Pharmaceutical Society of Australia

Standard and guidelines for pharmacists performing clinical interventions

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Contents

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Disclaimer

These guidelines are designed to provide advice or guidance to pharmacists on a range of issues, including appropriate and effective processes, desired behaviour or minimum standards of good practice, how duties and professional responsibilities may be best fulfilled, and expected outcomes.

The guidelines are not definitive statements of correct procedure but will usually represent agreement by experts in the field. The guidelines do not set a prescribed course of action or a mandatory standard that pharmacists must adhere to.

At all times, pharmacists are expected to exercise professional judgement in adapting the guidance provided to specific presenting circumstances.

The guidelines can also be used as an educational tool, can contribute to quality assurance processes and may assist in the resolution of legal disputes or ethical dilemmas.

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Guidelines for pharmacists performing clinical interventions

1. About the document

1.1 Background

Pharmacists routinely perform clinical interventions in order to improve the health outcomes of consumers. This document is intended to assist in formalising the process of performing clinical interventions, and to provide best-practice guidelines for the documentation thereof. The aims of clinical interventions are to:

- encourage pharmacists to work in partnership with consumers and other healthcare providers to reduce the occurrence of drug-related problems (DRPs);
- encourage communication between pharmacists, consumers, prescribers and other healthcare providers;
- increase the number of beneficial clinical interventions performed by pharmacists; and
- develop a quality system for the documentation of clinical interventions performed by pharmacists.[1]

It is intended that clinical interventions will complement other professional services such as in-pharmacy MedsCheck services (also known as Medicines Use Reviews), Home Medicines Reviews and the provision of Dose Administration Aids.

These guidelines draw on the research and findings from the series of Pharmacy Recording of Medication Incidents and Services electronically (PROMISe) projects[2] (see Appendix 1), conducted with funding provided under the Fourth Community Pharmacy Agreement. The guidelines include information on how to identify and classify DRPs and clinical interventions, and provide a best-practice procedure for their documentation.

A *DRP* is defined in the literature as '*an event or circumstance involving drug treatment that actually or potentially interferes with the patient experiencing an optimum outcome of medical care*'. Terms used to describe a DRP or subtype include 'medication-related problem', 'medication error', 'adverse drug event', 'adherence issues' and 'adverse drug reaction'.[3–6]

A *clinical intervention* may be defined as '*any professional activity by the pharmacist directed towards improving the quality use of medicines and resulting in a recommendation for a change in the patient's medication therapy, means of administration or medication-taking behaviour.*'[7] A clinical intervention is the process of a pharmacist identifying, and making a *recommendation* in an attempt to prevent or resolve, a DRP. It is acknowledged that pharmacists' recommendations to consumers or prescribers may not necessarily be implemented. The provision of the recommendations would still be considered a clinical intervention.

DRPs are a major burden on the Australian healthcare system, and many result in hospital admissions or visits to general practitioners (GPs) each year. A literature review revealed that in Australia, 2%–4% of all hospital admissions are drug-related, and up to three-quarters of those admissions are potentially preventable.[6] Furthermore, the National Prescribing Service (NPS) reviewed the literature and reported that adverse drug events were responsible for up to 30% of hospital admissions in the older age group (>75 years).[8] Another study reported that 10% of patients visiting their GPs had experienced a DRP within the past 6 months.[9] These studies have highlighted the need for improved detection and prevention of DRPs within the community, before a GP visit or hospital attendance or admission is necessary.

While pharmacists routinely undertake clinical interventions as part of their professional duty of care, they may not consistently document those interventions, or document them at all. In addition, some pharmacists may not always recognise that their decisions and actions constitute clinical interventions.

These guidelines are intended to provide a standardised best-practice process for pharmacists to classify and document DRPs and their clinical interventions. A summary of the clinical intervention process is on page 30.

Documenting and classifying DRPs and clinical interventions are important for several reasons, including:

- facilitating enhanced health outcomes for consumers;
- improving communication between pharmacists and other health professionals involved in the consumer's care;
- maintaining evidence to support a professional practice portfolio;
- developing tools which encourage pharmacists to perform and record more clinical interventions;
- providing a basis for quality audits and peer review;
- permitting analysis of the data for pharmacovigilance, economic review or other purposes; and
- adequately recording details for potentially litigious situations.

Researchers involved in the PROMISe projects[2] have developed and refined a classification system, termed the DOCUMENT DRP classification system, over the past 10 years.

1.2 Purpose of these guidelines

The aim of this document is to provide information and advice to pharmacists on professional issues related to performing

clinical interventions, and to assist pharmacists in meeting professional obligations associated with clinical interventions.

The intention is not to inform pharmacists about which DRPs should be identified or which clinical interventions should be made. Rather, the intention is to explain how to assess the DRP and then systematically document the intervention in a standard, consistent and auditable way.

It is important to review the Professional Practice Standard: *Clinical Interventions* in conjunction with these guidelines. A copy can be found in Appendix 2. Pharmacists are reminded that this standard must be applied in the context of other relevant Professional Practice Standards, which may include each of *Fundamental Pharmacy Practice*,[10] *Counselling*,[11] *Medication Review*,[12] *Dispensing*[13] and *Continuity of Care through Medication Liaison Services.*[14] For more information, refer to Appendix 3.

Pharmacists should be familiar with the 2011 Australian Standard (Quality Care Pharmacy Standard)[15] specifically 4.1, 4.2, 4.3 (equivalent to Quality Care Pharmacy Program Elements 1, 2 and 3). These guidelines provide pharmacies with a procedure with which to appropriately adhere to 4.2 i) *maintaining and following a system with appropriate documentation for the identification and recording and reporting of clinical interventions and adverse drug reactions*, which is equivalent to mandatory requirement 2.9 for accreditation under the Quality Care Pharmacy Program.[15]

In general terms, *guidelines* are not definitive statements of correct procedure, but are designed to provide advice or guidance to pharmacists on professional practice issues, desired behaviour for good practice, and how responsibilities may be best fulfilled.

Standards are objective statements of the minimum requirements necessary to ensure that a service or professional activity is delivered at a level of acceptable or intended performance. The standards relate to the systems in place for the delivery of a service or professional activity and provide a benchmark against which performance can be assessed.

1.3 Scope of these guidelines

It should be noted that the guidelines concentrate on the appropriate best-practice process for performing clinical interventions and are not intended to provide clinical information about identifying DRPs or performing clinical interventions.

The guidelines include a recommended procedure for identifying, classifying and documenting DRPs and clinical interventions on a day-to-day basis, to ensure that all important information is recorded in an effective and systematic manner.

Details of legislative requirements are not addressed in these guidelines. It is expected that pharmacists will comply with relevant Commonwealth and state or territory legislation governing therapeutic goods, drugs and poisons, pharmacists (health practitioners), pharmacies (premises), privacy and confidentiality and record keeping, in the provision of clinical interventions.

Furthermore, these guidelines do not address the issue of assessment of the outcomes of clinical interventions, and their consequent economic value.

It is expected that pharmacists will apply professional judgement in performing clinical interventions and in managing any associated risks. They will need to make risk–benefit assessments and other professional judgements from time to time based on the best available information. Any significant decisions should be documented wherever possible. Pharmacists are reminded that they have a professional and legal responsibility to ensure that any medicine they provide is appropriate and safe for consumers to use.

2. Introduction

2.1 Scope of clinical interventions

All consumers are potentially eligible for clinical interventions. Potential benefits of clinical interventions to consumers include:

- improved symptom control and therapeutic response;
- decreased incidence of adverse events related to medicines;
- decreased emergency visits and hospitalisations due to DRPs;
- improved adherence to and concordance with the prescribed medicine regimen;
- enhanced knowledge of medicines and disease states; and
- potential cost savings through rationalisation of medication therapy and avoidance of DRPs.

Identifying DRPs and performing clinical interventions must be considered part of the Medicines Management Pathway (see Figure 1),[16] including key components such as dispensing, medication review and counselling. Documenting clinical interventions is essential, and these guidelines provide comprehensive recommendations on how to classify DRPs and record interventions in a systematic manner.

Pharmacists have a fundamental role in and responsibility for optimising health outcomes and minimising medication misadventure. Clinical interventions may also provide a pathway into other professional services provided by pharmacists, such as the Dose Administration Aids Service,[17] the provision of Consumer Medicine Information (CMI),[18] Home Medicines Reviews,[19] Residential Medication Management Reviews,[20] MedsCheck (also known as Medicines Use Review) and the provision of medicines lists (see Figure 2).[21]

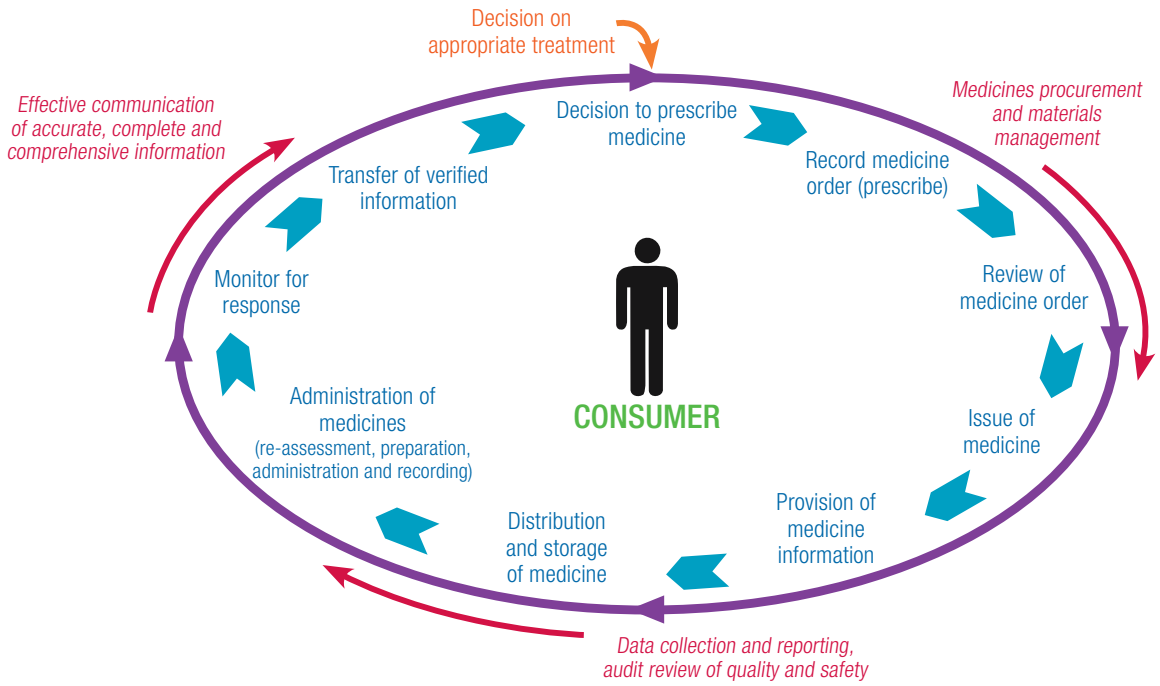
Collectively, these services and activities uphold the Quality Use of Medicines principles:

- selecting management options wisely;
- choosing suitable medicines if a medicine is considered necessary; and
- using medicines safely and effectively.

2.2 Relevance to funded programs

These guidelines have been developed to assist pharmacists performing clinical interventions under any service

Figure 1. The medicines management pathway



Modified from Stowasser, Allinson and O'Leary 2004[16]

arrangement. Where clinical interventions are performed under an externally funded program, pharmacists are responsible for meeting any specific operational requirements of the relevant program (sometimes referred to as 'business rules'). Pharmacists intending to perform clinical interventions under funding provided by third parties, such as private health insurers, must ensure that the program requirements implemented by the third party do not contravene any of the requirements of the Professional Practice Standards (e.g. disclosure of consumers' details to third parties without their informed consent).

These guidelines are not intended to provide instruction on funded clinical interventions under the Fifth Community Pharmacy Agreement (details of which are available at www.5cpa.com.au).

3. Performing clinical interventions in the pharmacy

Performing clinical interventions places a focus on the consumer's overall care rather than on the dispensing of medicines. It is about gathering information, assessing that information, planning what action to take, carrying out that action and recording it appropriately.

3.1 Issues to consider

To perform clinical interventions in a safe, effective and efficient manner, pharmacists need to consider the following issues:

- Ensure that all pharmacists have access to training and support for quality provision of clinical interventions.
- Provide information about clinical interventions to all staff.
- Estimate the impact of clinical interventions on staff resources, workload and workflow.
- Allocate adequate time and resources to enable the delivery of clinical interventions in addition to the existing functions and services of the pharmacy.
- Ensure appropriate record-keeping systems are utilised.
- Designate a consultation area with appropriate privacy considerations.
- Educate consumers that this is a professional activity provided by the pharmacy.

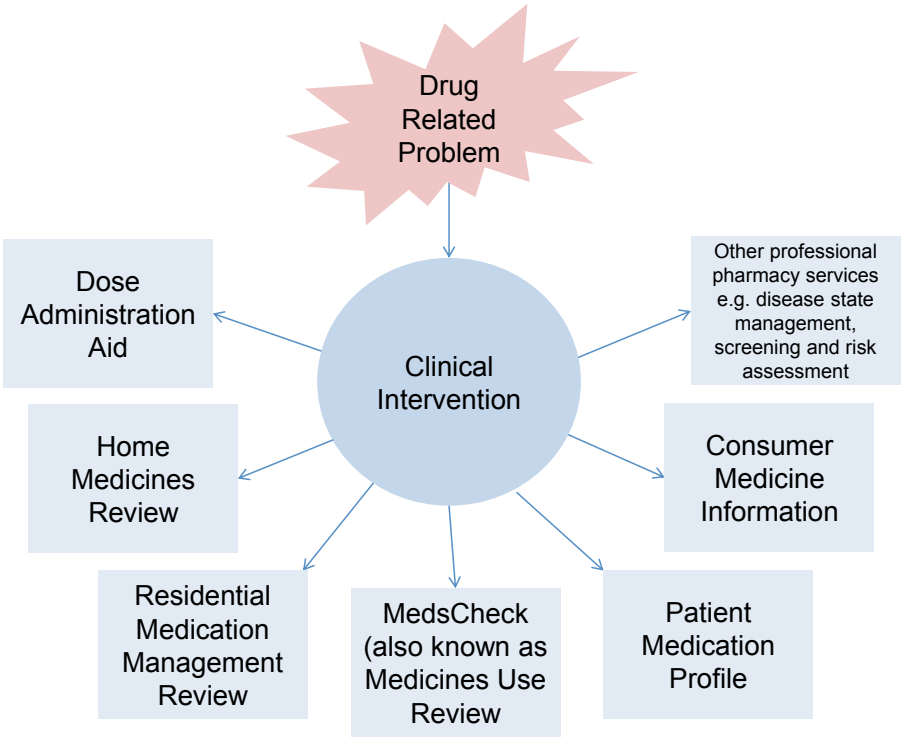
3.2 Privacy and confidentiality

Pharmacists must respect and safeguard the consumer's privacy and confidentiality at all times, particularly in relation to information acquired in the course of providing professional services.

Any consultation with the consumer must take place in an environment that safeguards their privacy and confidentiality. The pharmacist should endeavour to provide consultation without distractions or interruptions. Consultation areas must meet applicable occupational health and safety requirements.

Confidentiality must be maintained through the development of secure files (either electronic or hard-copy). Where there is doubt about the consumer's expectations for sharing of their personal information with other healthcare providers, it is preferable to gain their informed consent.[22]

Figure 2. Clinical interventions may identify the need for other professional pharmacy services



Pharmacists should refer to the *Privacy Act 1988* as well as any state or territory privacy legislation or health privacy frameworks. Pharmacists must also meet the relevant standard (Criterion 3 of the *Fundamental Pharmacy Practice* standard[10]) when performing clinical interventions.

3.3 Skills development

Pharmacists have a professional and legal obligation to work only within their area of competence. As with any activity, they must establish their competence to perform clinical interventions, where 'competence' means that the individual 'possesses the required knowledge, skills and attributes sufficient to successfully and consistently perform a specific function or task to a desired standard'.[23] Pharmacists should refer to the *National Competency Standards Framework for Pharmacists in Australia*[24] to identify competencies they will need to achieve to adequately perform clinical interventions (see Appendix 4).

Training programs may be established to support the development of pharmacists' skills to increase the performance of clinical interventions, and the subsequent documentation of DRPs and clinical interventions.

Areas in which pharmacists may identify a need for enhanced skills may include:

- assistance in identifying DRPs and performing clinical interventions (including up-to-date clinical knowledge);
- education about the DOCUMENT classification system for DRPs;
- instruction on how to document DRPs and clinical interventions; and
- advice on methods to improve their rate of DRP detection.

Some interventions may be identified because the dispensing process cannot proceed until the DRP is resolved. For example, when a prescription is presented without a strength specified, dispensing cannot continue until the dose and strength are established. This type of intervention is termed 'reactive' as the consumer presents with a DRP that leads to a clinical intervention. A proactive intervention may take place when the pharmacist has identified factors likely to affect the choice of drug therapy prescribed and brings this to the attention of the consumer and/or prescriber; for example, if the pharmacist is counselling a consumer on a beta-blocker medication and reviews the consumer's medication history for asthma therapies, or asks whether the consumer suffers from asthma. By gathering more information from the medical history, the consumer or the prescriber, pharmacists can identify more actual or potential DRPs and subsequently perform more proactive clinical interventions.

It is important to note that useful and cost-saving interventions are often quite simple and can be made by any pharmacist. For instance, DRPs often arise from poor communication, confusion or simple misunderstandings.

3.4 Communication with other healthcare providers

To perform clinical interventions in an efficient manner, it is critical to have effective collaboration with, and communication between, relevant members of the

healthcare team, including GPs, medical specialists, other pharmacists, consumers, carers, nurses and other healthcare providers.

The severity of the DRP, and the clinical judgement of the pharmacist, will determine the urgency and nature of communication with appropriate healthcare providers. Pharmacists should document all communications made with other healthcare providers in the consumer's history, for example in the form of clinical notes (see Section 4.4). Many clinical interventions result in a recommendation to the consumer to visit a healthcare provider to discuss or resolve actual or potential DRPs. A template for a referral letter to healthcare providers is included in Appendix 5.

In communications with other healthcare providers, pharmacists should be respectful, exercising appropriate professional tact. Pharmacists should be aware of and familiar with the PSA Code of Conduct, particularly Principle 6, which states that '*a pharmacist must respect the skills and expertise of other health professionals and work cooperatively with them to optimise the health outcomes of their mutual clients.*'[25] In addition, pharmacists should review the relevant Professional Practice Standards, particularly *Fundamental Pharmacy Practice*[10] and *Continuity of Care through Medication Liaison Services*,[14] and the relevant competency standards (that is, *Communication, collaboration and self-management*[26]).

3.5 Communication with consumers

Communication with consumers during the process of resolving DRPs is often necessary. When communicating with consumers it is important that pharmacists do so in a sensitive and effective manner, in order to provide the appropriate information without causing unnecessary alarm and to maintain the consumer's confidence in their prescriber.

4. Documentation of clinical interventions

Clinical interventions are performed by pharmacists with the purpose of preventing or addressing DRPs related to prescription or non-prescription medicines.

4.1 When to document clinical interventions

Pharmacists should record each clinical intervention they perform. For example, the following situations are clinical interventions and should be recorded:

- The pharmacist identifies potential over-use or duplication of medicines, or overtreatment of conditions.
- The pharmacist identifies a medical condition (e.g. poorly controlled hypertension) which may require enhanced therapy or improved medication adherence.
- The pharmacist identifies the need for preventive therapy, such as the requirement for adequate intake of calcium and vitamin D in a consumer with osteoporosis.
- Upon a consumer request for non-prescription pain relief subsequent to the use of an HMG CoA reductase inhibitor (statin), the pharmacist uncovers a possible myopathy-associated DRP.
- The pharmacist dispenses a repeat prescription from another pharmacy, and identifies that it had been previously dispensed incorrectly.
- A consumer requests further information regarding medicine or disease management.

Many activities undertaken by pharmacists are not clinical interventions and need not be documented; these include:

- routine consumer counselling and provision of CMI, such as when a consumer has been dispensed a new medicine;
- substitution of medication brand – unless the recommended brand has a unique characteristic to assist in the resolution of a DRP (e.g. a calendar pack, braille markings, gluten-free);
- routine assessment or management of minor ailments, such as provision of symptom relief for cold and flu, or assessment and treatment of allergic rhinitis; and
- administrative events (e.g. medicine ordering, prescription processing, determining PBS eligibility).

4.2 Methods of documentation

An appropriate recording system should be used to document clinical interventions. This might include an electronic system linked to dispensing systems or, if that is unavailable, a paper-based system.

Irrespective of the recording system used, the information that pharmacists should record is the same. It should include:

- date of the intervention;
- drugs involved, including those central to the DRP, and any recommendations for the resolution of the DRP (strengths and doses of medicines should also be recorded where possible);
- consumer details, including age range and gender;
- any communication with the consumer's prescriber;
- DOCUMENT and recommendation codes to classify the DRP and clinical intervention; and
- consumer history (clinical) notes, including any follow-up, outcomes or resolution details.

4.2.1 Electronic recording of clinical interventions

Intervention documentation software is to be developed for integration into dispensing systems, and should be adaptable to use for non-prescription medicines. The software should enable pharmacists to select a consumer and complete details concerning the intervention via their dispensing system. Help files may assist the selection of DRP and recommendation codes, and intervention records may be generated. The software may automatically generate some of the prescription and consumer information.

4.2.2 Paper-based intervention log

Pharmacies that do not have intervention software installed can use a paper-based recording system. A template is provided in Appendix 6. It is recommended that pharmacists enter a reference to the paper-based record in the pharmacy electronic dispensing system. The records are best organised by consumer surname and date.

The template provided in Appendix 6 may also be useful for pharmacists to make brief notes on while they are busy, before entering the data into an electronic system at a later stage.

4.2.3 Record keeping

Clinical intervention record management by pharmacists must comply with Commonwealth and state or territory legislation. Records need to be easily retrievable.

4.3 Audit and feedback

It is expected that pharmacists will regularly review and audit the types of interventions performed for quality assurance purposes. Common issues involved in clinical interventions could be identified, and measures could be taken to help prevent those issues recurring.

Any system utilised should have the capacity to generate intervention reports in formats suitable for review and audit purposes.

4.4 Consumer history (clinical) notes

Although the DOCUMENT classification system for DRPs in Appendix 7 is comprehensive, the provision of brief clinical notes will assist other pharmacists in interpreting what happened during the intervention. Pharmacists should record the clinical notes in a systematic manner, using a method such as 'Subjective, Objective, Assessment, Plan' (SOAP). Refer to Appendix 8 for guidance.

Clinical notes pertaining to follow-up of the intervention should be recorded, particularly where further pharmacist action is required. Notes relating to the outcome of the intervention should be added where resolution of the intervention has occurred. This will ensure that pharmacist resources are appropriately directed.

4.5 Recording the type of drug-related problem

The DOCUMENT system consists of eight categories to classify DRPs; each category encompasses between one and eight subcategories.

A classification flow chart is included in Appendix 9 to assist accurate classification of clinical interventions. It is important to note, however, that the comprehensive recording of the clinical intervention is paramount, not the categorisation of the DRP. Should pharmacists find it difficult to classify particular DRPs, they should make their best estimate of the appropriate category and include brief notes to assist interpretation of the scenario. However, it should be noted that there may often be grey areas and overlap when classifying DRPs.

All DRPs resulting in the consumer actually experiencing adverse effects or symptoms should be recorded under 'Toxicity or adverse reaction,' even if they could be classified under another category.

The types of DRP classified in the DOCUMENT system are defined below. The subcategories are summarised in table format in Appendix 7.

When to use	Example	When not to use
D **4.5.1 D – DRUG SELECTION** Problems relating to the choice of drug prescribed or taken		
4.5.1.1 Duplication (D1)		
There are no obvious adverse clinical effects of the two drugs together, but it is either inappropriate or very unusual to see them prescribed or used together as they are from the same therapeutic class. A situation where a person may be inappropriately taking two brands of the same generic drug.	Consumer taking two different brands of amiodarone at the same time.	The drugs involved are not of the same therapeutic class; use 'Drug interaction (D2)'.
4.5.1.2 Drug interaction (D2)		
There are no obvious adverse clinical effects of the drug interaction between two medicines that the consumer is taking or intending to take, but the interaction is serious enough to check whether the doctor is aware of it. The consumer presents with a non-prescription medicine request that could result in a major interaction if taken with their concurrent therapy.	Consumer asks to purchase an over-the-counter anti-inflammatory when taking warfarin.	The interacting drug is of the same therapeutic class as part of the consumer's existing therapy; use 'Duplication (D1)'. The drug is contraindicated due to an existing medical condition or previous adverse reaction to the medicine; use 'Contraindication apparent (D6)'.

When to use	Example	When not to use
4.5.1.3 Wrong drug (D3)		
The consumer is taking a medicine that has been incorrectly prescribed (prescribing error) or incorrectly dispensed (dispensing error).	A doctor prescribes carbimazole 20 mg bd but intended carbamazepine 200 mg bd.	A drug is discontinued or out of stock on a long-term basis and the doctor is contacted for a change in therapy; use 'Other drug selection problem (D0)'.
4.5.1.4 Incorrect strength (D4)		
The consumer presents with a new prescription that has no details about a drug's strength or incorrect details that may require clarification from the prescriber. A drug chart or hospital discharge shows a strength that appears to be incorrect.	Locum doctor prescribes irbesartan 150 mg daily, but previous therapy was 300 mg daily.	The consumer presents a prescription for an old medicine that has been replaced by a newer one that they should be taking; use 'Other compliance problem (C0)'.
4.5.1.5 Inappropriate dosage form (D5)		
The formulation of the product is inappropriate or incorrect in terms of the intended use of the product, including incorrect routes of administration.	A rectal topical product is prescribed or supplied for an eye problem.	The consumer has a physical problem with the administration of the dosage form as it is intended to be used (e.g. swallowing a particular form of the medicine whole, or arthritis limiting the use of an inhaler) or their difficulty is related to a lack of understanding on how to use the dosage form; use 'Difficulty using dosage form (C5)'.
4.5.1.6 Contraindication apparent (D6)		
There is a contraindication or precaution to the drug being used by a particular consumer due to their medical conditions, not their drug therapy. A drug or drug group is prescribed for a consumer who has previously had a major adverse reaction.	A doctor prescribes enalapril for a woman who is 7 months pregnant.	The drug is contraindicated due to existing drug therapy; use 'Drug interaction (D2)'. The drug is felt to be contraindicated due to therapeutic duplication; use 'Duplication (D1)'.
4.5.1.7 No indication apparent (D7)		
There is no clear reason apparent for the drug to be used.	A consumer is using steroid eye drops over the long term without a current indication.	The drug is felt to be unnecessary due to therapeutic duplication; use 'Duplication (D1)'.
4.5.1.8 Other drug selection problem (D0)		
The drug being used is out of date or has deteriorated in some other way. A drug is discontinued or out of stock on a long-term basis and the doctor is contacted for a change in therapy. The pharmacist believes a more effective drug is available and suggests it instead of the proposed therapy.	A consumer presents a prescription for trimethoprim for a UTI. The drug is out of stock for another 3 weeks, so the doctor is contacted with a suggestion for an alternative antibiotic.	Another brand must be substituted because the ordered brand cannot be used due to a physical problem related to the consumer taking the drug; use 'Difficulty using dosage form (C5)'.
O **4.5.2 O – OVER or UNDERDOSE PRESCRIBED** Problems relating to the prescribed dose or schedule of the drug		
4.5.2.1 Prescribed dose too high (O1)		
The total daily dose of a medicine prescribed is too high for the consumer, based on either previous dosage or reference dose ranges, including situations where the dose that is prescribed is too high by unintentional error. The dose is too high because of a particular parameter of the consumer, such as renal function, weight, age etc.	A consumer is prescribed dexamethasone 50 mg daily (the prescriber was thinking of prednisolone dose).	The consumer is taking too high a dose as a result of compliance issues; use 'Over-use by consumer (C2)'.
4.5.2.2 Prescribed dose too low (O2)		
The dose prescribed is either too low based on reference dose ranges or too low based on previous therapy. The dose prescribed is too low by unintentional error.	A 30 kg child is prescribed amoxycillin 125 mg tds (recommended dose 7.5–25 mg/kg tds).	The actual dose per day is correct, but the duration is too short; use 'Incorrect or unclear dosing instructions (O3)'. The consumer is taking a low dose of a drug as a result of poor compliance; use 'Under-use by consumer (C1)'.

When to use	Example	When not to use
4.5.2.3 Incorrect or unclear dosing instructions (O3)		
The specified dosing time is not optimal. The duration of use of the product is too short or too long, including incorrect dose titrations. The total dose of a medicine is suitable, but the frequency or the dosage schedule is inappropriate.	A consumer presents a new prescription for lamotrigine 100 mg bd with no instructions to increase slowly (dose should start at 25 mg/day for 2 weeks and increase by a maximum of 50–100 mg every 1–2 weeks; the starting dose should be even lower if the consumer is already on some other anticonvulsants).	The consumer is not taking the appropriate dose of a product as a result of a lack of understanding of the dosage regimen; a compliance-related code would be more appropriate.
4.5.2.4 Other dose problem (O0)		
Any other dosing problems for which the pharmacist is unable to identify a subcategory.		
C **4.5.3 C – COMPLIANCE** Problems relating to the way the consumer takes their medicine		
4.5.3.1 Under-use by consumer (C1)		
The consumer uses too little of a medicine as a result of forgetfulness or lack of understanding of the dosage regimen prescribed. The consumer chooses to take a medicine PRN instead of on a regular basis (when the latter was intended). The consumer chooses to discontinue a medicine.	Consumer only takes their lercanidipine when they believe their blood pressure is very high.	The under-use is appropriate because of the resolution of symptoms or a condition; use 'No indication apparent (D7)' and specify that the drug may no longer be required. The consumer has a physical problem with the administration of the dosage form, resulting in too little being used (e.g. swallowing a particular form of the medicine whole, or arthritis limiting the use of an inhaler); use 'Difficulty using dosage form (C5)'.
4.5.3.2 Over-use by consumer (C2)		
The consumer uses too much of a medicine as a result of forgetfulness or lack of understanding of the dosage regimen prescribed.	Consumer presents requesting a repeat prescription of simvastatin after 2 weeks because they were forgetting that they had taken it and often took two doses per day.	If the over-use is due to an appropriate increase in use because of increased symptoms; use 'Condition undertreated (U1)'. If the over-use consists of inappropriately taking two different brands or forms of the same ingredient or drug class unknowingly; use 'Duplication (D1)'.
4.5.3.3 Erratic use of medication (C3)		
The consumer is taking the medicine on an erratic basis.	A consumer presents for their venlafaxine prescription, which was dispensed 3 days ago, but prior to that it was dispensed 2 months ago.	The amount of medicine being taken can be easily quantified; use 'Under-use by consumer (C1)' or 'Over-use by consumer (C2)'.
4.5.3.4 Intentional drug misuse, including non-prescription medicines (C4)		
There is suspected intentional over-use of a particular, potentially abused, product, including non-prescription items. Includes situations where the prescription appears to be a forgery.	A consumer returns for a second prescription from a different prescriber for nitrazepam after 1 week, claiming she dropped the previous supply down the toilet.	The over-use is due to an appropriate increase in use because of increased symptoms; use 'Condition undertreated (U1)'.
4.5.3.5 Difficulty using dosage form (C5)		
The consumer lacks understanding of how to use the dosage form. The consumer has a physical problem with the administration of the dosage form or device as it is intended to be used (e.g. swallowing a particular form of the medicine whole, cannot appropriately insert suppositories, or arthritis limiting the use of an inhaler). A brand needs to be substituted to improve the consumer's ability to use the medicine.	A consumer cannot swallow sustained-release diltiazem capsules.	The formulation of the product is inappropriate or incorrect in terms of the intended use of the product, such as an incorrect route of administration; use 'Inappropriate dosage form (D5)'.

When to use	Example	When not to use
4.5.3.6 Other compliance problem (C0)		
The consumer wishes to collect a prescription for a medicine that has been ceased or replaced by a new medicine. A consumer is stockpiling medicines.	Consumer presents a prescription for ranitidine which has been ceased by the prescriber previously and replaced with omeprazole.	The compliance issue results in two drugs of the same therapeutic class being taken inadvertently; use 'Duplication (D1)'.
U **4.5.4 U – UNDERTREATED** Problems relating to actual or potential conditions that require management or prevention		
4.5.4.1 Condition undertreated (U1)		
The consumer has a symptom or disease that is not being treated adequately.	A consumer frequently requests glyceryl trinitrate spray but is not being treated with regular anti-angina medication.	The consumer has a condition that is not currently being treated with any medicine; use 'Condition untreated (U2)' The consumer requires additional therapy as a preventive strategy (e.g. potassium when on a loop diuretic); use 'Preventive therapy required (U3)'. The consumer takes too little and suffers worsening of their condition as a result; use 'Under-use by consumer (C1)'.
4.5.4.2 Condition untreated (U2)		
The consumer has a symptom or disease condition that is not currently being treated.	A consumer has a fall resulting in a hip fracture but is not on any osteoporosis medication.	The consumer has a condition that is currently being treated, but not adequately; use 'Condition undertreated (U1)'. The consumer requires additional therapy as a preventive strategy (e.g. potassium when on a loop diuretic); use 'Preventive therapy required (U3)'. The consumer takes too little and suffers worsening of their condition as a result; use 'Under-use by consumer (C1)'.
4.5.4.3 Preventive therapy required (U3)		
The consumer requires additional therapy to prevent a likely adverse event as a result of the consumer's therapy, coexisting diseases or risk factors. Not to be used if the consumer already has the condition.	A consumer commences on morphine slow-release without laxative therapy.	The consumer already has treatment for a particular problem, but it is not effective enough; use 'Condition undertreated (U1)'. The consumer already has a condition that is not currently being treated with any medicine; use 'Condition untreated (U2)'.
4.5.4.4 Other undertreated indication problem (U0)		
The consumer has any other problem relating to actual or potential conditions that appears to require management, but a subcategory for the intervention cannot be identified.		
M **4.5.5 M – MONITORING** Problems relating to monitoring the efficacy or adverse effects of a drug		
4.5.5.1 Laboratory monitoring (M1)		
In the absence of any adverse effects, it appears that a laboratory test is required (e.g. potassium, creatinine, white cell count, INR). Includes any laboratory test that is *not* done within the consumer's home, doctor's surgery or pharmacy. In the absence of any adverse effects, it appears that drug level monitoring is required.	A consumer taking warfarin was discharged from hospital 2 weeks ago and has not yet had a post-discharge INR.	The need for laboratory monitoring occurs as a result of a drug interaction; use 'Drug interaction (D2)' and the monitoring then becomes a recommendation, not the primary problem. The test will be occurring within the consumer's home, a pharmacy or a doctor's surgery; use 'Non-laboratory monitoring (M2)'.

When to use	Example	When not to use
4.5.5.2 Non-laboratory monitoring (M2)		
In the absence of any adverse effects, it appears that non-laboratory monitoring is required (e.g. BP, capillary BSL, temperature, weight). In the future, the self-monitoring of INR at home could also come under this category. The test may be undertaken as a screening process.	A diabetic consumer who has recently been prescribed insulin is advised to regularly monitor their blood sugar levels.	If monitoring of a parameter (e.g. weight, BSL, heart rate) is recommended as a result of another drug problem, then that recommendation be recorded in the Recommendation code section.
4.5.5.3 Other monitoring problem (M0)		
The consumer has another problem related to the monitoring of their medicines or medical conditions for either efficacy or adverse effects. The consumer should be having monitoring done, but has problems attending the laboratory or paying for the test or equipment needed.	It is recommended that a consumer monitor their breathlessness and weight to provide an indication of how effectively their heart failure medication is working.	
E **4.5.6 E – EDUCATION or INFORMATION** Where a consumer requests further information about a drug or disease state		
4.5.6.1 Consumer requests drug information (E1)		
The consumer has a reasonable understanding of their condition, but requests further information about their medicine.	After commencing hormone replacement therapy (HRT), a consumer requests further printed information about breast cancer and HRT.	The consumer is starting a new prescription item, and provision of CMI is a mandatory requirement. The consumer requests information primarily about the disease state, rather than a drug; use 'Consumer requests disease management advice (E2)'.
4.5.6.2 Consumer requests disease management advice (E2)		
The primary purpose of the interaction with the consumer is to inform them of critical aspects of the management or prevention of a disease or condition.	Information about fluid restriction is provided to a consumer with heart failure.	The consumer requests information primarily regarding a drug; use 'Consumer requests drug information (E1)'. The counselling is part of routine duties, such as counselling a consumer about their new medicine.
4.5.6.3 Other education or information problem		
Another healthcare worker (e.g. a doctor or another pharmacist) requests information. Any other education or information related problem.		
N **4.5.7 N – NOT CLASSIFIABLE** Problems that cannot be classified under another category		
4.5.7.1 Clinical interventions that cannot be classified under another category (N0)		
All prescriptions should usually be classified under another category; however, the 'N' category is to be used when a pharmacist feels that a clinical intervention does not belong elsewhere. Note that the intervention must still be clinical, not administrative.		The problem is administrative; it is not a clinical intervention and does not need to be recorded. For example: • when a prescription is illegal due to Commonwealth and state or territory law; • when the prescription does not meet PBS requirements (i.e. incorrect number of tablets or repeats); • when an authority prescription is not approved or incorrect; or • when the drug is unavailable from the manufacturer or is out of stock temporarily.

When to use	Example	When not to use
T **4.5.8 T – TOXICITY or ADVERSE REACTION** Problems relating to the *presence* of signs or symptoms that may be attributed to a drug.		
4.5.8.1 Toxicity, allergic reaction or adverse effect present (T1)		
The consumer has signs or symptoms that suggest toxicity, an allergic reaction or an adverse effect; also includes situations in which compliance issues have led to symptoms of toxicity. All significant adverse drug events should be reported to the Therapeutic Goods Administration via the Australian Adverse Drug Reaction Reporting System, available at https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase.		

4.6 Recording the recommendations made

Given that a clinical intervention, by definition, must involve a pharmacist making a recommendation to the consumer or prescriber, it is highly recommended that details of the recommendation(s) are included in the documentation process. A record of recommendations assists other pharmacists to interpret the situation. The recommendation codes enable pharmacists to easily record the type of recommendations made to resolve or prevent the actual or potential DRP. Pharmacists can select multiple recommendations per intervention, and recommendations can be grouped. A system to assist accurate classification of recommendations is outlined below.

These categories are summarised in table format in Appendix 7.

When to use	Example	When not to use
4.6.1 A change in therapy		
4.6.1.1 Dose increase (R1)		
The pharmacist recommends to the prescriber that the total daily dose of the medicine be increased.	The pharmacist recommends to the prescriber an increase in dose of antibiotics for a 4-year-old child after calculating the appropriate dose based on weight.	The total daily dose of the product does not change, but it is recommended that the schedule change; use 'Dose frequency/ schedule change (R6)'.
4.6.1.2 Dose decrease (R2)		
The pharmacist recommends to the prescriber that the total daily dose of the medicine be decreased.	Pharmacist recommends to the prescriber that the dose of gliclazide be reduced.	The total daily dose of the product does not change, but it is recommended that the schedule change; use 'Dose frequency/ schedule change (R6)'.
4.6.1.3 Drug change (R3)		
The pharmacist recommends a change in current medicines, including the addition or cessation of a drug. Note that in many cases 'Refer to prescriber (R9)' should also be selected.	Consumer describes ongoing drowsiness in the mornings with nitrazepam, and the pharmacist suggests a change to temazepam.	The change in medicine is a brand change to increase the consumer's ability to use their medicine; use 'Drug brand change (R5)'. The change in medicine is a change in the formulation (e.g. from cream to ointment, or plain tablets to controlled release); use 'Drug formulation change (R4)'.
4.6.1.4 Drug formulation change (R4)		
The active ingredient of the medicine and its total daily dose are not changed, but the formulation is changed.	The pharmacist suggests to the prescriber a change from metformin 500 mg 1 tds to metformin XR 500 mg 3 nocte.	The formulation change also results in a change in the total daily dose of the medicine; use 'Dose increase (R1)' or 'Dose decrease (R2)'.

When to use	Example	When not to use
4.6.1.5 Drug brand change (R5)		
The pharmacist suggests a change in brand of the drug (same drug, same dose), usually due to difficulty using a particular brand. Does not include routine brand substitution.	Pharmacist changes consumer from a brand that comes in blister packs to a brand that comes in a bottle as they find blister packs difficult.	The change in brand is to a different formulation of the same active ingredient; use 'Drug formulation change (R4)'. The change in brand is due to routine brand substitution for cost reasons; it is not a clinical intervention and therefore does not need to be recorded.
4.6.1.6 Dose frequency/schedule change (R6)		
The total daily dose of the product remains the same, but the pharmacist suggests a change in the number of times a day or the timing of the doses each day.	Pharmacist suggests changing roxithromycin from 150 mg twice daily to 300 mg once daily to improve adherence.	The suggestion results in a change in the total daily dose of the medicine; use 'Dose increase (R1)' or 'Dose decrease (R2)'.
4.6.1.7 Prescription not dispensed (R7)		
The circumstances mean that the current prescription is not dispensed at this time.	A consumer presents with prescriptions for atorvastatin and erythromycin. To reduce the risk of myopathy, the pharmacist advises that atorvastatin should not be taken until the course of antibiotics has been completed and subsequently does not dispense the atorvastatin.	
4.6.1.8 Other changes to therapy (R8)		
The pharmacist recommends another change to the consumer's current therapy.		
4.6.2 A referral required		
4.6.2.1 Refer to prescriber (R9)		
The problem is of sufficient seriousness for the consumer to see the prescriber again in order to resolve the problem. Includes referral to a prescriber to initiate any new therapies that the pharmacist has suggested.	A consumer presents with a rash from recently commenced antibiotics. The consumer is told to cease the capsules and is referred back to the prescriber for some different antibiotics. 'Drug change (R3)' should also be selected.	The pharmacist has already contacted the doctor to resolve the issue; therefore, the consumer does not require referral to the prescriber or only needs to collect a new prescription.
4.6.2.2 Refer to hospital (R10)		
The problem is of sufficient seriousness for the consumer to go to hospital in order to resolve the problem.	Consumer presents with melaena (black tarry stools) after commencing a NSAID.	
4.6.2.3 Refer for medication review (R11)		
The pharmacist initiates the process for a home medicines review (HMR) or MedsCheck for the consumer.	The pharmacist recommends a MedsCheck for a consumer who is having trouble understanding their medicines. The pharmacist refers a consumer who suffers from chronic pain and is having difficulty managing their medications for an HMR.	An 'ad hoc' review of the medicines is undertaken and general assistance is provided to aid the consumer's understanding; use 'Education/counselling session (R13)'.
4.6.2.4 Other referral required (R12)		
The pharmacist refers the consumer to another healthcare professional.	A consumer requires referral to another healthcare professional (e.g. dentist, podiatrist).	Referring to the consumer's prescriber; use 'Refer to prescriber (R9)'.
4.6.3 Provision of information		
4.6.3.1 Education/counselling session (R13)		
The pharmacist conducts a detailed counselling or education session with the consumer or carer; the session is specifically targeted at resolving the problem that has been identified.	A consumer has not been taking metformin correctly. The pharmacist gives details of how to take it in relation to food, how long it lasts and information regarding the complications and management of diabetes.	The discussion with the consumer is to determine the nature of the problem, rather than propose a recommendation or further education.

When to use	Example	When not to use
4.6.3.2 Written summary of medicines (R14)		
The pharmacist provides the consumer with a detailed list/profile of their medicines. Consider whether this recommendation is appropriate for all interventions categorised under compliance.	A consumer commences on three new medicines, so a PMP is produced to minimise potential confusion.	The information provided is simply a list of medicines with no additional information. If the information provided is in the form of self-care cards or other written information, use 'Other written information (R16)'.
4.6.3.3 Recommend dose administration aid (R15)		
The pharmacist suggests the use of a dose administration aid or a spacer. Consider whether this recommendation is appropriate for all interventions categorised under compliance.	The pharmacist recommends a dose administration aid for a consumer who has significant problems in understanding the schedule and timing of their medicines.	A written summary of the consumer's medicines and their schedule (e.g. PMP) is provided, in addition to the dose administration aid; also select 'Education/counselling session (R13)'.
4.6.3.4 Other written information (R16)		
The consumer requires additional written information; for example, in the form of Self Care Fact Cards or other written information.	The pharmacist provides written details of a reducing prednisolone regimen.	
4.6.4 Monitoring		
4.6.4.1 Monitoring: Laboratory (R17)		
The pharmacist suggests to the prescriber that they undertake some laboratory monitoring for efficacy or adverse effects of the medicine.	The pharmacist contacts the prescriber to suggest that they check the INR in a consumer taking warfarin who has commenced ciprofloxacin.	The monitoring relates to a test that can be done at home (e.g. BSL); use 'Monitoring: Non-laboratory (R18)'.
4.6.4.2 Monitoring: Non-laboratory (R18)		
The pharmacist suggests that the consumer undertake some non-laboratory monitoring for efficacy or adverse effects of the medicine. Includes blood pressure monitoring, blood sugar levels, temperature and weight.	The pharmacist suggests that the consumer weigh themself daily while they are taking an increased dose of frusemide for heart failure.	The monitoring involves a laboratory-based test; use 'Monitoring: Laboratory (R17)'.
4.6.5 No recommendation necessary		
4.6.5.1 No recommendation necessary (R19)		
A problem has been investigated, but it is found that the problem does not need to be addressed with any changes or monitoring.		

5. Conclusion

This document provides information and advice to pharmacists on professional issues related to performing clinical interventions, and will assist pharmacists in identifying, classifying and documenting DRPs and clinical interventions in a professional manner, to ensure that all important information is recorded in an effective and systematic manner.

Additional information resources that may assist pharmacists in this regard are detailed in Appendix 10.

A summary of the clinical interventions process is on page 30.

Appendix 1: The PROMISe clinical intervention studies

The PROMISe projects[2] involved the development and refinement of an electronic system for the classification and documentation of drug-related problems (DRPs) and clinical interventions by community pharmacists. In 2009, this research culminated in the PROMISe III project, in which documentation software was installed in 185 pharmacies in three states, allowing researchers to determine the frequency and types of pharmacist-led clinical interventions, and the factors which influence their performance and documentation. PROMISe III also demonstrated the economic value of these clinical interventions, showing that the average clinical intervention avoids approximately $360 in healthcare utilisation, thereby highlighting the potential healthcare savings which might be realised by the Australian Government if the number of clinical interventions performed by pharmacists were increased.

Reported clinical intervention rates, both in Australia and overseas, vary from 0.9 to more than 24 interventions per 1,000 prescriptions,[27–32] with differences in definitions accounting for some of that variation. The most recent PROMISe project reported an average intervention rate of 3 interventions per 1,000 prescriptions dispensed.[2] The results, however, also indicated that pharmacists did not document up to half of the interventions they performed, demonstrating that it is likely that the actual performance of clinical interventions was considerably higher.

The majority of interventions recorded in the PROMISe III project were related to either drug selection problems (1,837; 31%) or educational issues prompted by consumer requests (1,421; 24%). Pharmacists were able to assign up to four recommendations for each clinical intervention. Frequently, the type of recommendation made by the pharmacist related to a change in therapy (3,841 occasions; 40%), in particular a drug change or a dose change. Pharmacists also commonly provided a counselling and education session to the consumer (2,441 occasions; 41%) and referral to the prescriber (1,794 occasions; 30%).

A number of factors, some of which were demonstrated throughout the PROMISe projects, may increase pharmacists' intervention rates.[2] The following factors were shown to influence clinical intervention rates in the PROMISe projects:

- *Pharmacists' prescription workload.* Studies, including the PROMISe III project, have shown that as pharmacists' workload increases, their ability to identify drug interactions or other DRPs, or to perform clinical interventions, decreases.[33,34] In the light of this, a pharmacist's workload should be managed to ensure that they have sufficient time to identify DRPs and to perform and document clinical interventions. The Pharmacy Board of Australia's *Guidelines for Dispensing of Medicines* recommends a maximum of 150 prescriptions per pharmacist per day without assistance.[35]
- *Clinical knowledge.* Results from the PROMISe III project revealed that pharmacists who possess greater skills in this area are more capable of identifying DRPs and performing clinical interventions that benefit consumers than those with lesser clinical knowledge. Furthermore, pharmacists with additional qualifications, such as accreditation with the Australian Association of Consultant Pharmacists (AACP), graduate certificates, graduate diplomas, or additional degrees with clinical pharmacy background, were shown to record the highest number of interventions. These findings are consistent with the requirements of the Professional Practice Standards[36] and the National Competency Standards.[24] Enhancing clinical knowledge, therefore, is likely to be an effective way to maximise pharmacists' intervention rates and positive outcomes for consumers.
- *Continuing Professional Development (CPD).* Consistent with studies demonstrating that continuing medical education improves physician performance,[37–39] the PROMISe study revealed that, with an increased number of reported hours spent on CPD each year, the rate of clinical interventions recorded was increased. With the introduction of mandatory CPD activity for pharmacists, an increase in the number of clinical interventions performed is expected.

For further information, the PROMISe project reports can be found at www.guild.org.au/research/4cpa_project_display.asp?id=1874

Appendix 2: Professional Practice Standard: Clinical Interventions

Standard:

The pharmacist performs clinical interventions that involve the identification of actual or potential drug-related problems (DRPs) and the provision of recommendations to resolve or prevent them, and subsequently documents the clinical intervention, to improve health outcomes for consumers.

Scope of this standard

- This standard covers the key principles for identifying and documenting clinical interventions. For the purposes of this standard:
  - A *DRP* is defined as *'an event or circumstance involving drug treatment that actually or potentially interferes with the consumer experiencing an optimum outcome of medical care'*, and can broadly be related to adverse events, adherence issues or errors.
  - *Clinical intervention* is the process of a pharmacist identifying, and making a recommendation in an attempt to prevent or resolve, a DRP. It can be defined as '*any professional activity by the pharmacist directed towards improving the quality use of medicines and resulting in a recommendation for a change in the patient's medication therapy, means of administration or medication-taking behaviour.*'
- This standard is to be applied in conjunction with the *Fundamental Pharmacy Practice*, *Counselling*, *Medication Review* and *Dispensing* standards. Refer also to the *Dose Administration Aids Service*, *Continuity of Care through Medication Liaison Services*, *Disease State Management*, and *Harm Minimisation* standards for additional information.
- Legislative requirements are not addressed in this standard. It is expected that pharmacists will comply with relevant Commonwealth and state or territory legislation in the provision of this standard.
- Pharmacists performing clinical interventions should also be familiar with the *Guidelines for pharmacists performing clinical interventions*.

Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist maintains the relevant level of competence necessary to perform clinical interventions		
1. Maintains currency of knowledge and skills required to perform clinical interventions		• Pharmaceutical Society of Australia (www.psa.org.au) • Continuing Professional Development and Practice Improvement (CPD&PI) program • National Competency Standards Framework for Pharmacists in Australia (2010) • Pharmacy Board of Australia Guidelines on Continuing Professional Development (www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx).
2. Undertakes relevant continuing professional development activities to assist in identifying and resolving drug-related problems		
3. Regularly self-assesses the knowledge and skills required to perform clinical interventions		
Criterion 2: The pharmacist follows a systematic procedure to identify and address drug-related problems		
1. Is proactive in identifying and acting on potential or actual drug-related problems		• Pharmacy Guild of Australia Quality Care Pharmacy Program (QCPP) (www.guild.org.au/qcpp/). • Pharmaceutical Society of Australia (www.psa.org.au) • Professional Practice Standards, Version 4, 2010. Appendix 4: Adherence Assessment Tool, p. 87. • Pharmacy Board of Australia Guidelines for Dispensing of Medicines (www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx).
2. Reviews the consumer's medicines and disease states in relation to drug-related problems		
3. Ensures that pharmacy staff have adequate skills and training to support the pharmacist in identifying and addressing actual or potential drug-related problems		
4. Utilises and critically evaluates appropriate, evidence-based resources when managing drug-related problems		
5. Manages workload to ensure that sufficient time is available to perform and document clinical interventions		
6. Recommends other professional services that may benefit the consumer		
Criterion 3: The pharmacist works collaboratively with the consumer and other healthcare providers		
1. Uses the appropriate method of communication for the consumer and for other healthcare providers		• Pharmaceutical Society of Australia (www.psa.org.au) • Professional Practice Standards, Version 4, 2010. Appendix 10: Screening Record and Referral Form, p. 93. • Guidelines for pharmacists performing clinical interventions.
2. Contacts the prescriber about actual or potential drug-related problems when appropriate		
3. Promptly communicates with the appropriate healthcare provider according to the severity of the drug-related problem		
4. Refers consumers to other healthcare providers to assist in the resolution of drug-related problems where appropriate		

Indicators	Self check: Yes/No/NA	Resources
Criterion 4: The pharmacist documents the details of the drug-related problem and clinical intervention		
1. Records clinical interventions using suitable electronic or paper-based systems		• Pharmaceutical Society of Australia (www.psa.org.au) • *Guidelines for pharmacists performing clinical interventions* • Professional Practice Standards, Version 4, 2010. Appendix 6: Documenting Counselling Events and Interventions, p. 89. • *Privacy Act 1988* (Cwth) (www.privacy.gov.au/law/act).
2. Documents the clinical intervention, consumer details, drug(s) involved, consumer history notes, communications with healthcare providers and outcomes, ensuring that the intervention record is complete		
3. Ensures that clinical intervention records highlight the need for further action, follow-up or resolution		
4. Maintains legible and retrievable clinical intervention records		
5. Maintains the confidentiality and privacy of consumer information		
6. Ensures that records are stored for the required duration according to Commonwealth, state or territory legislation		
Criterion 5: The pharmacist addresses and follows up any issues arising from the clinical intervention		
1. Maintains a system to identify clinical interventions that require follow-up		
2. Records any follow-up actions, or outcomes resulting from the clinical intervention if known		
3. Maintains continuity of care through communication between pharmacists and other healthcare providers		
Criterion 6: The pharmacist maintains a system to monitor and evaluate the clinical interventions performed to enable continuous quality improvement		
1. Implements a system to evaluate clinical intervention records at regular intervals for quality assurance purposes		• Pharmacy Guild of Australia Quality Care Pharmacy Program (QCPP) standards (www.guild.org.au/qcpp/content.asp?id=807). • PROMISe benchmarking data (www.guild.org.au/research/4cpa_project_display.asp?id=1874)
2. Regularly reviews the system used for identifying and documenting clinical interventions		
3. Identifies trends and takes action to minimise potential drug-related problems		
4. Utilises benchmark and peer review measures and consumer feedback, where available, to evaluate performance		

Additional references

Australian Government Department of Health and Ageing. National Medicines Policy. At: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-index.htm

Australian Government Department of Health and Ageing. The National Strategy for Quality Use of Medicines (QUM) – Executive summary brochure. At: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-pdf-execsumbro-cnt.htm

Sansom LN, ed. Australian Pharmaceutical Formulary and Handbook, 21st ed. Canberra: Pharmaceutical Society of Australia; 2009.

Pharmaceutical Society of Australia. National Competency Standards Framework for Pharmacists in Australia; 2010.

Pharmacy Board of Australia. Guidelines on dispensing medicines. At: www.pharmacyboard.gov.au

Pharmacy Guild of Australia. Documenting clinical interventions in community pharmacy: PROMISe III. At: www.guild.org.au/research/4cpa_project_display.asp?id=1874

Appendix 3: Professional Practice Standards relevant to clinical interventions

Along with the *Professional Practice Standard: Clinical Interventions* (Appendix 2), pharmacists must be aware of the overarching standards framework as published in the Pharmaceutical Society of Australia's *Professional Practice Standards*, *Version* 4, 2010. The structure of that framework is such that, for completeness, this standard cannot be considered in isolation and must be applied in the context of other relevant standards. Some examples are outlined below; however, this list is not exhaustive.

The standards contained in the *Professional Practice Standards,* Version 4 publication can also be downloaded from PSA's website at www.psa.org.au/standards . All of the standards are intended for use as a self-assessment tool. The boxes against each indicator can be marked with a 'yes' or 'no'. If an indicator does not apply, mark 'N/A' next to the box and provide a brief explanation.

Standard	Relevance to clinical interventions	Examples of criteria (and issues) that may be relevant
1. Fundamental pharmacy practice	This is the universal standard for pharmacists and contains criteria common to all services.	1.1 Professionalism 1.2 Communication 1.3 Privacy 1.7 Referral 1.8 Documentation
3. Counselling	Tailored verbal and written information to ensure sufficient knowledge and understanding, facilitating the safe and effective use of medications.	3.1 Provision to all consumers 3.2 Evidence-based 3.3 Communication 3.5 Written information
4. Medication review	Systematic review of medication regimen and optimising health outcomes.	4.2 Collaboration 4.3 Systematic procedure 4.5 Documentation
5. Dispensing	Dispensed medications are consistent with the needs and safety of the consumer.	5.2 Medication history 5.3 Review and update 5.4 Adverse drug reactions and contraindications 5.5 Contact prescriber
9. Continuity of care through medication liaison services	Timely and tailored medication liaison services to consumers transferring between healthcare settings and providers.	9.1 Continuity of care 9.2 Collaboration 9.3 Identifies at-risk consumers 9.4 Tailors liaison services to needs of consumer 9.5 Accurate records

Appendix 4: Competency Standards relevant to clinical interventions

Effective performance of clinical interventions relies on pharmacists meeting the relevant competency standards as published in the *National Competency Standards Framework for Pharmacists in Australia 2010*. The *Guidelines for pharmacists performing clinical interventions* provide structure and formality to the relevant criterion. Some examples of relevant standards are outlined below; however, this list is not exhaustive.

The standards contained in the *National Competency Standards Framework for Pharmacists in Australia* can also be downloaded from the PSA's website at www.psa.org.au/standards . All of the standards are intended for use as a self-assessment quality audit tool for pharmacists to improve the quality of the professional services they provide. Pharmacists performing clinical interventions are encouraged to incorporate the following standards when customising a professional practice profile showing the competencies required for specific roles, positions or services.

Domain	Relevance to clinical interventions	Examples of standards (and the issues) that may be relevant
1. Professional and ethical practice	Responsibilities of pharmacists to maintain professional competence.	1.1 Practice legally 1.3 Deliver consumer-centred care 1.4 Manage quality and safety
2. Communication, collaboration and self-management	Communication with consumers and cooperation with colleagues and healthcare team.	2.1 Communicate effectively 2.3 Collaborate with members of the healthcare team
4. Review and supply prescribed medications	Review of prescriptions for inadvertent prescribing errors and potentially dangerous therapeutic duplications or interactions, and application of professional skills to optimise the results achieved from the use of prescribed medicines.	4.1 Undertake initial prescription assessment 4.2 Consider the appropriateness of prescribed medicines, including 'identifying any potential or actual drug-related problems,' and 'accurately code and record clinical interventions.' 4.3 Dispense prescribed medicines
7. Promote and contribute to optimal use of medicines	Contribution of pharmacists to the healthcare team, participation in the management and education of individual consumers, application of the best available evidence into professional practice, and identification and management of the risks associated with medicines use.	7.1 Contribute to therapeutic decision-making, including 'identifying clinically significant potential or actual medication related problems,' and 'uses professional judgement to determine whether changes in the medication treatment regimen are warranted in the interests of improved safety or efficacy.'

Appendix 5: Template: Referral letter

Note that guidance on specific content is provided in Appendix 8: Guidance for writing clinical notes: SOAP notes

(Healthcare provider's name)

(Healthcare provider's address)

(Pharmacist's name)

(Pharmacist's address)
(Contact phone number)

Date:

Dear *(Healthcare provider's name)*

Re: *(Consumer's name)*
(Consumer's address)

Date of intervention: *(dd/mm/yy)*

Discussed via phone: *(Y/N)*

I have referred *(consumer's name)* to you for review, following the identification of a potential issue concerning their care.

Potential issue: *(Describe the DRP briefly, including medications and/or medical conditions involved.)*

Recommendations: *(List recommendations here; e.g. drug change recommended.)*

Advice given to *(consumer's name)*: *(List recommendations here; e.g. dose administration aid recommended.)*

Additional notes:

References:

Next time you see *(consumer's name)*, please consider reviewing this potential medication-related issue. Please do not hesitate to contact me for any further information.

Yours sincerely

(Pharmacist's name, relevant post-nominals and signature)

Appendix 6: Template: Paper-based recording for clinical interventions

Modified from Peterson, Tenni et al. 2009[2]

Date: _____ Pharmacist: _____

Consumer: _____ Age: _____ Sex: _____

Drug involved in DRP: _____

Other drug(s): _____

_____

Relevant medical conditions/allergies: _____

_____

Notes: _____

_____

_____

_____

Drug Related Problem (please circle)				Recommendations (please circle)	
Drug Selection		Difficulty using dosage form	C5	Dose increase	R1
Duplication	D1	Other compliance problem	C0	Dose decrease	R2
Drug interaction	D2	**Undertreated**		Drug change	R3
Wrong drug	D3	Condition undertreated	U1	Drug formulation change	R4
Incorrect strength	D4	Condition untreated	U2	Drug brand change	R5
Inappropriate dosage form	D5	Preventive therapy required	U3	Dose schedule/frequency change	R6
Contraindications apparent	D6	Other untreated indication problem	U0	Prescription not dispensed	R7
No indication apparent	D7	**Monitoring**		Other changes to therapy	R8
Other drug selection problem	D0	Laboratory monitoring	M1	Refer to prescriber	R9
Over or underdose		Non-laboratory monitoring	M2	Refer to hospital	R10
Prescribed dose too high	O1	Other monitoring problem	M0	Refer for medication review	R11
Prescribed dose too low	O2	**Education**		Other referral	R12
Incorrect or unclear dosing instructions	O3	Consumer requests drug information	E1	Education or counselling session	R13
Other dose problem	O0	Consumer requests disease management advice	E2	Written summary of medications	R14
Compliance		Other education or information problem	E0	Dose administration aid	R15
Under-use by consumer	C1	**Not classifiable**		Other written information	R16
Over-use by consumer	C2	Not classifiable under another category	N0	Monitoring: laboratory	R17
Erratic use of medication	C3	**Toxicity or adverse reaction**		Monitoring: non-laboratory	R18
Intentional drug misuse	C4	Toxicity, allergic reaction or ADR present	T1	No recommendation	R19

Appendix 7: DOCUMENT DRP and recommendation classification codes

Modified from Peterson, Tenni et al. 2009[2]

Drug Related Problem

Category	Subcategory	Code
Drug selection (Problems relating to the choice of drug prescribed or taken)	Duplication	D1
	Drug interaction	D2
	Wrong drug	D3
	Incorrect strength	D4
	Inappropriate dosage form	D5
	Contraindications apparent	D6
	No indication apparent	D7
	Other drug selection problem	D0
Over or underdose (Problems relating to the prescribed dose or schedule of a drug)	Prescribed dose too high	O1
	Prescribed dose too low	O2
	Incorrect or unclear dosing instructions	O3
	Other dose problem	O0
Compliance (Problems relating to the way the consumer takes the medication)	Under-use by consumer	C1
	Over-use by consumer	C2
	Erratic use of medication	C3
	Intentional drug misuse (incl. non-prescription medicines)	C4
	Difficulty using dosage form	C5
	Other compliance problem	C0
Undertreated (Problems relating to actual or potential conditions that require management or prevention)	Condition undertreated	U1
	Condition untreated	U2
	Preventive therapy required	U3
	Other untreated indication problem	U0
Monitoring (Problems relating to monitoring the efficacy or adverse effects of a drug)	Laboratory monitoring	M1
	Non-laboratory monitoring	M2
	Other monitoring problem	M0
Education or information (Consumer requests further information about a drug or disease state)	Consumer requests drug information	E1
	Consumer requests disease management advice	E2
	Other education or information problem	E0

Drug Related Problem

Category	Subcategory	Code
Not classifiable (Problems that cannot be classified under another category)	Clinical Interventions that cannot be classified under another category	N0
Toxicity or adverse reaction (Problems relating to the presence of signs or symptoms that may be attributed to a drug)	Toxicity, allergic reaction or adverse effect present	T1

Recommendations

Category	Subcategory	Code
Change of therapy	Dose increase	R1
	Dose decrease	R2
	Drug change	R3
	Drug formulation change	R4
	Drug brand change	R5
	Dose frequency/schedule change	R6
	Prescription not dispensed	R7
	Other changes to therapy	R8
Referral required	Refer to prescriber	R9
	Refer to hospital	R10
	Refer for medication review	R11
	Other referral required	R12
Provision of information	Education or counselling session	R13
	Written summary of medications	R14
	Recommend dose administration aid	R15
	Other written information	R16
Monitoring	Monitoring: Laboratory	R17
	Monitoring: Non-laboratory test	R18
Other	No recommendation necessary	R19

Appendix 8: Guidance for writing clinical notes: SOAP notes

The consumer history (clinical) notes regarding the intervention are important, and should be recorded in a concise but comprehensive manner so they can be accurately interpreted at a later date or by other health professionals (e.g. other pharmacists employed in the pharmacy). A consumer-centred format commonly used for the documentation of clinical notes is SOAP (Subjective, Objective, Assessment and Plan).

S – Subjective. Subjective observations may include a summary statement from the consumer and/or carer regarding descriptions of any symptoms they might be experiencing and their perception of the situation.

O – Objective. Objective observations are based on the perceptions of the pharmacist and signs or symptoms that are actually seen or measured by the pharmacist.

A – Assessment. Assessment of the situation is based on the subjective and objective observations; may include a tentative diagnosis or summation of the issue and identification of DRPs.

P – Plan. The plan for resolving the DRP(s), which forms the basis of the recommendations made by the pharmacist to the consumer or prescriber.

Example

Amoxycillin 125 mg three times daily is prescribed for a 30 kg child. The pharmacist contacts the prescriber, who approves an increase in dose to 225 mg three times daily.

DRP category: Prescribed dose too low (O2)

Recommendation(s): Dose increase (R1); refer to prescriber (R9)

Drugs involved: Amoxycillin

Clinical notes:

S – Consumer presents new prescription for amoxycillin.

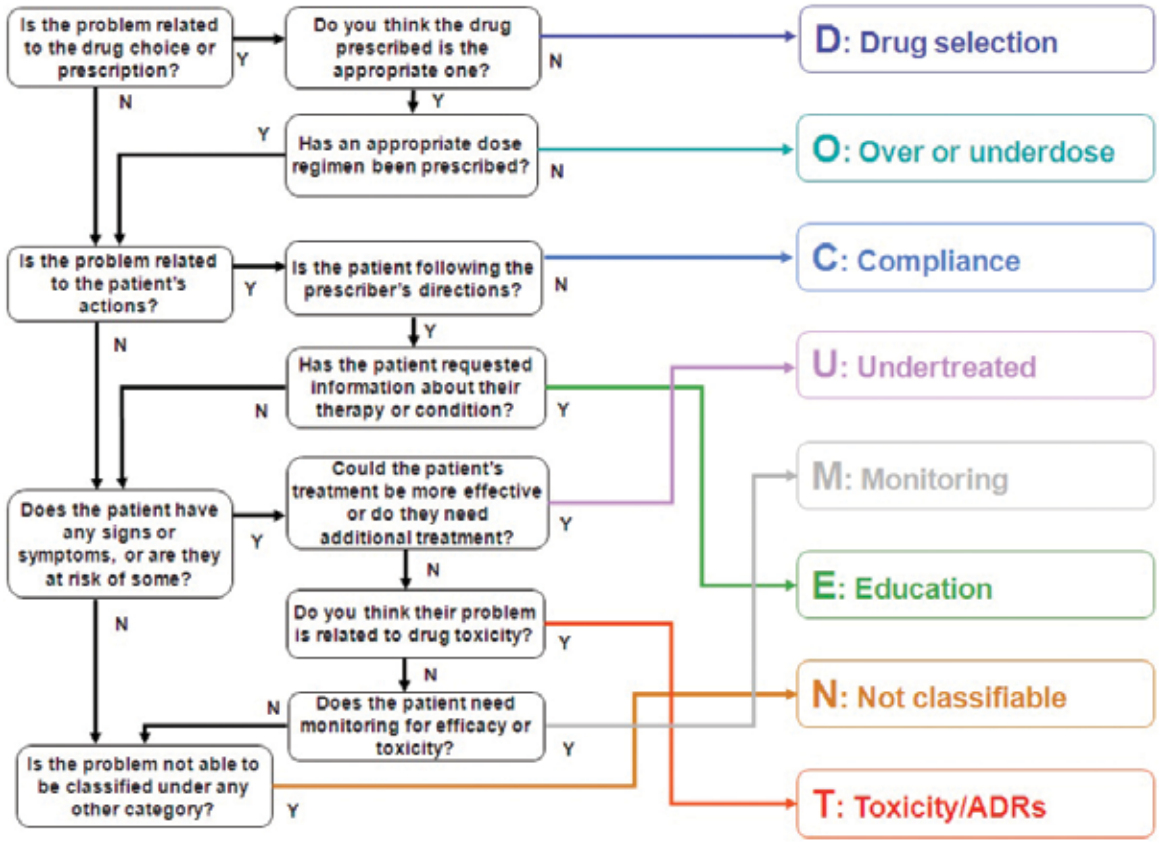
O – Child weighs 30 kg; dose prescribed 125 mg tds

A – Dose prescribed too low (should be 7.5–25 mg/kg tds)

P – Phoned GP and recommended increasing dose to 225 mg tds (accepted by GP)

Appendix 9: DOCUMENT classification flow chart

Modified from Peterson, Tenni et al. 2009[2]



Appendix 10: National Prescribing Service: guide to Australian medicines information resources

From www.nps.org.au/health_professionals/guide_to_medicines_information_resources

Free resources

- *Australian immunisation handbook*. At: www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home
- *Australian Prescriber*. At: www.australianprescriber.com
- *Australian Public Assessment Report (AusPAR) for prescription medicines*. At: www.tga.gov.au/pmeds/auspar.htm
- Clinical Practice Guidelines Portal. At: www.clinicalguidelines.gov.au
- Local drug information centres (refer to locality guides)
- *Medicines Safety Update* (formerly *ADRAC bulletin*). At: www.tga.gov.au/adr/msu.htm
- Medicines.org.au. At: www.medicines.org.au
- NHMRC health guidelines. At: www.nhmrc.gov.au/guidelines/health_guidelines.htm
- *NPS News*. At: www.nps.org.au/health_professionals/publications/nps_news
- NPS prescribing practice reviews. At: www.nps.org.au/health_professionals/publications/prescribing_practice_review
- NPS RADAR. At: www.nps.org.au/health_professionals/publications/nps_radar
- PBAC public summary documents. At: www.health.gov.au/internet/main/publishing.nsf/Content/pbac-outcomes-and-public-summary-documents
- PBS Portal. At: www.pbs.gov.au/pbs/home
- Pharmacy Board of Australia codes and guidelines. At: www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx
- Poisons Information Centre (phone 131 125 from anywhere in Australia, 24 hours a day)
- *Prescribing Medicines in Pregnancy* (TGA). At: www.tga.gov.au/docs/html/medpreg.htm
- RACGP guidelines. At: www.racgp.org.au/guidelines
- TGA safety alerts. At: www.tga.gov.au/safety/index.htm
- The Cochrane Library. At: www.thecochranelibrary.com/view/0/index.html

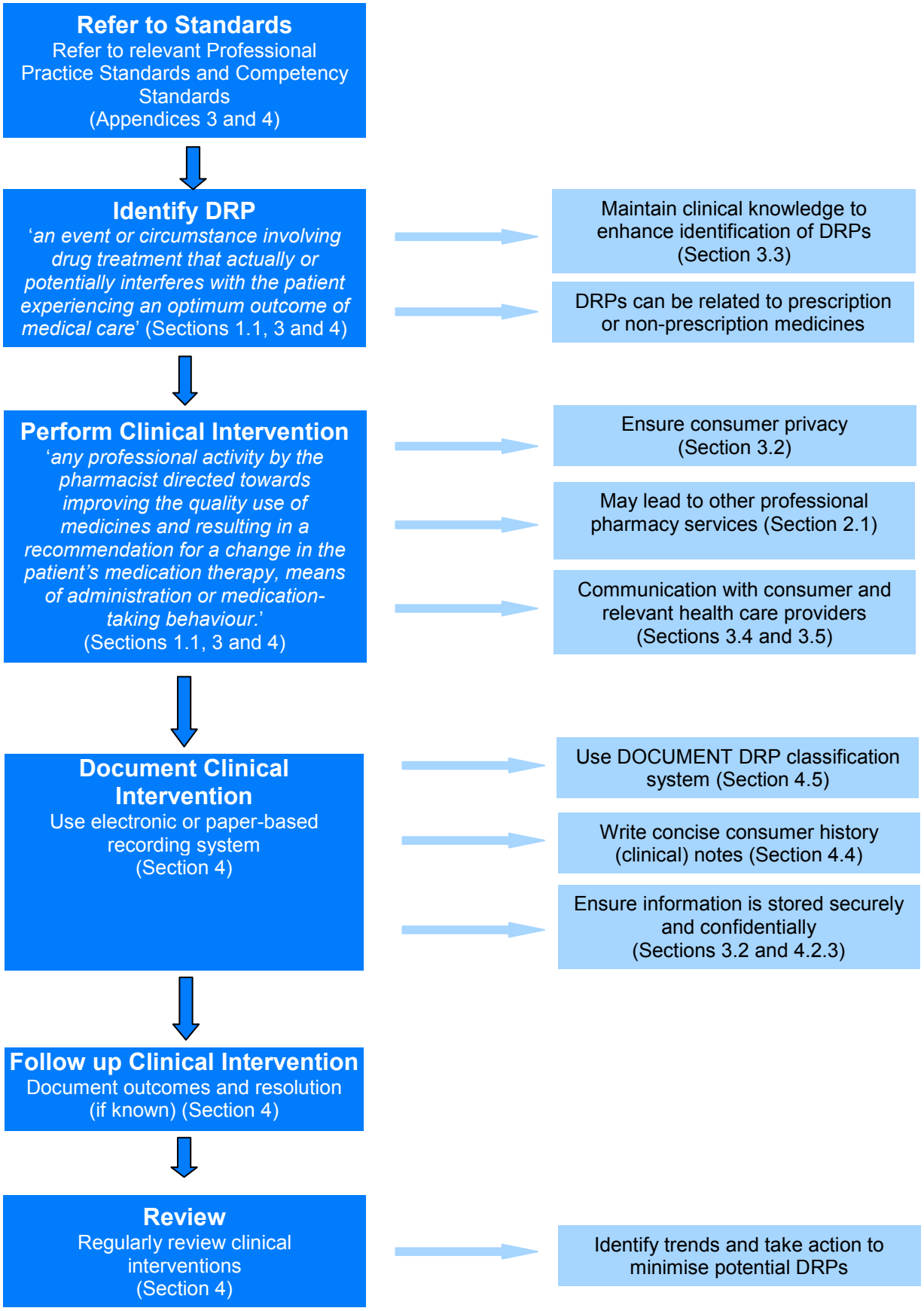
Other resources

- AusDI Advanced
- *Australian Medicines Handbook*
- *Australian Pharmaceutical Formulary and Handbook*
- *British Medical Journal – Clinical Evidence*
- *MIMS*
- *Pregnancy and breastfeeding medicines guide*
- Royal Children's Hospital (Melbourne) *Paediatric Pharmacopoeia*
- Therapeutic guidelines

References

1. Australian Government Department of Health and Ageing. Fifth Community Pharmacy Agreement fact sheet 2010. At: www.health.gov.au/internet/main/publishing.nsf/Content/fifth-community-pharmacy-agreement-copy
2. Peterson GM, Tenni PC, et al. Documenting clinical interventions in community pharmacy: PROMISe III. Pharmacy Guild of Australia; 2009. At: www.guild.org.au/research/4cpa_project_display.asp?id=1874
3. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 1990; 47(3):533–43.
4. Bourgeois FT, Shannon MW, Valim C, Mandl KD. Adverse drug events in the outconsumer setting: an 11-year national analysis. *Pharmacoepidemiol Drug Saf* 2010; 19(9):901–10.
5. Wu TY, Jen MH, Bottle A, Molokhia M, Aylin P, Bell D, *et al*. Ten-year trends in hospital admissions for adverse drug reactions in England 1999–2009. *J R Soc Med* 2010; 103(6):239–50.
6. Roughead EE, Semple SJ. Medication safety in acute care in Australia: where are we now? Part 1: a review of the extent and causes of medication problems 2002–2008. *Aust New Zealand Health Policy* 2009; 6:18.
7. Peterson GM, Tenni PC et al. Evaluation of clinical interventions within community pharmacy (PROMISe II). Pharmacy Guild of Australia; 2007.
8. National Prescribing Service Limited. Medication safety in the community: a review of the literature. National Prescribing Service Limited; Jun 2009. At: www.nps.org.au/__data/assets/pdf_file/0008/71675/09060902_Meds_safety_June_2009.pdf
9. Miller GC, Britt HC, Valenti L. Adverse drug events in general practice consumers in Australia. *Medical Journal of Australia* 2006; 184(7):321–24.
10. Pharmaceutical Society of Australia. Professional Practice Standards, Version 4, 2010. pp. 11–14. At: www.psa.org.au/site.php?id=1089
11. Pharmaceutical Society of Australia. Professional Practice Standards, Version 4, 2010. pp. 20–23. At: www.psa.org.au/site.php?id=1089
12. Pharmaceutical Society of Australia. Professional Practice Standards, Version 4, 2010. pp. 24–27. At: www.psa.org.au/site.php?id=1089
13. Pharmaceutical Society of Australia. Professional Practice Standards, Version 4, 2010. pp. 28–32. At: www.psa.org.au/site.php?id=1089
14. Pharmaceutical Society of Australia. Professional Practice Standards, Version 4, 2010. pp. 44–46. At: www.psa.org.au/site.php?id=1089
15. Pharmacy Guild of Australia. Quality Care Pharmacy Program: Standards. At: www.guild.org.au/qcpp
16. Stowasser DA, Allinson AY, O'Leary KM. Understanding the medicines management pathway. *J Pharm Pract Res* 2004; 34:293–6.
17. Pharmaceutical Society of Australia. Dose Administration Aids Service. Jul. 2007.
18. Pharmaceutical Society of Australia. Consumer Medicine Information and the Pharmacist. Jan 2007.
19. Pharmaceutical Society of Australia. Guidelines for Pharmacists Providing Home Medicines Review (HMR) services. 2010.
20. Pharmaceutical Society of Australia. Guidelines and Standards for the Collaborative and Pharmacist Residential Medication Management Review (RMMR) Program and Associated Quality Use of Medicines (QUM). 2006.
21. Pharmaceutical Society of Australia. Medication Profiling Service. Oct 2007.
22. Pharmaceutical Society of Australia. Professional Practice and the Privacy Act. 2001.
23. Pharmaceutical Society of Australia. Competency Standards for Pharmacists in Australia. 2003.
24. Pharmaceutical Society of Australia. National Competency Standards Framework for Pharmacists in Australia. 2010.
25. Pharmaceutical Society of Australia. Pharmaceutical Society of Australia Code of Professional Conduct. At: www.psa.org.au/site.php?id=628
26. Pharmaceutical Society of Australia. National Competency Standards Framework for Pharmacists in Australia. 2010. pp. 21–31. At: www.psa.org.au/site.php?id=1089
27. Tenni P, Peterson G, Williams M. Abstracts of the PCNE 7th Working Conference: Clinical interventions in Australian community pharmacies. *Pharmacy World & Science* 2009; 31(4):494–508.
28. Krahenbuhl JM, Kremer B, Guignard B, Bugnon O. Practical evaluation of the drug-related problem management process in Swiss community pharmacies. *Pharm World Sci* 2008; 30(6):777–86.
29. Leemans L, Veroeveren L, Bulens J, Hendrickx C, Keyenberg W, Niesten F *et al*. Frequency and trends of interventions of prescriptions in Flemish community pharmacies. *Pharmacy World & Science* 2003; 25(2):65–9.
30. Westerlund T, Almarsdottir AB, Melander A. Drug-related problems and pharmacy interventions in community practice. *International Journal of Pharmacy Practice* 1999; 7(1):40–50.
31. Irvine-Meek J, Ellis H, Grant-Black S, Greenfield R. A study of drug therapy interventions in New Brunswick community pharmacies. *Canadian Pharmaceutical Journal* 1994; 127(9):23–53.
32. Van Mil F, van Heel MCD, Boersma M, Tromp D. Interventions and documentation for drug-related problems in Dutch community pharmacies. *American Journal of Health-System Pharmacy* 2001; 58(15):1428–31.
33. Becker ML, Kallewaard M, Caspers PWJ, Schalekamp T, Stricker BH. Potential determinants of drug–drug interaction associated dispensing in community pharmacies. *Drug Safety* 2005; 28(5):371–8.
34. Malone DC, Abarca J, Hansten PD, Grizzle AJ, Armstrong EP, Van Bergen RC, *et al*. Identification of serious drug–drug interactions: results of the partnership to prevent drug–drug interactions. *Journal of the American Pharmacists Association* 2004; 44(2):142–51.
35. Pharmacy Board of Australia. Guidelines for dispensing of medicines. Undated. At: www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx
36. Pharmaceutical Society of Australia. Professional Practice Standards, Version 4, 2010. At: www.psa.org.au/site.php?id=1089
37. Davis D, Galbraith R. Continuing medical education effect on practice performance: effectiveness of continuing medical education: American College of Chest Physicians Evidence-Based Educational Guidelines. *Chest* 2009; 135(3 Suppl):42S–48S.
38. Davis DA, Thomson MA, Oxman AD, Haynes RB. Evidence for the effectiveness of CME. A review of 50 randomized controlled trials. *JAMA* 1992; 268(9):1111–17.
39. Marinopoulos SS, Dorman T, Ratanawongsa N, Wilson LM, Ashar BH, Magaziner JL, *et al*. Effectiveness of continuing medical education. *Evid Rep Technol Assess (Full Rep)* 2007; 149:1–69.

Clinical interventions summary



Notes

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