


POSITION PAPER

Achieving effective medicines governance: guiding principles for the roles and responsibilities of Medicines and Therapeutics Committees in Australian hospitals

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Abstract

Robust medicines governance is an essential component of good clinical governance for health service organisations. Standardisation of hospital medicines governance supports consistency in clinical care and equity in medicines access for patients both within those hospitals and at transitions of care. Medicines and Therapeutics Committees (MTCs) provide the strategic lead for medicines governance in Australian hospitals and have done so for many decades. Changes to the healthcare environment in which MTCs operate, however, have necessitated adaptation and evolution of these committees. Contemporary guidance is therefore required to support MTCs to provide consistent, high-quality medicines governance in Australia's modern healthcare environment. *Achieving effective medicines governance: Guiding principles for the roles and responsibilities of Medicines and Therapeutics Committees in Australian hospitals* was released in July 2025 with recommendations for the purpose, functions, structure, processes, documentation, communication and resourcing for Australian MTCs. The guidance is accompanied by a checklist to measure the performance of MTCs and other supporting resources. Australian hospital MTCs are encouraged to measure their practice against these guiding principles, using the associated tools, to achieve the best possible medicines governance within their available resourcing. Practice across jurisdictions is variable, and working to align individual MTC practices with the guiding principles will promote standardisation in approach to hospital medicines governance.

Introduction

Robust medicines governance is an essential component of good clinical governance for any health service organisation and supports quality use of medicines. Medicines and Therapeutics Committees (MTCs) have played an important role in medicines governance for Australian hospitals for more than four decades,¹ but in that time there have been significant changes to the healthcare environment. New health technologies, changing patient care settings and innovative treatment modalities have expanded the potential scope of these committees.² Changes have also occurred in the wider governance structures that Australian MTCs operate

within, such as the introduction of statewide formularies in some jurisdictions³ and evolving challenges associated with complex healthcare funding models.⁴

In both Australia and overseas, MTCs have had to respond to change. Modern MTCs provide comprehensive systems of medication governance, structured to holistically support the safe, appropriate, ethical and fiscally responsible use of medicines.⁵ With new responsibilities, expanded scope of work and ongoing budgetary pressures, modern MTCs require clear and structured guidance to continue to practice to the highest possible standards.

The Council of Australian Therapeutic Advisory Groups (CATAG) is a collaborative of representatives from state and territory MTCs and therapeutic advisory groups (or equivalents), ideally placed to provide consensus guidance to Australian MTCs. CATAG recognises

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that inconsistent processes can lead to large variations in care and so strives to standardise and optimise medicines use in Australia's public hospitals and at transitions of care.

Methods

In 2013, CATAG published *Achieving effective medicines governance: Guiding principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals* to provide guidance on the role, operation and evaluation of Australian MTCs. Over a decade on, review of the document determined that it was still largely relevant in the current medicines governance environment, but that it required contemporising for present-day MTCs.

CATAG convened an expert advisory group (EAG) from across Australia to inform the update. This group comprised individuals with expertise in therapeutics, quality use of medicines, medicines governance and MTC operations. A review of literature published since 2013 was undertaken and structured qualitative interviews conducted with representatives from 16 MTCs across all Australian states and territories, representing regional, district and state-wide MTCs to provide comprehensive coverage and broad reflections of current MTC practices. Both the review of literature and qualitative interview findings were used to inform the update to the guiding principles and supporting resources.

Stakeholder consultation was undertaken with CATAG member organisations and 48 additional stakeholder organisations, including public and private hospitals, state and territory health departments and national professional organisations. Feedback on the document was considered by the EAG, and the final document was endorsed by the Council of Australian Therapeutic Advisory Groups on 30 June 2025. Funding support for this work was provided by the Australian Commission on Safety and Quality in Health Care.

Achieving Effective medicines governance: Guiding principles for the roles and responsibilities of Medicines and Therapeutics Committees in Australian hospitals (version 2 – June 2025)⁶

This is a summary of the CATAG guiding principles for MTCs. Please refer to the full document (available at www.catag.org.au) for more information.

MTC purpose, functions and structure

Guiding principle 1: – MTCs provide governance and oversight of medicines-related systems within a hospital, local health district/network or state/territory

Medicines governance is an essential element of clinical governance. It is therefore important that all health service organisations have access to the advice and services of an adequately resourced MTC.

MTCs require visibility and oversight of all health service activities that relate to medicines. This allows the MTC to identify and manage medicine-related risks and support quality use of medicines throughout the organisation, whether this is a single hospital or a network of health facilities.

Guiding principle 2 – the MTC's place within the organisation's governance structure is clear and supports the scope and functions of the committee

To perform its medicines governance role well, MTCs need clear, multi-directional communication channels within the organisation it serves. This supports accountability and provision of advice to the organisation's executive, facilitates collaboration with other related committees, and provides clear pathways for actioning MTC decisions or advice in the provision of healthcare.

Guiding principle 3 – MTCs consider the local governance environment when defining their scope and functions

While comprehensive medicines governance is important for any health service organisation, its MTC may not be responsible for all aspects of this. The MTC will likely be part of a wider clinical governance structure and therefore will need to consider areas already managed by other committees (e.g. a statewide formulary committee, a medication safety sub-committee) when defining their scope and functions.

Guiding principle 4 – MTCs have clear terms of reference (TOR) that articulate their role, processes and position within the organisation's clinical and corporate governance structure

An important aspect of good governance for any area is clear TOR for the committee providing that governance. In addition to general advice regarding MTC TOR, a

detailed appendix is included to assist with writing a new MTC TOR or reviewing an existing TOR document. This includes example statements, areas to consider when drafting a scope statement or membership list, and aspects of meeting procedures to consider in the TOR.

Guiding principle 5 – MTCs are interdisciplinary, including members with a range of expertise and skills to reflect the functions of the MTC

For comprehensive medicines governance, a diverse skill set is required. The guiding principles provide advice for the MTC membership mix that should be considered when establishing an MTC, and tips for reviewing the existing membership against the purpose and work of the committee. This is done both in general terms within the guiding principles and with more explicit examples in the appendices.

The guiding principles also provide advice regarding the induction process for new members and meeting the ongoing training needs for both clinician and consumer representative members. The resources section within the document has been expanded, providing training examples to assist in meeting these needs.

MTC processes

Guiding principle 6 – MTCs define and implement standardised procedures and criteria for decision-making

To support fair process and equitable decision-making, MTCs need to be consistent in their deliberations. Defining and following principles, criteria or frameworks for decision-making can assist in achieving this consistency. The guiding principles outline areas for MTCs to consider for various decision types and provide resources to support decision-making.

Guiding principle 7 – MTCs implement transparent and ethically robust processes

Consistent, equitable decisions are essential for ethically robust practice. The guiding principles encourage MTCs to consider aspects such as:

- Long-term budget and resource sustainability to allow consistent decision-making for subsequent applications
- The opportunity cost of allocating financial resource to medicines if there are other areas of healthcare where more valuable outcomes may be achieved with the same spend

The guiding principles also discuss conflicts of interest, confidentiality and other member responsibilities for ethically robust MTC practice.

Guiding principle 8 – MTCs are both proactive in medicines governance and responsive to issues arising

MTCs need to be able to react responsively to newly identified risks, challenges and opportunities. As far as resourcing allows, MTCs should also look to be proactive in their medicines governance. The guiding principles provide advice on how this can be achieved including a range of methods that MTCs can use for horizon scanning.

Guiding principle 9 – MTCs undertake risk assessments within the health service organisation with respect to medicines use and recommend strategies to mitigate identified risks

The mix of expertise within the MTC, coupled with a broad view of the medication management systems of the health service organisation, means that the MTC is well placed to identify medicines-related risks and advise on mitigation strategies. Depending on the scope of the MTC, this may include such diverse areas as medication safety, health service budget risks or work health and safety risks relating to medicines handling. Examples of tools that can be used to assess medicines-related risk are included within the guiding principles.

Guiding principle 10 – MTCs identify quality improvement (QI) initiatives and assign priorities, responsibilities and timeframes for their completion

Through the routine work of most MTCs, opportunities for medicine-related QI activities are identified. To provide impactful outcomes from QI activities undertaken, MTCs should document these opportunities as they are identified and assign priority for completion based on the risk posed by current practice and the available staffing resource to complete the necessary work.

Guiding principle 11 – MTCs use monitoring systems to evaluate their effectiveness

To maintain efficient and effective practice, meeting the needs of the health service organisation that it supports, all MTCs should regularly evaluate their performance. A checklist has been included as an appendix to the

guiding principles document to assist in this evaluation process as well as suggestions for other metrics that may be used to evaluate effectiveness.

MTC documentation and communication

Guiding principle 12 – MTCs employ timely and accurate documentation and communication strategies

MTCs need to accurately document committee discussions, decisions (including rationale) and the information used in decision-making. Storage of this documentation should support accurate and timely recall of information to support consistency in future decision-making.

Committee communication strategies should be documented and clear for all health service staff, to support communication both to and from the MTC.

Guiding principle 13 – MTCs engage with internal and external stakeholders to strengthen medicines governance and promote quality use of medicines

Networking with internal and external stakeholders supports quality decision-making, enabling both advocacy and a wider view of issues relating to medication management, medication safety or Quality Use of Medicines policy decision-making. MTCs should consider a multi-layered approach when communicating and networking with stakeholders, identifying relevant local, state and national stakeholders.

MTC resourcing

Guiding principle 14 – MTCs are supported and adequately resourced to undertake their functions and responsibilities by the hospital, local health district/network or state/territory that they service

Provision of medicines governance requires staffing resources, and in some cases additional budget for items such as MTC member training. The guiding principles provide examples of resourcing required for modern MTCs, acknowledging that under-resourcing inhibits robust medicines governance, posing risks for patients, clinicians and the wider health service organisation.

For the future

Through review of the guiding principles, areas were identified that could be expanded to provide enhanced support to Australian MTCs. Centrally produced MTC member training packages, a nationally agreed decision framework for medicines access decisions, and detailed guidance on productive and ethically robust interaction of MTCs with the pharmaceutical industry were all considered to be high-priority areas that CATAG hopes can be addressed in the future. In the meantime, CATAG will continue to work closely with member organisations, promoting consistency in approach to medicines governance nationally.

Discussion

Adoption of these guiding principles by MTCs across Australia will have far-reaching benefits. At an organisational level, updating existing medicines governance structures will assist in meeting the expectations of the National Safety and Quality Health Service Standards, particularly those relating to clinical governance and medication safety.⁷ Where MTCs are appropriately resourced to provide proactive, consistent, effective and efficient medicines governance, this will support clinicians to provide the best and safest care that the system can afford. For patients of these health services, timely and equitable access to safe and effective medicines, supported by optimal medication management systems, will support patients to achieve their goals of care.

The healthcare environment in Australia will no doubt continue to evolve in response to factors such as demographic change and disease management advancements.⁸ Principle-based guidance that can be applied in a variety of settings is therefore expected to be of greatest benefit. At a national level, wide adoption of these guiding principles will help to standardise medicines decision-making and governance across jurisdictions, promoting equitable access to consistently high-quality care in Australian hospitals. As an annex to this work, if a nationally agreed and validated decision-making framework can be developed for medicines access decisions, this will further enhance this consistency, while also facilitating improved collaboration between MTCs for efficiency of process.

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Data availability statement

Research data are not shared.