



Australian Health Ministers' Advisory Council
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Health Policy Priorities Principal Committee
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Mental Health Standing Committee
Safety & Quality Partnership Subcommittee

**FRAMEWORK FOR
REDUCING ADVERSE MEDICATION EVENTS
IN MENTAL HEALTH SERVICES**

**Endorsed by the Mental Health Standing Committee
6 February 2009**

PREAMBLE

The Safety and Quality Partnership Subcommittee (SQPS) of the Mental Health Standing Committee is responsible for providing advice on the implementation of the national safety priorities identified in the *National safety priorities in mental health: a National Plan for Reducing Harm*.

A priority focus of the National Plan for Reducing Harm includes reduction of adverse medication events in mental health services. The key objectives relating to this priority area are to:

- reduce adverse drug events (ADEs) in mental health services;
- reduce medication errors involving psychotropic medicines within mental health services and other health services;
- increase safe and quality use of psychotropic medicines in mental health services;
- and
- reduce ADEs relating to mental health clients in other health services.

The Framework for reducing adverse medication events in mental health seeks to guide service development and quality improvement activities in relation to medication events and provide a nationally consistent approach where appropriate. The proposed approach recognises both the sovereignty of each State and Territory to develop its own policies in this field, and the desirability of flexibility for individual jurisdictions to adapt the framework to local circumstances and systems as they see fit. It is not intended to prescribe individual State or Territory policy or legislation. However, in implementing or reviewing policy in the area of adverse medication events in mental health services, States and Territories are urged to utilise the information for best practice proposed in this Framework.

It is an established principle that in all aspects of mental health service provision consumers and carers must be involved to the fullest extent possible and this is reflected in this report. In this framework the term carer or carers means the person or persons identified as such by the consumer or in the absence of such identification can include parents, partners, brothers, sisters, friends or children of any age. A carer can also be a State and Territory Guardianship Board or Tribunal appointed guardian or administrator.

Release of information to an identified carer or carers will be subject to the relevant jurisdictional legislation, which may include legislation that supports the involvement of carer(s) including release of information to a carer and/or limiting legislation that restricts the release of personal information to support the consumer's right to privacy and confidentiality. The principle that carers must be involved to the maximum extent possible is to be implemented in practice but this must occur within the respect for privacy and confidentiality and associated legislative requirements.

Wherever in this report "where appropriate" appears it is to be interpreted on the basis of identification of the carer(s), compliance with any jurisdictional legislative requirements such as obligatory consent for release of personal information, but at all times maximizing the opportunities for involvement of the carer(s) in all aspects of the consumer's care including general discussion and relevant information to enable the carer's understanding and involvement.

BACKGROUND

The Reducing Adverse Medication Events in Mental Health Working Party (RAMEMHWP) was established to:

- provide expert advice and recommendations to the SQPS on the development of strategic directions and practical applications that can reduce adverse medication events in mental health consistent with national mental health initiatives; and
- to develop recommendations for the SQPS on the development of State and Territory frameworks for the implementation of the safety and quality agenda in relation to reducing adverse medication events in mental health services.

The *Mental Health and Quality Use of Medicines Report* and *The National Strategy for the Quality Use of Medicine* document provided useful guides for RAMEMHWP's deliberations. The former was developed as a result of a workshop coordinated by the Mental Health Council of Australia (MHCA), which brought together stakeholders and experts working 'at the coalface' of mental health and Quality Use of Medicines (QUM). The latter report sets out the approach and principles necessary to achieve QUM in Australia and supports the QUM Strategic Action Plan.

In addition, the RAMEMHWP recognized the need to be consistent with the aims of the sub program *Medication Safety* as outlined in the Work Plan of the Australian Commission on Safety and Quality in Health Care (ACSQHC) as the issues in regard to adverse medication events in mental health were, by and large, the same as those issues pertinent to general health.

Furthermore, the RAMEMHWP focused on developing a framework that was practical and achievable, with States and Territories having the responsibility for developing and implementing their individual policies and protocols for medication safety and management adverse medication events.

In undertaking this work, the RAMEMHWP undertook a literature search, which demonstrated that there has been limited research carried out in the area of reducing adverse medication events. In addition, there is no substantiated evidence base to indicate what type of adverse medication events are more common than others and a small evidence base specific to mental health.

As part of the work undertaken to date, the RAMEMHWP conducted a jurisdictional mapping of activity related to safety and quality in medication usage. The results of the mapping exercise, based on a standard template developed in consultation with a range of people including key stakeholders in Western Australia who are involved in the area of medication safety, indicated that while there is a lot of activity in this area there is a lack of coordination and networked communication across the area nationally and in most jurisdictions. Furthermore, it is acknowledged that there is limited evidence for best practice in this area.

In developing the Framework for Mental Health Services, the RAMEMHWP was concerned about the tendency for strategies to improve medication quality and safety being developed in "silos", which in turn resulted in duplication of activity, disparate approaches to similar problems and implementation of similar, yet uncoordinated, activities in different areas of practice.

Accordingly, the focus of the Framework is on prioritising objectives that:

- best meet the needs of consumers and carers;
- provide practical solutions that can make a difference;
- identify strategies that are achievable within current levels of resourcing whilst recognising the need for supporting those that will require increased levels of resourcing; and
- differentiate strategies for implementation at the National and State/Territory level.

THE FRAMEWORK

Introduction

The Framework is structured in three parts, with the first part of the Framework focusing on interventions for reducing adverse events that address the key areas of prevention, risk-reduction and system learning.

The second part of the Framework focuses on the processes of prescribing, dispensing and administration of medication. The final part of the Framework focuses on the adverse medication event itself.

It is recognised that there is some overlapping of content within the Framework, as the functions described in the structured sections are not mutually exclusive.

For the purposes of the Framework it was agreed that all RAMEMHWP definitions must be consistent with the national definitions as outlined on the ACSQHC website.

In light of this an adverse event is defined as:

"An incident in which harm resulted to a person using health care."*

The RAMEMHWP has defined an adverse medication event as:

"An incident involving medication prescribing, dispensing or administration in which harm resulted to the person receiving the health care."*

*Where "harm" may include psychological as well as the more common physical manifestations.

The RAMEMHWP particularly notes that further work needs to be undertaken to ensure consistency in definition for the threshold of adverse medication events and for consistency in reporting.

PART 1

The first part of the Framework focuses on an intervention framework of reducing adverse events.

I. Prevention

For effective education about the consumer's medication and conditions, it is important to encourage prescribers to provide, and consumers and carers to ask for, written information in addition to oral advice, and preferably the combination of both. Consumers and carers need to be educated about how to use medication and other treatments effectively – in particular how to take medications correctly, what effects to expect, when to expect the results, how to monitor the effects, what to do if the treatment does not work as expected and what to do if an adverse drug reaction is experienced. The risk of adverse medication events also occurring in the long term with the use of certain medications – in many cases over a number of years – needs to be recognised and this information communicated by prescribers and dispensers to consumers and carers.

All prescribed medications are required to incorporate *Consumer Medicine Information* (CMI) but some reviews of the effectiveness of the CMI have been critical. It is therefore important that the CMI is accompanied by careful explanation and advice by prescribers as to the specifics of the particular medication. This supplementary advice could be enhanced by a separate document that accompanies the CMI that could be provided at both the prescribing point and the dispensing point. It is therefore important for prescribers and pharmacists to work together to communicate and educate consumers, and where appropriate carers, about the medication. This additional document would ideally include appropriate and useful information such as general information about the condition for which the particular medication is prescribed. Additional information in relation to general groups of psychotropic medications, the possibility of adverse medication events occurring with the use of these medications in the long term, associated side effects and concerns regarding safety issues should also be provided as appropriate. Together with the CMI, this document should be available through a variety of pathways including on a national website, which is linked to other relevant sites.

Improvements in medication management systems and associated tools, such as the Medication Safety Assessment Tool, when properly implemented have assisted improvement in reducing adverse medication events. However, these tools are not consistently available in all settings. A range of resources need to be available to Community Mental Health Centres, private psychiatrists and general practitioners to provide information for consumers and carers to further enhance the safety and effectiveness of medication use, specifically associated with the treatment of people with mental health problems.

In addition, adverse event reporting needs to be enhanced in a significant way for consumers, carers and providers. A variety of "channels" to achieve this should be made available, including through print and electronic media and through peer group channels.

- **Provide oral and written advice regarding medications**
- **Educate on correct use of medications**
- **Advise of possible side effects and how to monitor possible effects**
- **Advise course of action in case of an adverse drug reaction.**

II. Risk Reduction

Consumers and carers require education in relation to medication use and should be encouraged to directly discuss all issues of medication use with the prescriber. This discussion should take into account the consumer's own responsibility for his/her health and long-term management, particularly the importance of medication compliance. Hospitals also have a responsibility to inform consumers and carers about the importance of continuing medications and other treatments, particularly when transitioning in and out of inpatient care. Specialists also have a responsibility to discuss medication maintenance issues with consumers, both prior to and post hospitalisation.

In particular, mental health services in both the public and private sectors may need to consider resourcing requirements to provide follow up within 14 days of discharge to:

- check the consumer's progress;
- check for side effects and any indications of toxicity;
- provide counselling to consumer and carer;
- check consumer's, and where appropriate the carer's, understanding of the condition and what needs to be done to aid recovery;
- check the consumer has a recovery plan;
- check the consumer, and where appropriate the carer, knows what to do to reduce risks of further events and prevent further harm;
- check the consumer has all the medications prescribed. Consider accessing a 'home medication review' by a specially qualified pharmacist following a request from a GP;
- check medication use; and
- check the consumer's links with doctors, pharmacists, nurses, rehabilitation, physiotherapists and specialists.

Continued research is necessary to find medications that are better tolerated by consumers and further research required into complementary, herbal and alternative medicines in order to develop a more useful and accessible evidence base for their use (or non use) by consumers and health practitioners.

Adverse events reporting by consumers, carers and health professionals needs to be encouraged and enhanced and this information integrated into national or jurisdictional databases which can be used for trend analysis and reporting. It is important to resource consumer and carer tools and training on the monitoring of medication, including its positive and negative effects.

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| <ul style="list-style-type: none">• Stress importance of medication compliance• Ensure medication supply and continuity at transitioning points including discharge• Follow up within 14 days of discharge |
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III. System Learning

Professional bodies and Government need to find demonstrable ways to improve communication between prescribers and pharmacists and promote these methods to the professions. Pharmacists are in a unique position to often know about the totality of the prescribed medications and complementary medicines that a consumer is taking and there needs to be more effective communication channels developed between them and prescribers about the combination of medications that a consumer is taking at any one point.

Medical practitioners, nurse practitioners and other practitioners, who may be authorised to prescribe in the future, should be informed of prescribing and dispensing options that help consumers manage their medications, including the cost of treatment.

It is also important to increase community understanding of mental illnesses and treatments to enable a balanced discussion of benefits and harms of medication use.

System learning, from data analysis of adverse medication events reporting, is an important part of the application of the QUM framework. System learning will follow from the improvements in reporting at the jurisdictional and national levels. Improved reporting, in turn, will help focus application of specific remediation at the particular points where problems are identified and will thereby contribute to reduce adverse medication events.

Improvement in QUM relies on changing the behaviour of the participants and involving key people in the process. This approach has been successful in areas such as diabetes and asthma where consumers, professional bodies, federal and state governments and the community have been part of a successful education process. Attempts to engage with mental health have been less successful and mental health is now recognised as a prime focus for development. It is important to develop and resource more effective educational methods to encourage positive change in health professionals' prescribing behaviour.

There is international evidence demonstrating that data sets are critical in improving QUM. In Australia we have a number of data sets that could be used to improve the quality of medication management at the clinical team, hospital, jurisdictional and national levels. It is important to make use of existing information, particularly as data collection is enhanced, to inform continuous improvement of data sets. In addition, to be most effective, these data sets need to be brought together and aggregated and coordinated more effectively. The National Prescribing Service (NPS) has a major and central role in this process. It is also important to continue to build a better understanding of what QUM is amongst consumers and carers.

Evaluation and outcome measurement for different types of interventions as part of QUM is an important aspect in understanding the effectiveness of such interventions and continuous improvement. A number of interventions have already been assessed in an attempt to understand the nature of risks, gaps and remediation in QUM. This includes Disguised Observer Studies, Unit Dose Drug Distribution System Studies and Chart Analysis Studies. Other approaches have included stratifications to assist specific interventions including a focus on identification of high risk medication groups and particular drugs and high risk situations.

There has been only a relatively recent focus on these types of approaches and it is expected that there will be further developments to assist in the identification and understanding of safety and risk in QUM. Additional findings will need to be progressively incorporated in the framework as they apply to this area.

- **Improve communication between prescriber and dispensing agent**
- **Ensure system learnings are incorporated into local level protocols**
- **Systematic improvement of data collection and incorporation into continuous improvement of addressing adverse medication events.**

PART 2

The second part of the Framework focuses on the processes for reducing adverse events.

IV. Prescribing

Before commencing medication, prescribers need to explain to consumers, and where appropriate carers, why initially switching and changing doses is often necessary. They should also explain how long it may take to find a medication or combination of medications that will be effective and suit the individual. Before commencing use, consumers, and where appropriate carers, should also be provided with information on possible side effects, how long they may last, how to respond to these side effects and the possibility of adverse medication events occurring in the long term with certain medications – e.g. antipsychotic medications associated with an elevated risk of tardive dyskinesia and metabolic syndrome. This advice should be provided as a supplement to the information in the CMI, as part of the supplementary document to accompany the CMI as proposed in the Section on Prevention.

There is a strong case for the development and maintenance of a national central repository of information. This would include educational materials, clinical practice guidelines, availability of health services, support groups etc. The central repository would provide information for fully informing consumers and carers of the process of commencing new medications, what to expect, what side effects are likely to occur, and how to deal with these side effects. This information could be part of a national, standardised set of information for consumers, carers and health professionals and include information on psychotropic medications.

Consumers should be involved in making decisions about their medications, and their input should be highly valued and respected. It is important to engage consumers, and where appropriate carers, to have a comprehensive discussion with health providers before they make treatment decisions. This discussion should include the consumer's health and medical history, options for treatment, benefits and risks of each option, concerns about side effects, and the appropriate response and constraints on treatments such as cost, lifestyle and family support. In addition, consumers should be educated to inform **all** of their health care providers about **all** of the medications that are being used.

GPs, Nurse Practitioners and specialists should be encouraged to:

- ask consumers, and where appropriate their carers, about all the medications, alternative treatments, alcohol and illicit substances they are using, before prescribing;
- document this use and encourage consumers to keep their own record; and
- advise consumers, and where appropriate carers, on possible adverse reactions and interactions including the possibility of adverse medication events occurring in the long term with certain medications. Prescribers should also pay attention to any contributory factors to facilitate early detection of such adverse events.

There is some evidence to indicate that computerised prescribing with **decision support and safety alerts** can contribute to the reduction of adverse medication events. As such, prescribers should be encouraged to use existing facilities in prescription software to print a medication record for consumers.

- **Access available information, including educational and clinical practice guidelines, from central repository when established.**
- **Encourage consumers, and where appropriate carers, to have a comprehensive discussion with the relevant health provider about treatment options, including drug therapies, prior to prescribing a new medication.**
- **Encourage consumers to disclose information about all medications to all health care providers.**

- **Encourage health care providers to seek comprehensive information on all medications and substances being used by the consumer prior to prescribing a new medication.**
- **Advise consumers, and where appropriate carers, the appropriate course for reporting an adverse drug reaction.**

V. Dispensing

Pharmacists should also ensure a thorough discussion with consumers prior to dispensing medications. Specifically, they should ask consumers (in a setting that ensures privacy) about complementary, over-the-counter and prescription medicines they are using, before dispensing medications, and advise consumers on possible adverse effects and interactions including, as stated above, the possibility of adverse medication events occurring in the long term with certain medications. Any queries regarding the prescription, including possible errors in the prescription, should be clarified with the prescriber prior to dispensing.

Pharmacists, together with other health professionals, should be encouraged to reduce the number of medicines and doses that consumers have to take e.g. combination medications and slow-release tablets. Packet information and labels for medications should be legible and easily understood – for example, pharmacists should ensure they do not cover important information on the packaging with their own pharmacy stickers.

It is important to recognize a consumer's possible confusion about generic and brand name medicines. After consulting with the prescriber, the pharmacist should provide an explanation of the pros and cons of the use of these medicines to consumers, and where appropriate carers. The pharmacist has a role in communicating with other health professionals to minimise any consumer confusion prior to dispensing medications. It is vital that CMI and the proposed supplementary information discussed in Part 1 is provided to the consumer.

Consumers, and where appropriate, with the support of their carers, should be encouraged to persist with their medications and to discuss any side effects with their doctor.

It is noted that medication management is the subject of review by a number of bodies including in the context of Quality Use of Medicines, by consumer and carer organisations and by professional bodies such as the Pharmacy Guild of Australia. These initiatives will contribute to improving medication safety on an ongoing basis and should be regularly incorporated into local and centralised medication management policies.

- **Engage in a comprehensive discussion with consumers about all medications they are using, including prescription, over-the-counter and complementary.**
- **Consider and recommend drug modalities that ensure better compliance, including minimising frequency by considering slow release drugs.**
- **Ensure all information is legible and highlighted to the consumer.**
- **Minimise confusion between brand name and generic medicines.**
- **Encourage perseverance with medication.**
- **Advise consumers, and where appropriate carers, to monitor, and course for reporting, an adverse drug reaction.**

VI. Reporting

Despite the work that has already been conducted, national data on the incidence of adverse medication events is limited. The reporting of adverse medication events outside the hospital setting is at a low level and there is a need to enhance a community reporting system as much as the hospital system.

The Adverse Drug Reactions Advisory Committee (ADRAC), a subcommittee of the Therapeutic Goods Administration, which advises on the safety of medicines, maintains data on adverse reactions. However, this data is reliant on how comprehensively and consistently these incidents are reported. There is recognition that reporting to ADRAC needs to be improved.

The National Prescribing Service (NPS) Adverse Medicine Events (AME) Line is another avenue for reporting adverse reactions which specifically targets reporting by consumers. The AME Line is not well used and therefore the data is not representative of the adverse medication events that are occurring in the community. It is understood that the NPS will continue to work in this area.

In general reporting mechanisms at present are insufficient to represent the incidence and prevalence of adverse medication events. Available studies suggest that electronic reporting is a most effective way to overcome these difficulties. In the interim, consumers and carers and all health professionals involved in the prescribing/dispensing chain, should be encouraged to report adverse medication events to the relevant local authority and ensure that this information is conveyed to ADRAC and AME. This will include reporting the incidence of adverse medication events that occur in the long term. This may present problems because of the time lapse before the adverse event becomes apparent and this will require constant reinforcement of the need to report such events as soon as possible, analyse the information and present the findings.

More education and awareness is required at a national level about what reporting mechanisms are available and means of access. The NPS has a major role in educating consumers, carers and health professionals about the use of medications and also encouraging consumers and carers to report adverse medication events. To date, in mental health, this has primarily been focussed on the use of antidepressants. A greater focus by the NPS on educating consumers about reporting adverse medication events may require increased resources, particularly if this is to ensure accommodating the specific needs of Indigenous consumers and carers and those from culturally and linguistically diverse backgrounds.

- **Improve education and awareness of the benefits of reporting adverse medication events, the mechanisms available and means of access for reporting.**

VII. Administration

There is current activity, at both national and jurisdictional levels, around development of standard procedures and medication record for consumers' medication details at admission. A standardised system would minimise duplicate recording of those details and may contribute to decreasing medication errors due to variation across settings. National consistency around education, training and protocols for the use of a 'Standard Medication Record' would further enhance medication safety.

Current work around medication conciliation may include one-step recording of medication at admission. It is important to develop a way to ensure that all those people with an interest in administering medications (consumers, carers, nurses, clinical assistants, hostel supervisors and others) are able to do so safely. Recognising the complexity of the consumer journey through the healthcare system, it is important that the consumer has a record of his/her current medications to accompany him/her when seeing a new health professional. In particular, accurate and timely transfer of medication history is critical at the handover points in care.

The development of a national Standard Medication Record is seen as a significant contributor to improving safety and quality in administration of medications generally.

- **Promote development of a 'Standard Medication Record' to support improved medication safety.**

PART 3

The third part of the Framework focuses on the adverse medication event itself.

VIII. Adverse Medication Event

When the adverse medication event happens there are a number of issues to be considered including:

- Early Detection – this may include risk factor identification and close monitoring following commencement of the medication regimen.
- Disclosure – as soon as possible notify the consumer and where appropriate the carer of the adverse medication event and provide opportunities for debriefing and support as consistent with the jurisdictional health disclosure policy. Engage the consumer and carer in discussions about the response plan as consistent with the jurisdictional health disclosure policy.
- Early Response/Action – may include dissemination of information about the ADE to improve overall system response and awareness of the issue and thereby reduce future ADEs.
- Early Prioritising of Actions. Aspects to be considered include:
 - The most effective action
 - The most comprehensive action and
 - The ability to achieve an immediate outcome
- Longer Term Planning.

Underlying these issues is the need to establish a course of action, which may have strategic timelines e.g. three to five years, during which the first area of focus is on hospital level of reporting of adverse medication events. This reporting should be in such a way that the results are reasonably comparable even though the actual results may be delivered from a variety of proprietary information system programmes, or via manual documentation. Such a process would include an initial survey of the current methods of recording adverse events, definitions used, software programmes used, manual recording systems used, and a comparison between these systems and the National Information System. Then a feasibility analysis should occur, to determine the extent that this information can be drawn together at a national level. Barriers to integration need to be identified, and appropriate funding directed in a targeted way to overcoming those barriers. The aim would be to have meaningful national data on adverse events. It would also be sensible to have a parallel aim from the outset, of including a recording system for community-based reports of adverse events. Such community-based reports could be reported, and an analysis of trends also reported from that information. The organisation could elaborate this process further, notably from ADRAC.

There have been a number of studies to more specifically identify risks, gaps and deficiencies as described earlier in the Framework and these studies and similar studies will form part of the necessary means to identify specific adverse medication events and the areas that will need attention and related data collection. The particular area of focus that has been highlighted is identification of high risk drugs and high risk situations and it is expected there will be further developments in these and similar areas. A further important area is the development of long term side effects in patients - both those currently recognised (e.g. tardive dyskinesia, metabolic syndrome) and those that may be identified in the future. This focus will require the longitudinal monitoring and studies of cohorts over many years. The outcomes may then be reflected into promotion and prevention as well as monitoring and trend analysis.

The private sector is likely to cooperate with a system like this, but a barrier will be the extra cost involved in any changes to existing systems, and in providing reports for National collections. Such barriers need to be identified early, and the most cost-effective ways to collect and report data should be investigated. Systems that simplify National

reporting by using data systems used at the local level to create local and National reports at the same time are likely to be the most acceptable. The use of a standard data dictionary and common messaging languages (e.g. XML, HL7) may be key aspects of the early analysis. A more definitive version of the process would need to be taken back to the hospitals at an early stage to determine their view of the feasibility. These approaches should build on work already in train by the national e-health transition authority (NEHTA) and related areas of work that have been commenced by other organisations.

- **Survey current methods of recording adverse events at the hospital reporting level including definitions used, software programs used and manual programs used.**
- **Determine how the above information can be integrated at a national level.**
- **Consider ways of including a recording system for community based reports of adverse events.**
- **Consider ways to involve the private sector in the development of a national information system.**
- **Consider cost effective ways to collect and report data.**
- **Build on approaches already in place by organisations such as National E-Health Transition Authority (NEHTA) and related areas of work commenced by other organisations.**

MEMBERSHIP REDUCING ADVERSE MEDICATION EVENTS IN MENTAL HEALTH SERVICES WORKING PARTY

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Ms Melanie Cantwell (until February 2008) Mr. Sebastian Rosenberg (from February 2008)	Mental Health Council of Australia
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