Building sustainable governance of electronic medication management

Guiding Principles for Drug and Therapeutic Committees in NSW

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NSW TAG — NSW Therapeutic Advisory Group Inc.

NSW GOVERNMENT | eHealth

Index of acronyms

ACSQHC	Australian Commission on Safety and Quality in Health Care
CATAG	Council of Australian Therapeutic Advisory Groups
CDS	Clinical Decision Support
DTC	Drugs and Therapeutics Committee
DUE	Drug Use Evaluation
eMeds	electronic Medication Management
eMR	electronic Medical Record
HREC	Human Research and Ethics Committee
ICT	Information and Communication Technology
IPU	Individual Patient Use
LHD	Local Health District
NIMC	National Inpatient Medication Chart
NSQHS	National Safety and Quality Health Service
NSW MoH	NSW Ministry of Health
NSW TAG	NSW Therapeutic Advisory Group
PD	Policy Directive
QUM	Quality Use of Medicines
TOR	Terms of Reference

These principles build on key concepts from the following previous work:

1. Council of Australian Therapeutic Advisory Groups (2013). Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutic Committees in Australian public hospitals. Council of Australian Therapeutic Advisory Groups; and

2. Australian Commission on Safety and Quality in Health Care (2012). Electronic Medication Management Systems – A Guide to Safe Implementation. 2nd edition, ACSQHC, Sydney.

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Executive summary

Drug and Therapeutics Committees (DTCs) are responsible for the medication management practices, policies and procedures in their assigned facilities to ensure safe, quality and rational use of medications in patients attending those facilities.[1]

The purpose of these Guiding Principles is to assist NSW hospitals and local health districts and specialty health networks to expand their existing medication management governance processes to incorporate safe and effective electronic medication management (eMeds) design, use and ongoing optimisation. NSW Health policy mandates that the DTC[1#] of a hospital, local health district (LHD) or speciality health network provide local governance of medication-related processes. These Guiding Principles aim to provide a framework that enables DTCs and hospital/district executive to develop a flexible and scalable model of eMeds clinical governance, whilst continuing the oversight of medicines management that is not related to eMeds.

Clinical governance describes a systematic and accountable approach to safe-guarding and maintaining high healthcare standards and improving the quality and safety of healthcare services. There are many different structures or processes used to deliver sound clinical governance, however its fundamental purpose is to ensure that responsibility and accountability for clinical quality and safety is designated and acted upon.

Although these Guiding Principles have been developed primarily for consideration by DTCs, there are a number of different audiences, such as electronic medical record (eMR) program managers, Information and Communication Technology (ICT) directors and hospital/district executive, for which these Guiding Principles are applicable. Consideration of medication safety, quality use of medicines and medicines legislation must be applied to decision making for all medication-related processes and workflows in all electronic applications.

For the purposes of these Guiding Principles, the term 'eMeds' refers to all electronic medication management systems that have functionality for the prescribing, ordering, reviewing, reconciling, dispensing and/or recording of administration of medicines. This applies to integrated eMeds systems, as well as stand-alone systems for specific services such as oncology, intensive care, antimicrobial stewardship and pharmacy, whether they be hospital or district wide systems.

eMeds are but one element of integrated digitised clinical care. The digitisation of health presents new challenges for clinical governance in health organisations worldwide and is driving a review of information and communication technology (ICT) governance in healthcare. Drawing a solid border around eMeds functionality and governance within an integrated electronic medical record (eMR) is challenging. Traditional governance frameworks are insufficient when eMeds is implemented as there is frequent cross-over with other eMR functionality and governance structures.

The introduction of eMeds (and eMR) by a hospital typically has two phases. The first is a planning and implementation phase, whilst the second is an ongoing review and optimisation phase, commonly referred to as 'business as usual'. A high level of continuity in governance is required within and between these phases. DTCs are the logical entity to be responsible for ongoing oversight of the quality use of medicines and medication safety in eMeds programs throughout both phases, with medication management policies and procedures reflected in eMeds systems once implemented. However, the increased functions and responsibilities required and the need for additional expertise and resources means that a review of the governance processes and structures are required with the introduction of eMeds.

These Guiding Principles discuss potential eMeds clinical governance models or frameworks that might be used in a hospital/district. The choice of (or preference for) a governance model or framework may be influenced by the current status of other eHealth systems already implemented within the hospital and/or district, and whether future implementation of eMeds is planned for a stand-alone facility only or for multiple sites across a district. The overarching Guiding Principles, encompassing clinical governance, risk management, clinical audit and monitoring for eMeds safety and effectiveness, education and training, research and data custodianship are:

[#] A DTC may also be known as a Medicines Advisory Committee, Pharmacy and Therapeutics Committee, Drug Committee, Drug and Therapeutics Advisory Committee or Quality Use of Medicines Committee

Guiding Principles

1 • Existing medication management and ICT governance frameworks should be reviewed, and future requirements mapped in order to create an over-arching co-ordinated clinical governance structure that incorporates eMeds clinical governance.

2 • The eMeds clinical governance committee that will be responsible for governance of the 'optimisation' phase should be involved in decision-making during the 'implementation' phase.

3 • The eMeds clinical governance framework(s) should be flexible to simultaneously accommodate sites and programs in both 'implementation' and 'optimisation' phases.

4 • The eMeds clinical governance committee should proactively participate in the eMR governance framework and processes.

5 • Membership of the eMeds clinical governance committee should have appropriate skills and expertise to fulfil the scope pertaining to eMeds.

6 • Management of eMeds clinical risk requires clinical governance oversight that incorporates DTC expertise and appropriate information technology resourcing.

7 • An eMeds clinical governance framework requires a clearly defined and documented process for change implementation, outlining accountability and roles and responsibilities for each committee involved in the process.

8 • Appropriate oversight and monitoring of quality assurance and improvement of eMeds systems is required.

9 • The eMeds clinical governance framework should incorporate adequately resourced capability to support analysis of hospital/district medicines use.

10 • An appropriate and timely documentation strategy for all decisions involving eMeds should be developed.

11 • The eMeds clinical governance committee should provide clinical oversight of the training materials to ensure that mitigation strategies addressing identified risks are appropriately incorporated.

12 • The eMeds clinical governance committee should champion workforce capability in clinical informatics, and knowledge transfer.

13 • Existing data governance frameworks should be reviewed to incorporate a data custodian and representation from the eMeds clinical governance committee.

Purpose

The purpose of these Guiding Principles is to assist NSW hospitals, local health districts and specialty health networks to expand their existing medication management governance processes to incorporate safe and effective electronic medication management (eMeds) design, use and ongoing optimisation. The hospital/district management of medicines is complex and requires dynamic, comprehensive and detailed review that ensures medicines use is judicious, appropriate, safe, effective and cost-effective.

NSW Health policy mandates that the DTC of a hospital, local health district (LHD) or speciality health network provide local governance of medication-related processes.[1] These Guiding Principles aim to provide assistance to NSW hospitals, LHDs and specialty health networks seeking to develop or refine frameworks to achieve effective and sustainable governance of eMeds programs, by providing a framework that enables DTCs and hospital/district executive to develop a flexible and scalable model of eMeds clinical governance, whilst continuing the oversight of medicines management that is not related to eMeds.

Although these Guiding Principles have been developed for consideration by DTCs, there are a number of different audiences, such as electronic medical record (eMR) program managers and Information and Communication Technology (ICT) directors and hospital/district executive for which these Guiding Principles are applicable. Consideration of medication safety, quality use of medicines (QUM) and medicines legislation must be applied to decision making for all medication-related processes and workflows in all electronic applications.

The Guiding Principles are vendor- agnostic and are applicable to all public hospitals in NSW. In general, the Guiding Principles can be applied during the eMeds implementation planning process, the eMeds project phase and in eMeds review and optimisation phase, to enable or facilitate the development of a consistent path for eMeds clinical governance across NSW.

Definition

For the purposes of these Guiding Principles, the term 'eMeds' refers to all electronic medication management systems that have functionality for the prescribing, ordering, checking, reconciling, dispensing and/or recording of administration of medicines, whether they be hospital or district wide systems. This applies to integrated eMeds systems e.g. Cerner Millennium™, EPIC™ and CSC MedChart™, as well as stand-alone systems for specific medication services used in oncology (e.g. MOSAIQ™, ARIA™ and CHARM™), intensive care (e.g. Metavision™), antimicrobial stewardship (e.g. Guidance MS™ and eASY™) and pharmacy. iPharmacy™ analytics, clinical decision support during prescribing and smart pumps programming are other examples of eMeds systems that should be covered by an overarching clinical governance framework. It is recognised that the complexity of the clinical governance framework should be proportional to the scale of eMeds systems implementation. As the scope of eMeds implementations may also change over time, the clinical governance framework should be reviewed regularly with the implementation of further digitised systems.

Background

Clinical governance describes a systematic and accountable approach to safe-guarding and maintaining high healthcare standards and improving the quality and safety of healthcare services. Key elements of clinical governance include provision of on-going education and training for staff and management, use of clinical audit to monitor performance and improvement, policies and protocols to ensure clinical effectiveness, promotion of research and development, and policies directed at openness, risk management and information management. There are many different structures or processes used to deliver sound clinical governance, however its fundamental purpose is to ensure that responsibility and accountability for clinical quality and safety is designated and acted upon.

NSW Health policy mandates that the DTC of a hospital, local health district (LHD) or speciality health network provide local governance of medication-related processes.[1] In particular, DTCs have remit over medicines policy development and review, medication safety and its evaluation, application of relevant legislation, risk assessments of

processes involving prescribing, dispensing, administration and storage of high risk medicines, antimicrobial stewardship and approval of formulary and individual use of medicines using sound and consistent decision-making.

The emergence and continual evolution of healthcare digitisation presents new challenges for clinical governance in health organisations worldwide. Increasing implementation of digitised clinical systems requiring clinical governance oversight is driving a review of existing ICT governance in health care. eMeds are but one element of integrated digitised clinical care. It is difficult to draw a solid border around eMeds functionality and governance within an integrated eMR, further complicating the prospect of identifying appropriate governance frameworks, as there will be cross-over with other eMR governance structures as well as non-eMR clinical governance activities.

Implementations of eMeds (and eMR) typically have two phases, with different governance structures. The first is a planning and implementation phase. The second is an ongoing review and optimisation phase, which may also be referred to as 'business as usual'. A high level of continuity in governance is required within and between these phases. DTCs are the logical entity to be responsible for the oversight of the quality use of medicines and medication safety in eMeds programs throughout both phases, with medication management policies and procedures reflected in eMeds systems once implemented. In recognition of the potential for poorly implemented eMeds programs to result in risks to patient safety, the Australian Commission on Safety and Quality in Health Care (ACSQHC) developed an implementation resource to assist Australian hospitals to recognise and minimise risk.[2] Directors of Pharmacy and DTCs are identified as principle stakeholders and decision makers in this resource. In particular, it recommends the DTC or equivalent group within the hospital must play an integral and active role in all stages of the electronic medication management implementation and ongoing operations processes, with input from relevant clinician groups.[2]

In general, the eMeds steering committees and project teams, supported by clinical reference groups, have made medication management decisions during the eMeds design, development and implementation phase. The responsibilities of project steering committees should include project scheduling, budgeting, resourcing, risk management and trouble-shooting; however clinical system design should be the responsibility of eMR/eMeds clinical governance committees or sub-committees. Consultations identified varying involvement of the DTCs in eMeds clinical governance during implementation and post-implementation phases across NSW sites. Typically, governance of eMeds during the initial implementation phase has been held by project steering committees, with support from clinical reference groups. Post-implementation, there are varying models of eMeds governance with a number changing as the scope of electronic systems within facilities and districts increase. For example, some hospital DTCs have expanded their responsibilities to include eMeds clinical governance or established a DTC sub-committee. Others have allocated the responsibility to an overlapping committee, such as a medication safety committee aligned with the DTC. Furthermore, over time, as single facility eMeds implementations have progressed to multi-site implementations, eMeds clinical governance models have been modified to enable governance to be held at a district level rather than at an individual hospital level.

An exceptionally high volume of decisions relating to eMeds (and eMR) design and configuration must be made during the planning and implementation process for each clinical system. These decisions form the foundation of the function and operation of the system and are integral in shaping the clinical workflow for system use. Due to their various existing roles and responsibilities, DTCs are busy committees with full agendas. This may be a barrier to effectively engaging the DTC in eMeds decision making, and because of this, project steering committees may have had a greater role in eMeds design decisions.

There is a considerable amount of maintenance and optimisation work for eMeds, as medicines continually change and new risks and challenges may be introduced. Similarly, changes to medicines legislation, policies and procedures as well as the introduction of new medication safety and quality initiatives may require the review of existing eMeds solutions.

Clinical governance activities in eMeds

Effective and consistent clinical governance of the initial design process and of the ongoing optimisation of eMeds systems is crucial. There are broadly three activities which require long term clinical governance:

1. Implementation of new eMeds functionality (e.g. clinical decision support (CDS) software or tools)

2. Ongoing optimisation and quality improvement activities of existing eMeds functionality (e.g. updating existing medicines, review of incidents and errors, review and modification of work flows; prioritisation of improvement requests from end-users; clinician support and training)

3. Extension of existing eMeds functionality to cover additional uses (e.g. creation of medication order sets for specific disease states).

For these activities, a clinical governance group (or groups) with appropriate medicines and ICT expertise is required to:

➢ Undertake impact analysis of proposed changes against baseline (seeking to identify unintended consequences of proposed change)
➢ Understand policy and regulatory implications of the proposed changes
➢ Ensure that the proposed change is supported by a well-considered and feasible clinical workflow
➢ Document all outcomes / decisions and the rationale
➢ Have ownership of clinical risk management. This includes risks pertaining to implementation and use of new functionality such as CDS and other integrated software, as well as review of errors and incidents and proposed mitigations.

Role of NSW Therapeutic Advisory Group

Through a variety of strategies, NSW Therapeutic Advisory Group (NSW TAG) supports the quality and safe use of medicines in NSW public hospitals and the wider community. NSW TAG was a key contributor to the development and implementation of the 'Council of Australian Therapeutic Advisory Groups (CATAG) *Guiding Principles for the roles and responsibilities of DTCs in Australian public hospitals 2013'* (in addition to other relevant Guiding Principles for DTC functions and medicine use by Australian hospital clinicians).[3]

A fundamental role of NSW TAG is to support Chief Executives and the work of DTCs, by '*promoting Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees to achieve effective medication governance'* (NSW Ministry of Health Policy Directive_2013_043).[1] Since June 2013, with funding from eHealth NSW, NSW TAG has employed a project officer to assist implementation of the state-wide eMeds program and ensure quality use of medicines principles are embedded in NSW eMeds programs. This collaboration recognises NSW TAG's longstanding role in the NSW public healthcare system and its network of healthcare professionals with expertise in the quality use of medicines.

In acknowledgment of this expertise and successful collaboration, NSW TAG was commissioned by eHealth NSW to develop draft guiding principles for sustainable governance of eMeds in NSW hospitals. These Guiding Principles are complementary to and do not supersede *CATAG Guiding Principles for the roles and responsibilities of DTCs in Australian public hospitals 2013*.[3]

Guiding Principles – Scope and functions

GUIDING PRINCIPLE 1

Existing medication management and ICT governance frameworks should be reviewed, and future requirements mapped in order to create an over-arching co-ordinated clinical governance structure that incorporates eMeds clinical governance.

As part of the clinical governance framework in a hospital/district, DTCs have responsibilities for all medicines management within the hospital/district. DTCs have diverse roles and responsibilities ranging from formulary management that enables rational use and cost containment to patient safety and promotion of evidence-based medicines.[3] The introduction of eMeds adds a further complexity to this diverse scope and functions. Moreover eMeds enables integration with other hospital systems not previously possible (e.g. linkage of pathology results to medicines use and monitoring; linkage with medication-related risk assessment tools such as the prevention of venous thromboembolism). For these reasons, the implementation of eMeds (and other eHealth projects) requires a strategic and long-term view of organisational structure in the clinical governance and ICT governance frameworks within a hospital or LHD. The existing medication management governance and ICT governance frameworks must be reviewed, and future eMeds clinical governance requirements and responsibilities mapped in order to ensure the integration of eMeds clinical governance occurs in a coordinated fashion. All key stakeholders must be consulted when determining the eMeds clinical governance framework and final decisions must be made by the hospital or LHD executive.

Changes to existing governance frameworks will require the critical analysis of the roles and responsibilities of each committee and its membership, and a collaborative approach to generate a new clinical governance model with coordinated involvement of the ICT directorate and potentially other eHealth programs. Adequate time must be allocated for discussion of existing medication management processes and proposed eMeds processes, enabling mapping of 'current state' versus 'future state' governance requirements. Allocation of new responsibilities and appropriate expertise to existing or new committees is required.

Governance frameworks for eMeds implementations may vary between hospitals and LHDs, and may vary over time. Current NSW policy requires the DTC to have governance and oversight of medication management within a facility or districts unless otherwise delegated by the Chief Executive.[1] Currently NSW DTCs have different scopes across NSW. Some LHDs have a district-wide DTC that manages formulary and district-wide policy with facility-level medication safety or QUM committees responsible for implementing policy and monitoring medication safety. The facility committees report to the district DTC. These facility committees may also manage individual patient use (IPU) requests and approvals depending on the financial impact of the requests. Alternatively some LHDs have facility DTCs managing formulary and generally working independently within the district, although there may also be a district quality use of medicines (QUM) committee that oversees district-wide policy development and implementation.

To accommodate the expanded responsibility for governance and oversight of medicines management within hospitals with eMeds, there must be a designated multidisciplinary eMeds clinical governance committee. This eMeds clinical governance committee could be the existing DTC albeit with additional resources and expertise, a sub-committee of the DTC, or a similar multidisciplinary committee with an appropriate mix of expertise and strong links to the DTC and clinical governance. This applies equally to individual hospitals and LHDs; however over the long term, implementations of eMeds (and other eHealth applications) will occur across districts, and therefore ultimately governance for the eMeds system as a whole is likely to be held at the district level, rather than at individual hospitals. This will also facilitate safety as clinicians move between facilities within a district.

Certain eMeds decisions will require escalation to an over-arching clinical governance committee, which will require appropriate clinical and technical expertise and support from the eMeds clinical governance committee and the ICT departments, respectively. A formal reporting structure to this over-arching committee should also be established. This aligns with the intent of National Safety and Quality Health Service (NSQHS) Standards 1 and 4.[4]

In order to efficiently and effectively govern all medication-related issues, re-allocation of traditional activities of the DTC may be required. DTCs should consider separating existing functions such as formulary management and individual patient use (IPU) requests and approvals, from the use of medication (protocols and guidelines) and medication safety functions. Practically, this can be achieved through the creation and oversight of sub-committees by the DTC to manage specific tasks, including the governance of eMeds systems. This is articulated in the NSW Ministry of Health Policy Directive-2013_043 and the CATAG DTC Guiding Principle 6.[1,3] There must be appropriate expertise within each committee to optimally perform their functions.

In summary and in simple terms, there are at least three different eMeds clinical governance models that warrant consideration:

1. A model where the role and responsibilities of the DTC expand to incorporate eMeds clinical governance. This model is the least preferred as the workload will dramatically increase, the membership will require expansion and it is unlikely to be a long term solution.

2. A model where a subcommittee of the DTC with the responsibility of clinical governance for eMeds is established. The subcommittee will require new membership with relevant expertise. This model may have sufficient longevity if the facility is a stand-alone facility. This model has the advantage of maintaining the existing clinical governance framework within a hospital. Alternatively this could be the initial governance model with a view that the eMeds clinical governance framework may change over time as other facilities within the district implement eMeds.

3. A model whereby a new multidisciplinary eMeds clinical governance committee is established within the clinical governance stream but independent of the DTC. This model would require the Chief Executive of a hospital or LHD to formally delegate authority for eMeds clinical governance to a committee other than the DTC. There will need to be some shared membership and close links with and reporting lines to the DTC. In this model there is potential for the responsibilities of the existing DTC to be changed. There will need to be clear communication lines between these committees and with the over-arching clinical governance model.

The choice of (or preference for) a clinical governance model or framework may be influenced by the current status of other eHealth systems already implemented within the hospital and/or district, and whether future implementation of eMeds is planned for a stand-alone facility only or for multiple sites across a district. Irrespective of the model, appropriate constitution, reporting lines and methods and ownership of decisions (documented in Terms of Reference) is required for these committees. Furthermore hospitals or districts may commence with one model but later adopt another model better able to meet their expanding needs.

GUIDING PRINCIPLE 2

The eMeds clinical governance committee that will be responsible for governance of the 'optimisation' phase should be involved in decision-making during the 'implementation' phase.

Expertise in medication management is required for ongoing governance of eMeds systems. Implementation projects have end dates, however eMeds programs will continue to evolve; it is therefore essential that the project governance committee includes representation from the committee responsible for eMeds in the optimisation phase, to ensure there is consistent eMeds clinical governance. The committee with the responsibility for eMeds clinical governance should be determined prior to the eMeds implementation phase, to allow for consistency in eMeds decision-making processes and ownership of risk during the implementation phase and at transition to optimisation phase. This provides corporate memory of the rationale for all eMeds decisions made during implementation. For example, during implementation of eMeds applications, project steering committees are often tasked with eMeds decision-making, with support from clinical reference groups. In doing so, the project steering committee owns the eMeds risk management on behalf of the hospital or LHD. When the project steering committee is disbanded at transition to optimisation phase, ownership of eMeds risk management must be transferred to another governance committee. A governance committee with no involvement in eMeds decision-making during the implementation phase may be reluctant to accept ownership of eMeds risk management as well as lacking expertise in the decision-making process for eMeds.

DTCs have existing governance over non-electronic medication management. DTCs apply complex knowledge of legislation, regulatory and policy aspects of medication management to existing approval and review processes for medication related protocols and procedures. DTCs also have expertise in medication safety and its evaluation, and risk assessments of processes involving prescribing, dispensing and administration. The same complex knowledge and expertise must be applied to all eMeds decisions. Although project steering committees may include a DTC member, this does not constitute DTC endorsement of decisions made by the project steering committee. This could be a barrier to the transfer of the ownership and management of eMeds risk to the DTC, a sub-committee or a newly formed eMeds clinical governance committee at transition to optimisation phase.

GUIDING PRINCIPLE 3

The eMeds clinical governance framework(s) should be flexible to simultaneously accommodate sites and programs in both 'implementation' and 'optimisation' phases.

Facilities within a LHD will be at different stages in clinical system implementation and optimisation. The eMeds clinical governance framework(s) should have flexibility to accommodate individual sites within an LHD or specialty health network existing simultaneously in the implementation phase and optimisation phase. There should be a single entity within this framework, other than the project steering committee, that is responsible for the whole clinical system design at the district or network level.

Integrating new eMeds system design within an existing system should be the responsibility of the eMeds clinical governance committee (and sub-committees). Ongoing design enhancements should be made available to all facilities with eMeds systems within a district so that early adopters are not disadvantaged (and does not preclude a staged approach to implementation). In doing so, a shared vision for system optimisation across all district sites will be promoted. For example, a facility in the implementation phase develops a new solution for subcutaneous insulin charting or IV fluid prescribing and administration. These solutions could then be implemented at other sites within the district that are in the optimisation phase.

Similarly, as eMeds design and verifying processes become more sophisticated, all sites in the ongoing optimisation phase will need to revisit or expand current eMeds solutions. This may also be required as single site implementations progress to multi-site implementations, in order to accommodate the needs of other facilities in the LHD.

GUIDING PRINCIPLE 4

The eMeds clinical governance committee should proactively participate in the eMR governance framework and processes.

Medicines expertise is a critical component for eMeds decision making. Many decisions primarily related to eMeds may have impact on electronic systems for health records, pathology and radiology and vice versa. Hence eMeds clinical governance requires close collaboration and communication with or establishment within an eMR governance framework to ensure safe, effective and efficient implementation of a relevant decision within the hospital or LHD. The initial extent of collaboration may depend on the maturity of the eMR within the hospital but will grow as eMR develops. All local or district clinical and non-clinical electronic systems which may impact medication management should be reviewed by the eMeds clinical governance committee and outcomes of the review documented. All decisions regarding eMeds design and document change, along with their rationale, must be owned by the eMeds clinical governance committee. There can be a number of eMR decisions that may not be immediately recognised as medication-related. For example, expanding end-users functions or scope of practice can impact workflow and indirectly affect optimal medication management (e.g. ensuring end-users have relevant access to system functionality to optimise their clinical input).

The absence of strong links between the eMeds clinical governance committee and the broader governance of eMR is likely to result in poorly informed risk assessments of medication-related processes in eMeds and/or other eMR applications.

The eMeds clinical governance committee, either through the DTC/Director of Clinical Governance or the eMR governance committee should have close links to the hospital/district executive given the high investment, critical function, degree of adoption and future capabilities of eMeds and eMR. The Terms of Reference (TOR) describing accountability, the formal organisational structure and the reporting lines of the eMeds clinical governance committee, as articulated in CATAG DTC Guiding Principle 4, should be in place.[3]

The eMeds clinical governance committee should be involved in reviewing the build of medication-related protocols and solutions in all new specialised systems (such as oncology and ICU) to ensure consistency and continuity with existing eMeds functionality, and that medication quality and safety principles are embedded.

GUIDING PRINCIPLE 5

Membership of the eMeds clinical governance committee should have appropriate skills and expertise to fulfil the scope pertaining to eMeds.

The principles for DTC membership, as outlined in CATAG DTC Guiding Principle 5, should be adapted and applied to the membership of the eMeds clinical governance committee.[3] The committee should be resourced with a mix of appropriately skilled members, who have expertise in medication safety/governance and clinical informatics, in order to advise on and to review eMeds design and design changes. The committee should be multidisciplinary and include members from medicine, nursing and pharmacy as well as clinical informatics and clinical governance. Consideration should also be given to the periodic or ongoing inclusion of non-medical prescribers depending on the scope of local practice. There must also be a nominated Chair with appropriate expertise and strong leadership skills.

Membership of the eMeds clinical governance committee should include clinicians, eMeds application specialists[+] and data architects[≠] with critical appraisal skills who are capable of making eMeds-related decisions in a timely manner. Frontline clinicians who experience eMeds-related issues at an operational level should also be represented, in order to provide end-user understandings, perspectives, and innovative concepts to the eMeds clinical governance committee. All committee members should have dedicated time to devote to their responsibilities and should champion the committee's objective to improve the safety and effectiveness of eMeds systems, within the broader eMR governance framework. There should also be appropriate secretarial support to enable the committee to optimise its functionality.

There should be an orientation processes for members that outlines their roles and responsibilities and includes a review of the eMeds clinical governance committee's TOR. New members should also have an understanding of the principles involved in eMeds decision making and knowledge of how the system works for medical, nursing and pharmacy staff.

If it is determined that eMeds clinical governance will be held by the DTC as a single entity or by a sub-committee of the DTC, membership of the existing DTC must be reviewed and expanded (where necessary) to incorporate expertise in clinical informatics. If eMeds clinical governance is to be held by a separate committee with links to the DTC, it is recommended that membership of the over-arching DTC includes an application specialist with knowledge of the application build and experience with eMeds and clinical practice workflows. It is also recommended that clinicians and ICT personnel agree upon and use common terminology. A glossary of agreed terminology may be useful.[5]

[+] An eMeds application specialist is a pharmacist with experience in medication management processes and eMeds problem identification, analysis and resolution.

[≠] A data architect is an ICT specialist that can determine how data will be utilised, stored and integrated with other IT systems and applications.

Risk management

GUIDING PRINCIPLE 6

Management of eMeds clinical risk requires clinical governance oversight that incorporates DTC expertise and appropriate information technology resourcing.

Medicines risk management requires a proactive and responsive approach to issues and incidents as they occur.[3] DTCs have traditionally had oversight of medication safety issues, as they are comprised of members with the necessary skills and expertise to assess medicines safety and risk management. The introduction of eMeds adds additional complexity to medicines safety and risk management and thought must be given to how incidents will be managed. Hence depending on the eMeds clinical governance framework, the DTC or new eMeds clinical governance committee (containing relevant members of the DTC) must be involved in the assessment and management of clinical risk pertaining to eMeds. Decisions include (but are not limited to) the level of CDS functionality that will be implemented, maintained and enhanced over time; the quality of the information provided by CDS software; the extent to which alerts such as drug interactions are implemented; the impact of alert integration into clinical workflows; legality/liability (e.g. consequences of failure to warn versus over-warning) and technical and human factors. Monitoring and evaluating the clinical impact of, for example CDS and maintaining currency of content will be ongoing responsibilities of the committee assigned eMeds risk management responsibilities.

Risks that cannot be solved solely by system re-design (for example, ordering or ceasing medications on the wrong patient record) should be recorded in a risk register, with mitigations identified, implemented and monitored. The eMeds clinical governance committee would be the appropriate group to action this. This aligns with CATAG DTC Guiding Principle 11, which recommends that DTCs undertake risk assessments with respect to medication use within their organisation and develop risk management strategies.[3] Adequate clinical and technical resourcing including support from the information technology and patient safety departments is required to ensure efficient, timely and appropriate risk management.

GUIDING PRINCIPLE 7

An eMeds clinical governance framework requires a clearly defined and documented process for change implementation, outlining accountability and roles and responsibilities for each committee involved in the process.

The change implementation process for all eMeds system changes in the optimisation phase should be defined and have clear principles for prioritisation of tasks and escalation. All proposed changes must undertake a clinical and technical assessment. Change decisions should be evidence-based (where possible) and be concordant with best clinical practice. The following step-wise approach for changes to eMeds should be adopted:
1. A rationalisation of the need for a change or enhancement
2. The development of potential solutions (including technical feasibility assessments)
3. An eMeds clinical governance committee review of solutions for appropriateness and safety
4. An eMeds clinical governance committee endorsement of the proposed solution
5. A plan to conduct the system change or enhancement
6. The communication of changes to relevant groups and users
7. The integration of changes into training resources and programs if required.

The eMeds clinical governance committee should consider the method and access point for staff to request changes to eMeds functionality and scope, and ensure appropriate processes are followed before any changes are enacted. Depending on the clinical governance map this may be the DTC, a DTC sub-committee or aligned eMeds clinical governance committee.

The eMeds clinical governance committee will oversee the activities of the eMeds change processes and may delegate these tasks to a change implementation group. The processes must be established or maintained post-implementation phase to action the design build and changes recommended by the eMeds clinical governance committee. There should be prioritisation principles for working through an eMeds issues list. According to these

principles, some changes could be enacted without recommendation, such as a change in naming conventions (e.g. amoxicillin 'y' to an 'i') whereas others (e.g. international harmonisation of medication names such as adrenaline/epinephrine) would require direction from the eMeds clinical governance committee. If an issue cannot be resolved, it should be escalated to the eMeds clinical governance committee.

Centralised governance: Where there is a district or jurisdictional governance authority, there should be clarity regarding the allowable changes that can be made at a local hospital or LHD level, respectively. Changes that will affect more than one hospital (or district) should not be made locally. There must be evaluation of eMeds solutions in response to NSW Ministry of Health policy directives, safety alerts and other state-wide or national requirements (for example, the incorporation of venous thromboembolism prophylaxis section on the National Inpatient Medication Chart (NIMC) required analysis and eMR solution). Therefore the eMeds clinical governance committee must be able to respond to internal and external quality use of medicines (QUM) and medication safety issues.

Escalation process: Where possible, decisions should be made quickly (within agreed limits) and reported. Escalation should occur by exception. This process must be supported by appropriate personnel who can act quickly when required to do so. Prioritising decisions for escalation should be based on legislation, policy mandated by NSW Ministry of Health, patient safety, changes to workflow, patient outcomes and limitations of the system. Complex risk management issues should be escalated to the over-arching clinical governance.

Clinical audit and monitoring for eMeds safety and effectiveness

GUIDING PRINCIPLE 8

Appropriate oversight and monitoring of quality assurance and improvement of eMeds systems is required.

It is essential that evaluation and quality improvement of eMeds systems are conducted. Audit must occur to monitor user- interaction with the eMeds system and to facilitate evidence-based, iterative improvements to ensure safe use of the system. Recommendations arising from outcomes of eMeds-related quality assurance and improvement projects, including projects undertaken by other groups, should be reviewed by the eMeds clinical governance committee before they are referred to a change implementation group.

As part of the eMeds monitoring process, regular reports should also be configured to routinely and seamlessly provide quality and safety data from eMeds systems (for example, rate and type of pharmacist interventions) and subsequently be presented to the eMeds clinical governance committee as a standing agenda item. System issues should be matched with clinical incidents reports (where possible) to understand the causation factors and identify possible mechanisms to prevent future incidents. Thematic analysis of these types of incidents and implementation of mitigation strategies will reduce patient harm and clinician liability. Any enhancements should be fed back to eHealth NSW and other NSW Ministry of Health pillars where appropriate, such as the Clinical Excellence Commission, the Agency for Clinical Innovation and the Health Education and Training Institute to facilitate state-wide learning.

Prior to implementation of eMeds, baseline data should be obtained for the rate and type of pharmacist interventions and rate of medication errors (where possible), to allow the eMeds clinical governance committee to compare data obtained for these parameters post eMeds implementation.

GUIDING PRINCIPLE 9

The eMeds clinical governance framework should incorporate adequately resourced capability to support analysis of hospital/district medicines use.

Realisation of the eMeds investment will be expedited with the efficient and effective use of data. The eMeds clinical governance framework should incorporate adequately resourced capability to undertake statistical and qualitative analysis of medicines use and monitoring of eMeds safety and effectiveness. These activities are critical to the realisation of the full potential of eMeds systems.

Drug use evaluation (DUE) and QUM pharmacists currently analyse medication use in hospitals, however the capacity of many hospitals to undertake these activities has diminished due to resource depletion, altered priorities and lack of a multidisciplinary approach. Up-skilling of relevant multidisciplinary staff may be required for optimal extraction, analysis and interpretation of eMeds data and reporting of eMeds data for research and quality improvement purposes. As long as capability is adequately resourced and led, DUE activity and monitoring of QUM principles should be enhanced as a result of eMeds implementation.

The DTC comprises members with expertise and skills to assess results from DUE and QUM monitoring projects and guide any follow-on studies and implement quality improvement strategies related to medicines use. Depending on the eMeds clinical governance framework, the DTC (or sub-committee) or new eMeds clinical governance committee (containing relevant members of the DTC) should be involved in the oversight of eMeds-enabled DUE and relevant QUM projects. Examples of improved research efficiency and capability with eMeds may include the ability to examine indications for antibiotic use; overrides; missed doses; alert fatigue for drug interactions and perform sub-analyses for certain population groups. Adequate clinical and technical resourcing including support from the information technology and patient safety departments is required to ensure efficient, timely and appropriate research output and action. DTCs as well as other appropriate committees (e.g. eMR committees) should receive reports of these activities and a collaborative approach to quality improvement taken.

Design and configuration decision documentation

GUIDING PRINCIPLE 10

An appropriate and timely documentation strategy for all decisions involving eMeds should be developed.

Documentation of all eMeds design decisions and changes (and testing) must occur before being implemented. Changes that are not accepted should also be documented. There should be a designated, separate, accessible repository to record all decisions and changes, in order to facilitate regular monitoring of eMeds. Where there is centralised district-wide governance authority for changes, these should be uploaded to a central repository on a regular basis.

The eMeds clinical governance committee should have mechanisms in place for the systematic review of eMeds decisions or solutions to ensure ongoing system optimisation and, where necessary, suitability across multiple sites. Review dates should be documented. Maintaining current access to the documentation of all previous eMeds decisions and solutions is crucial to this process.

There must be comprehensive documentation of all committee meetings and appropriate correspondence with other relevant committees or groups. There should be a standing item on the DTC agenda for reporting changes in eMeds business processes, such as: quick lists created/reviewed/amended; protocols created/reviewed/amended; clinical decision support rules created/reviewed/amended; dose ranges; formulary updates (including admission to high risk group); and, locally added drugs. There should be appropriate, standardised processes and documentation for eMeds-related agenda items (accompanied by appropriate secretarial support) as per recommendations made in CATAG DTC Guiding Principle 9.[3]

A release schedule for communication of information around decision making is recommended. For example, changes should be regularly enacted on a certain day of the release schedule (e.g. every second Tuesday). Communication should be sent to relevant staff one week prior to the change. Urgent issues requiring only a small change could be done out of the release schedule, but a good communication process must be ensured.

Education and training

GUIDING PRINCIPLE 11

The eMeds clinical governance committee should provide clinical oversight of the training materials to ensure that mitigation strategies addressing identified risks are appropriately incorporated.

Comprehensive education and training is a key principle in eMeds implementation and optimisation phases, and content should be owned by the eMeds clinical governance committee. Education and training of eMeds support teams, testers and end-users should be on-going and flexible to meet the specific needs of eMeds systems. Training resources should be regularly reviewed in the light of design and/or workflow changes. Ongoing updates and generation of new training materials in support of system   optimisation is critical to ensuring the ongoing safe use of clinical applications.

GUIDING PRINCIPLE 12

The eMeds clinical governance committee should champion workforce capability in clinical informatics, and knowledge transfer.

Building workforce capability in eMeds is required for the ongoing adoption and optimal use of eMeds systems by all users. Career opportunities in clinical informatics are growing and suitable staff should be identified and up-skilled. Incentives for developing skills such as the provision of cadetships and /or internships may be one method by which this could be achieved. Continued reliance on specific 'champions' who have led project implementation may put the facility at risk due to burn-out and loss of knowledge transfer and should be avoided. The eMeds clinical governance committee should advocate for building and maintaining workforce capability in clinical informatics.

Consideration of effective knowledge transfer between clinicians with governance responsibilities (and possibly others) at various phases of eMeds implementation is also required. Hence clinicians at hospitals implementing eMeds systems should be enabled to learn from those hospitals where roll-out has been completed and those at rolled-out hospitals should provide support to those at implementing hospitals. The eMeds clinical governance committee should facilitate this sharing of knowledge.

Research and data custodianship

GUIDING PRINCIPLE 13

Existing data governance frameworks should be reviewed to incorporate a data custodian and representation from the eMeds clinical governance committee.

The DGI Data Governance Framework states that "*Data Governance is a system of decision rights and accountabilities for information-related processes, executed according to agreed-upon models which describe who can take what actions with what information, and when, under what circumstances, using what methods.*" [6] Local sites will have accountabilities around data, and therefore a data governance committee is required. Existing committees such as Human Research and Ethics Committees (HRECs) will have processes in place for research-related data requests. Privacy of certain population groups who may be identifiable by medicines use (e.g. HIV medicines) must be protected. There should be a data custodian to provide, control and monitor access to the data. There must also be governance around the reporting of accessed data and ensuring the limitations of the data are understood. The eMeds clinical governance committee should be represented in the data governance committee.

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Appendices

Appendix 1: Informing and developing these Guiding Principles

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A project team was established by NSW TAG to develop these Guiding Principles, supported by NSW Health, and with additional funding from eHealth NSW. Consultation was undertaken to develop guidance, and occurred in two phases:

1. An environment scan focussing on NSW hospitals with eMeds implementations was undertaken (SLHD, St Vincent's Hospital, Prince of Wales Hospital and Children's Hospital Westmead).
2. External consultation with face-to-face meetings occurred with interstate health services and hospitals to learn from experiences with eMeds/eMR implementations.

Records of interviews were analysed to identify recurring themes and principles. Proposed governance structures and the terms of reference for committees with involvement in eMeds clinical governance were kindly provided.

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Application: A program or piece of software designed to fulfil a particular purpose.[1]

Application specialist: A pharmacist with experience in medication management processes and eMeds problem identification, analysis and resolution.

ARIA™: A commercial oncology information and image management application combining radiation, medical and surgical oncology information.

Business as usual: The normal execution of operations within an organisation.[2]

Change control: A formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. It reduces the possibility that unnecessary changes will be introduced to a system without forethought, introducing faults into the system or undoing changes made by other users of software.[3]

CHARM™: A commercial oncology information management application for cancer care clinical coordination and management.

Clinical informatics: The application of informatics and information technology to deliver healthcare services.[4]

Clinical governance: A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. This is achieved by creating an environment in which there is transparent responsibility and accountability for maintaining standards and by allowing excellence in clinical care to flourish. [5]

Data architect: A practitioner of data architecture, an information technology discipline concerned with designing, creating, deploying and managing an organization's data architecture. Data architects define how the data will be stored, consumed, integrated and managed by different data entities and IT systems, as well as any applications using or processing that data in some way.[6]

Data custodian: Data custodians are responsible for the safe custody, transport, storage of the data and implementation of business rules.[7]

Drug and Therapeutics Committee: The group assigned responsibility for governance of the medication management system, and for ensuring the safe and effective use of medicines in the health service organisation.[8]

Drug usage evaluation (DUE): An authorised, structured, ongoing system for improving the quality use of medicine within a health service organisation. Medicine use is evaluated using pre-determined standards, and efforts are initiated to correct patterns of use which are not consistent with these standards. It includes a mechanism for measuring effectiveness of these corrective actions.[9]

eASY™: A commercial web-based application for streamlining communication between clinicians involved in the use of antimicrobials.

Electronic medication management: The entire electronic medication management process from the prescriber's medication order, to the pharmacist's review of the medication order and supply of medication, to the nurse's documentation of the administration of the medication, and all the processes in between.[10]

Formulary: A continually updated list of medications and related information, representing the clinical judgement of physicians, pharmacists and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medicines and medicine-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organisational guidelines.[11]

Guidance MS™: A commercial application for managing medicine stewardship and clinical guidelines.

Individual patient use: A request to or approval by the DTC for the use of a medicine by an individual patient outside the formulary regulations.[12]

iPharmacy™: A commercial hospital pharmacy dispensing application. It incorporates pharmacy dispensing, inventory and cost centre accounting requirements.

MetaVision™: A commercial electronic medical record and clinical decision support application for intensive care units.

MOSAIQ™: A clinical information application for medical and haematological oncology services.

Multidisciplinary: Professionals from a range of disciplines with different but complementary skills, knowledge and experience working collaboratively. [12]

Near miss: An incident that did not cause harm, but had the potential to do so. [13]

Quality Use of Medicines (QUM): The judicious, appropriate, safe and effective use of medicines.[14]

Risk management: The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution. [13]

Steering committee: is a committee that provides guidance, direction and control to a project within an organisation.[15]

Terms of reference: These are used to describe the purpose, roles and structures of projects, working groups, reference groups and committees. These are guidelines for the way group members will work together.[12]

Thematic analysis: A categorisation strategy for qualitative data.

Vendor agnostic: Not restricted or limited to the products of a specific company.

Appendix 3: Glossary References

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