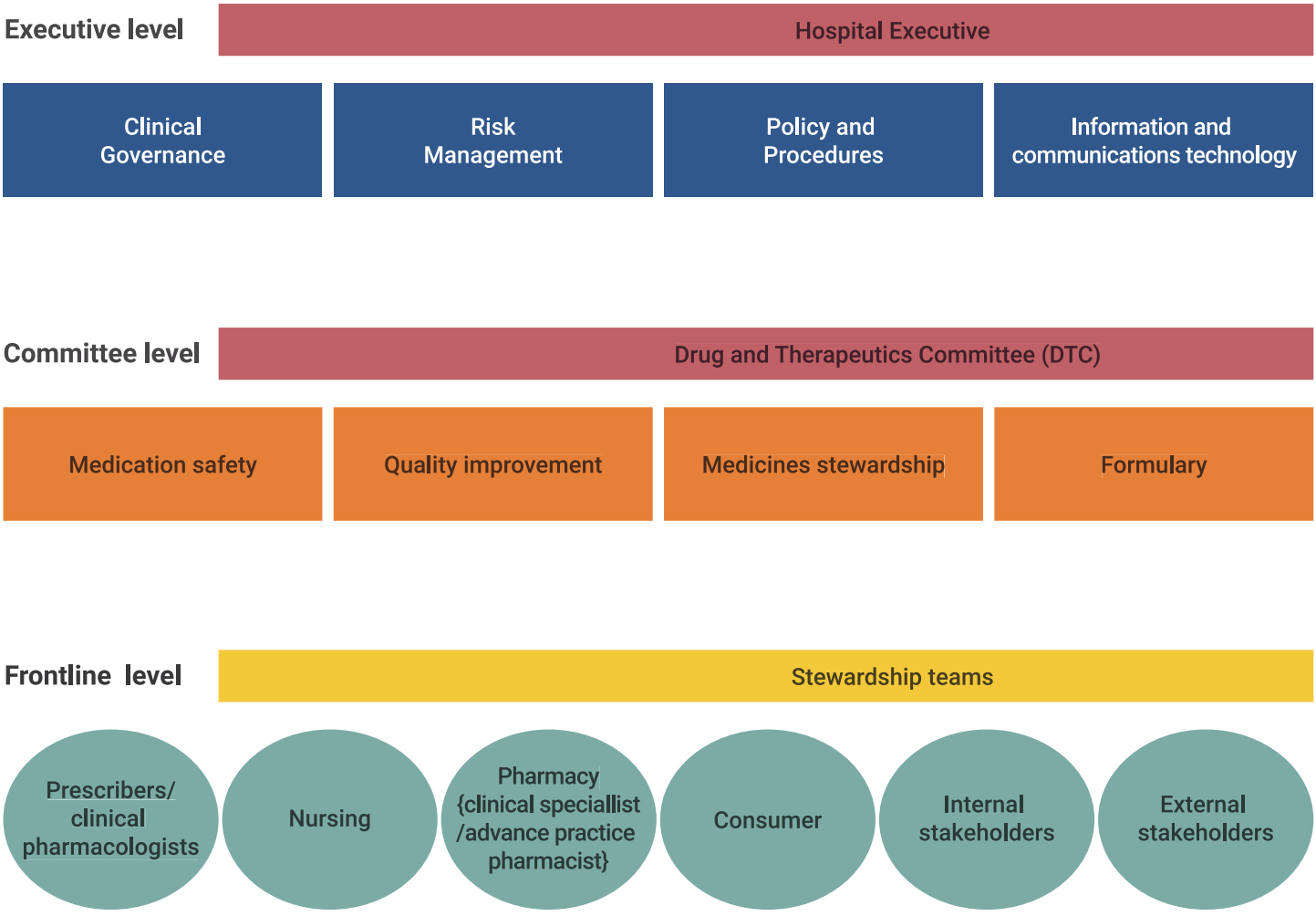
Good clinical governance supported by executive and clinical leadership is required to develop, implement and sustain any medicines stewardship program. Good governance means that the medicines stewardship program will be:

- empowered to support and facilitate the interventions that the stewardship program requires
- funded so that there is sufficient resourcing and time to enact change
- accountable for achieving the desired outcomes and managing program risks.

The accountability of stewardship programs should lie with the highest level of corporate and clinical governance and management within an organisation.[10] Accountability at the executive level is required to support the implementation of any program measures and/or improvement strategies. Stewardship activities should connect with existing safety and quality structures and systems in the organisation, with appropriate pathways of communication and collaboration.[18] The medicines stewardship program lead should use the safety and quality systems from the NSQHS Clinical Governance Standard[19] when implementing policies and procedures for QUM and identifying and managing medicines stewardship risks.

CATAG's Achieving effective medicines governance: Guiding principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals, suggest it is appropriate for DTCs to establish subcommittees to manage specific medicines stewardship programs (Figure 1). These programs require clearly defined operational and reporting lines to the appropriate governing bodies, such as the health service executive, director of clinical governance, patient safety and quality improvement committee, medication safety committee and the DTC.

Figure 1 below demonstrates a generic governance structure for medicines stewardship programs.



••Figure 1: Example of a governance structure for a medicines stewardship program

| GUIDING PRINCIPLE 3A |

A culture of safety and quality improvement should be embedded within the healthcare organisation to support medicines stewardship.

The importance of a safety and quality improvement culture is articulated in a range of the documents from the Commission, including the NSQHS Standards, the National Model Clinical Governance Framework and the Communicating for Safety program.

Key aspects of an effective safety and quality improvement culture include:

- management commitment and visibility; lead by example
- good communication, at and between all levels, within the organisation
- a strong culture of peer learning and knowledge sharing
- active employee participation in designing quality improvement strategies and implementing change.[20]

Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventative measures. These key aspects are necessary to implement and support an effective medicines stewardship program.

Importantly, leaders in healthcare organisations are required to foster and develop a culture of safety and quality improvement.[19] This can be challenging given the way healthcare organisations are commonly organisationally structured through speciality, occupational or service location, which can give rise to individual subcultures. Mannion et al state that hospitals represent a "dynamic cultural mosaic made up of multiple, complex, and overlapping subgroups with variably shared assumptions, values, beliefs, and behaviours".[21] As a result, leaders must understand their subcultural diversity and, where required, advocate for cultural shifts through their language and actions. If needed, leaders can also actively engage and participate in activities to bring about culture change. Without this culture and engagement by leaders, medicines stewardship programs are likely to be less effective and may not be sustainable in the longer term.

Strategies to promote a safety culture may include principles of leadership, team training and team communication tools, executive walk rounds and interdisciplinary rounding and Comprehensive Unit-Based Safety Programs.[22]

Providing opportunities for professional development and upskilling staff (supported at the organisational or executive level) improves cultural attitudes towards quality improvement and QUM. Team members should take advantage of every interaction with prescribers, the clinicians who administer medicines, the person receiving care and their carers, as an educational opportunity. Ongoing provision and facilitation of professional development can also be helpful in ensuring the skillset is maintained in the organisation.

| GUIDING PRINCIPLE 4A |

Medicines stewardship programs should be appropriately resourced to optimise effectiveness, build capability and capacity, and ensure the sustainability of improvement strategies.

| Resourcing |

To improve QUM at a health systems level, local, jurisdictional and national level resources should be assigned to provide a cohesive framework to address gaps.[23] It is essential that health service organisations recognise the need to build organisational capacity and capability, by appropriately resourcing programs to achieve their goals.

The resourcing required depends on the program's therapeutic focus, the size of the health service and may include:

- a program lead, manager and/or program officer
- clinical champions to communicate, liaise with stakeholders, educate and implement interventions
- allocation of time for clinical staff to attend and participate in stewardship program-related meetings (including time to review meeting papers)
- development, review and maintenance of specific stewardship-related policies, interventions and other materials
- allocation of time for information technology
- data collection, analysis and report generation, including key performance indicator (KPI) reports
- participation in national stewardship and quality improvement activities, for example national benchmarking projects.

Quality improvement and patient safety staff can advocate for adequate resourcing and the integration of interventions into quality improvement efforts.

It is important to recognise that resourcing varies between and within health service organisations. Smaller organisations, or those in regional and remote areas, may lack support for these programs and are often unable to implement medicines stewardship programs to the same extent as their larger counterparts. This represents a gap in the equitable care of all Australians. Smaller hospitals may consider building capacity through partnering with a larger health service organisation, within their network. Development of a hub-and-spoke model could be supported remotely through use of technology. Alternatively, stewardship program activities could be incorporated within existing teams that are already dedicated to patient safety and quality improvement. These teams may also consider collaborating with other smaller regions/facilities, where they might share similar challenges and issues, and share resources and co-ordinate activities.

| CAPACITY AND CAPABILITY BUILDING |

For a medicines stewardship program to be successfully embedded into a health service organisation, it requires the organisation to build both its capacity and capability.

Capacity building is an approach to the development of sustainable skills, organisational structures and commitment to healthcare improvement.[24] Capacity building incorporates advocacy and relies on partnerships. Capacity building taps into existing abilities of individuals, communities, organisations or systems to increase involvement, decision-making and ownership of issues. It includes initiatives to support individuals, teams, organisations and networks.[25] For clinicians it may mean working in new and different ways, creating partnerships and building ongoing, trusting relationships. It means working together with others to find solutions and building skills to implement solutions. In medicines stewardship, where there may be limited capacity to implement new strategies, it is essential that the health service organisation commits to developing their capacity to progress programs.

Effective capacity building results in positive outcomes for the individual, community and the organisation, as well as systemic effects, as seen in Table 1.
*Adapted from Capacity building for health promotion, Vic Health.[25]

The **outcomes of capacity building** may relate to:	
Individual	Participation levels, skills (leadership, problem-solving, negotiation), knowledge, values, empowerment, increased engagement with (or connection to) the community, and desired behaviour changes.
Community	Changes in membership, technical abilities and interpersonal skills (confidence, communication) of individuals, collective knowledge, planning and evaluation skills, and resource management (financial or non-financial).
Organisational	Changes in decision-making, organisational policies, resource allocation, partnerships, collective attitudes and values.
Systemic	Changes in inter-organisational planning and/or collaboration, new legislation, resource allocation, values, cultural norms, societal values.

••Table 1: Outcomes of capacity building

Successful quality improvement and medicines stewardship programs not only require capacity but capability of the people involved. It is not possible to achieve transformational change without a considerable number of people having explicit recognised improvement skills. The range of knowledge and capability needed to achieve sustained improvement across a system is far greater than individual experts can be expected to possess on their own. It may be more productive to think in terms of teams, that between them have a range of expertise, with the skills, resources and networks that can tap into sources of insight and capability from elsewhere. The health service organisation should ensure that

teams have access to expertise, energy, time and resources to learn – and to put what they have learned into action.[26]
Further information can be found in the Institute for Healthcare Improvement publication entitled Building capacity and capability for improvement: embedding quality improvement skills in NHS providers and the Clinical Excellence Commission Capability Development Guide for Employees.

| SUSTAINABILITY |

Once the medicines stewardship program is established, attention needs to be focused on sustaining the program and embedding associated changes into routine medication management practices and behaviours. Ongoing quality improvement activities are a required routine component of clinical practice to maintain and improve on this level of practice and behaviour in the longer term.

To ensure the continuity of improved outcomes and to implement the change into all aspects of healthcare practice across all care transitions, the program should spread beyond the acute public hospital system. To achieve this goal, collaboration with relevant stakeholders outside of the health service organisation is recommended. For instance, with Primary Health Networks, aged care and/or local primary care service providers.

If support for a medicines stewardship program is not sustained, then the outcomes are also unlikely to be sustained. Health service organisations need to maintain their investment in medicines stewardship programs for ongoing improvements in the safe and quality use of medicines, including impact on clinician behaviours and outcomes of care.

| PART B.
Principles for the medicines stewardship program |

| GUIDING PRINCIPLE 1B |

Medicines stewardship programs should be led by a team that draws on a range of multidisciplinary skills, expertise and knowledge.

The multidisciplinary composition of a medicines stewardship team is a critical element to ensure the program is fit for purpose and builds capacity and capability within the workforce to ensure implementation of program measures and sustainability of desired outcomes.

Medicines stewardship team's expertise and skills should reflect the function of the program. The team should include core representation from:

- executive (representing the ownership/ sponsorship of the program and/or finance or clinical governance)
- medical profession (including, where available, a clinical pharmacologist)
- nursing
- pharmacy (including specialist/advanced practice pharmacists)
- allied health
- consumers, patient advocate, or community representative.

Members of the medicines stewardship team should be experienced clinicians that are able to provide a holistic system perspective and represent the specialities and consumer population the stewardship program is addressing. The stewardship team should also include junior clinicians whose experience at an operational level can bring new perspectives, insights and ideas and champion program objectives and practice change amongst their peers.

The skills, knowledge and expertise required during program initiation may differ to those required during the maintenance phase of a program. Therefore, regular assessments should be undertaken to understand and respond to the requirements of the program

| GUIDING PRINCIPLE 2B |

Medicines stewardship programs should be developed and tailored to the local context and stakeholders.

Stewardship programs should be tailored to the health service organisation, clinical areas, the local context and include a range of stakeholders. Stewardship programs should be designed with the whole-of-care system in mind including transitions of care.

Stakeholders may include people in the following categories:

- clinicians
- executive/management
- support/administrative staff
- consumers/patients
- external stakeholders.

Stakeholder mapping and analysis should occur to define and understand stakeholders by interest and/or influence, including supporters and resisters of change. Stakeholder mapping is a dynamic and iterative process.

Stakeholder mapping consists of:

1. Defining your stakeholders
2. Analysing stakeholders by impact and influence
3. Planning stakeholder communications and reporting
4. Engaging with your stakeholders

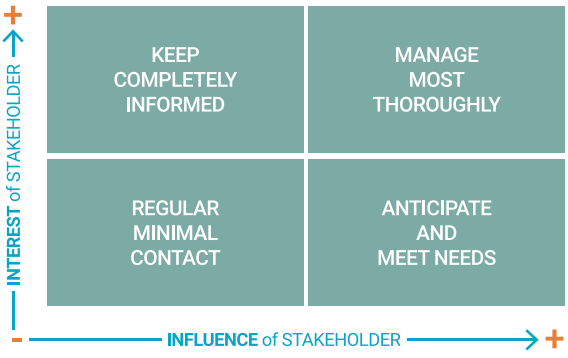


Figure 2: Stakeholder matrix **From:** www.smartsheet.com[27]

| EXTERNAL STAKEHOLDERS |

Medicines stewardship can only be maintained through a collaborative partnership with consumers and the community, including at transitions of care. As QUM across the continuum is increasingly important, where appropriate, stewardship programs should engage with primary care providers early and throughout the life of the program, for example via Primary Health Networks and local primary care service providers such as community pharmacists, general practitioners and Aboriginal Medical Services.

| PARTNERING WITH CONSUMERS |

Consumers are the singular continuous partner with healthcare workers throughout their healthcare journey, and without their (and/or their carers') engagement any changes will be harder to sustain, even when they have a direct benefit for the individual. Understanding the voice of the consumer will facilitate program design and maximise the agreement and acceptance by the community of program measures and related interventions or changes and increase the likelihood of the program's success.[28] The inclusion and engagement of consumers that are reflective of the diversity of the community the organisation services will ensure the program design and interventions are acceptable.[28] This can be achieved through focus groups, surveys and/or committee representation.

| GUIDING PRINCIPLE 3B |

Medicines stewardship programs should include a multifaceted strategy that uses proven methodologies in behavioural change and clinical practice improvement.

Successful implementation of a medicines stewardship program requires a multifaceted intervention strategy. This strategy recognises the importance of active partnerships with clinicians in their respective fields and multidisciplinary consultative and collaborative work to effect timely and sustainable change. The implementation of a medicines stewardship program should utilise improvement science principles which include:

- a sequential structured method of spreading focused improvement techniques
- the development of clearly defined intervention/s, the components of which are optimised to reflect the evidence
- a small trial of the intervention, in one or a few selected settings, followed by a systematic effort to replicate it in other settings
- the replication occurring partly by identifying and dealing with barriers and using facilitators.

A multifaceted intervention strategy should be selected and tailored to the local environment to influence clinician behaviour. The multifaceted intervention strategy should:

- tailor the intervention for a variety of audiences e.g. consumers and clinicians
- include specific objectives and content for each target audience e.g. for clinicians these could be segmented further into career stages such as undergraduates, early-career, specialist or for consumers, those people who use English as a second language
- incorporate competency standards for professions e.g. Australian prescribing competency framework for all prescribers[29]
- include a mix of passive and active educational activities as well as restrictive, persuasive and enablement strategies
- include the evaluation of all activities
- include reporting and evaluation that includes feedback about successes, failures and lessons learned, and is also tailored to the target audience (including department managers).

The utilisation of implementation science principles within a quality improvement program such as medicines stewardship enables a more adaptive approach that recognises the need to think flexibly, respond to local context and adapt the intervention to achieve best fit for different settings.[30]

The impact of a program and its flow-on effects should be considered, as implementation of an intervention in a complex adaptive healthcare ecosystem may have some undesirable effects.

| The role of clinical champions |

A clinical champion is an individual within an organisation who is responsibile for advocating for change, motivating others and using their position and expert knowledge to facilitate the adoption of a particular innovation.[31] In a hospital setting, clinical champions should be accessible to large numbers of staff from diverse work areas. They should act as a knowledge and skill resource, as well as actively promote the stewardship program activities.

| GUIDING PRINCIPLE 4B |

Medicines stewardship programs should include a communication strategy that focuses on timely, effective and appropriate communication tailored to the intended audience.

Effective communications are a critical aspect of successful quality improvement activities and, ultimately, the delivery of safe and high-quality patient care.[32] They are also a key component of behavior change methodology.[32]

The first step of effective communication is the development of a communication strategy, that improves awareness and understanding of a program. A communication strategy should address the what and the why, providing positive, clear and consistent framing of key messages.[32] Internal and external stakeholders should be considered and engaged to support the communication strategy.

A communication strategy should:

- leverage the natural connections between and within healthcare organisations– existing relationships are powerful connectors[33]
- leverage the existing organisational structure – use the existing organisational structure when designing a communication plan, e.g. area health services or networks, peer-to-peer interactions[33]
- raise awareness to attract adopters of the intervention
- share technical content needed by adopters to make improvements
- identify and implement a feedback mechanism for communication
- include specific communication methods for awareness
- include specific communication methods for knowledge transfer
- include reporting and evaluation that includes feedback about successes, failures and lessons learned.

Communication strategies for consumers should include considerations of language barriers and medicines/health literacy.

| GUIDING PRINCIPLE 5B |

Medicines stewardship programs should evaluate, monitor and report on the impact and effectiveness of implemented quality improvement strategies.

Measurement is critical to identify opportunities for improvement and to assess the impact of interventions. Stewardship program interventions should involve evaluation of the impact of interventions on structures, processes and care outcomes.[34] For example, stewardship programs should evaluate if appropriate governance is available (structural measure), if policies and guidelines are being adhered to (process measures) and if interventions have improved patient outcomes (outcome measures). Measures should also have face validity (i.e. are credible) and content validity (i.e. cover all appropriate areas of the program).[35] The different type of measures used in the evaluation of medicines stewardship programs include measuring outcomes, performance and variation in medicines use.[5,6,36]

Evaluation and monitoring of the medicines stewardship program should be an ongoing and cyclical process, with regular reporting or feedback to key stakeholders, the medicines governance group and the executive. Where appropriate, baseline measurements and evaluations are essential to effectively monitor and evaluate the achievements or under achievements of aspects of the program.

The stewardship team should agree and recommend suitable measures or KPIs for the program after considering the local context and goals of the program. These measures should be endorsed via appropriate governance mechanisms, for instance, via the DTC or health service organisation executivee.

| MEDICINES STEWARDSHIP TOOLKIT |

These Guiding Principles are accompanied by a Medicines Stewardship Toolkit, which provides detailed information regarding the development, implementation, evaluation and sustainability of any stewardship program.

Guiding Principles for Medicines Stewardship Programs

AIM: to provide safe and Quality Use of Medicines to improve overall health outcomes

Part A

For health service organisations

Guiding principle 1A

The principles of QUM should underpin the medicines stewardship program.

Guiding principle 2A

Medicines stewardship should be integrated into existing medicine governance systems and frameworks supported by executive and clinical leadership.

Guiding principle 3A

A culture of safety and quality improvement should be embedded within the healthcare organisation to support medicines stewardship.

Guiding principle 4A

Medicines stewardship programs should be appropriately resourced to optimise effectiveness, build capability and capacity, and ensure the sustainability of improvement strategies.

Part B

For medicines stewardship program

Guiding principle 1B

Medicines stewardship programs should be led by a team that draws on a range of multidisciplinary skills, expertise and knowledge.

Guiding principle 2B

Medicines stewardship programs should be developed and tailored to the local context and stakeholders.

Guiding principle 3B

Medicines stewardship programs should include a multifaceted strategy that uses proven methodologies in behavioural change and clinical practice improvement.

Guiding principle 4B

Medicines stewardship programs should include a communication strategy that focuses on timely, effective and appropriate communication tailored to the intended audience.

Guiding principle 5B

Medicines stewardship programs should evaluate, monitor and report on the impact and effectiveness of implemented quality improvement strategies.

APPENDICES

APPENDIX 1: GLOSSARY

Term	Definition
Capacity	Refers to the following characteristics: • the ability to receive, hold or absorb new knowledge and skills • the maximum or optimum amount of knowledge and skills individuals can absorb and retain • the ability to learn or retain information • the power, ability or possibility of doing something or performing • a measure of volume; the maximum amount that can be held.[37]
Capability	While capacity provides the potential for improvement, it is the active application and use of improvement approaches and practices that determine whether improved results will be realised.[37]
Clinical governance	This 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.[17]
Clinicians	Includes nurses, midwives, medical practitioners, pharmacists and other registered individuals who deliver health care.
Consumer	An individual receiving care, their carers and/or families. A healthcare consumer may also act as a consumer representative to provide a consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in decision-making processes.[19]

Term	Definition
Health service organisation	A separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body. A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. It can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, consumers' homes, community settings, practices and clinicians' rooms.[19]
Medication management pathway	Describes nine (cognitive and physical) steps and three background processes, which should be involved in the best practice organisation of pharmaceutical products, with the consumer as a central component and involved in all steps. The nine steps include: decision on appropriate treatment and decision to prescribe medicine; record of medicine order/ prescription; review of medicine order/prescription; issue of medicine; provision of medicine information; distribution and storage; administration of medicine; monitor for response; transfer of verified information.[38,39]
Medicines Use Evaluation (MUE)	Previously known as Drug Use Evaluation (DUE), MUE is carried out to improve the quality, safety, and cost-effectiveness of medicine use, and is an integral part of QUM. MUE is an authorised, structured, ongoing quality improvement cycle of medicine use within a healthcare organisation, where medicine use is evaluated by using pre-determined standards. Interventions and actions are initiated to correct patterns of use which are not consistent with these standards. This may include a mechanism for measuring the effectiveness of any corrective actions.[40]
Stakeholder	Defined as "any person, group or institution with interests in a project…who may be directly or indirectly affected by the process or the outcome."[41]

APPENDIX 2: HOW THESE GUIDING PRINCIPLES WERE DEVELOPED

This document was prepared by the CATAG Project Team in consultation with an Expert Advisory Group (EAG). The EAG was comprised of individuals with recognised expertise in a range of areas, such as medicines stewardship/QUM, evidence-based medicine use, medicines governance and patient issues. All feedback was discussed and agreed upon for incorporation into these Guiding Principles.

During the development of the document, CATAG member organisations undertook consultation, at various stages, with their wider constituents, including hospital drug and therapeutics committees, hospital pharmacy departments and clinicians. External consultation with key national organisations was also undertaken. A final version was approved by the EAG.

These Guiding Principles were developed in consultation, with and endorsed by, representatives from the CATAG member organisations listed below:

- Canberra Health Services
- New South Wales Clinical Excellence Commission (CEC)
- NSW Therapeutic Advisory Group (NSW TAG)
- Northern Territory Drug and Therapeutics Committee
- Queensland Health Medicines Advisory Committee (QHMAC)
- South Australian Medicines Advisory Committee (SAMAC)
- The Tasmanian Medication Access and Advisory Committee (TMAAC)
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