Medication safety in mental health

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Preface

The Australian Commission on Safety and Quality in Health Care (the Commission) has a commitment to promote, support and encourage safety and quality in the provision of mental health services. Medication is an integral part of treatment for many people living with serious mental illness, who often use medication for years. People with mental and physical comorbidity have shorter life expectancy relative to the general population. The side effects of medications used to treat mental illness can lead to the development or exacerbation of physical health problems. Addressing medication safety in mental health can contribute to tackling this problem.

The Literature Review: Medication Safety in Australia, conducted for the Commission in 2013 by a team from the University of South Australia led by Professor Libby Roughead, noted there was limited evidence of research on medication safety in mental health. To extend the evidence from this initial literature review, the Commission engaged the University of South Australia to undertake the scoping study Medication safety in mental health. This study included national and international literature that focused on the extent of medication-related harm in mental health settings and interventions to reduce harm. The study was also informed by consultations with key stakeholders in Australia.

Key findings

The scoping study finds that there is variation in a number of key medication practices in mental health. This variation occurs in the context of differing levels of uptake of standardised medication safety practices.

There is evidence that the use of prn (pro re nata or ‘as needed’) medication for treating symptoms of mental illness is widespread in mental health services. There is, however, wide variation in the quality of prescribing of these medications, evaluation of their effects and documentation of the reason for, or effect of, prn medications.

The study also finds that consumers and carers report they need more personalised information about their medicines. Consumers and carers also expressed a need to be more engaged in shared decision making around treatment options, including the use of medicines.

Another finding is that monitoring of the effects and side effects of medication is frequently inadequate, with confusion about the responsibilities of different clinicians contributing to the problem.

The findings suggest that existing medication safety practices and strategies may not be in widespread use in mental health services. The report identifies areas where further work is indicated so that this knowledge is effectively implemented.
Recommendations of the report

The authors of the report recommend that strategies that have been successful in improving medication safety in general health can successfully be adapted to mental health settings. These strategies include:

- Standardised processes for prescribing, administering and monitoring medicines
- Clinical pharmacy services
- Electronic medication management, bar code scanning and individualised patient supply systems
- Medication reconciliation services.

The authors recommend improvements in the process of using *prn* medications, including prescription, decision-making support around choice of therapy, documentation of the reason for a *prn* (pro re nata or ‘as required’) medication, and communication regarding the effectiveness of the medication in symptom management.

The authors also recommend improvements to the monitoring of the long-term side effects of medication, including metabolic monitoring.

Next steps for the Commission

The Commission will consider the report’s recommendations in ongoing consultation with key stakeholders. The Commission will use the findings from the report to inform current and future work on medication safety in mental health, building on previous work, including the National Quality Use of Medicines Indicatorsiii, and the National Inpatient Medication Chart User Guide.iv Classifying antipsychotic medications as high-risk medicines will support improved performance of their high monitoring requirements.

The Commission will use the report to develop resources to support implementation of the National Safety and Quality Health Service (NSQHS) Standards (second edition). In addition to a Medication Safety Standard, the NSQHS Standards (2nd ed.) support health service organisations to partner with consumers. Practices such as incorporating shared decision making with consumers on medication choices, guidance on appropriate use of *prn* medication, and improving understanding of informed consent are critical to medication safety. This complements Commission work on the use of antipsychotics in older people. Further work could highlight the importance of integrating consumer wellness and medication management plans into comprehensive care planning.

The Commission has also developed the *National Consensus Statement: Essential elements for recognising and responding to deterioration in a person’s mental state*. The consensus statement supports recovery oriented practice, which includes informed choices around medication. The Commission will develop resources that reflect the intersection of these patient-centric practices, incorporating information from this report to protect the public from harm and improve the quality of health service provision.


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REPORT
Prepared for the Australian Commission on Safety and Quality in Health Care

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Executive summary

Use of medications is one of the major therapeutic interventions for people with serious mental illness. The 2011–12 Australian Health Survey found three-quarters of people who reported experiencing a mental or behavioural problem reported taking medicines in the prior two weeks. Use of medicines is frequently associated with problems, errors and adverse events, many of which are avoidable. This report focuses on what is known about medication safety problems within the mental health care setting. In this report, we have synthesised information obtained from the Australian and international literature on medication safety in the mental health care setting, with information gathered from experts in medication safety and mental health, as well as mental health consumers and carers, to provide an overview of the challenges with medication safety in the mental health care setting and potential solutions.

What do we know about medication safety in mental health?

There are significant gaps in the research into understanding the extent of medication problems, errors and adverse events during inpatient stays in mental health facilities. We found no Australian studies that assessed the rate of medication-related hospital admissions to mental health wards, or the accuracy of patients’ medication histories on admission to mental health units; nor were there any studies examining the extent of medication administration errors in mental health units. The rate of prescribing errors in mental health units appears to be similar to that found in the general health setting, with, on average, one clinical prescribing error per patient, per admission; while discharge summaries were not provided for one in five patients within the mental care setting.

Some medicines to treat mental illness are used ‘when required’ or pro re nata (prn) to manage symptoms of distress or agitation, as well as to assist with sleep or to manage side effects. Australian studies show between 60% and 97% of adults and between 25% and 50% of children treated in a mental health unit receive prn psychotropic medicines. Both the literature review and our consultations highlighted challenges in administering prn medicines, including people’s different interpretations of when the symptoms for use are present. For example ‘for agitation’ could be interpreted anywhere along the spectrum from mild to severe. A number of studies had assessed documentation of the reason for administration and outcome of administration of prn medicines, with the reason for use being documented in 70% of cases and the outcome being documented in 50% of cases, on average. Communication about use of prn medicines could be improved during staff handover sessions, particularly in evening handover sessions, where up to 65% of prn administrations were not discussed.

A number of Australian studies have assessed use of multiple antipsychotics, a practice not generally recommended, demonstrating that on average 35% of people with serious or difficult to treat mental illness were prescribed multiple antipsychotics. People taking more than one antipsychotic were also more likely to be prescribed doses exceeding the maximum recommended antipsychotic dose.
Interview participants were concerned about chemical restraint in mental health units; it was acknowledged however, that there is a grey area between appropriate treatment and inappropriate chemical restraint, and no studies investigating the appropriateness of use of psychotropic medicines across this continuum were located.

There are significant gaps in what is known about medication errors and adverse events relating to psychotropic medicine use in the community setting. Studies undertaken in the community have shown that people with mental illness who receive a collaborative medicines review have between four and seven medication-related problems per person, including problems with adverse drug reactions and drug interactions. These findings are similar to the number of problems identified during medicines reviews among the general Australian population.

Australian studies show that more than 80% of people with a psychotic illness endure unpleasant side effects from their medicines and one in three live with moderate to severe impairment due to side effects. Although cardiovascular risk factors should be routinely monitored in people taking antipsychotics, low levels of monitoring of blood sugar, cholesterol and weight have been documented in both the hospital and community settings. Interventions have been developed to improve monitoring, however there is often failure to follow-up and treat patients when elevated cardio-metabolic risk is detected.

The overwhelming majority of consumers and carers expressed a need for more information about their medicines and in particular, a need to be included in the decision-making processes about their medicines. Despite this, studies suggest that only 6% to 20% of people living in the community have a care plan, and in most cases these plans are not shared with other health professionals involved in the person’s care. Confusion over which health professional, the general practitioner, psychiatrist or community mental health centre, was responsible for care decisions, particularly where the problem related to physical health but was a result of medicines prescribed for mental health, was identified as an issue on multiple occasions. Consumers, carers and healthcare professionals participating in our consultations highlighted the need for more discussion with consumers when commencing a medicine, particularly about side effects. In one Australian study, just over half of the inpatients and one third of the community-based patients surveyed did not receive any medication information.

What can we do to improve medication safety in mental health?

Improving medication safety in mental health will require a systems approach and involvement of all stakeholders. Evidence for successful strategies to improve medication safety in the general healthcare setting supports the use of clinical pharmacy services, medication reconciliation services, standardised systems for medication ordering and administration, electronic medication management systems, individual patient supply systems, systems requiring double checking, smart pumps with hard alerts for intravenous administration, bar code scanning systems, multidisciplinary team care, collaborative home medicines reviews and systems-wide initiatives using quality improvement cycles.

These interventions, which have been proven to work in the general health setting, are
equally applicable in the mental healthcare setting, however, some may still require adaptation and trialling in the mental health care setting to ensure their effectiveness.

Evidence from the mental health setting internationally, supports the use of clinical pharmacy services in mental health units\(^3^4\), discharge liaison services that include home visits post-discharge from psychiatric wards\(^3^5\), and multiple, structured educational sessions delivered at frequent intervals for people with mental illness to improve medication knowledge and improve insight into their illness.\(^3^6\) Medication reviews for clients of community mental health centres have been judged by peer review to support identification and resolution of medication-related problems.\(^2^2\)

The evidence base for improving \textit{prn} medicine use is limited, however, one international study suggests requiring documented voluntary consent of patients prior to administration of psychotropic medicines for agitation and disallowing intramuscular injection orders as \textit{prn} orders, is effective in reducing use.\(^3^7\) With regards to reducing multiple antipsychotic use, international studies examining direct trials where patients are switched from multiple therapy to monotherapy have shown that between 50\% and 80\% of people with serious illness can be successfully converted to monotherapy\(^3^8\)-\(^4^1\), however, they have also reported greater drop-out rates in the groups switched to monotherapy. No Australian studies have been undertaken in this area. Multifaceted educational programs targeting health professionals have had mixed success in reducing multiple antipsychotic use.\(^4^1\) There is Australian evidence demonstrating cardio-metabolic monitoring rates can be improved in the acute mental health care sector\(^2^6\),\(^2^8\), with trials underway in the community sector trialling the effect of dedicated cardio-metabolic health nurses.\(^4^2\)

There are many gaps in the evidence base to support improvements in medication safety in the mental healthcare setting with regards to identifying the extent of the problems and testing solutions that work in the Australian mental health care setting. The analysis in this report suggests some high priority areas for action. These include improving cardio-metabolic monitoring and cardio-metabolic outcomes for people on antipsychotics, integrating clinical pharmacy services within the mental healthcare setting, providing discharge liaison services and supporting coordination of care, particularly across the mental healthcare service and primary healthcare service interface. Both the literature and our consultations suggest there is an urgent need to clarify clinician responsibilities for care. This was particularly evident for cardio-metabolic monitoring where there appears to be confusion over which clinician is responsible for monitoring and follow-up actions. Our consultations highlighted that the development of national guidance would be helpful to support appropriate use of \textit{prn} medicines, and depot injections. An international study provides some evidence that mandatory guidance for \textit{prn} medicine use can reduce use. Guidance on multiple antipsychotic use, as well as interventions to support appropriate antipsychotic use, may assist given significant international evidence to suggest many patients, but not all, can be successfully transitioned to monotherapy. Our consultations suggested improved documentation for \textit{prn} medicine use, depot injections and metabolic monitoring were areas where action could be taken. Improved documentation for care plans that included space to identify physician responsibility for actions was also highlighted as an area for action. Existing evidence-based strategies, including medication reconciliation and the \textit{Top 5} program\(^4^3\), were highlighted as issues that could be adapted to better suit the mental health sector. Suggestions included trialling medication reconciliation services within the outpatients setting when patients were well, rather than on admission, and adapting
programs such as Top 5, to assist with managing agitation in people with mental illness. Across Australia, a number of activities are underway or have been implemented to improve care, however, formal evaluation is limited and support for evaluation of activities is required.
1. Introduction

Use of medications is one of the major therapeutic interventions for people with serious mental illness. The 2011–12 Australian Health Survey found three quarters of people who reported suffering a mental or behavioural problem reported taking medicines in the prior two weeks. Half reported taking antidepressants, nearly a quarter reported taking analgesics, one in four reported taking supplements and one in six reported taking a sedative or antipsychotic medicine.

Because medicines are commonly used for mental illness, errors with medicine use are also likely to be common. We have previously reported the extent of problems with medicine use in both the hospital and community settings in Australia. In this report we focus on what is known about medication safety problems within mental health care.

The Australian Commission on Safety and Quality in Health Care (the Commission) engaged us to review the published literature, and gather knowledge from medication safety and mental health experts about:

- Things that can go wrong with medications used for mental illness
- Things that make it difficult to improve medication use in mental illness
- Strategies which have been shown to make a difference
- Steps which could be taken to improve medication safety in mental health in Australia.

In developing this report we undertook a literature review and consulted widely around Australia. The literature review included studies published between January 2000 and January 2015 that focused on the extent of medication-related harm in the mental health setting in Australia. For example, studies of prescribing errors or rates of administration errors in the mental health setting were included, as were studies assessing the extent of problems in the community. We also examined studies that assessed interventions to reduce medication-related harm in the mental health care setting. We focused on studies that had been undertaken in Australia, however, we also reviewed studies that had been undertaken in other countries if they had used a controlled trial to assess the effectiveness of the intervention. A full description of the search strategy is in Appendix 2.

We also consulted with people with mental illness, their carers and health professionals who care for people with mental illness. Viewpoints from consumers and carers, nurses, pharmacists, psychiatrists, psychologists and policy makers from all Australian states and territories were sought during the consultation process. Twelve semi-structured interviews involving 39 participants were conducted between March 2015 and May 2015. In addition, a roundtable discussion in which 19 people participated was held in May 2015 to further explore barriers and enablers to medication safety in mental health, and identify potential solutions.

This report focuses on medication safety issues in mental health across hospital and community settings. Issues relating to recreational drug use, opioid substitution therapy, complementary medicines, medication cost and adherence were not the focus of this review. This report begins with an overview of what is known about medication safety in the
Australian healthcare system as a whole, we then provide the evidence specific to the mental health care setting.
2. Medication safety in Australia: An overview

Undesirable events associated with medications can happen throughout the health system. In this section we provide an overview of what is already known about medication safety in Australia. We begin with a summary of this evidence, because the issues and the solutions for improving medication safety identified in the general health setting are equally applicable to the mental health setting. In the second section of this report we focus on what is known about medication safety in the mental health care setting and on what works to improve medication safety in the mental healthcare setting.

2.1 What is known about medication safety in the general hospital setting in Australia?

Much is already known about the frequency of medication errors and medication-related problems along the continuum of a person’s journey through their hospital stay. Problems with medications may be the cause of a hospital admission, while other undesirable events occur during a hospital stay. Undesirable medication events can occur at the time of admission to hospital, when prescriptions are written, when medicines are administered, at the time of discharge and even after discharge from hospital. Common types of undesirable events include:

- The incorrect documentation of a person’s medication history at the time of admission
- The prescription of an incorrect dosage of a medicine
- The omission of therapy when it should have been administered or administration of the wrong medicine
- The continuation of medicines only intended for during a hospital stay, at discharge
- The administration of a medicine when there is a history of allergy or contraindication
- The administration of a medicine that interacts with another medicine
- Lack of explanation to consumers and community healthcare providers about medication changes made during a hospital stay.

Figure 1, which has been constructed based on data from a series of studies on the extent of medication errors in the hospital setting, shows the frequency of medication errors across the hospital journey. Most of this evidence comes from large teaching hospitals which care for very sick people with complex care needs.
2.2 What is known about medication safety in the community setting in Australia?

Medication-related problems are also common in the community setting and the risk of error increases in the community if people have multiple illnesses and see multiple doctors. A series of Australian surveys of general practitioners have consistently shown that approximately 10% of people attending the general practice have had an adverse drug event, the majority of which were adverse reactions, in the last six months. Of these, between 5% and 8% were severe enough to require hospital admission. Adverse drug events are not limited to prescription-only medicines, with 7% of people using complementary therapy indicating they had suffered an adverse drug event, and of these, 7% indicating the event was severe enough to require hospitalisation. In the community sector, the risk of error increases if people have multiple illnesses and see multiple doctors.

Pharmacists are funded in Australia to provide medicines reviews for people at high risk of medication misadventure. Case notes from the pharmacists' reviews also highlight the extent of medication-related problems in the community, with a number of Australian studies now showing that between three and five medication-related problems are identified per person during a review. The types of problems include adverse reactions, and also include under-use of medicines, as well as over-use of medicines and the need for information or other support services, such as administration aids, to facilitate improved medication management.

Similarly to the hospital setting, the accuracy of the medication history in the community setting may also be problematic. One study found 52% of people indicated that there were discrepancies between the medication history documented in their general practitioners’ case notes and what they were taking.
2.3 What works to improve medication safety in Australia?

The Australian Commission on Safety and Quality in Health Care (the Commission) has previously commissioned reviews of the literature on medication safety in Australia, and we provide a summary from those reviews of strategies known to be effective in improving medication safety (see Figure 2).2,32,33

Things that help the accuracy of a patient’s medication history on admission to hospital include a pharmacist-led medication reconciliation service, provision of the person’s own medicines at the time of admission to hospital and contact with the person’s community pharmacy to obtain a list of their medicines.48,60

Computerised prescription ordering and entry systems have been found to reduce prescribing errors3,50, and international evidence demonstrates that they can lead to reductions in adverse events.61 Standardised forms also reduce error.62

There is strong evidence internationally that clinical pharmacy services reduce medication error across the hospital setting.81 There is also Australian evidence that prescribing by pharmacists in the peri-operative setting can reduce errors.63

With regards to administration errors, individual patient supply systems reduce errors, as does the use of bar code scanning technology and the use of nurse double checking systems.32,33 One of the significant factors that contribute to error is interruption of the nurse when administering medicines, with each interruption causing a 13% increase in the chance of a clinical error.64 Other factors that have been reported to contribute to error include nurse inexperience, heavy workloads and violence on the wards.65 Errors have been reported to be less frequent for planned admissions, when nurse educators are present and when housekeeping staff are available.65 Smart pumps with ‘hard alerts’ (those that cannot be overridden by the user) reduce infusion errors.66

Errors are less likely on discharge if medication reconciliation services are available, and errors are less likely if post-discharge services are available that include the pharmacist providing follow-up care for the patient after they have left hospital.67-69

Within the community setting, pharmacist-led, collaborative medication review services have been shown to resolve medication-related problems and reduce harm.70-73
Figure 2: Interventions and factors that reduce the change of medication error

The majority of these interventions and factors are likely to be effective for improving medication safety in the mental health setting.
3. Mental health care in Australia

3.1 How common is mental illness in Australia?
Mental illness is common, with almost half of all Australian adults experiencing a mental illness at some point in their life. The 2007 National Survey of Mental Health and Wellbeing found one in five adults experienced a mental illness in the previous year. Anxiety disorders were the most common mental illness, affecting 14% of Australian adults, followed by affective disorders such as depression and bipolar affective disorder (6%), and substance use disorders (5%). Another national survey found that 0.5% of the adult population live with a psychotic disorder such as schizophrenia or schizoaffective disorder. Mental illness is also common among children and adolescents. It is estimated that 14% of Australian children and adolescents experience mental illnesses such as anxiety, depression, aggressive behaviours or attention-deficit/hyperactivity disorders.

3.2 How do we approach mental health care in Australia?
The recovery-focused approach to mental health care aims to facilitate a process whereby individuals with mental illness lead a hopeful, flourishing life. That is, the best possible life with hope for the future, a right to self-determination and active engagement in discussion and decision-making about their illness, treatment and expectations about management. This requires a collaborative approach to care that includes identification and integration of the person’s own goals, values and preferences, now and in the future, into care, thus, enabling individuals to have a dignified, personally meaningful and gratifying life.

3.3 Why are we focusing on medication use in mental health?
Medicines are commonly used to treat mental illness. The medicines for mental illness are known collectively as psychotropic medicines. Throughout this report we use the term psychotropic medicines as an inclusive term, encompassing the many different types of medicines used to treat mental illness, including antipsychotics, antidepressants, anti-anxiety agents (anxiolytics), sedatives, mood stabilisers and hypnotics.

Within mental health units, medication use is the major intervention and more than 90% of inpatients may be prescribed psychotropic medicines. Use of psychotropic medicines is also common outside of hospital. 12% of all prescriptions dispensed in Australia in 2013-14 were for psychotropic medicines. General practitioners (GPs) prescribe the majority of psychotropic medicines (86%), followed by psychiatrists (8%) and other specialists (6%).

One of the reasons to refocus our efforts on medication safety in mental illness is because the overall use of medicines to treat mental illness has increased significantly over the last 20 years. Antidepressant use has risen 10–fold since 1990, while antipsychotic use has risen two and a half-fold (Figure 3). Use of hypnotics and anxiolytics, however, has declined in recent times. Overall, these increases mean many more people are now taking medicines for mental illness, with the resultant potential for an increase in undesirable medication events, such as errors or adverse events. In addition, there is significant variation in the use
of medicines for mental health across Australia. For example, after the exclusion of the outlier regions, the use of medicines for attention-deficit/hyperactivity disorder varied seven-fold across the regions assessed, while there was a three-fold variation across regions in antidepressant use in adults aged less than 65 years of age and a four-fold variation in children and adolescents. It is not yet clear how much of the variation reflects differences in the prevalence of disease or differences in treatment patterns, but this high level of variation is also suggestive that some use may be inappropriate.

Figure 3: Use of medicines for mental illness in Australia, 1990 to 2014
4. Medication safety in mental health in Australia: What do we know about the problem?

In this section, we have synthesised the Australian literature on medication safety in mental health with information gathered from mental health consumers and carers, and experts in medication safety and mental health, to provide information on the extent of medication safety problems in the mental healthcare setting.

4.1 Medication safety in hospital mental health units

There are significant gaps in research into the extent of adverse medication events, medication errors and undesirable medication events that occur during stays in mental health units. We found no Australian studies that assessed the accuracy of consumer’s medication histories on admission to mental health units, nor were there any studies examining the extent of medication administration errors in mental health units. There was one study examining prescribing errors in mental health units and two studies assessing the provision of discharge summaries, but no studies assessing errors at discharge. Figure 4 summarises what is known about the extent of medication errors across the patient journey in the inpatient setting in mental health care.

Figure 4: Summary of what is known about undesirable medication events occurring during an inpatient stay in a mental health unit

20,500 admissions to hospital
* per annum due to intentional overdose
* Not limited to mental health units
4.1.1 What adverse medication events occur in mental health units?

There have been no Australian studies that provide an estimate of how often undesirable medication events lead to hospital admissions in the mental health care setting.

One Australian study assessed rates of adverse drug events associated with hospital admissions in people who were clients of mental health facilities compared with the broader population.80 This study included adverse medication events that were the cause of the hospital admission and those that occurred during admission. The study found a 2.7-fold increased risk of hospitalisations associated with adverse drug events. What we don’t know from this study is whether this risk is greater in people with mental illness compared with people who have a general medical illness. Studies using a similar method have been undertaken in the diabetes population81 and the general population82-84 and while not undertaken as comparative studies, the results show higher rates (approximately double) of hospital admissions associated with adverse drug events in the population with diabetes (7.2%) compared with the general populations (2.7%, 3.3%, 3.4%).2 Direct comparisons are still required to determine if people with mental illness are more likely to have hospitalisations associated with adverse events than people with physical illnesses.

One other study gives us insight into factors that may contribute to some hospital admissions. One Australian study examined whether recommended care had occurred prior to admission for older people admitted to hospital for bipolar disorder or acute confusion.85 It found:

- 43% of people hospitalised for bipolar disorder had been hospitalised for bipolar disorder previously and were taking lithium, but had not had a measurement of their serum lithium concentration in the three months before admission
- 61% of people admitted for confusion received three or more psychotropic medicines in the three months before admission.

It is not known if measuring the lithium blood level would have prevented the admission for bipolar disorder, however the study does highlight gaps in practice that could be addressed. With regards to the number of psychotropic medicines, Australian evidence shows that people taking multiple psychotropic medicines are at an increased risk of being admitted to hospital for confusion and falls, and this risk increases as the number of psychotropic medicines rises.86,87

4.1.2 What do we know about people being hospitalised as a result of intentional over-dose?

While we don’t know how often hospital admissions occur due to problems with medicine use, we do have estimates of how often people are admitted to hospital due to intentional overdose. Many of these admissions are likely to be related to a mental illness, either diagnosed or unrecognised. In 2010-11 there were 20,499 hospitalisations in Australia due to intentional over-dose with medicines.88 Rates of intentional overdose with medicines among women have been rising slightly over the last 10 years, while the rate has been relatively stable for men (Figure 5).
One in three people admitted to hospital for intentional overdose had taken benzodiazepines or paracetamol, one in four had taken an antidepressant and one in six had taken an opioid medicine. Rates of intentional overdose involving paracetamol have risen by approximately 50% over the last ten years and are now at a rate of 30 per 100,000 people. Rates of intentional overdose with opioids have doubled over the last 10 years and are now at a rate of approximately 12 per 100,000. When people are hospitalised as a result of intentional overdose, the hospital stay is usually three days. In 1.5% of cases, people die as a result of intentional overdose with medicines.

**4.1.3 What do we know about problems when people with a mental illness are admitted to hospital?**

Admission to hospital is often a point in care where errors can occur because no accurate medication history is available for the person admitted. We were unable to find any Australian studies that assessed the accuracy of medication histories for consumers admitted to a mental health unit. Our consultations, however, highlighted that this is a particular issue for people with mental illness as many are not well enough to provide details about their medicines on admission to hospital.

> Sit down with somebody, take a medication history, ask about highs and lows, when was it good, when were you able to take medication. But you can’t do that in an inpatient unit. You’ve got to do that when people are more stable.  
> Registered nurse

> As the admission progresses and patients start becoming well, that’s about engaging them at that point and getting that collaborative history.  
> Pharmacist

People with mental illness also highlighted the potential problems when an inaccurate or incomplete medication history was taken, or the history provided by the person was not considered. For example, a number of people reported that their medicines were sometimes...
switched back to ones that didn’t work for them, despite discussion with the hospital staff providing their care. One participant recalled a discussion with a mental health consumer about these difficulties:

He said, you know, these guys are talking yet again about putting me on Clozapine and I’ve told them what my history is with it, I’ve been through the whole process with it or I’ve told them that another type of antipsychotic, I always have an adverse reaction to and often being dismissed… the danger with that is the person keeps going through this loop but it can also affect their medication because you don’t get continuity in medication.

Employee, government mental health organisation

Interview participants suggested that a comprehensive medication record, describing medicines taken in the past and the reasons why medicines were stopped, may help to prevent use of medicines which have not previously been successful.

I think you’d get a high level of consensus amongst consumers about the value of their medication, but the desire to have that accurate history and not to have to restate it. So, if you had a sort of authoritative document which said, you know, this is a sort of ‘clinician-stamped’, and the very least it has is an accurate history of medication. So, you know, (it says) ‘Not for Clozapine’, or ‘Not for, you know, one of the other psychotropic drugs’.

Employee, government mental health organisation

Referring to the emergency department: as soon as you can get a medication history that’s where all the great interventions can happen. Huge safety rewards by doing an accurate history on admission. Working in mental health, getting the accurate medication history and especially from two different sources, you need to be innovative because often that second source doesn’t include the patient at the start of the admission.

Pharmacist

4.1.4 What is known about prescribing errors in mental health units?

Prescribing errors can happen when prescriptions are written and these errors are sometimes characterised as procedural errors or clinical errors. Procedural errors refer to errors such as a signature missing from the prescription or lack of documentation of the route of administration or unit of measurement. Clinical errors include errors due to the wrong medicine or wrong dose being ordered. Examples of different types of errors include:

- A 78 year-old woman was taking haloperidol 4mg daily for treatment of psychotic depression. On admission to hospital she was inadvertently prescribed haloperidol 0.5mg twice a day (25% of her usual dose). If errors like this are not detected, there is the potential to make a person’s condition worse

- A person admitted to the mental health unit was prescribed risperidone 50mg via intramuscular injection in the morning, instead of every two weeks. If errors like this are not detected, then patients get too much medicine and in this case would result in an adverse event.

The only Australian study to assess the rates of prescribing errors in mental health units suggests prescribing errors occur at a similar rate to other parts of the health system, with one clinical prescribing error occurring per person, per stay. The most frequent types of clinical prescribing errors were wrong dose, wrong route, wrong rate of administration and orders duplicating therapy. The study assessed errors when both a paper-based system and
an electronic prescribing system were in use. The electronic system resulted in reduction of procedural errors, but had no effect on the rate of clinical errors (Figure 6). This was a small study and the electronic system to assist prescribing that was assessed was not a system that included decision support.

![Graph showing rate of prescribing errors per patient at a mental health unit](image)

**Figure 6: Rate of prescribing errors per patient at a mental health unit**

The extent to which medication errors in mental health units are recognised and rectified is unknown. A study from the general hospital setting found that only 22% of clinically important prescribing errors had incident reports filed. Incident reports are the way staff document incidents and errors that they have identified. It may be that some errors are recognised and rectified but no reports are lodged, but these study results may also indicate that a proportion of errors are not recognised.

The problem of having both electronic and paper-based systems for prescribing was noted by our interview participants, particularly where prescribers switch between forms, either from paper to electronic or from electronic to paper.

So, a lot of the new prescribers have actually never prescribed on paper… and that leads to a lot of deficits in the basics. So legibility, filling in all of the gaps, which I guess is mandated by the electronic environment, whereas on paper, you know, if you forget to sign the order a nurse can administer that for three days prior to somebody picking that up.

**Pharmacist**

### 4.1.5 What do we know about administration errors in mental health units?

We found no Australian studies that assessed the extent of medication administration errors in mental health units, however, our consultations highlighted the types of issues that arise.

We have had incidents where people, due to wrong patient identification, (were) being given an antipsychotic depot (injection) when they've never even had an antipsychotic previously.

**Pharmacist**
People (are) getting double depots in the remote environment, and that's due to the systems that they use for both prescribing and administering. … they use electronic systems which is great for the prescription, but on that electronic system the administration … doesn't sit on a medication chart, it sits within case notes electronically, which is a huge safety risk, and if people are in a rush, not reading that (the case notes) thoroughly.

Pharmacist

4.1.6 What other medication-related problems occur in mental health units?

Additional insight into the types of undesirable medication events occurring in mental health units comes from reports by clinical pharmacists. One study involved 47 pharmacists, of whom 62% reported they were specialist mental health pharmacists. The pharmacists provided 277 reports of clinical interventions, within which 322 medication-related problems were identified. The most common problem identified by the pharmacists was medicine selection (37%), followed by dosing problems (18%), under-treatment (14%), side effects (11%), need for education or information (8%), compliance issues (7%), and need for monitoring (5%).

One other Australian study provides some insight into the potential for medication error in the acute mental health care setting. The study compared changes to medicines that were documented on the patient’s medication chart (the national medication inpatient chart) with documentation in the patient’s progress notes about the changes made and the reasons for change. The study was set in a public psychiatric inpatient unit and records of 54 patients reviewed. In total, 519 changes to medicines were documented on the medication chart; an average of 10 per person. When compared with the progress notes, 58% of changes were documented in the progress notes, however, the documentation was frequently incomplete. The rationale for the change was only recorded in 42% of cases. In 27% of cases, evidence of patient involvement in the decision was documented. While this study is not an assessment of error, it does highlight potential gaps in communication between practitioners through lack of documentation of sufficient information about reasons for medication changes in the patients’ progress notes.

Several of our interview participants spoke about the need to upskill the workforce to ensure knowledge of medications and their side effects when prescribing and administering medicines in mental health units.

They have all these things, you know, the fire safety, you know this, you know that, but actually we're asking them to case manage complicated patients. Sometimes people are on clozapine. They don't know what side effects to look for. They don't know the red flags. And that's not okay.

Psychiatrist

So, in a system… if I have 600 staff in my service, where do they go to for information about that (medicines)? What kind of training do they get around (medicines)? So, you think CPR (cardiopulmonary resuscitation) is important and you think those things are important, well, equally, how many of your people actually have a cardiac event as opposed to an adverse medication event? So why isn’t that important?

Registered nurse
4.1.7 What do we know about administration of pro re nata (prn) psychotropic medicines in mental health units?

There have been a number of Australian studies that have examined use of psychotropic medicines that are administered pro re nata (prn), which is also known as ‘when required’ or ‘when necessary’. Prn medicines may be given for a number of reasons, including to reduce agitation and aggression, to alleviate escalating distress, to manage symptoms, to assist with sleep or to manage side effects. In some instances, other therapeutic interventions may be trialled prior to administration of prn psychotropic medication.

Use of prn psychotropic medicines is common among people treated in mental health units. Australian studies show between 60% and 97% of adults and between 25% and 50% of children treated in a mental health unit receive pm psychotropic medicines. The number of prn doses given per person ranged from five to 10 across the studies. In one Australian study of prn psychotropic medicine use, no other therapeutic intervention had been documented as trialled prior to administering a pm medicine in approximately three quarters of cases. It should be noted that lack of documentation doesn’t mean that other therapeutic interventions were not trialed, however no detail is available as to the use of prior therapeutic options.

Some of the challenges with administering prn medicines were highlighted during our consultation process. One challenge is the definition of the reason or indication for use - with health professionals having different views about the need for prn medications. Participants also highlighted that at times it is difficulty to select the medicine to administer because the medication chart lists multiple psychotropic medicines that can be used prn, as well as to determine when to dose.

At times we don’t use sufficient medication early enough. Prn could be used far better, and more appropriately than it currently is, and could be used to reduce the risk of extreme distress and the development of post-traumatic stress disorder (PTSD).

I went around to all of the doctors and asked them to give me a definition, their own definition of agitation… and we went around as a group and there wasn’t one definition that matched each other…. And what you will see is multiple agents all prescribed for agitation with no guidance as to whether they should be given together, which one should be given first, for example, how long I need to wait before trying the second agent… And when we went around and talked about what agitation was, you know it varied from somebody humpbugging for a cigarette all the way through to somebody punching a wall. ... We need clearer descriptions around when quetiapine could have been used versus a benzodiazepine or if they should have been given together.

Pharmacist

Administering sedation and not waiting sufficient time for the medication to work and keep adding in more and more agents or wrong combinations and people getting over-sedated.

Registered nurse

We located one small qualitative study which involved three doctors and 16 registered nurses. It highlighted that health professionals report factors such as the person’s level of distress, agitation, aggression, psychoses, as well as concern for the safety of the consumer or others, and an individual consumer request as all influencing the decision to administer a
prn medicine. However, other factors including the environment, the level of staffing and the custom of the ward were also found to have an influence.

Documenting the reason for, and effect of prn medicines may assist to improve use, however, a number of Australian studies have shown the reason for prn administration, the person who initiated the medicine and the effects of the medicines were not always documented (Figure 7).7-12

Figure 7: Documentation of reason for administration and effect of psychotropic medicines administered ‘as required’ in adult mental health inpatient units

Similar findings were reflected during our consultation process:

Well, see, there are procedures about using prn you know? About documenting and documenting effect, but that's, you know, you'd have to say that, generally speaking, somebody will get something, you know, and there won't be a clear reason why they were given prn.
Registered nurse

If a prn was given inappropriately, there's no follow-up to that. And, in terms of the physical monitoring for prn administration, that is pretty much non-existent unless it's in a rapid tranquilisation situation.
Pharmacist

I think that's sometimes where there are gaps in practice, where they get the person calmer or sedated and then kind of forget about them. They often escalate again and that's when there's a period of risk.
Registered nurse

Documentation of the effect is important as very often people with mental illness experience side effects from the medicines administered. One study found that 37% of people receiving prn medicines experienced medication side effects, compared to 3% of people who received regular medicine only.6 The increase in side effects was apparent when either antipsychotics
or benzodiazepines were administered, and was also associated with increased frequency of prn administration. Extrapyramidal symptoms, excess sedation and confusion, as well as autonomic disturbance were the most common side effects reported. In some circumstances, such as when a person was suffering extreme distress, very disabling anxiety or agitation with psychotic features, the need to administer the medicine was considered to be so strong that on balance, clinicians and patients may decide it is reasonable to proceed with careful monitoring knowing some side effects will follow.

Documentation also assists communication about the administration and outcomes of prn medicines when staff change shift. While clinical handover occurs at shift change, information on the outcomes of prn medicine use is not always provided. A prospective audit of 500 handovers found that the administration of prn medicines was discussed at 79% of morning handovers, 70% of afternoon handovers, but at only 35% of night handovers.13

When medicines are administered, it is important that patients understand what they are taking. Patients’ experience of being administered prn medicines suggests they need more information. In one study, 51% of clients felt they did not receive enough information about medicines administered prn and 30% stated they had received a specific prn medicine without knowing why it was administered.93 Audits of medical records also suggest this is an issue. A review of 268 prn administrations of psychotropic medicines found that provision of face-to-face counselling was documented in 17% of cases prior to the administration of the prn medicine and in 1.5% of cases afterwards.8 It is important to note that documentation may not reflect actual practice and counselling may have been provided and not documented, however the extent of the practice is unknown.

Treating staff often did not tell me what was about to occur. Yes, I was psychotic, but it is best practice to respect the client and consider their psychological risk and terror and to inform them of what is about to occur (without their consent) even if you think they can’t hear you or won’t understand… Sometimes, consumers experiencing psychosis understand more than they appear to and being informed about what is happening can help to make the experience of forced treatment less distressing when you're piecing it together later… because you can recall being informed.94

Our consultations also showed there is a need for clarity of what prn means, particularly for medicines to be used at home.

A person, a carer saying this person’s been discharged with these medications and it also says, ‘as necessary’… How do I know when it might be necessary? How do I know how often I can give that? How do I know? So this is language that clinical staff understand, but it’s not language that (consumers understand), and that really struck me as something that was such an oversight. If you’re giving someone prn and going home on prn, what advice have you provided to them about how they might use it?

Registered nurse

4.1.8 What do we know about prn medicines and chemical restraint?

We found no Australian studies which investigated the use of psychotropic medications for restraining people in mental health units. We located one small Australian study undertaken in the general hospital setting involving 28 elderly patients that compared the use of medicines administered prn for management of violent behavioural disturbances, with guideline recommendations.95 It found that practice was consistent with guidelines in 64% of
cases. The use of haloperidol, which was not recommended, was the most common reason practice was not consistent with guidelines. Poorly controlled pain was one of the factors found to be associated with violent behaviour.95

Concerns were expressed during the consultations about the use of chemical restraint in mental health units, prison hospitals, aged care facilities and the disability sector. Concerns were also expressed about the grey area between appropriate treatment and inappropriate restraint.

The use of medication, for example, for restraint is a really common thing. So, I remember at the forensic hospital saying to people, why is this man on such large doses of medication and why did it happen on Friday afternoon? That sounds suspiciously like it was to do with the weekend shifts…Oh no, no, no (name), he was very difficult to control.

Employee, government mental health organisation

And so the whole thing of chemical restraint in a sense, versus the concept of therapeutic use of medication, is a grey area that has not been properly defined, therefore there are no real safety things around it. It's not particularly measurable and it's not been reported on, and that's an area I want to raise because it's a real concern to consumers and carers.

Consumer and carer representative

So prn is sometimes used punitively as well, so they'll medicate somebody – and sometimes its justified, you know? If they know the client, perhaps they know what the tipping point (is) – they can see the rise. But other times it's used to quell people.

Registered nurse

4.1.9 What do we know about continuity of care?

When people are in hospital, very often changes are made to the types of medicines or dosages of medicines that they take. Sometimes this is a temporary change, but sometimes the change is intended to be continued after hospital discharge. For this reason, information about medication changes in hospital needs to be provided to community-based healthcare professionals. This information is usually provided as part of a hospital discharge summary.

We located two Australian studies which showed that up to 22% of patients may not receive a discharge summary in a timely manner.4,5 One study audited records from 15 mental health inpatient services across Queensland for patients discharged with a diagnosis of schizophrenia after the implementation of a state-wide mental health clinical collaborative. Discharge summaries were available at the time of discharge for 78% of patients discharged in June and 84% of patients discharged in November.5 Similarly, data reported for 41,040 inpatients from 68 public and private healthcare organisations participating in the Australian Council on Healthcare Standards Clinical Indicator Program showed that 78% of mental health clients had a discharge summary provided on discharge.4 We didn’t locate any Australian studies that assessed errors in the discharge summaries.

Problems with timely transfer of correct information across all interfaces of care were acknowledged as a major challenge in mental health care during our consultations.

There is no integration between the services… The registrar who is in the inpatient (unit) should be looking after the outpatient and there should be better communication with the GP. Like chasing the GP. Getting the GP to ring back - it didn't happen. In the end, I just chased the man down. Getting the GP's notes was really a mission. There is just this huge divide
between every single service. Nothing is simple.

Psychiatrist

The biggest challenge now for us is to get it (medication information) from (the) inpatient setting to (the) community, and then from community mental health services to the primary sector. And that’s a huge challenge.

Pharmacist

With the recovery focus, a person with mental health conditions being treated in the community gets their medicines filled out at a community pharmacy… But that means that that community pharmacy is part of that person’s healthcare team. But they don’t know that, and they don’t know how to join back with anyone else. So there is this massive disconnect by people. We’ve made community pharmacists effectively be part of that person’s team, but they can’t join with anyone else.

Pharmacist
5. Medication safety in the community setting

In this section of this report, we examine what is known about the extent of undesirable medication events in the community setting. There are significant gaps in the research into understanding the extent of medication errors and adverse events relating to psychotropic medicine use in the community setting. We identified however, several medication safety issues relating to psychotropic use from the small number of studies that were located and from our consultation processes.

We found that people with severe mental illness may have between four and eight medication-related problems per person on average, including drug interactions and adverse drug reactions. Several medication safety issues relating to the use of antipsychotics were identified, including use of more than one antipsychotic at the same time, excessive dose and increased ‘off-label’ use. We found that a considerable number of consumers taking antipsychotic medicines endure unpleasant medication-related side effects, whilst a third of consumers with a psychotic illness live with moderate to severe impairment due to side effects. Further, the system for monitoring cardio-metabolic risk factors, and acting upon any abnormal results in people taking antipsychotics, is fragmented and practice is inconsistent.

The overwhelming majority of consumers and carers expressed a need for more information about their medicines, and in particular, a need to be included in decision-making processes about their medicines. They wanted to be listened to, to be treated more holistically and they wanted to have appropriate conversations about how to deal with the impact of medicines on their physical health and quality of life.

5.1 What do we know about medication-related problems in the community setting?

Studies undertaken in the general population have shown that people who participate in medicines review services have between 2.5 to five medication-related problems per person, identified during the medicines review. The results are similar when medication reviews are undertaken among people living with mental illness. Case notes from medicines reviews for 48 patients of a mental health service showed an average of 4.4 medication-related problems per person. There were 2.3 medication-related problems per person, on average, specifically relating to mental health. The most common problem, accounting for 39% of problems, was medicine selection. This grouping included adverse drug reaction problems and drug interactions; 22% of problems were for management issues and 17% related to the medicine regimen.

A separate study examined medication-related problems among 49 people with mental illness living in the community and referred for a pharmacists’ ‘Home Medicines Review’ by their general practitioner. The majority of patients had depression (73%). Pharmacists identified approximately seven medication-related problems per person. The study found inaccuracies in the general practitioner medication history: the general practitioner reported patients to be on an average of eight medicines, while the pharmacists found people to be taking nine medicines on average. This study also reported a high rate of suspected adverse reactions, thought to be present in 47%-55% of people reviewed. Other common problems...
identified were that the medicine was not the most appropriate for the indication (in 35% of patients) and a potential drug interaction (in 37% of patients).\textsuperscript{21}

The prevalence of drug interactions has also been studied among people treated in a community mental health team.\textsuperscript{16} Pharmacists conducted interviews with 56 people with long-term mental illness who were taking at least one medicine, and found that 66% of people interviewed were taking medicines that could interact with each other. The most common types of drug interactions were the co-administration of medicines that could affect cardiac rhythm (prolong QT interval) and combinations which could increase the risk of drug-related movement disorders, also known as extrapyramidal symptoms. 41% of people were taking more than one antipsychotic, which contributed to the high prevalence of drug interactions observed in this study.\textsuperscript{16}

Drug interactions can also occur among people taking antidepressants. Antidepressants act on a neurotransmitter named serotonin, and taking more than one antidepressant can increase the risk of serotonin toxicity, as can antidepressant use combined with other medicines that affect the serotonin system. Evidence suggests that 3% to 5% of Australians taking an antidepressant take two or more prescription antidepressants concurrently\textsuperscript{108, 109} and up to 8% take other medicines that affect the serotonin system with antidepressants.\textsuperscript{109, 110} Up to 8% of antidepressant users also take St John’s Wort, a complementary therapy that also affects serotonin, concurrently.\textsuperscript{111-113} The example provided by a mental health pharmacist illustrates how duplicate antidepressant use can lead to harm:

\begin{flushleft}
A young woman was taking sertraline (an antidepressant) for depression. She had also received treatment for a periodontal abscess (a type of infection) on more than one occasion, which led to pain in the face. The woman was later prescribed a low dose of amitriptyline for the facial pain. Amitriptyline is an antidepressant, but it is also used in low doses to help with pain. The woman was later admitted to hospital with a high temperature, agitation, irritability, an unstable heart rate and unstable blood pressure. Many tests were performed to identify the cause of these symptoms without success. The combination of two antidepressants was later identified as the reason for her symptoms. Her symptoms resolved after the sertraline and amitriptyline were stopped and she was discharged from hospital.

Pharmacist
\end{flushleft}

Drug interactions involving lithium, a medicine used in the treatment of mental illnesses such as bipolar disorder, have also been assessed among older Australians. One study of 278 older people receiving lithium found that interactions that were potentially hazardous were common with 18% receiving an angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor (ARB) inhibitor (an antihypertensive), 4% received frusemide (a diuretic), and 3% received a phenothiazine-type medicine.\textsuperscript{114} Another study assessed interactions among 39 aged care residents taking lithium and found that many had potentially hazardous interactions: 21% of people also received haloperidol, 26% received an ACE inhibitor or an ARB inhibitor, 18% were taking frusemide and 5% took a phenothiazine-type medicine.\textsuperscript{115}

\subsection{5.2 What do we know about antipsychotic use?}

Antipsychotic medicines are used for people with severe mental illness and have been associated with a range of problems, including dosage problems, duplication of therapy and poor monitoring of side effects.
5.2.1 Multiple antipsychotic therapy

In general, it is not recommended to use multiple antipsychotics to manage mental illness. There may be a need for more than one antipsychotic medicine in certain circumstances however, such as transitioning from one antipsychotic to another. A number of Australian studies have reported the prevalence of multiple antipsychotics, with average prevalence rates of 23%, and the highest rates occurring in people with severe mental illness where rates average 35% (Figure 8). The studies all involved a review of patient case notes, but the studies rarely defined how multiple antipsychotic therapy was defined, nor the proportion of people receiving dual oral therapy compared with depot injections and oral therapy. Thus, it is unclear how much of dual use could be due to transitions in therapy. However, the high rates of concomitant use do suggest considerable rates of duplication of therapy.

![Figure 8: Prevalence of multiple antipsychotic use by study setting or user group.](image)

5.2.2 Antipsychotic dosage problems

We found two Australian studies that assessed antipsychotic doses among people receiving treatment through a community mental health team. A study of 56 people who received a home medicines review found that 29% took one or more antipsychotics exceeding the recommended dosage. A second study of 38 patients found 34% had an antipsychotic dose higher than recommended.

One of the dangers of taking multiple antipsychotics is the potential for excessive dose. In one study, 22 of the 23 people on multiple antipsychotics exceeded the maximum dose, with one dosage being seven times the maximum recommended dose.

5.2.3 Prescribing and administration of antipsychotic depot injections

Depot antipsychotics are injected into the muscle, allowing absorption of the drug over time. This method of dosing can be advantageous where patients may have difficulty in adhering to oral therapy. No studies were located that assessed the prescribing and administration of depot antipsychotic injections. Our consultations however, revealed problems such as
omission of depot antipsychotic injections from medication lists and failure to taper off oral medications after commencing a depot antipsychotic. Failure to account for the dose of the depot antipsychotic when adding other medicines, as well as rapid increases in the dose administered before the depot antipsychotic has reached full effect, were also described. Clinicians raised concerns about inadvertent injection of depot antipsychotics into fat and subcutaneous tissues, rather than into muscle. They cited the findings of an inquest into the stabbing death of a person by a man in a psychotic state. To summarise the case, the coroner reported the perpetrator’s psychotic state was the result of a low level of zuclopenthixol, due to poor injection technique. A blood sample taken from the patient following his arrest revealed a very low level of zuclopenthixol, even though at the time, he was receiving 300mg of the drug intramuscularly each fortnight. It was expected that a concentration close to the maximum level would be seen only six days after administration of the drug, due to its slow-release, oil-based formula. One possible explanation was that the last injection administered did not penetrate the muscle layer and instead lodged in the fat and subcutaneous tissues above the muscle, resulting in ineffective absorption of the drug. A possible explanation for the incorrect position of the needle and future recommendations was offered:

The increasing incidence of obesity in the community, here and overseas, has resulted in a gradual recognition that there should be some revision of the guidelines for the administration of intramuscular medication, particularly for psychiatric patients. In other words, the needles may need to be longer than the ones currently in use. This problem is said to be exacerbated by the fact that antipsychotic medications like zuclopenthixol can cause significant weight increase. 116

One participant described a lack of understanding about the appropriate injection technique and side effects, and problems with documentation.

I’ve been involved in this project over the last few years, improving long acting intramuscular injections for antipsychotics, and there’s a lot of myth and misunderstanding… people’s lack of understanding about an intramuscular injection. Fatty tissue isn’t muscle.
Registered nurse

5.3 What do we know about off-label psychotropic use?

The prescribing of medicines for reasons other than their licenced indication is known as ‘off-label use’. Off-label use is sometimes justifiable as regulatory decisions may lag behind evidence from clinical trials.105 Some off-label use however, is for indications that have little or poor evidence to support them. Use of medicines for indications that are not supported by robust evidence can have safety implications for the person taking the medicine.105

No Australian studies have assessed off-label use of psychotropic medicines among adults with mental illness. We did locate one study that assessed off-label antipsychotic use in mental health units for older people. Almost 22% of antipsychotic use was off-label, including use for bipolar disorder (9%), unipolar depression without psychosis (6%) and behavioural disturbance without dementia (4%).104

Two small studies assessed off-label use of antipsychotics in children and adolescents.106, 107 One study examined the concordance of antipsychotic use compared to existing evidence in 103 children and adolescents admitted to hospital and who had been administered
Overall, 60% of the antipsychotic prescriptions were consistent with licensed indications and the doses were prescribed in the recommended dosage range. A further 11% of prescriptions were supported by evidence from randomised controlled trials and 18% were supported by evidence from observational studies, case series or expert recommendations. Eleven per cent of prescriptions were classified as being inappropriate or not evidence-based. Another study conducted in the same children’s hospital six years later, found that 60% of use was considered consistent with guidelines. In the 20 instances of administration of antipsychotics for patients with an intellectual disability, only four (20%) were considered consistent with guidelines. In eight instances, administration was to children with conduct disorder, of which only four (50%) were considered consistent with guidelines.

Concerns about off-label psychotropic use among children and adolescents also emerged during our consultations.

And also these drugs, the antipsychotics, are being used on people under the age of 18 and, by goodness, under the age of 15 and under the age of 12. If you read the packaging, they’ve not been road tested on that age group; there are no control trials on that age group.

Consumer and carer representative

Clinicians felt there was a need for consistent regulation and improved coordination around off-label prescribing, better documentation and a need for a peer review mechanism.

The lack of documentation makes those clinical decisions harder to justify. So, even that the conversations have happened about the decisions, and the fact that you know it hasn’t been approved for use in, for example a patient under 16 years and your child is 14, but I think they’ll benefit from this, this is the reasons why. I think we need to try this. Given the risks as well. So that documentation to me happens very poorly if at all. And that opens the question too, do the conversations happen in full? Which I don’t know, because I’m not involved in all of them.

Pharmacist

5.4 What do we know about the frequency of therapeutic drug monitoring?

Some of the medicines to treat mental illness require monitoring of serum concentrations to ensure that there is enough medicine in the body for it to be effective, and not so much that it will cause side effects. Lithium is a medicine in this category.

Studies assessing the frequency of therapeutic drug monitoring of lithium suggest inadequate monitoring of therapy. A small prospective study of 77 patients with bipolar disorder attending community mental health clinics found only 38% of people using lithium had their serum levels measured within a 12 month period. This compares with the study assessing sub-optimal processes of care prior to hospital admission, that found 43% of people were taking lithium, but had not received a lithium drug level in the three months before admission. Other medicines that require blood level monitoring that people took to manage bipolar disorder included sodium valproate and carbamazepine. Serum levels were not monitored in 38% of sodium valproate users and 87% of carbamazepine users.

One of the potential barriers to monitoring therapy is recognition of which health professional is responsible for the monitoring. A survey of general practitioners found that 31% were
unclear about who was responsible for monitoring the serum levels of the patients that were jointly managed by the GP and private psychiatrists or community mental health clinics.\textsuperscript{117}

5.5 What do we know about the side effects of psychotropic medicines?

Many medicines used to treat mental illness cause side effects. Poor management of side effects can interfere with effective treatment. Australian studies show side effects from medicines to treat mental illness are common, with results showing that over 80% of people on medicines for psychotic illness experience side effects, and that one-third live with moderate to severe impairments due to medication-related side effects (Figure 9).\textsuperscript{23} People taking multiple antipsychotics are at higher risk of side effects. National survey data shows that 90% of people taking multiple antipsychotics experience at least one side effect, compared to 80% of people taking one antipsychotic.\textsuperscript{20}

People on antipsychotics may also experience multiple side effects. A small study of 81 young adults receiving an antipsychotic, conducted in one urban and one rural area of Victoria in 2004, found 53% experienced several side effects concurrently, which were considered of low clinical importance.\textsuperscript{118} 43% experienced side effects of medium clinical importance however and 4% of high to very high clinical importance. Over 60% reported side effects such as difficulty remembering and concentrating on things, tiredness or sleepiness, weight gain, and restlessness.\textsuperscript{118} People who take multiple antipsychotics also reported experiencing more side effects than those on one antipsychotic.\textsuperscript{20}

![Figure 9: Prevalence of medication-related side effects among adults with psychosis](image)

\begin{itemize}
\item Public specialised mental health services 1997-98 survey (n=687) (%)
\item Public specialised mental health services 2010 survey (n=1211) (%)
\end{itemize}
Our consultations and the literature\textsuperscript{119} also highlighted consumers’ experiences of side effects, some of which were considered unacceptable, and some of which had longer-term consequences.

I had extreme physical and mental fatigue, sexual dysfunction and dry mouth. I was a zombie and it ruined me. It made my mental health worse and it made my path through the mental health system worse.

Consumer

I’ve seen two of my family members have those drugs, almost every single one tried on them with horrendous side effects. To see a 12-year-old lactate on risperidone. To watch somebody on olanzapine at age 14 go from 62kg to 112kg in three months, and it affect their entire metabolism at age 14, and then take five or six years to bring their glucose back down and to bring their body back down, and affect their whole self-image. Do we want that happening to the young people of Australia?

Consumer and carer representative

Sometimes I get some dizziness which is a pretty major effect of that, if I get up too fast… And the other side effect I might have is dry mouth, but I use stuff for that, and sometimes my appetite gets out of control.

Consumer taking quetiapine

That kid would gain, you know, 10 kilos with, while on the ward with olanzapine, and by the time the outpatient doctors meet him, we would already be accustomed to the fact that they are on olanzapine and that they've gained a lot of weight, and by the time we take them off olanzapine it would be another three months and they've gained 25 kilos of weight, and it’s very common for young people to gain a lot of weight before things get changed.

Psychiatrist

Ah. They said you might feel a bit dizzy, like lightheaded – which I have been feelin' since I've been on the tablets, I haven't really felt like myself, like – feelin' lazy and feelin' like, really slow, and I’m starting in basic terms, like a robot Stiff neck, cramps in the guts, cramps in the kidneys, legs ah going stiff and that you know.\textsuperscript{119}

There was only one small study that assessed medication-related side effects in children and adolescents. All the children were on risperidone, with an average time of three years on therapy, and nearly all, 89%, were taking at least one other psychotropic medicine. More than two-thirds of the children and adolescents reported they live with some side effects from their antipsychotic medicines, such as tiredness and difficulty concentrating and remembering things. Some of these symptoms may be associated with the illness for which the medicine was prescribed however, or the other psychotropic medicines they were taking. One third reported side effects such as dry mouth, blurred vision and constipation, which are likely to be associated with the treatment.\textsuperscript{120} Our consultations highlighted more severe side effects in children than adults.

Some medication side effects are treatable. The following story illustrates how a treatable side effect, constipation, can be debilitating and impact on quality of life if not discussed and managed in the best way.

I had a lady in my clinic. She was on olanzapine, very, very psychotic, a very unwell lady. And she came into the room and I offered my hand for a handshake. She just sat down and sat on her hands. And then when she was leaving I thought it was just a rapport thing. And then we
had this really good rapport because I'm a rapport-builder. And I went to shake her hand at the end and she still wouldn't. And I just said, look, I know this is a weird thing, but have I offended you in some way? Is there a reason why you don't want to shake my hand? And she just went, Oh. And she goes, look, I haven't been able to go to the toilet for over a month properly and I had to really dig it out this morning. I've washed my hands and stuff but... And that was the only time I hadn't asked (about constipation). And I knew I felt bad. I'm pleased that I asked about the handshake, but it's like, I always ask (about constipation).

Psychiatrist

5.5.1 Providing information about side effects when a new medicine is commenced

Most people want to know about potential side effects of medication before starting the treatment. They also want to know what they can do to reduce the impact of any side effects. Despite this, consumers and carers report receiving limited information about side effects when commencing a medicine.

When people experience side effects of medicines or have concerns about their medicines, there is the need for an appropriate response, however this does not always occur. In a Victorian study, 81 adults with a diagnosis of schizophrenia were interviewed to assess their satisfaction with their healthcare professionals’ knowledge and ability to deal with their concerns about antipsychotic medicines. Ten per cent of patients were not satisfied with how their concerns about their antipsychotics were dealt with by their case manager or psychiatrist. This rose to 16% with their general practitioner (Figure 10).

I was not informed about side effects… Never happened to me. I've seen several psychiatrists, doctors. They don't tell you…

Consumer

Referring to a psychiatrist in the inpatient unit: ‘He said, I think you should take Effexor.’ (an antidepressant). So I said, What are the side effects of effexor, can you tell me? He goes, ‘Oh medication has, you know, lots of side effects.’ And my God, it was like trying to squeeze blood from a stone… It was as if they were saying ‘take the effexor and that’s all you’ll ever need.’

Consumer
Figure 10: Consumer satisfaction with clinician’s knowledge and actions

Our consultations also highlighted that some side effects may be difficult for either patients with mental illness or their clinicians to discuss and that proactive measures are required.

Acute sexual side effects are one thing that we often try to make an effort to bring up with young people because they don’t talk about it, and it’s a big… it’s got a big impact on their quality of life… often, say if there is a young male case manager, that might (make) it difficult to talk to a young female consumer about that. So there may be some barriers… The sexual dysfunction is quite common, and they’re not telling us why they’ve stopped it [taking medication], and we’re escalating into, you know, more aggressive treatment.

People with mental illness also felt it was important for clinicians to enquire about side effects on a regular basis. One consumer suggested allocating a set period during a consultation for discussion of side effects may help.

Make it that part of the time that you see someone is that your side effects are listened to, not told that you will have them, but listened to, because I’ve been brushed off many a time with my weight stuff.

Consumer

5.6 What do we know about cardio-metabolic side effects and medication use?

People with severe mental illness die 15-25 years earlier than other people and they don’t die of mental illness; they die of all of those, you know, diabetes, heart disease, all of those things which are often driven by their medications or poorly controlled use of medications.

Employee, government mental health organisation

Many antipsychotics are associated with cardio-metabolic side effects, meaning they can cause changes in blood sugar levels, blood pressure and blood cholesterol, resulting in increased risk of weight gain, diabetes, cardiovascular problems and kidney problems. Cardio-metabolic syndrome, the collective name given to all of these abnormalities, is a strong risk factor for premature and severe cardiovascular disease and stroke.122 Cardio-
metabolic risk is common among people with serious mental illness, with studies demonstrating prevalence between 55 to 70% (Figure 11).26,123-125

![Figure 11: Prevalence of metabolic syndrome in persons with serious mental illness]

Participants from our consultations reflected that while there is now a greater understanding of metabolic risk factors, there remains a focus on the treatment of mental health issues with psychotropic medicines, rather than finding a balance between mental health and physical health:

> We would have treating teams saying oh look, we’re very pleased that, you know, Mr Brown has now, his symptoms are now stable and you’d say well, sure, but he’s put on nine kilograms in the last six months and he’s on, you know… say he’s on four different antipsychotic medications. Clearly that’s not sustainable, because you couldn’t release him into the community on that and clearly, his metabolic syndrome is such that it’s out of control. And, for a long time, the impression I often got back to that was one of but his symptoms are under control, and you’d just say well, right but where’s the trade-off between that and his health and all that sort of stuff...."

Employee, government mental health organisation

Cardiovascular risk factors should be routinely monitored in people taking antipsychotics. Opportunities for monitoring include during a hospital stay, as well as during a visit to a community mental health centre or general practice. Low levels of monitoring weight, blood sugar and cholesterol have been documented within many settings, including hospitals, a forensic unit, among clozapine users and within a community mental health service (Table 1).24-27
Table 1: Percentage of people on antipsychotics monitored for cardio-metabolic risk during their stay of care

Children and adolescents are also at risk of developing cardio-metabolic syndrome. Monitoring for risk factors in this age group however remains fragmented. In a study of children and adolescents who had been prescribed antipsychotics for at least one month, and who were currently in hospital, only 19% had a current antipsychotic monitoring chart and only 7% were monitored for risk factors. Studies of psychiatrists who treat children and adolescents show that even psychiatrist self-report of monitoring in this age group suggests significant under-monitoring.

Table 2: Child and adolescent psychiatrist self-report of cardio-metabolic side effect monitoring

Australian studies show that clinicians don’t believe they have enough time to perform physical assessments and that monitoring equipment is not always within easy reach. Clinicians are also uncertain about how often to monitor, and which medical practitioner is primarily responsible for monitoring and acting on abnormal results. Concerns about the need for improved communication and action when abnormal results are detected were also voiced during our consultations.
5.7 What do we know about valuing the patient experience and medication safety?

5.7.1 Taking a person-centred approach to care

Recovery in the context of mental illness takes into account a person-centred approach to care. A person-centred approach is concerned with human connectedness: the capacity for the needs of a person with mental illness, his or her family, carers and clinicians, entering into an interactive process of conversation and information exchange. A person-centred approach to mental health care is one where a person is afforded an opportunity to contribute a perspective on what actually lies behind their situation, life difficulty or aspiration to live a healthy and socially engaged life.\(^{130}\)

Engaging with consumers and respecting their wishes is a key part of the recovery process and safe medication usage. Participants reflected on times when they felt there was a lack of respect for their understanding about their own needs.

I’ve got a sensitivity to phenothiazines and the unfortunate side effect of that is actually the swollen larynx where you can’t breathe, which is a pretty bad side effect. Yeah it’s not very nice. And yet you know people still want to prescribe me things like when I’m nauseated, want to give me (prochlorperazine) … Now I only realised in, you know after looking up phenothiazines that (prochlorperazine) and some of those drugs actually have that as a base. …. and I say, hang on, you know, don’t give me phenothiazines. Oh a little bit won’t hurt you. Well actually they’re wrong. So treating me like you know I have no idea about what my sensitivities are I think is a really poor issue. And I know if someone’s actually, where they, no matter what your level of education is, you will usually know if something doesn’t agree with you and if you say look I can’t; if someone said, I can’t take penicillin, that would be, you know immediate allergic red flag. But I say to a doctor, GP or psychiatrist, I’m sensitive to phenothiazines, it kind of seems to go straight over their head. But that’s an emergency department situation for me.

Consumer

A lack of awareness and understanding of cultural differences among people from different backgrounds was acknowledged as a barrier to engaging with consumers and their carers about their mental illness, medicines and recovery process.

I’m coming from, you know, Asian background, come from Vietnam as a refugee a long time ago. So in those Asian countries there’s no such thing as social anxiety disorder. So for me, when he got it, I really got no idea, no knowledge about that.

Carer

People with mental illness and carers spoke about the time pressures on clinicians which meant that medications rather than talking-based therapies were often the only option considered.

Time-poor doctors would reach for their prescription pad rather than to delve more deeply into people’s problems. So, you’d have this terrible practice of six minute medicine where you come in and they go, here’s an antidepressant… there is this emphasis, like especially from psychiatrists, that they would rather prescribe medication and they don’t use psychotherapy. It’s slowly changing. But that was my experience.

Consumer
People were concerned about being medicated too early, particularly among younger people, and being over-medicated.

When I first sought help, this was after I was bullied and I finished high school, I saw a psychiatrist. Assessed me for five minutes. You know, it wasn’t even a thorough, lengthy psychological assessment. Missed out on the anxiety. He said, you’ve got depression. Prescribed me (fluoxetine), an antidepressant, (haloperidol), an antipsychotic, and (lorazepam) (a benzodiazepine) all at the same time. And, so yeah, so I, so later, you know I generally, after hearing the perspective of different mental health professionals, I believe I was prematurely medicated and over-medicated.

Consumer

Over 80% of consumers participating in the Scoping Study on the Implementation of National Standards in Mental Health Services reported that they felt mental health services did not treat people with mental illness holistically. Consumers highlighted their need for informed choice about medicines that have long-term adverse physical effects. Consumers emphasised the need for a more holistic approach to care and wanted to know about non-pharmacological approaches to help with their symptoms.

But the thing is, I guess there’s so much evidence now for other therapies. I mean, you know, coupled with whatever medications needed at the time, or in crisis, or, you know, or, in a major event. But we are not. We are still not instituting those therapies and I think that’s the really unfortunate part. Yes, let’s use the meds in an acute phase or in a crisis or someone has, you know, entrenched schizophrenia, to try to limit their distress or minimise their distress, but let’s get real and have some of the things that are actually recognised as working for people, in terms of helping them to actually recover. Actually get a quality of life that they currently don’t have and push them forward. Not getting them stuck. We’re getting people stuck.

Consumer

We did not locate any studies which assessed the way medicines are prescribed, administered and discussed with consumers when the person is receiving compulsory treatment. Our consultation process suggests there is often a lack of partnership and collaboration around medication administration when a person receives compulsory treatment.

When you come into hospital, particularly if you’re coming in as a compulsory patient, the fact that someone’s going to tell you, you have to take this whether you like to or not, is actually quite a difficult thing to hear. So, my recollection of one instance is this woman saying, I’ve been prescribed medication and I’ve always only taken homeopathic medicines and I’m not wanting to take this medication. So the nurse comes up, asks the first time, no, I don’t want it, and the second time two nurses come, this time you’re going to have it by injection. No, no, I’ll take it now, too late, you know, so I think it’s around how the interactions occur. And so, when I say I come from looking at it from the rights-based perspective, it’s also understanding the context in which mental health treatment occurs and whether or not people practice in a way that’s sensitive to that and understands where that person’s coming from and that we may know that we have the right to administer things. But, giving that person time and space, and particularly where you’ve come, you’ve had a conflict of the person around whether or not they should take the treatment you’re about to administer, then maybe leaving it for a bit, you know, I think, and trying maybe someone else because you’ve set up a dynamic, the person
has time to think about it, all of those things. So, to me that experience of taking medication, if it starts on that kind of premise, it’s then very difficult to make the person feel comfortable about medications.

Registered nurse

5.7.2 Constructing care plans with consumers

Agreed treatment plans are a cornerstone of good medication management, particularly for people with chronic illness or multiple chronic illnesses. There is variable information on the extent to which people with mental illness have care plans. The Australasian Clinical Indicator Report 2008-15 included information about care plans from five community mental health organisations. Data included 8,420 consumers, of which 20% had a completed care plan.4

There is some evidence the care planning that occurs with consumers’ active involvement and agreement is lacking. In one study of 228 consumers, carers and family members, only 6% reported they had a care plan, and 39% said they did not have enough say in decisions about care and treatment.30 In a review of 57 care plans in Western Australia, there was evidence of consumer involvement and consent in 23% of cases, and only 5% of consumers received a copy of their care plan.29

Another challenge is the distribution of care plans to other health providers involved in patient care. In the Western Australian Auditor General’s Report 2009, a review of 73 case files of people with mental illness found 78% had a care plan, however, in only 19% of cases there was evidence that the care plan had been shared with other health professionals.29

5.7.3 Providing people with mental illness and their carers with information about medicines

Several studies have also shown people with mental illness and their carers do not receive sufficient information about their medicines. A survey conducted within a mental health service providing inpatient and community services found issues with the provision of medicines information to people with mental illness and carers.31 Interviews were conducted with 407 patients and 50 carers. Just over half of the inpatients and one third of the community-based patients surveyed did not receive any medication information (Figure 12). Of these, less than half of the inpatients and two thirds of the community-based patients who received medication information found it helpful. Carers were even less likely to receive medication information or to be included in discussions or decisions regarding medication use.31

My long-term concern is the lack of information, support and encouragement for people who wish to lower their dose of medication, or to come off it altogether. Where does one go to find out the best information, other than the internet? Where are the experts in (my area)?

Consumer

I feel like angry in a sense that, look, the mental health system or the health system, it really failed me miserably and I was angry. I got angry and him too. And then I always thought why no one talks, psychiatrists, like talking a bit about it and I just sitting there hoping something, nothing. Okay prescription. Okay go home and take it and that. The first 10 years I really, you know the trust, put my son into your trust, into your hands, I trust you. But 10, 12 years later it didn’t get anywhere and that time you felt so, so terrible that, and myself eventually that I changed another GP and then first thing she said that to me, (name), you need help. And I realised that. Where did I get help? And then I found out all these websites… then I started to
join them and I got some information slowly, slowly you know about the issue, the mental health issues. And I was so, at that time I’m angry, angry that why I was not involved? Carer

Figure 12: Percentage of patients and carers who did not receive information about medications

Telephone calls to medicines information lines also highlight lack of medicines information as an issue for people taking psychotropic medicines, with lack of information on side effects a key feature. The NPS MedicineWise medicines information lines provide an avenue for consumers, their carers or family members to discuss issues about their medicines. Of the calls made between 2002 and 2010, 57% relating to antipsychotics were about safety concerns such as side effects, interactions and risk-benefit profile. Information gaps are also evident for children and adolescents. Of the 286 calls to the NPS MedicineWise line about psychotropic medicine use in children and adolescents between 2002 and 2005, 62% related to safety concerns.

Further insight into consumer information needs is provided by a Victorian study that included 96 interviews with parents of children with attention-deficit/hyperactivity disorder. Almost all parents wanted to have access to information about symptoms, causes and associated problems with the disorder, behavioural management and educational strategies, social skills and medicines.

A Victorian study conducted in 2006, aimed at exploring possible barriers that may prevent people with serious mental illness from obtaining information about their medicines, found their knowledge and access to consumer medicines information leaflets was poor. Of the 36 consumers who participated in the study, 58% did not know what a consumer medicines information leaflet was, almost 70% reported never having received one and 94% reported that they had never asked for a consumer medicines information leaflet. Almost half of the consumers indicated they preferred to receive information about medicines in both a written and verbal format in simple non-jargon language they could understand. Consumers conveyed their preference for information to include the purpose, dosage, how the medicine worked, side effects and the benefits of the medicine. Consumers also acknowledged that
while some of the barriers to obtaining medicines information were related to health professionals (44%), they themselves were sometimes that barrier (28%).  

### 5.8 Psychotropic medicine use in aged care facilities

Studies assessing use of medicines in residential aged-care facilities in Australia have shown that approximately half of all residents take at least one psychotropic medicine. Between 20% and 30% of residents of aged-care facilities are treated with an antipsychotic medicine and as many as 30-40% take a benzodiazepine. The level of inappropriate use of these medicines has not been widely assessed, but given that non-drug strategies are available for mild symptoms of psychological distress, there is concern that much of the psychotropic medicine-use among residents of aged-care facilities represents inappropriate use.

The high prevalence of use of psychotropic medicines in aged care is of concern because of the effect it can have on patient’s cognition. The following story illustrates the difference in alertness and cognition following a decrease in the amount of psychotropic medication administered to a resident.

I saw my mum in a really glamorous sort of aged-care facility, where pretty much you could predict if you went there at 10am in the morning, everyone would be asleep, you know. And when we raised these issues and got an independent pharmacotherapy review done for my mum, and the person, this guy, said she shouldn’t be on all this stuff, she shouldn’t be on this stuff and changed her therapy. She emerged. What had really, we thought for probably upwards of 18 months, that she was pretty much gone, she was, you know, non-communicative, unable to go anywhere. And through just having this independent review done and this medication change, such that the nursing home couldn’t medicate her contrary to the thing, the next time I walked into the nursing home, I walked around the corner and she said where the bloody hell have you been? It was that frank. It was obvious, you know. And interestingly, within I’d say, at the second or third visit, when I went there that other morning, no-one was asleep. So, it did have an effect, they obviously changed something.
6. Improving medication safety in mental health

6.1 Strategies to improve medication safety in mental health in Australia

This section reviews Australian studies evaluating strategies to improve medication safety in mental health in the community, hospital outpatient or ambulatory care setting. We included studies involving the use of randomised controlled trial or non-randomised controlled trial designs, and pre- and post-intervention studies. Quality improvement activities described by interview participants to improve medication safety in mental health are also reported.

6.1.1 Which interventions improve prescribing and administration?

Standardised medication charts and documentation of reason for prn medicines

In the first section of this report, we highlighted a number of studies that had shown there was poor documentation of the reason for and the outcome of administration of prn or ‘when required’ medicines by nurses.7-12 Documentation of the reason for administration of medicines to be used prn is necessary both at the time the prescription is written and when the medicine is administered. There has been one Australian study comparing the effect of different chart designs on the documentation of the indication (reason for use) of medicines that are to be used prn.145 The original medication charts did not have a designated area for the prescriber to record the indication for each prn medicine order. A new medication chart, with a specific area for the prescriber to record the indication for each prn medication order, was introduced. A retrospective audit was undertaken for 47 children and adolescents who were hospitalised in a 10-bed psychiatric unit in Brisbane, between October 2003 and December 2005. Results showed only 33% of orders for prn medicines had the reason documented by the prescriber using the charts that had no field for the indication, compared to 85% of orders having the reason for administration documented by the prescriber on the charts with a specific field for that information (p<0.01).145 We did not find any studies that had been developed to improve documentation at the time of administration of the medicines.

The National Inpatient Medication Chart was implemented in 2006 to improve medicines safety through standardisation of medication ordering in general hospitals.5 The chart has been shown to be effective in reducing procedural errors associated with medication prescribing in the general hospital setting.62 The utilisation of the chart in psychiatric services was recommended in 2012.146 A survey of practitioners working in mental health services who were using the chart found that 70% agreed that the section of the report for prn medicines met the needs for documentation for the majority of patients. Some respondents indicated the chart did not have enough room for orders for prn medicines, while other respondents indicated more space would discourage review of the doses available. No independent evaluation is available to determine how well orders for medicines to be used prn are documented.

Standardised antipsychotic depot administration charts

The lack of standardised practice in ordering and administering depot medicines has been identified as a risk factor for errors. Practitioners responding to the survey of mental health
practitioners who were using the National Inpatient Medication Chart could not reach a consensus regarding the ordering of depot or intermittent medications. 40% agreed or strongly agreed that the chart was able to accommodate intermittent medications in its current format, while an equal 40% disagreed or strongly disagreed that it could. Creating a separate section on the chart to be used for documenting depot medicines, with adequate room provided for two registered nurse signatures, documentation of when last given, and when next due, as well as administration site used, was recommended by the majority of participants. A few respondents reported or suggested use of a separate chart but this was more widely regarded as a risk for error. We are not aware of any independent evaluations of the intermittent medicine section on the chart in mental health units, and our consultation suggests variation exists in the antipsychotic depot administration charts currently used in different jurisdictions.

A national standardised clozapine titration chart for adults
A national adult clozapine titration chart is available to assist with the prescribing, monitoring and administration of clozapine in acute services. Supportive materials, including a user guide and PowerPoint presentation slides, are available from the Australian Commission on Safety and Quality in Health Care website. There has been no independent evaluation of the chart to determine whether this has reduced errors with clozapine in the acute setting.

Improving the technique of intramuscular antipsychotic injections
During our consultation process, one participant talked about a project to improve administration of long-acting intramuscular antipsychotics that has been successfully implemented locally. The project was initiated after a coroner’s investigation into the murder of a person by a psychiatric patient showed the patient’s levels of zuclopenthixol were extremely low. The team conducted a comprehensive literature review which revealed the method for identifying the injection site primarily used for long-acting intramuscular antipsychotics, the dorso-gluteal site, led to unpredictable results with regards to consistently achieving injection into the muscle. In addition, there was a risk of damaging the sciatica nerve. The ventro-gluteal site was determined to be more appropriate for administering depot antipsychotic injections.

We came up with the ventro-gluteal site which is – everyone thinks, Oh my God. I’m going to hit bone. But it’s a good site because there’s muscle, there’s not a lot of underlying structures, and we’ve been transitioning now for the last nearly a year… So the advantage of ventro-gluteal over dorso-gluteal is better muscle mass and some literature suggests that the dorso-gluteal has 20% per cent poorer absorption than the ventro-gluteal. Some of the anecdotal reports are that people are having their doses reduced… a lot of the depot nurses have been talking to the clients about why I’m doing this, so that helps with engagement with the client. Registered nurse.

The project team developed training materials and redesigned depot administration charts to record the injection site used and promote rotation of injection sites. Consumers were involved in the development of patient resources to ensure they were relevant and easily understood. While the study has yet to be evaluated in respect to dosage reductions, anecdotal reports suggest both nurses and consumers have embraced the change.
6.1.2 Which interventions improve monitoring?

Cardio-metabolic monitoring

Australian interventions have successfully increased cardio-metabolic screening among children and adults taking antipsychotics, however, follow-up remains problematic.

One study assessed the effect of a multifaceted intervention to improve cardio-metabolic screening among people who were taking an antipsychotic and attending an early psychosis clinic of a youth mental health service in Melbourne.\textsuperscript{28} Prior to developing the intervention, psychiatrists were interviewed to identify barriers and enablers to routine cardio-metabolic monitoring. The intervention included development and distribution of monitoring guidelines on a wall poster for clinicians, educational seminars for clinicians that also included a discussion of pre-intervention audit results, placement of paper-based monitoring sheets in every patient file, development of a service policy on metabolic monitoring, use of a local metabolic ‘champion’ from the research team to promote monitoring, and ensuring monitoring equipment (including measuring tapes, scales and blood pressure cuffs) was available in each psychiatrist’s room. The intervention period was January 2008 to July 2008. Consecutive patients presenting to the clinic between January 2006 and June 2006 were included in the pre-intervention audit. Case notes for these patients were reviewed and screening tests in the preceding 18 months were extracted. The post-intervention audit included consecutive patients presenting between September 2008 and February 2009 and assessed screening in the preceding six months. Twenty two per cent of patients in the pre-intervention period had their body mass index, lipids and blood glucose measured at any time in the six months after starting an antipsychotic compared to 81\% of patients in the post-intervention period (\textit{p}<0.001). Only 2\% of patients in the pre-intervention period were screened at baseline and at least once during the first six months of therapy, increasing to 40\% in the post-intervention period (\textit{p}<0.001). However, no patients in either audit period received all recommended metabolic monitoring at baseline, one month, three months and six months after commencing antipsychotic therapy. The proportion of patients documented as receiving a follow-up intervention to address weight gain and metabolic side effects increased from 7\% in the pre-intervention period to 29\% in the post-intervention period (\textit{p}<0.001)\textsuperscript{28}, highlighting the need for further work to address follow-up.

Improvements in metabolic monitoring in people taking clozapine have been demonstrated in a study undertaken within a mental health service in Brisbane.\textsuperscript{26} The intervention, called ‘Let’s Get Physical,’ was designed to increase metabolic monitoring among individuals taking clozapine by identifying two months in the year within which physical health would be the focus. The health service’s protocols were amended to incorporate monitoring of fasting blood glucose, lipids, body mass index and girth for each person during the physical health month. The intervention was implemented in 2012. In the month prior to the intervention, laboratory test order forms were attached to case notes, monitoring equipment (scales, tape measures, blood pressure monitors) was placed in the consulting rooms and consumers were provided with written information about the investigations. During the intervention month, a template for recording assessments was attached to case notes, appointment times were made longer and an audit and feedback loop was established to support psychiatrist’s adherence to the service protocol. Six educational sessions to support the clinicians were also provided. A pre-intervention audit of a random sample of 107 patients prescribed clozapine, and meeting international criteria for metabolic syndrome was
undertaken in December 2011. Post-intervention data for each intervention month were collected for all patients prescribed clozapine (224 patients in May 2012 and 232 patients in December 2012). Comparison of recording in the pre-intervention period and after the first intervention, showed significant increases in the proportion of clients receiving fasting lipid tests (13% vs 92%, p<0.001), fasting plasma glucose tests (13% vs 90%, p<0.001), blood pressure assessment (16% vs 95%, p<0.001) and having weight recorded (49% vs 97%, p=0.001). Similar findings were observed after the second intervention in December 2012. Overall, there were 120 clients (54%) who received all recommended assessments after the first intervention and 118 (51%) received all recommended assessments after the second intervention. Follow-up plans were only documented for one third of clients who were screened and met the diagnostic criteria for metabolic syndrome, highlighting a gap in prevention opportunities.

A randomised trial assessing the effectiveness of a cardio-metabolic health nurse consultations on self-reported health behaviours concerning physical activity, nutrition, smoking and alcohol use in people with serious mental illness, is currently underway. The trial is located within community mental health services and aims to recruit 154 participants. For the intervention group, all participants receive at least two consultations with the cardio-metabolic health nurse, one of which occurs at study entry. Tailored strategies are subsequently developed, based on the initial consultation. A comparison group receiving usual care served as the control. The intervention does not address medication issues. Current evaluation is limited, with results reported for 11 participants in the intervention group only, who have completed the trial. Several other Australian studies describing initiatives to improve metabolic monitoring were located however, we have not discussed these studies as the percentage of patients monitored before and after the intervention was not reported. We are aware that other health organisations have implemented metabolic monitoring charts but were unable to locate any evaluation studies.

Clozapine-related monitoring
One study described the implementation of a clozapine management system in South Australia, following concerns about variation in clozapine management and the mortality rate among people prescribed clozapine. A multidisciplinary working group was convened in 2010 and a multifaceted, state-wide intervention was designed. The intervention was implemented across the Adelaide metropolitan regions and partially implemented in rural areas. The intervention included the development of general practice shared care pathway and standardised protocols and documentation forms to be used throughout the services in the state. Five new forms were developed, including forms for monitoring metabolic and cardiac risk, as well as a consumer self-report questionnaire to assist with monitoring mental state, side effects, changes to medicines and compliance. The intervention also included implementation of nurse-led clinics for patients who were stable and required four-weekly monitoring. Capacity building for staff occurred through the provision of three-day educational programs and opportunity for four-day placements in the nurse-led clinics. In addition, computer-based systems for providing hospitalisation alerts and access to laboratory results were developed. The intervention was implemented in a stepped fashion, beginning in 2010 and completed mid-2012. The majority of the reported evaluation was process evaluation, including the number of people with mental illness who used clozapine (n=982). One death from physical causes (excluding cancer) was reported in the 15 months following roll-out, compared to five deaths per year between 2007 and 2011. Medical
outpatient visits were reported to have decreased by 119 per week in the metropolitan area, however, no time series assessment was provided and numbers per year for comparison were not reported. The proportion of patients who received a clinical assessment within 48 hours of having their blood tested rose from 75% to 83%. These study results are suggestive that a state-wide quality improvement program may be effective for people prescribed clozapine, however, the data presented were limited. There were no details on the method of data collection and no statistical assessment was made, all of which limit the conclusions that can be made about the effectiveness of the program.

### 6.1.3 Which interventions improve medication management?

There is Australian and international evidence demonstrating collaborative medication review services reduce medication-related problems and adverse events.\(^{155}\) No controlled trials undertaken in the Australian mental healthcare setting assessing the effect of medication review services were identified. However, a peer-assessment study of the effect of medication review in the mental health care setting suggested that the service is beneficial in this setting\(^{22}\).

**Medicines reviews**

The potential for comprehensive medicine reviews to improve medicine use in people with mental illness has been assessed in a NSW study involving five community mental health services.\(^{22}\) Case managers recruited clients who they thought would benefit from a medication review and who were aged 18 years or older and taking at least one medicine for mental illness. Pharmacists conducted the review with clients at the community mental health service. The pharmacist reviewed each client’s medication history and community pharmacy dispensing records and identified actual and potential medication-related problems. Written reports that included recommendations to resolve the problems were presented at face-to-face multidisciplinary case conference meetings. Reviews were conducted with 48 clients and an average four medication-related problems per person were identified. An expert panel, which included a consultant psychiatrist, a general practitioner, a pharmacist with a speciality in psychiatry and a pharmacist accredited to undertake medicine reviews, independently evaluated the findings. The panellists agreed with 76% of the 209 findings from the review and considered that 81% of the 208 recommendations were appropriate. Collectively, 69% of recommendations were considered likely to be implemented. Seventy-seven per cent of reviews (n=37) were deemed potentially to have a positive clinical impact.\(^{22}\) While this study was uncontrolled, the results are similar to those obtained from controlled studies of comprehensive medication review in the general Australian population\(^{155}\), and so suggest the service is beneficial in resolving medication-related problems in people with mental illness. Further controlled trials measuring patient outcomes to assess the impact of comprehensive medication review services for mental health clients in the community would confirm this result.

During our consultation, a collaborative model of medicines review, where both the pharmacist and the mental health clinician were present during interview, was described. This model has not yet been fully evaluated.

Comprehensive medication reviews have been conducted by a mental health pharmacist for consumers within the community mental health setting at high risk of medication misadventure. A face-to-face interview was conducted with the consumer to assess
adherence, efficacy, side effects, and consumer medication knowledge. The clinical pharmacist and a mental health clinician were present during the interview. Medicines information was also provided to the consumer. Information from the consumer's general medical practitioner, community pharmacy and hospital records were collated, and the pharmacist reviewed potential drug interactions, metabolic monitoring, pathology results and therapeutic drug monitoring. Information and recommendations from the review were shared with the multidisciplinary treating teams and community stakeholders.

There is a current longitudinal intervention study underway in Queensland, Northern New South Wales and Western Australia aimed at educating community pharmacists and pharmacy assistants to engage and better support people with mental illness, and their carers, in the management of medications.\textsuperscript{156-158} As part of the study, a comprehensive mental health education package has been developed for community pharmacists and pharmacy assistants to increase their understanding of the experience of mental illness and improve their communication skills. The study also involved a medication support intervention, during which community pharmacists recruited people taking medicines for mental illness and worked with them over time, with the aim of improving their medication management and wellbeing. The project is still under evaluation.

6.1.4 Which interventions improve provision of medicines information for consumers?

In the previous section, we highlighted that lack of information about medicines provided to people living with mental illness, and their families or carers. One Australian study, undertaken in a metropolitan hospital in Melbourne, developed and assessed a weekly medicines information forum for inpatients.\textsuperscript{135} The forum was led by both the senior mental health pharmacist and the Professor of Psychiatry. Participants were provided with psychiatric medication information fact sheets which were written in plain English and described how the medicines worked, possible side effects and how to manage the side effects. The forums, which lasted up to one hour, aimed to be interactive and address any questions participants had about their medicines. The program has only been evaluated using participant satisfaction, based on questionnaires completed by participants at the end of each forum. Responses from 48 participants who attended at least one forum in the first three months of the program showed that only 48% had positive attitudes towards the medication for their mental illness before the forum, and this rose to 96% after the forum. Overall, 84% of respondents found learning and sharing information during the forum helpful and all participants reported the psychiatric medication information sheets were very useful.

Medication information forums have also been run in the community setting, but we were unable to locate any studies assessing the outcomes of these forums.

**Personalised care tips for improving medicine use**

During our consultations, a number of participants suggested that care directives that were prepared while a person was well and that outlined what each person’s preferences were for care during exacerbations of illness would be helpful. It was anticipated the directives could include information such as the things that assist to make the person calm or reduce their agitation, as well as the factors known to contribute to increasing anxiety or agitation. While we found no Australian studies evaluating initiatives such as this for people with mental
illness, there is some evidence that personalising communication and care for older people with dementia may lead to a reduction in antipsychotic use.43

The Top 5 program was developed to personalise hospital care for people with dementia.43 Within the program, hospital staff engaged with carers to learn more about the person with dementia. The five most important tips or strategies to personalise care and support communication with the patient were recorded on a standardised form, which was placed at the bedside. The program was implemented in 20 public hospitals and five private hospitals in New South Wales. Strategies used to implement the program included formation of an implementation team in each local health district, site visits, educational sessions, development of a toolkit, and local site liaison forums. There were 1,277 Top 5 programs initiated at 21 sites during the study period. Overall, 91% of the 292 staff surveyed during or after the intervention agreed or strongly agreed the program was easy to use. The effects of the program on falls and antipsychotic usage were evaluated in selected facilities. There were five hospitals that reported at least one fall involving a person with dementia in the two months after the program was implemented. Among these five hospitals, the total number of falls decreased from 33 the first month after the program commenced, to 21 falls per month at six months post-implementation. Two hospitals collected data on antipsychotic use before and during the Top 5 program implementation period. One hospital compared antipsychotic usage during the program implementation period against usage at the same time in the previous year, and found that average monthly expenditure decreased by 68% in the post-implementation period. The total amount spent on antipsychotics during these periods was not reported, and it is unclear if this was a statistically significant decrease in expenditure. At another hospital, time series analysis was used to assess changes in the monthly usage of antipsychotic medications in the wards participating in the Top 5 Program in 18 months before the intervention, and in the seven months after the program was implemented. A reduction in the use of orally-dispersible risperidone tablets (~67mg per month, p<0.1) was reported after the program was implemented, which corresponded with clinician’s perceptions of less need for physical or chemical restraint.43,159

Allowing consumers to express their experiences of the side effects of their medicines

Side effects associated with taking psychotropic medicines can be severe and debilitating. Improving communication about side effects may assist in reducing harm. A pilot study using the Enhancing Quality Use of Medication Self-Reported Questionnaire (EQUIM-SRQ) was conducted in a Western Australian mental health outpatient population involving people taking one or more psychotropic medicine.160 The EQUIM-SRQ is a 75-item questionnaire for people taking psychotropic medicines to list their current medications and a checklist of side effects experienced. Participants were able to rank the three most bothersome side effects, describe the frequency and severity of each one and comment on related experiences, including thoughts of ceasing medicines. The response rate for the survey was relatively low (18%), however, the questionnaire was thought to have potential for clinical application to facilitate discussions between people taking psychotropic medicines and clinicians, about the medicines and which ones might work and which ones might not.161 Since this initial study, a validated version of the questionnaire has been developed, which is known as the My Medicines and Me (M3Q) side effect questionnaire.162 Usability and acceptability studies have been undertaken.163,164 Larger trials are still required to determine if it improves communication and side effect management in practice.
6.1.5 Which interventions improve use of psychotropic medicines in aged-care settings?

Controlled trial evidence and time series evidence is available on the effectiveness of interventions to reduce psychotropic medicine use in the residential aged-care setting and among people with dementia.\textsuperscript{165-167}

A six-month controlled trial in 25 Tasmanian nursing homes (13 intervention and 12 control homes) during 2008-09 aimed to reduce the prescribing rate of antipsychotics and benzodiazepines. The pharmacist-led intervention included two medication audit and feedback cycles, development of guidelines by locally-based clinicians, educational sessions for staff, print and promotional material, academic detailing for the doctors attending the nursing home, interdisciplinary reviews of sedative medicine use that included the staff, general practitioners, carers and pharmacists, and educational material for residents and carers. A two-day training workshop for the participating pharmacists was held prior to the intervention. Results indicated the prevalence of both regular antipsychotic medicine use (20.3\% to 18.6\%, \textit{p}<0.05) and benzodiazepine (31.8\% to 26.9\%, \textit{p}<0.005) use decreased significantly in the intervention homes, whereas usage in the control homes did not alter over the same six month period. Reductions in the doses of benzodiazepines were also observed with 40\% of residents in the intervention homes having doses reduced or stopped, compared with 18\% (\textit{p}<0.0001) in the control homes.\textsuperscript{166} Data collected 12 months after the initial study found the effects of the intervention on benzodiazepine use were sustained, with reductions in benzodiazepine use and dose falling by 25\% and 24\% respectively in the intervention homes.\textsuperscript{167} The effect on antipsychotic use was not sustained however, and levels had returned to base-line, suggesting the need for repeated interventions for sustaining changes in use of antipsychotics.

Delivery of patient-specific audit and feedback to general practitioners has also been demonstrated to be effective in reducing antipsychotic use in elderly people. The Veterans’ Medicines Advice and Therapeutics Education Services (Veterans’ MATES) program delivered patient-specific feedback supported by educational material to general practitioners. Educational materials were also provided to pharmacists, and veterans. The Veterans MATES intervention targeting use of antipsychotics in the elderly with dementia was evaluated using time series analysis. The intervention resulted in a 14\% reduction in the use of antipsychotics at the time of the intervention (\textit{p}<0.0001), with a further sustained reduction in use of 3\% per month, for the subsequent 20 months post-intervention.\textsuperscript{168}

A longitudinal study assessing the impact of a multifaceted intervention to reduce the use of antipsychotic medicines in aged-care facilities is currently underway in Sydney.\textsuperscript{168} The outcomes of this study have not yet been published.
7. Strategies to improve medication safety in mental health: The international experience

This section includes a review of studies from the international literature describing interventions to improve medication safety in mental health. The studies that were included were generally limited to randomised controlled trials and systematic reviews, where available.

7.1 Improving prn medicine use

A US study suggests prn medicine use for agitation can be improved by issuing mandatory guidance. Under the new guidance, staff were required to document that patients had voluntarily consented to administration of oral medicine for agitation. Further, the use of intramuscular prn medicine for agitation was no longer acceptable practice. Intramuscular injections for agitation required a physician order, resulting in nurses having to consult with a physician prior to administration. Time series analyses demonstrated that the guidance was effective in reducing administration of both oral and injectable ‘prn’ medicines. Administrations of oral prn medicine reduced from an average of 165.4 ± 20.7 per month per 1,000 patient days, to 116.3 ± 24.3 per month per 1,000 patient days (p = 0.002). Administration of intramuscular ‘prn’ medicine use declined from an average of 35.9 ± 6.5 per month per 1,000 patient days, to 18.2 ± 4.9 per month per 1,000 patient days (p = 0.002). This change occurred with no effect on the rate of assaults occurring in the ward or on the rate of use of seclusion.

7.2 Reducing multiple antipsychotic use

Collectively, Australian studies suggest that on average, 35% of patients with serious mental illness are on multiple antipsychotic therapies. While we did not find any Australian randomised controlled studies that assessed strategies to reduce multiple antipsychotic use, a systematic review of interventions to reduce multiple antipsychotic use included three trials (one randomised and two open-label) where patients were switched from dual therapy to monotherapy. In the randomised controlled trial (n=127 outpatients), a joint decision between the doctor and patient was made about which antipsychotic to cease. Overall, 69% of patients were successfully switched to monotherapy, with better weight control in the monotherapy group and no difference in psychiatric symptom changes or in hospitalisations. There were however, more drop-outs in the monotherapy arm. In one open-label trial, involving 14 difficult-to-treat patients, 43% of patients were successfully converted to monotherapy. In the other open-label trial, involving 47 patients, 77% were successfully converted to monotherapy. In this latter trial, 23% improved while on monotherapy, while 55% remained stable. Three more recent randomised controlled trials provide further evidence that patients on dual antipsychotic therapy can be successfully switched to monotherapy. In one 12-week trial involving 35 patients, patients were randomly allocated to monotherapy or maintained on their existing therapy. Fourteen of the 18 patients in the monotherapy were successfully transitioned to monotherapy without deterioration. In the second study, involving 39 patients followed for 24 weeks, improvements in attention, daily living skills and work skills were observed in the group that switched to monotherapy, compared to the control group. Two of the patients in the switching group had worsening
symptoms and dropped out for this reason.40 A longer-term, 52-week, US-based, randomised controlled trial provides some evidence that switching from dual therapy to monotherapy may be associated with worsening symptoms, over time.39 This US study included 90 patients with schizophrenia or schizoaffective disorder who were randomly allocated to ‘switching to monotherapy’ or ‘maintaining dual therapy’. While 81% of the switch group who had at least 60 days of follow-up remained on monotherapy, there was a significantly greater rate of drop-out in the monotherapy arm and an increase, on average, in positive symptoms in the monotherapy arm, over time.39 The proportion that did not develop worsening symptoms was not reported.

The systematic review of interventions to reduce antipsychotic polypharmacy also included 14 studies that aimed to reduce antipsychotic polypharmacy by targeting physicians.41 Three of the studies were randomised controlled trials, all of which included multiple strategies as the intervention. One of these trials, further described below, resulted in a significant reduction in antipsychotic polypharmacy, however the other two failed to show effect. In addition to the randomised controlled trials, there were three single-arm trials that assessed simple or modest educational programs, such as dissemination of pamphlets and videos or a treatment algorithm, and eight single-arm trials that assessed multiple component educational interventions. While effect sizes varied, the single-arm trials all reported some effect, however, in some the outcome included assessment of all psychotropic medicines, not solely multiple antipsychotic use41, and the lack of control arms limits our ability to conclude the intervention was successful.

The randomised controlled trial that demonstrated the effectiveness of educational interventions targeting physicians to reduce multiple antipsychotic use was undertaken in the UK.169 The multifaceted intervention included:

- A 30 minute ‘academic-detailing’ session by a specially-trained clinical psychiatric pharmacist
- A workbook for nurses and doctors containing educational materials and specific cognitive techniques to challenge health professionals thinking about the need for multiple antipsychotic use and the range of alternative treatments
- A booster pamphlet sent eight weeks after distribution of the workbook
- A medication chart reminder system, in which pharmacists applied stickers to medication charts when patients were prescribed more than one antipsychotic and removed them when multiple use was no longer prescribed
- A guideline on antipsychotic prescribing.

The study found that after delivering the multifaceted intervention aimed at doctors and nurses, the odds of being prescribed multiple antipsychotics on mental health wards, compared with a single intervention consisting of a guideline, was reduced (OR 0.43, 95%CI 0.21-0.90, p=0.028). No follow-up beyond the six month rotation period was conducted, so the success of the intervention over time is not known.

### 7.3 Reducing cardio-metabolic risk

Australian studies have targeted clinicians to improve cardio-metabolic risk factors26,28, however we did not locate any Australian studies that targeted people with mental illness and focused on encouraging them to make changes in their dietary and exercise patterns to
reduce cardio-metabolic risk. Three international trials were located and suggest this approach is also successful in reducing cardio-metabolic risk in people with mental illness.\textsuperscript{170-172}

In two studies, multiple and frequent structured educational sessions were delivered to patients in the intervention groups by trained healthcare professionals, and compared with controlled groups who did not receive the intervention.\textsuperscript{171,172} Participants in the intervention group of one study were educated by a dietician about important nutritional concepts, including the importance of regular eating, healthy snacking, low calorie foods, cooking preparation, food shopping and reading food labels, as well as diet planning and keeping a food diary.\textsuperscript{172} Participants were also urged to keep an exercise diary and a coordinator evaluated their exercise regimens and helped with the planning of each session. Weight loss and a reduction in body mass index (BMI) was significant in participants in the intervention group, compared with the control group.\textsuperscript{172}

Participants in the intervention group of the second study met twice a week for two hours for the 12 month study period.\textsuperscript{171} One session focused on buying, preparing and cooking healthy foods, and the other session focused on finding a suitable physical activity for each participant, along with some theory emphasising the importance of physical activity, avoiding smoking, alcohol and substance use, staying motivated and avoiding injuries. The expected reduction in weight, waist circumference, BMI and improvement in fitness in the intervention group was not seen, compared with the control group, however, participants in the control group did put on weight and their BMI and waist circumference increased, which did not happen in the intervention group.\textsuperscript{171}

The third study, conducted in a community setting in the US, examined the benefits of adding 12 months of ‘wellness’ training to basic primary care for 309 patients with mental illness. Participants in the intervention group, in addition to basic primary care, had access to an individually administered training program to improve skills in self-assessment, self-monitoring, and self-management of physical health problems, including effective use of health services. The ‘wellness’ training was tailored to be flexible and fit in with individual participant’s lives. Written information was provided in a format that accommodated different levels of cognition and language skills. Participants were encouraged to use resources accessible to them, including health education materials. Results indicated physical functioning in participants in the intervention group significantly improved over time (p=0.02), as did their general health (p=0.006).\textsuperscript{170}

### 7.4 Providing clinical pharmacy services

There is significant international evidence demonstrating that clinical pharmacy services reduce error and reduce adverse events in the general hospital setting.\textsuperscript{61} A systematic review of controlled or comparative studies published between 1972 and 2003 of pharmacy services in mental health care provides further evidence that clinical pharmacy services in the mental health care setting improve care.\textsuperscript{34} The review included 16 studies, six of which were prospective designs. Study settings included inpatient facilities, outpatient facilities, primary care clinics and the disability sector. The interventions included pharmacist participation at multidisciplinary team meetings, clinical pharmacist services, and pharmacists as care managers, with or without prescribing rights. Collectively, the evidence was positive, however, variations in setting, interventions and implementation limit making
strong conclusions. Three of the prospective studies examined clinical outcomes, one of which was positive in patients with depression and psychosis. Three studies included economic assessment, all of which suggested the service was cost-effective.34 The majority of studies were undertaken prior to the year 2000, however the results are consistent with the literature in the general health setting that demonstrates clinical pharmacy services are associated with safer health care.61 A more recent non-randomised, open, controlled trial of pharmacist-led medication reviews within non-acute psychiatric wards, provides further evidence of the impact of pharmacist services.173 The intervention included medication reconciliation at admission, and medication review at discharge and three months post-discharge. Telephone follow-up at 1.5 and six weeks post-discharge occurred. In addition, pharmacists participated in ward rounds. Analysis showed appropriateness of therapy, as measured by the medication appropriateness index, improved in the intervention group compared to the control group. In addition, there were, on average, three medication-related problems per person identified at admission in both groups. This reduced to 0.4 per person in the intervention group, compared to 2.3 per person in the control group (p<0.05), demonstrating the service was successful in resolving medication-related problems.173

7.5 Improving discharge liaison services
There is Australian literature to suggest discharge liaison services are effective in reducing medication-related problems in the general health setting.32 This is likely to be applicable to the mental health setting with international evidence demonstrating positive results when discharge liaison services were provided to patients discharged from psychiatric wards.35 A Scottish study, involving 97 patients, was undertaken in 1995-96. Patients in the intervention arm received a needs assessment prior to discharge, medicines information and a discharge plan - the latter was sent to the patient’s community pharmacy. In addition, domiciliary visits were undertaken at one, four and 12 weeks post-discharge. The mean number of medication-related problems was lower in the intervention group at 12 weeks, compared with the control group. Knowledge scores increased in both groups post-discharge, but were not significantly different from each other. There was a greater improvement in compliance in the intervention group than the control group35, but the statistical significance of the results was not reported.

7.6 Providing education to people with mental illness
Australian evidence suggests that provision of medicines information to people with mental illness during their inpatient stay improves knowledge in the time period immediately after the intervention.135 A systematic review of the international literature on the effect of educational interventions for people with mental illness found that multiple, structured educational sessions delivered at frequent intervals were better than single sessions in improving knowledge and were useful as part of treatment programs for people with mental illness.174 The review found that people with mental illness can sustain knowledge and have an improved insight into their illness after such interventions.
8. The way forward

Evidence for successful strategies to improve medication in the general healthcare setting supports the use of clinical pharmacy services, medication reconciliation services, standardised systems for medication ordering and administration, electronic medication management systems, individual patient supply systems, systems requiring double checking, smart pumps with ‘hard alerts’ for intravenous administration, bar code scanning systems, multidisciplinary team care, collaborative home medicines reviews and systems-wide initiatives using quality improvement cycles. These interventions, which have been proven to work in the general setting, are equally applicable in the mental healthcare setting.

Collectively, the findings from our consultations and review of the evidence highlight additional issues specific to the mental health setting that could be trialled or considered for further implementation. Additional activities that may further support medication safety in the mental health setting are described below. Some of the issues identified in the consultation require the building of an evidence base, as there has been limited study of the issue and the extent of the problem is not well defined. Some of the strategies suggested are ideas that were put forward in the consultation and will require trials to determine their effect before being implemented more widely. Other suggestions arise from the evidence base, but may require adaptation to the mental healthcare setting.

8.1 Policy development and implementation

Throughout our consultation, people highlighted the usefulness of the recovery principles for supporting appropriate care and medication management in mental health and the need to incorporate psychosocial issues into all aspects of medication safety. The incorporation of the recovery principles within medication safety policy and initiatives was considered to have the potential to provide an overarching framework to support improvements in medication safety in mental health care settings.

8.2 Facilitation and co-ordination

Our consultations highlighted that there are a number of opportunities that exist for improving medication safety in the mental health setting, but facilitation is required to maximise uptake. These opportunities include:

- Use of the personally controlled electronic health record, My Health Record, for people with mental illness
- Developing a culture of medication safety for people with mental illness across primary health care networks
- Coordination and integration of activities across the continuum of care, particularly between the acute mental health care sector and the primary care sector
- Facilitation of further pharmacy services specifically for mental health care.
8.3 Objective information
Within our consultations, the lack of a collective resource for therapeutic information was considered an issue, with many agencies accessing information from different sources. This was considered to contribute to variations in practice and a collective resource was considered likely to assist in reducing variation in practice. In particular, decision support tools for *prn* medicines were identified as required.

8.3.1 Decision support tools for ‘prn’ medicines
Our literature review highlighted that use of *prn* psychotropic medicines is common\(^6\)-\(^10\), and both the literature\(^92\), and our consultations highlighted that variation in use or *prn* medicines can occur due to systems issues and to differences in understandings of when to use ‘*prn*’ medicines. Our consultations suggested that decision support tools for use in the acute care setting may be a mechanism to assist staff to make more consistent decision making concerning *prn* medicines use, however, there have not yet been any Australian trials to determine the effect of decision support tools in this area. Development and trailing of decision support for *prn* medicines use could be considered for improving medication safety in mental health care.

8.4 Education and training

8.4.1 Medication education for consumers and carers
Information gathered from the literature and during our consultation process shows there is a need for consumers and carers to receive more information about their medicines and the associated side effects.\(^31\) Weekly, interactive medicines information forums for consumers and carers within the acute mental health care setting have been shown to improve knowledge and attitudes towards medicines.\(^135\) Multifaceted, structured educational interventions delivered frequently have been shown to improve and sustain knowledge in consumers with a mental illness.\(^36\) Studies also show that participants with mental illness gain insight into their illness.\(^4\) Consideration could be given to furthering implementation of these successful initiatives.

8.4.2 Training for health professionals
Within our consultations, the need for training in privacy legislation, recovery principles and the psychosocial dimension of mental health was identified.

Training concerning the privacy legislation
Within our consultations, consumers and carers noted that health professionals were not always aware of the privacy legislation and, on occasions, inadvertently refrained from providing needed information about medicines to family members, friends and carers due to a mistaken interpretation of the privacy principles. This was considered to have the potential to contribute to medication error and harm. Within our consultations it was recommended that education for health professionals, both undergraduate and postgraduate, on the privacy principles and their application in the mental health setting, should be considered.
Incorporating the ‘recovery principles’ into educational curricula
Within our consultations it was noted that the concept of ‘recovery’ is not embedded throughout all aspects of health professional curricula, even though recovery and wellness action plans exist in some settings. Within our consultations this was identified as a cultural challenge, and it was considered that embedding the recovery principles in both undergraduate and postgraduate curricula may be beneficial.

Incorporating a psychosocial dimension into medication safety training
Medication safety processes employed in the general health setting are likely to be successful in the mental health setting. Our consultations highlighted however, that there is the need to integrate a psychosocial dimension to both safety and quality in this setting. For example, pharmacists need training to consider psychosocial issues when counselling about medicines. The safe storage of medicines was cited as an example which may be problematic if people are homeless; similarly, continuity of supply may be challenging when someone is unwell, and pharmacists could consider providing support services to ensure continuity of supply. The dispensing of safe quantities of medicines is an area where pharmacists may also be able to assist when individuals are considered to be at risk of self-harm. Similarly, pharmacists can educate consumers, their families and carers to recognise and understand medication safety as a suicide prevention activity. Removal of expired or unused medication from the home, for example, acts as a protective factor for people with thoughts of self-harm, actual self-harm, suicidal ideation or for those who have attempted suicide.

8.5 Services and interventions

8.5.1 Improving medication history on admission to mental health care units: Medication reconciliation
Medication reconciliation has been shown to reduce errors on admission to hospital in the general health care setting in Australia\(^4\), however, we located no studies of the effectiveness of this service in the mental health care setting in Australia. While medication reconciliation services conducted in the general health setting are likely to be effective in the mental health care setting, the most appropriate timing for medication reconciliation in the mental health care setting and the need for inclusion of iterative histories within medication reconciliation services was highlighted in our consultations as an issue where further development could occur.

Our consultations highlighted that the timing of provision of medication reconciliation services in the mental health setting may need to differ from the general setting as information may be difficult to obtain from people with mental illness at the time of an acute event. Further, our consultations highlighted that information on past therapeutic failure or therapeutic intolerability (adverse events and allergies), which is an issue for patients in all sectors of health care, was considered a particular challenge for people living with mental illness. Our consultations highlighted that in the mental health care setting a range of circumstances may collide which can all play a part in the chance to increase the risk of errors. For example, when an unwell person is admitted to hospital he or she may not be able to provide an accurate history and, at the same time, there may have been staff turnover, so none of the health professionals know the person. This combination of factors
may lead to situations where staff prescribe a medicine known to have failed in the past. Consumers and carers highlighted this as a common experience.

An alternative model that was proposed was regular medication reconciliation in the outpatient setting. The development of ‘My Health Record’ may facilitate this. In addition, it was proposed that including space on medication reconciliation documentation to support documentation of past therapeutic failure, or the use of the medication action plan for documenting past therapeutic failure and therapeutic intolerability, may assist in enabling an accurate history to be available at all times. Our consumer consultations highlighted that consumer input into the reasons why medicines were ceased would also facilitate person-centred care and integrating this with medication reconciliation may be advantageous. Our consultations highlighted that many consumers use traditional, complementary and alternative medicine and treatments, and medication reconciliation in the outpatient setting may assist with improved documentation of these treatments. This model has not yet been evaluated in the Australian mental healthcare setting.

Where medication reconciliation takes place within the inpatient setting, our consultations highlighted that at times when a person is acutely unwell and may have difficulty communicating their needs, the involvement of a peer support worker may be beneficial.

8.5.2 Improving administration of prn medicines and depot injections

The use of standardised charts has been shown to reduce errors in the general healthcare setting. Within our consultations, current charts were considered to be sometimes inadequate for appropriate documentation of medicines that are to be administered ‘when required’ or by depot injection. Surveys of Australian health professionals also highlighted conflicting views on the appropriateness of current charts. No data were available to determine the extent to which errors occur with the current charts.

Our consultations highlighted that there was variation in the decision to use a prn medicine and selection of therapy for administration. The consultations highlighted that at times when there were prescriptions written for multiple prn psychotropic medicines, this contributed to uncertainty and inconsistency about which one to use. It was noted within the consultations that the use of standardised definitions of indications, such as ‘agitation’, and a format for health professionals to document a plan for selection, administration, and assessing the effect of prn medicines may assist with this process in the acute care setting. This has yet to be evaluated in the Australian setting.

Our literature review highlighted that routine discussion of use of prn medicines at nursing handover is sometimes omitted, particularly at the night handover session. Checklists for use during handover, which include identifying the need to communicate information about reasons for and outcome of prn medicines may assist with information sharing and continuity of care. This has not yet been evaluated in the Australian setting.

Within our consultations it was noted that there was variation in how depot injections were given and it was considered that a national intramuscular administration protocol, which included documentation of issues such as site of delivery, would be likely to be beneficial in reducing errors.
8.5.3 Obtaining care directives for managing exacerbations
Our consultations highlighted that information on patient preferences or knowledge of ‘what works for me’ when someone is acutely unwell, is challenging to collect. Care directives, developed in the community setting when people are well, highlighting patient preferences for treatment during exacerbations or emerging agitation, would be helpful both in the community and hospital settings. While evidence to support this approach within the acute mental health care setting is lacking, the Top 5 program\textsuperscript{43}, which focused on people with dementia, provides a model that could be adapted and trialled in the mental health care setting. Our consultations suggested care directives could also include things like ‘the top five things that upset me’ and strategies to assist with management of upsetting situations. It was suggested in our consultations that in some states, the local mental health legislation may override advance care directives, and any models developed may need to consider this.

8.5.4 Reducing multiple antipsychotic use
Collectively, Australian evidence suggests 35\% of people with severe mental illness might be on multiple antipsychotics\textsuperscript{14-20}, while international evidence suggests up to half may be able to be successfully converted to monotherapy.\textsuperscript{41} The international review found some evidence to support multifaceted educational strategies targeting clinicians, with greater effect observed in direct patient trials, where both patients and physicians jointly choose which antipsychotic to trial ceasing.\textsuperscript{41} Strategies suitable for the Australian setting that support trialling transition from dual therapy to monotherapy in routine practice still require evaluation.

Off-label use of psychotropic medicines does occur and our consultations highlighted that mechanisms to support peer review may assist prescribers with decision making in this area. The value of pharmacists in providing objective information was recognised. Consistent with the recommendations of the National Review of Mental Health Programmes and Services\textsuperscript{176}, incentives to promote evidence-based practice are required. The best mechanisms for incentives require investigation.

8.5.5 Improving cardio-metabolic monitoring and reducing cardio-metabolic syndrome
A standardised cardio-metabolic monitoring chart
There is evidence that cardio-metabolic monitoring in people with serious mental illness is inadequate\textsuperscript{24-26}, despite cardio-metabolic effects being a well-known adverse event of antipsychotic medicines. Our consultations highlighted that variation exists in the recording and monitoring of physical and cardio-metabolic health assessments in different settings, with no standardised chart available for metabolic monitoring. A standard chart for metabolic monitoring was developed for use in children and adolescent mental health care wards, however, use of the chart was shown to be suboptimal\textsuperscript{107}, suggesting strategies to support implementation are also required. Consideration could be given to developing a standardised metabolic monitoring chart for routine use in the mental health care setting. Strategies to support implementation and evaluation would be required.
**Interventions to reduce cardio-metabolic syndrome**

Australian literature indicates up to 50% of people with severe mental illness develop cardio-metabolic syndrome.\(^{26,123,124,177}\) International evidence suggests multifaceted, structured educational interventions targeting people with mental illness, which are delivered frequently can reduce cardio-metabolic risk.\(^{170-172}\) These studies suggest a program relating to healthy eating, regular exercise, and regular cardio-metabolic monitoring may aid in reducing risk factors, such as weight, blood sugar levels and high blood pressure in consumers with mental illness. Trials of this type of intervention that would be suitable for widespread implementation within Australia are still required.

Australian evidence supports the implementation of multifaceted interventions targeting clinicians within the acute mental health care setting to improve monitoring, however, evidence is lacking for improvements with longer term follow-up, as well as the effect on health outcomes over time.\(^{26,28}\) One Australian randomised trial in the primary care setting was identified, but full trial results are still to be reported.\(^{42}\) Our consultations highlighted challenges in continuity of care, with practitioners being unclear as to who was responsible for monitoring and follow-up actions.

Priority needs to be given to improving cardio-metabolic monitoring and outcomes in people with severe mental illness. Consideration needs to be given to testing models within the community sector that support cardio-metabolic monitoring and follow-up, and which include protocols that identify the health professional responsible for actions.

Coordination of care may breakdown due to multiple providers being responsible for care. This is a particular challenge for people with mental illness, who may be managed by their psychiatrist for their mental illness and their general practitioner for their physical illness. This can lead to situations where it is unclear as to who is responsible for cardio-metabolic monitoring and who is responsible for actioning plans in response to problems being detected, in particular where the medicines used to treat the mental illness may be contributing to the cardio-metabolic problems or other physical illness. An overarching care plan is required that governs care across all health settings. An area in the agreed care plan that identifies and documents governance responsibilities would assist. This still requires trialling in the Australian setting. Interventions assessing the best mechanisms for disseminating care plans are also required.

### 8.5.6 Improving clozapine management

Patients taking clozapine need to have regular blood tests, along with other checks to monitor for serious side effects. There is some Australian evidence suggesting improvements in management of clozapine can be made. This comes from a multifaceted intervention that included the development of general practice shared care pathways, standardised protocols and documentation forms for clozapine-related monitoring in South Australia.\(^{154}\) Further evaluation data are required to determine if this should be implemented on a larger scale.

### 8.5.7 Integrating recovery plans and medication management plans

Recovery plans may be written for people with mental illness, as may medication action plans or medication management plans. Integration of these plans, including providing
comprehensive medicines information in recovery action plans, in a stepwise approach, is needed to support the recovery process.

Two strategies suggested to foster a collaborative partnership and facilitate shared decision making are the use of peer support workers in inpatient settings to advocate for what the consumer considers important and secondly, having consumers present and engaged during handover and clinical discussions. This is to find out what aspects of treatment the consumer considers vital and how best to incorporate their views in a recovery plan.

**Involving clinical pharmacists**

There is substantial evidence that medication safety improves when clinical pharmacy services are provided, with clinical pharmacists as part of the multidisciplinary team.61 This evidence is applicable in the general hospital setting61 and mental health units.34 Within our consultations, concerns about staff knowledge and skills with regards to pharmacology and pharmacokinetics of psychotropic medicines were raised. The contribution of clinical pharmacists in the routine provision of evidence-based medicines information is a potential solution to address this gap. Additionally, within our consultations, under-investment in clinical pharmacy services in mental health was highlighted as an issue. The current level of involvement of clinical pharmacy services in the mental health care setting is unknown. Mapping clinical pharmacy services in hospital, outpatient and community settings in Australia would be useful to identify gaps in current service provision and support planning for appropriate service delivery.

Our consultations also highlighted that pharmacists are well-placed to support consumers with mental illness in the community. For example, community pharmacists are able to detect if prescriptions are not being dispensed regularly and observe for worsening symptoms. While community pharmacist medication review services within community mental health services have now been trialled22, additional mechanisms to support community pharmacists to take a more proactive and collaborative role in mental health care could be trialled. Opportunities for pharmacists to work in mental health care in the primary care setting may be available through the *Sixth Community Pharmacy Agreement*. Within this program, $50 million has been allocated to trial new and expanded community pharmacy programs which aim to improve clinical outcomes for consumers or extend pharmacy services in primary health care.178

Australian controlled trials in the general setting have shown that a home medicines review within seven days of discharge as part of a discharge liaison service is effective in reducing medicine-related problems.32 International literature provides further evidence of the effectiveness of discharge liaison services in the mental health care setting.34 Trialling of this service within Australia should be a high priority, as during our consultations some clinicians indicated that pressures on bed space in the inpatient setting meant many patients were discharged when on the way to recovery, but who were not fully recovered and, thus, were at risk of medication-related misadventure. Evaluation of discharge liaison models with multidisciplinary participation, for example having the pharmacist and mental health worker both present during the home visit, is required.
8.5.8 Promoting communication

Interview guides and patient self-completed questionnaires
The difficulty of communication and shared decision making in the mental health setting was highlighted often in our consultations. Suggested solutions included interview guides for health professionals that assist them in having conversations with people with mental illness about issues such as alternative treatments, medication compliance or adherence, what ‘success’ or ‘working’ looks like (how do I know if the medicine is working?), managing side effects, and understanding of what are intolerable side effects for the consumer (from the consumer perspective) and what side effects are tolerable and with which the consumer may be prepared to live. The My Medicines and Me Questionnaire (M3Q), a validated questionnaire to encourage communication about side effects,162-164, is one such tool for which an implementation trial could be undertaken. Our consultations highlighted that patient self-report questionnaires that could be completed in doctors’ waiting rooms prior to the consultation may facilitate improved communication. Pre-consultation forms have been tested for feasibility and acceptability in the general health setting179,180 and in the mental health setting for adverse event detection.160,161 Our consultations suggested mood review forms and consumer tools comprising a series of questions or prompts to assist consumers to talk about their medicines and ongoing treatment plan with clinicians may improve communication. Trialling and evaluation of these interventions is required.

8.6 Strategic research and data collection
The lack of research on medication safety in the mental health care setting was noted as a significant issue. We located no research quantifying the extent of medication-related problems and harms in mental health units in Australia. There were also no studies assessing medication safety for people detained and treated without consent under mental health legislation. In addition, there was very little research evaluating strategies for improving medication safety in mental healthcare settings in Australia. During our consultations, many jurisdictions indicated they were undertaking activities to improve medication safety in mental health care, however, evaluation of these activities was not always undertaken. This was seen as a missed opportunity for improving mental health care. Facilitation of evaluation of activities in these settings would strengthen evidence supporting effective interventions in the mental health setting.

National data collection of sentinel events
The lack of a national data collection on sentinel medication incidents in the mental health care setting was also raised during our consultations as an area of concern and an issue that could be addressed in the future. Participants in our consultations indicated that mechanisms to support sharing of information on sentinel events that lead to harm would provide opportunity to consider prevention strategies in other settings.

Providing evaluation support for interventions that are being implemented
During our consultation process, we became aware of a number of examples where changes in practice had been implemented, but without formal evaluation. For example, in one jurisdiction there had been a change to administration of depot antipsychotics with regards to injection site and technique for administration. While anecdotal reports indicated the program was a success, there had not been any formal evaluation to determine overall
effectiveness or potential application for other mental health settings. A formal evaluation or study to assess this would further strengthen evidence to support the best injection site and technique. A mechanism is required to identify key practice changes and support evaluation of the new practice to inform whether widespread implementation should be recommended.
9. Conclusion

There are many gaps in the evidence base to support improvements in medication safety in the mental health care setting with regards to identifying the extent of the problems and testing solutions that work in the Australian mental health care setting.

The analysis in this report suggests some high priority areas for action. These include improving cardio-metabolic monitoring and cardio-metabolic outcomes for people on antipsychotics, integrating clinical pharmacy services within the mental health care setting, providing discharge liaison services and supporting coordination of care, particularly across the mental health care service and primary health care service interface. Both the literature and our consultations suggest there is an urgent need to clarify clinician responsibilities for care. This was particularly evident for cardio-metabolic monitoring where there appears to be confusion over which clinician is responsible for monitoring and follow-up actions.

Our consultations highlighted that the development of national guidance would be helpful to support appropriate use of prn medicines, and depot injections. An international study provides some evidence that mandatory guidance for prn medicine use can reduce their use. Given significant international evidence to suggest many patients, although not all, can be successfully transitioned to monotherapy, guidance on multiple antipsychotic use, as well as interventions to support appropriate antipsychotic use, may assist in reducing multiple antipsychotic use in mental health care.

Our consultations suggested improved documentation for prn medicine use, depot injections and metabolic monitoring were areas where action could be taken. Improved documentation for care plans that included space to identify physician responsibility for actions was also highlighted as an area for action.

Existing evidence-based strategies, including medication reconciliation and the Top 5 program, could possibly be adapted to better suit the mental health sector. Suggestions included trialling medication reconciliation services within the outpatients setting when patients were well, rather than on admission, and adapting programs such as Top 5\textsuperscript{13}, to assist with managing agitation in people with mental illness.

Across Australia, a number of activities are underway or have been implemented to improve care, however, formal evaluation is limited and support for evaluation of activities is required.
# Appendix 1. Glossary

Key terms used in this report are summarised below.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse drug event</td>
<td>An adverse drug event can be defined as an incident that results in harm from a drug and includes adverse drug reactions.</td>
</tr>
<tr>
<td>Adverse drug reaction</td>
<td>An adverse drug reaction is a response to a drug which is unintended, causes harm and occurs at doses normally used.</td>
</tr>
<tr>
<td>Agreed care plan</td>
<td>An agreed care plan is a mental and physical health ‘road map’ that is discussed and agreed upon by the consumer and healthcare team. It allows the healthcare team to work with the consumer to determine goals and aspirations for the future in a respectful way.</td>
</tr>
<tr>
<td>Anxiolytic</td>
<td>This term is used to describe a group of medicines used to treat anxiety.</td>
</tr>
<tr>
<td>Antidepressant</td>
<td>A medicine used to treat depression. Some antidepressants are also used at low doses in pain management. The antidepressants amitriptyline, sertraline and venlafaxine are mentioned in this report.</td>
</tr>
<tr>
<td>Antipsychotic</td>
<td>A medicine used to treat psychotic disorders. Antipsychotics are sometimes classified as conventional (first generation) antipsychotics or atypical antipsychotics. Risperidone, quetiapine, olanzapine, clozapine and haloperidol are some of the antipsychotics mentioned in this report.</td>
</tr>
<tr>
<td>Benzodiazepine</td>
<td>These medicines are used to treat conditions such as anxiety, agitation, insomnia, alcohol withdrawal, muscle spasm and seizures.</td>
</tr>
<tr>
<td>Cardio-metabolic monitoring</td>
<td>Fasting blood glucose, body mass index, fasting lipid profile, waist circumference, blood pressure and symptoms of diabetes are measurements that are recommended when monitoring cardio-metabolic risk factors. It is recommended that they are monitored from when antipsychotic medicines are started, then every three months during the first year and every six months after that.</td>
</tr>
<tr>
<td>Care plan</td>
<td>A care plan is similar to an agreed care plan, but it is usually developed without discussion or agreement from the consumer.</td>
</tr>
<tr>
<td>Chemical restraint</td>
<td>Chemical restraint occurs when medication is given primarily to control a person’s behaviour.</td>
</tr>
<tr>
<td>Complementary medicines</td>
<td>Complementary medicines are also known as ‘traditional’ or ‘alternative’ medicines and include vitamin, mineral, herbal, aromatherapy and homoeopathic products.</td>
</tr>
<tr>
<td>Continuity of care</td>
<td>Continuity of care is the delivery of a ‘seamless service’ through the communication, coordination and sharing of information between different healthcare providers and institutions.</td>
</tr>
<tr>
<td>Depot injection</td>
<td>A depot injection is a medication, given by intramuscular injection, which is absorbed and is slowly released into the body over a period of time.</td>
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<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>number of weeks.</td>
<td></td>
</tr>
<tr>
<td>Discharge summary</td>
<td>A discharge summary is a form of ‘handover’ from the hospital/institution to the community health provider, often the general practitioner (GP). It needs to be delivered in a timely manner, be accurate, concise and complete with all relevant information for the GP to continue care for the consumer.</td>
</tr>
<tr>
<td>Drug interaction</td>
<td>A drug interaction occurs when two drugs are taken together and a chemical or physiological reaction occurs that would not be seen with either drug alone. When the antidepressant paroxetine is combined with metoprolol (a medication used for high blood pressure), there is a high risk of a harmfully slow heart rate (bradycardia) that would not be seen otherwise.</td>
</tr>
<tr>
<td>Hypnotics</td>
<td>Hypnotics are usually prescribed when someone has difficulty sleeping. They include benzodiazepines and non-benzodiazepines such as zolpidem.</td>
</tr>
<tr>
<td>Medication action plan</td>
<td>A medication action plan is a form for nurses, pharmacists or doctors to record a list of the medicines taken by a consumer prior to presenting at the hospital, and is used to reconcile medicines on admission, intra-hospital transfer and at discharge.</td>
</tr>
<tr>
<td>Medication error</td>
<td>A medication error is a mishap that occurs during prescribing, transcribing, dispensing, administering, adhering to, or monitoring a drug and has the potential to lead to harm of the patient. Examples of medication errors include misreading or miswriting a prescription. For example, a transcription error may result in an order for risperidone 0.25mg being accidentally copied as risperidone 25mg. A pharmacy department may make a dispensing error that results in the wrong medication being supplied and administered. A nurse may overlook an order on the medication chart, meaning that an important dose of a medicine may be missed, which has potential to lead to harm for the patient.</td>
</tr>
<tr>
<td>Medication history</td>
<td>A medication history is an accurate and complete history of all medicines taken by a consumer. Taking an accurate medication history is part of the medication reconciliation process (see below).</td>
</tr>
<tr>
<td>Medication incident</td>
<td>A medication incident is any event where the expected course of events is not followed. It can involve the wrong patient, medicine, dose, time or route of administering a medicine or an out of date medicine, a lack of documentation or monitoring, refusal by a consumer to take a medicine or the incorrect storage or supply of a medicine.</td>
</tr>
<tr>
<td>Medication reconciliation</td>
<td>Medication reconciliation is the process of obtaining and verifying a complete and accurate list of a person’s medicines to gain a full understanding of their medicine regimen. It includes matching medicines the patient should be taking with medicines they are actually taking, discussing with the patient any discrepancies found and documenting reasons. Medication reconciliation is vital to the continuity of care at points of transition between wards, hospitals or home.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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</tr>
<tr>
<td><strong>Medication-related problem</strong></td>
<td>This term is used to describe one of eight categories of problems associated with medications. These can include issues with drug selection, dosage selection, the decision to treat, adverse effects, drug interactions, issues with adherence, problems with medication access and others.</td>
</tr>
<tr>
<td><strong>Mood stabiliser</strong></td>
<td>Mood stabilisers are medicines that treat acute depression and mania, and prevent depression and mania. Medicines such as lithium, carbamazepine and sodium valproate can be used as mood stabilisers.</td>
</tr>
<tr>
<td><strong>Off-label medication use</strong></td>
<td>Use of medicines for reasons other than their licenced indication is known as off-label use.</td>
</tr>
<tr>
<td><strong>Person-centred care</strong></td>
<td>Person-centred care exists when consumers are treated with dignity and respect, information is shared with them and participation and collaboration in healthcare processes are encouraged and supported to the extent that consumers choose.</td>
</tr>
<tr>
<td><strong>Prescribing errors</strong></td>
<td>These are errors occurring when medicines are prescribed. Prescribing errors are sometimes characterised as procedural errors or clinical errors. Procedural errors refers to errors such as a signature missing from the prescription or lack of documentation of the route of administration or unit of measurement. Clinical errors include errors due to the wrong drug or wrong dose being ordered.</td>
</tr>
<tr>
<td><strong>Pro re nata (prn)</strong></td>
<td>Pro re nata is a Latin phrase used to indicate when medicines are to be used ‘when required’. It may be abbreviated as <em>prn</em>.</td>
</tr>
<tr>
<td><strong>Psychotropic medicine</strong></td>
<td>This is an inclusive term encompassing the many different types of medicines used to treat mental illness, including antipsychotics, antidepressants, anti-anxiety agents, sedatives, mood stabilisers and hypnotics.</td>
</tr>
<tr>
<td><strong>Recovery</strong></td>
<td>Recovery in the mental health care context is described as ‘a deeply personal, unique process of changing one’s attitudes, values, feelings, goals, skills and/or roles. It is a way of living a satisfying, hopeful and contributing life. Recovery involves the development of new meaning and purpose in one’s life as one grows beyond the catastrophic effects of psychiatric disability’.</td>
</tr>
<tr>
<td><strong>Sedatives</strong></td>
<td>A sedative is a substance that induces calm by reducing irritability or excitement.</td>
</tr>
<tr>
<td><strong>Side effects</strong></td>
<td>A side effect is an expected and known effect of a drug that is not intended as the therapeutic effect. An example of a side effect is weight gain that is commonly seen in people taking an antipsychotic.</td>
</tr>
<tr>
<td><strong>Therapeutic drug monitoring</strong></td>
<td>Some of the medicines used to treat mental illness require the blood levels of the drug to be monitored to ensure that there is enough medicine in the body for it to be effective, and not so much that it will cause side effects. Medicines such as lithium require therapeutic drug monitoring.</td>
</tr>
<tr>
<td><strong>Undesirable</strong></td>
<td>In this report we use the term ‘undesirable events’ to describe all</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>-----------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>medication events</td>
<td>adverse drug events.</td>
</tr>
</tbody>
</table>
Appendix 2. Methodology

We conducted a literature review and consultations with medication safety and mental health experts to examine barriers and enablers to medication safety in mental health.

**Literature review**

We reviewed quantitative studies published between January 2000 and January 2015 to:

- Determine the incidence to medication-related harm in mental health in Australia
- Identify Australian interventions to reduce medication-related harm in mental health.

We also reviewed controlled trials and systematic reviews of interventions undertaken in other countries to reduce medication-related harm in mental health settings.

Papers about incidence of medication safety or harm occurring in Australian hospitals, including studies of prescribing errors after emergency department admissions, or rates of transcription errors on discharge, were included. Studies assessing the incidence of medication safety issues in the community were also included. We excluded data from conference abstracts and presentations that were not published. Selected qualitative studies were included to provide further detail as needed.

This report focuses on medication safety issues in mental health across hospital and community settings. Medication safety issues relating to psychotropic medicine use in residential aged-care facilities, prisons and the disability sector are briefly mentioned, but are not the focus of the report. Issues relating to recreational drug use, opioid substitution therapy, complementary medicines, medication cost and adherence were not the focus of this review.

**Search strategy**

Australian interventions to improve medication safety in mental health which met the following criteria were eligible for inclusion:

- English language
- Conducted in the community, hospital or ambulatory care settings
- Measured at least one patient outcome, e.g. medicine-related hospitals admissions
- Adverse events
- Mortality
- Decreased quality of life
- Symptoms
- Surrogate health endpoints
- Medication knowledge or changes in the quality of medicine use

Papers which meet these criteria, describing strategies to reduce rates of medication adverse events, such as clinical pharmacist services, computerised decision support measures, and multifaceted approaches, were eligible for inclusion. We included pre- and
post-intervention studies without control, randomised controlled trial or non-randomised controlled trial designs.

Descriptions of evidence-based international interventions aimed at reducing rates of medication error were obtained from systematic reviews of controlled trials in the international literature, and overseas-conducted controlled trials published in English.

Evidence was sought from the following databases: Medline, Embase, Cinahl, Informit, PsychInfo, International Pharmaceutical Abstracts and Joanna Briggs Institute Database.

To identify publications about incidence, the following terms were used (phrase followed by / denotes subject heading, * denotes a truncation in a keyword search): Medication Errors/, Medication Reconciliation/, Medical Errors/, Inappropriate Prescribing/, Diagnostic Errors/, Safety Management/, Quality of Health Care/, Drug-Related Side Effects and Adverse Reactions/, Quality Assurance, Health Care/, Adverse Drug Reaction Reporting Systems/, Patient Safety/, Patient Transfer/, medica* error*; medica* reconcile*; appropriate medica*; appropriate prescri*; inappropriate medica*; inappropriate prescri*; duplication; diagnosis* error*; safe* manag*; quality of health care; drug toxic*; patient* safety; medication* safety; adverse drug event*; adverse drug react*; medication mishap*; medica* incident*; medica* mishap*; medica* mistake*; medica* misadventure*; drug misadventure*; drug* toxicity; medication related harm*; medication related incident*; medication related problem*; medication reporting system*; pharmaceutical reporting system*; medica* prescri* error*; drug* prescri* error*; prescri* error*; medica* dispensing error*; drug* dispensing error*; dispensing error*; medication* administra* error*; drug* administra* error*; administra* error*; medication* related admission*; drug related admission* or patient transfer*; key words above and Incidence/; Prevalence/; Drug Substitution/; incidence; prevalence; Rate*; drug substitution; therapeutic shift*; brand substitution*; generic substitution*.

To identify other publications about quality use of medicines and medication safety, the following terms were used: Medication Adherence/; Medication Reconciliation/; Medical History Taking/; Self Medication/; Self Administration/; Medication Therapy Management/; Drug Utilization/; Physician's Practice Patterns/; Off-Label Use/; Drug Interactions/; Herb-Drug Interactions/; Drug Monitoring/; Drug Utilization Review/; Self Administration/; Self Medication/; Health Knowledge, Attitudes, Practice/; Patient Education as Topic/; Inappropriate Prescribing/; Patient Compliance/; Drug Therapy, Combination/; Polypharmacy/; medicine* management; medication* management; drug therapy management; medic* complian*; drug complian*; drug* administ*; medicine* administ*; medication administ*; medic* reconcil*; drug reconcil*; medication* histor*; medicine* histor*; drug* history*; self administ*; drug* utilif*; drug* interact*; drug* monitor*; medicine* monitor*; medication* monitor*; prescri* pattern*; drug* knowledge; medicine* knowledge; medication* knowledge; drug* pattern*; medicine* pattern*; medication* pattern*; drug* regimen*; medicine* regimen*; medication* regimen*; inappropriate prescri*; drug* prescri*; medicine* prescri*; medication* prescri*; drug* relat* problem*; medicine* relat* problem*; medication* relat* problem*; drug* select*; medicine* select*; medication* select*; drug* overuse*; medicine* overuse*; medication* overuse*; drug* underuse*; medicine* underuse*; medication* underuse*; quality use of medicine*; drug* overdose*; medicine* overdose*; medication* overdose*; drug* educat*; medicine* educat*; medication* educat*; drug* information*; medicine* information*; medication* information*; underdos*; undertreat*; overtreat*; wrong drug*; wrong medicine*; wrong medication*; medicine* utili##*; medication*
To identify publications for specific intervention strategies, the following terms were also used: Clinical Pharmacy Information Systems/; Medication Errors/; Medication Systems/; Medical Order Entry Systems/; Medical Records Systems, Computerized/; Decision Support Systems, Clinical/; Electronic Prescribing/; Safety Management/; Drug Packaging/[Adverse Effects, Supply & Distribution]; Pharmacy Service, Hospital/; Community Pharmacy Services/; Pharmaceutical Services/; Medication Therapy Management/; Medication Reconciliation/; Quality Improvement/; Continuity of Patient Care/; Referral and Consultation/; Patient Transfer/; pharmac* informati* system*; medicat* error*; medicat* system*; medical order entry system*; computer#ed medica* record* system*; clinical decision support system*; e-prescri*; electronic prescri*; computer* decision support*; safety management; error reduc*; bar cod*; robot* distribution; automat* distribution; individual patient supply; self* administrat*; pharmac* service*; medication therapy management; medicat* review*; SMS*; smart* device*; medication reconciliation; automat* dispens*; continuous quality improvement; continuity of care; liaison; hospital* transfer*; hospital to home; or hospital to aged care.

The literature was restricted to mental health studies using the terms: Psychotropic Drugs/; Antipsychotic Agents/; Antidepressive Agents/; Anti-Anxiety Agents/; Hypnotics and Sedatives/; Antimanic Agents/; Mental Health/; Psychiatry/; Psychotic Disorders/; Schizophrenia/; Bipolar Disorder/; Depression/; Anxiety/; Anxiety Disorders/; Mood Disorders/; Mental Disorders/; mental* dis*; psychotic*; psycholeptic*; antipsychotic*; antidepress*; anxiolytic*; hypnotic*; mood stabilizer*; mental* health*; psychiatry*; psychosis; psychotic; psychiatrist* dis*; schizophren*; bipolar* dis*; depressi*; anxiety*; mood dis*.

Studies conducted in the Australian healthcare setting were identified using the terms: Australia/ or Australian Capital Territory/ or New South Wales/ or Northern Territory/ or Queensland/ or South Australia/ or Tasmania/ or Victoria/ or Western Australia/ or Australia or Victoria or Tasmania or New South Wales or Queensland or Australian Capital Territory or Northern Territory or Western Australia or Australia*.

The database search was supplemented with searches of relevant websites, including:

The Australian Commission on Safety and Quality in Health Care (www.safetyandquality.gov.au)
NPS MedicineWise (http://www.nps.org.au/)

**Interviews with key stakeholders**

Qualitative research methods were used to explore medication safety issues in mental health, identify barriers and enablers to medication safety in mental health in Australia, and identify potential solutions to these problems. This research was approved by the University of South Australia Human Research Ethics Committee (protocol number 0000033966).

Twelve semi-structured interviews with mental health and medication safety experts, mental health consumers and carers (n=39 participants) were conducted between March 2015 and
May 2015. Each interview was conducted by two members of the project team. A roundtable discussion was facilitated by the research team in May 2015, to further explore barriers and enablers to medication safety in mental health, and identify potential solutions. Nineteen people participated in the roundtable discussion. Viewpoints from nursing, pharmacy, psychiatry and other disciplines, policy makers, and consumers and carers, were sought during the consultation process and perspectives were provided from all Australian states and territories.

Individual interviews and focus groups were recorded using a digital recorder, and notes were taken to allow for a more thorough understanding of the digital data. Recordings were transcribed verbatim for analysis, with any identifying information removed to preserve participant and organisation anonymity. Following Braun and Clarke’s procedure, thematic analysis was used to illuminate content within the transcripts. The process first involved data familiarisation, whereby members of the research team read the transcripts carefully and repeatedly, and then organised the contents of the data into categories and sub-categories informed by the interview schedule. The second level of analysis involved categories being inductively generated from the transcribed data within the composite responses to individual and focus group questions. These sub-categories were reviewed and sorted by the research team through a process informed by the key themes arising from the literature review. Categories and themes were then presented in the form of statements and questions for open discussion with stakeholders at the May roundtable. Data arising from the roundtable was then discussed by the team until a consensus was reached regarding recommendations for the way forward.
Appendix 3. Data tables

Hospitalisation as a result of intentional over-dose

Table 1: Mechanism of intentional self-harm injury cases, Australia, 2010–2011

<table>
<thead>
<tr>
<th>Drugs, medicaments and biological agents</th>
<th>20,499</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychotropic drugs</td>
<td></td>
</tr>
<tr>
<td>Antidepressants</td>
<td>8,872</td>
</tr>
<tr>
<td>(43.3%)</td>
<td></td>
</tr>
<tr>
<td>Anti-epileptics, sedative-hypnotics, antiparkinsonism</td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>5,216</td>
</tr>
<tr>
<td>(25.4%)</td>
<td></td>
</tr>
<tr>
<td>Non-opioid analgesics, antipyretics, anti-rheumatics</td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>8,523</td>
</tr>
<tr>
<td>(41.6%)</td>
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</tr>
<tr>
<td>Narcotics and psychodysleptics (hallucinogens)</td>
<td></td>
</tr>
<tr>
<td>Other opioids</td>
<td>7,158</td>
</tr>
<tr>
<td>(34.9%)</td>
<td></td>
</tr>
<tr>
<td>Primarily systemic and haematological agents</td>
<td>7,042</td>
</tr>
<tr>
<td>(34.4%)</td>
<td></td>
</tr>
<tr>
<td>Drugs primarily affecting the cardiovascular system</td>
<td>5,915</td>
</tr>
<tr>
<td>(28.9%)</td>
<td></td>
</tr>
<tr>
<td>Drugs primarily affecting the autonomic nervous system</td>
<td>3,764</td>
</tr>
<tr>
<td>(18.4%)</td>
<td></td>
</tr>
<tr>
<td>Other and unspecified drugs, medicaments and biological substances</td>
<td>2,849</td>
</tr>
<tr>
<td>(13.9%)</td>
<td></td>
</tr>
<tr>
<td>Drugs primarily affecting the gastrointestinal system</td>
<td>1,243</td>
</tr>
<tr>
<td>(6.1%)</td>
<td></td>
</tr>
<tr>
<td>Hormones and their synthetic substitutes and antagonists</td>
<td>783</td>
</tr>
<tr>
<td>(3.8%)</td>
<td></td>
</tr>
<tr>
<td>Systemic antibiotics</td>
<td>671</td>
</tr>
<tr>
<td>(3.3%)</td>
<td></td>
</tr>
<tr>
<td>Other and unspecified drugs, medicaments and biological substances</td>
<td>612</td>
</tr>
<tr>
<td>(3%)</td>
<td></td>
</tr>
<tr>
<td>Systemic antibiotics</td>
<td>344</td>
</tr>
<tr>
<td>(1.7%)</td>
<td></td>
</tr>
<tr>
<td>Other and unspecified drugs, medicaments and biological substances</td>
<td>292</td>
</tr>
<tr>
<td>(1.4%)</td>
<td></td>
</tr>
<tr>
<td>Other and unspecified drugs, medicaments and biological substances</td>
<td>1,034</td>
</tr>
<tr>
<td>(1.5%)</td>
<td></td>
</tr>
</tbody>
</table>
Administration of ‘when required’ psychotropic medicines in mental health units

Table 2: Documentation of reason for administration and effect of psychotropic medicines administered “as required” in adult mental health inpatient units

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Study period</th>
<th>No. given a prn dose (%)</th>
<th>No. of prn doses given</th>
<th>prn doses with appropriate documentation in case notes (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geffen &lt;sup&gt;11&lt;/sup&gt;</td>
<td>Inpatient mental health units from two Brisbane hospitals</td>
<td>Dec 1998–Feb 1999</td>
<td>302 (82%)</td>
<td>1,786</td>
<td>1,054 (59%)</td>
</tr>
<tr>
<td>Curtis &lt;sup&gt;7&lt;/sup&gt;</td>
<td>Secure nine-bed inpatient mental health unit, NSW</td>
<td>Oct 2001</td>
<td>43 (80%)</td>
<td>450</td>
<td>409 (91%)</td>
</tr>
<tr>
<td>Dean 2008.</td>
<td>12-bed child and adolescent inpatient mental health unit, Brisbane</td>
<td>Apr 2002–Sept 2003</td>
<td>62 (51%)</td>
<td>42 patients</td>
<td>(68%)</td>
</tr>
<tr>
<td>Curtis &lt;sup&gt;9&lt;/sup&gt;</td>
<td>20-bed inpatient mental health unit, regional hospital in NSW</td>
<td>Feb 2005</td>
<td>47 (73%)</td>
<td>268</td>
<td>154 (57%)</td>
</tr>
<tr>
<td>O’Brien &lt;sup&gt;12&lt;/sup&gt;</td>
<td>Eight-bed close observation area within an inpatient mental health unit</td>
<td>One month period; year not recorded</td>
<td>15</td>
<td>119</td>
<td>96 (81%)</td>
</tr>
<tr>
<td>Usher &lt;sup&gt;7&lt;/sup&gt;</td>
<td>Inpatient mental health units from a regional and metropolitan hospital in QLD</td>
<td>One month period; year not recorded</td>
<td>57 (63%)</td>
<td>268</td>
<td>170 (63%)</td>
</tr>
<tr>
<td>Stein-Padbury &lt;sup&gt;10&lt;/sup&gt;</td>
<td>Four inpatient mental health units, Sydney</td>
<td>Two month period; year not recorded</td>
<td>408 (97%)</td>
<td>3868</td>
<td>2,445 (63%)</td>
</tr>
</tbody>
</table>
## Antipsychotic use

### Table 3: Prevalence of multiple antipsychotic use by study setting or user group

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Study period</th>
<th>Number (%) of people taking an antipsychotic that received two or more antipsychotics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital inpatients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Botvinik&lt;sup&gt;36&lt;/sup&gt;</td>
<td>Retrospective audit of consecutive adults admitted to a private psychiatric hospital in Melbourne (n=100)</td>
<td>July 2002</td>
<td>11/59 (19%)</td>
</tr>
<tr>
<td><strong>Hospital discharge</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plever&lt;sup&gt;7&lt;/sup&gt;</td>
<td>Audit of discharge dispensing records for patients discharged with a Diagnosis Related Group for schizophrenia from 15 mental health inpatient services across Queensland after implementation of a state-wide Mental Health Clinical Collaborative</td>
<td>Time 1: Oct 05– Aug 07</td>
<td>Time 1: 8.7% Time 2: 10.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time 2: Sept 06 – May 07</td>
<td></td>
</tr>
<tr>
<td>John&lt;sup&gt;100&lt;/sup&gt;</td>
<td>Retrospective audit of patients discharged from a WA metropolitan mental health service and prescribed an antipsychotic for schizophrenia or schizoaffective disorder (n=229)</td>
<td>2010</td>
<td>99 (43%). Prescription of ‘when required’ antipsychotics was not assessed</td>
</tr>
<tr>
<td><strong>Forensic unit</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bains&lt;sup&gt;14&lt;/sup&gt;</td>
<td>Audit of patients in three forensic hospitals in NSW (n=105)</td>
<td>unknown</td>
<td>23 (22%) received oral atypical + depot conventional. 10 (9.5%) received oral + depot conventional</td>
</tr>
<tr>
<td>Martin&lt;sup&gt;101&lt;/sup&gt;</td>
<td>Audit of patients admitted to prison hospital in NSW taking an antipsychotic (non-consecutive patients) (n=73)</td>
<td>1999 – 2004</td>
<td>20 (27%)</td>
</tr>
<tr>
<td><strong>Geriatric psychiatry units</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tiller&lt;sup&gt;104&lt;/sup&gt;</td>
<td>Current inpatients taking antipsychotics who were treated by a convenience sample of psychiatrists servicing 18 Australian geriatric psychiatry units (n=321)</td>
<td>2004 – 2005</td>
<td>36 (11%)</td>
</tr>
<tr>
<td>Restifo&lt;sup&gt;103&lt;/sup&gt;</td>
<td>Retrospective audit of discharge medication for patients with behavioural and psychological symptoms of dementia discharged from three inpatients units in Perth (n=89)</td>
<td>July 2008 – June 2009</td>
<td>4/52 (8%)</td>
</tr>
<tr>
<td>Clients with an intellectual disability</td>
<td>McGillivray(^{127})</td>
<td>People with an intellectual disability who were subjects of report to the Intellectual Disability Review Panel concerning use of chemical restraint (n=873)</td>
<td>March 2000</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Doan(^{186})</td>
<td>Cross-sectional, self-reported data taken from a Randomised Control Trial (the Advocacy and Health Study) among community-dwelling adults with intellectual disability, Brisbane (medicines use reported for 117/138 RCT participants)</td>
<td>2000 – 2002</td>
<td>3/24 (12%)</td>
</tr>
<tr>
<td>Community-based studies</td>
<td>Callaly(^{187})</td>
<td>Audit of 792 patients managed by a regional community mental health service, Victoria. (n=572 taking an antipsychotic)</td>
<td>April 1999</td>
</tr>
<tr>
<td></td>
<td>Bains(^{14})</td>
<td>Audit of 40 'treatment-resistant' patients from three supervised group homes in the community. Treatment resistance not defined</td>
<td>unknown</td>
</tr>
<tr>
<td></td>
<td>Lowe(^{17})</td>
<td>Audit of 38 patients receiving intensive case management from a community mental health centre in Melbourne. Patients received ≥52 contacts with the service yearly</td>
<td>Jan 1998 – March 2003</td>
</tr>
<tr>
<td></td>
<td>Gisev(^{16})</td>
<td>Psychiatric drug use among patients of a community mental health service receiving an HMR (n=56). Antipsychotic polypharmacy defined as receiving ≥2 antipsychotics concurrently</td>
<td>Jul 2005 – Mar 2006</td>
</tr>
<tr>
<td></td>
<td>Gisev(^{15})</td>
<td>Patients on community treatment orders</td>
<td>April 2010</td>
</tr>
<tr>
<td>Source</td>
<td>Description</td>
<td>Year</td>
<td>Findings</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
<td>------</td>
<td>----------</td>
</tr>
<tr>
<td>Waterreus*</td>
<td><em>Survey of High Impact Psychosis: Australia’s second national psychosis survey; people aged 18 – 64 years. In Phase II, 1 825 people identified with psychosis in Phase I were randomly selected and interviewed</em></td>
<td>2010</td>
<td>20% of patients reported taking two antipsychotics concurrently, 2% took three or more. 15% of patients took two or more atypical antipsychotics concurrently. 1% took two conventional antipsychotics concurrently. Among clozapine users, 25% were taking another atypical antipsychotic, with 5% taking clozapine + atypical + conventional.</td>
</tr>
<tr>
<td>Pai†‡</td>
<td>Cross-sectional audit of patients taking clozapine (n=84) who were treated by one of 12 clinicians in a regional area of NSW</td>
<td>May 2011</td>
<td>46 (55%) took one other antipsychotic. 5 (6%) took two other antipsychotics.</td>
</tr>
<tr>
<td>Vecchio†</td>
<td>Retrospective audit of patients with psychotic illness treated for one year by the Assertive Community Team (ACT) in metropolitan Western Australia (n=38)</td>
<td>2012 – 2013</td>
<td>16 (42%)</td>
</tr>
</tbody>
</table>

**Children and adolescents**

<table>
<thead>
<tr>
<th>Source</th>
<th>Description</th>
<th>Year</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dean†‡</td>
<td>Retrospective audit of charts for 122 inpatients from a child and adolescent mental health service in Brisbane</td>
<td>Apr 2002 – Sep 2003</td>
<td>2/38 (5%) received atypical + conventional.</td>
</tr>
</tbody>
</table>
## Cardio-metabolic monitoring

Table 4: Percentage of patients receiving antipsychotics who were monitored for cardio-metabolic risk factors

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients and setting</th>
<th>Study period</th>
<th>No. of patients</th>
<th>Received recommended monitoring (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Weight</td>
</tr>
<tr>
<td></td>
<td>Nguyen**</td>
<td>Oct 2005</td>
<td>93</td>
<td>65 (65%)</td>
</tr>
<tr>
<td></td>
<td>Patients with schizophrenia discharged from three public psychiatric hospitals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sazhin***</td>
<td>July 2003 &amp; Jan 2006</td>
<td>44</td>
<td>17 (39%)</td>
</tr>
<tr>
<td></td>
<td>Males with major mental illness treated involuntarily in a forensic hospital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wilson***</td>
<td>Dec 2011</td>
<td>107</td>
<td>49%</td>
</tr>
<tr>
<td></td>
<td>Randomly selected patients prescribed clozapine mental health, centre</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ellis***</td>
<td>3/12 – 6/12</td>
<td>54</td>
<td>10 (19%) had a monitoring chart</td>
</tr>
<tr>
<td></td>
<td>Children admitted to hospital and prescribed antipsychotics for &gt;1 month</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 5: Percentage of adults with psychosis with cardio-metabolic risk factors

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Tobacco use</th>
<th>Sedentary lifestyle</th>
<th>Increased blood pressure</th>
<th>Overweight/obese</th>
<th>Abdominal obesity</th>
<th>Increased blood sugar level</th>
<th>Increased lipids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gladigau</td>
<td>60</td>
<td>67</td>
<td>Not reported</td>
<td>40</td>
<td>50 = obese</td>
<td>84</td>
<td>36</td>
<td>67</td>
</tr>
<tr>
<td>Foley</td>
<td>1</td>
<td>642</td>
<td>Not reported</td>
<td>42</td>
<td>77</td>
<td>82</td>
<td>29</td>
<td>22</td>
</tr>
<tr>
<td>Galletly</td>
<td>1</td>
<td>825</td>
<td>81</td>
<td>48</td>
<td>76</td>
<td>82</td>
<td>29</td>
<td>33</td>
</tr>
<tr>
<td>Tirupati</td>
<td>221</td>
<td>Not reported</td>
<td>Not reported</td>
<td>83</td>
<td>88</td>
<td>71</td>
<td>64</td>
<td>81</td>
</tr>
<tr>
<td>Herriot</td>
<td>261</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
<td>Rosenbaum</td>
<td>85</td>
<td>49</td>
<td>Not reported</td>
<td>25</td>
<td>43</td>
<td>43</td>
<td>10</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

### Table 6: Percentage of adults with psychosis with cardio-metabolic syndrome

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients and settings</th>
<th>Study period</th>
<th>No. of patients</th>
<th>% with metabolic syndrome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tirupati</td>
<td>An audit of clinical and laboratory assessments of patients with a psychotic disorder attending a rehabilitation centre within the NSW Hunter New England area</td>
<td>Unknown</td>
<td>221</td>
<td>68</td>
</tr>
<tr>
<td>Galletty</td>
<td>Randomly selected adults with psychosis in the second Australian survey of psychosis</td>
<td>1,825</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>Wilson</td>
<td>Randomly selected patients prescribed clozapine at Metro North Mental Health, Brisbane</td>
<td>Dec 2011</td>
<td>155</td>
<td>68</td>
</tr>
<tr>
<td>Rosenbaum</td>
<td>Audit of young patients presenting to a first-episode psychosis service in Sydney; average age 21</td>
<td>2011</td>
<td>85</td>
<td>11</td>
</tr>
<tr>
<td>Gladigau</td>
<td>A cross-sectional audit of medical files on patients receiving community care in Melbourne</td>
<td>May 2012</td>
<td>60</td>
<td>66</td>
</tr>
</tbody>
</table>
### Agreed care plans

Table 7: Percentage of mental health consumers receiving care plans

<table>
<thead>
<tr>
<th>Study</th>
<th>Study period</th>
<th>Surveys completed</th>
<th>% of patients who did not have enough say in decisions about care and treatment</th>
<th>% of patients who had not had the diagnosis discussed with them</th>
<th>% of patients who received a care plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Western Australian Auditor General's Report[^29]</td>
<td>2007–2008</td>
<td>73 consumer case files reviewed</td>
<td>Not reported</td>
<td>Not reported</td>
<td>78% had a care plan. 23% had consumer involvement 5% of consumers received a copy of their care plan</td>
</tr>
<tr>
<td>Australasian Clinical Indicator Report[^4]</td>
<td>2013</td>
<td>8,025 consumers</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Consumers were involved in 20% of plans Carers were involved in 6% of plans</td>
</tr>
</tbody>
</table>
### Provision of information to consumers and carers

Table 8: Percentage of mental health consumers receiving insufficient information about medications

<table>
<thead>
<tr>
<th>Study</th>
<th>Study period</th>
<th>Surveys completed by consumers, carers and family members or close friends</th>
<th>Insufficient information given to patient (about condition or treatment)</th>
<th>Purpose, benefits and side effects of medicines NOT fully explained</th>
<th>Inadequate information given to family and friends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parslow, Lewis &amp; Marsh$^{190}$</td>
<td>1997</td>
<td>10 641</td>
<td>19%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mendoza$^{191}$</td>
<td>2013</td>
<td>561, of which 87% received treatment</td>
<td>30% (70% felt they were given the ‘right’ amount or at least ‘some’ information)</td>
<td>45%</td>
<td>54%</td>
</tr>
<tr>
<td>Mental Health Council of Australia Report$^{30}$</td>
<td>2004</td>
<td>215</td>
<td>41%</td>
<td>76%</td>
<td>60%</td>
</tr>
<tr>
<td>Parslow, Lewis &amp; Marsh$^{190}$</td>
<td>2007</td>
<td>8,841</td>
<td>24%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National Survey of Mental Health and Wellbeing study$^{74}$</td>
<td>2007</td>
<td>Approximately 630,000</td>
<td>29%</td>
<td>10% for specifically medicines information</td>
<td></td>
</tr>
</tbody>
</table>
Reference list


19. Vecchio D, Spence C. A review of antipsychotic polypharmacy, high-dose prescribing and evaluation of adherence to local physical health monitoring guidelines, within the assertive


83. Hauck K, Zhao X. How dangerous is a day in hospital?: A model of adverse events and length of stay for medical inpatients. Medical Care 2011;49(12):1068-75.


106. Chan WS. Antipsychotic prescribing in young people at the Women's and Children's Hospital, Children, Youth and Women's Health Service. Adelaide: University of South Australia; 2006.

91. Parslow RA, Jorm AF. Use of prescription medications and complementary and alternative medicines to treat depressive and anxiety symptoms: Results from a community sample. J Affect Disord 2004 Oct 1;82(1):77-84.


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