

## SHPA Standards of Practice for Hospital Pharmacy Outpatient Services

*These are standards of professional practice and not standards prepared or endorsed by Standards Australia. They are not legally binding.*

### INTRODUCTION

These standards of practice for hospital pharmacy outpatient services supersede the previously published SHPA practice guidelines for outpatient services.<sup>1</sup>

Outpatient services are one aspect of a comprehensive hospital pharmacy service. While the function of medication supply is fundamental, it is important for pharmacists working in outpatients to understand the clinical role (e.g. medication review, optimisation of therapy, education) in this setting. A knowledge of the Medicines Management Pathway, will aid in this understanding (Figure 1).<sup>2</sup> These standards of practice should be read in conjunction with the SHPA Standards of Practice for Clinical Pharmacy.<sup>3</sup>

The SHPA Code of Ethics provides guidance on professional conduct and its principles form the basis of the roles and responsibilities of pharmacists practising in hospitals and related areas.<sup>4</sup> Reference should also be made to the Competency Standards for Pharmacists in Australia as it outlines the fundamental competencies for the provision of quality pharmacy services in all aspects of professional practice.<sup>5</sup> National principles and policies relating to the quality use of medicines should also be consulted.<sup>6,8</sup>

These standards of practice refer to the practice of hospital pharmacy outpatient services. They should be read as general principles and if a conflict exists with individual jurisdiction's legislative and policy requirements the latter should take precedence. Compliance with all legislation and related documents relevant to the management and handling of medicines is required; for example, each jurisdiction's Medical, Nursing and Pharmacy Act and Board guidelines.

The term medicine is used to include all chemical substances given with the intention of preventing, diagnosing, curing, controlling or alleviating disease or otherwise enhancing the physical or mental welfare of people. Includes prescription and non-prescription medicines, including complementary healthcare products, irrespective of the administered route.<sup>7</sup>

### OBJECTIVES

Outpatient pharmacy services provide optimal pharmaceutical care through the provision of medicines to patients in an accurate and timely manner. This includes reviewing all medicine orders, assisting clinicians where necessary with therapeutic and logistical prescribing decisions, effective counselling on all

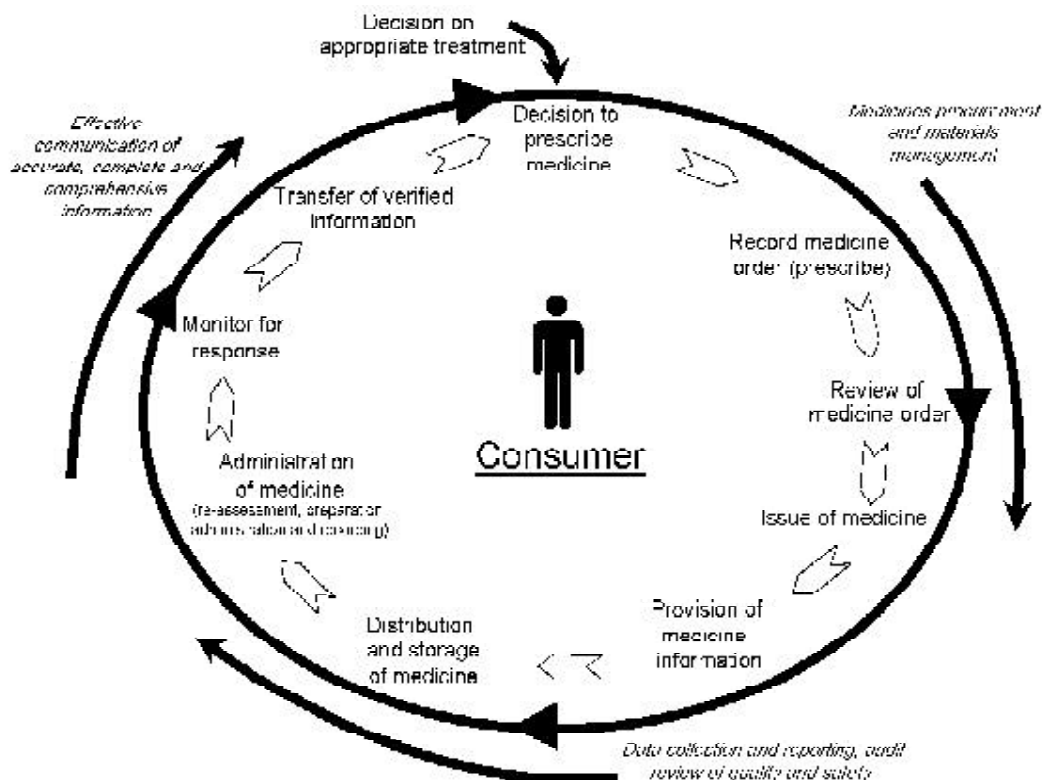


Figure 1. Overview of the medicines management pathway cycle (reproduced from J Pharm Pract Res 2004; 34: 294.)

Authors: Nicolette Burrridge, Alice Chow, Andrew Cording.  
Address for correspondence: Nicolette Burrridge, Project Pharmacist, SHPA, Suite 3, 65 Oxford Street, Collingwood Vic. 3066, Australia  
E-mail: nburridge@shpa.org.au

prescription and non-prescription medicine use, and communication with patients or carers and other healthcare providers regarding matters which will optimise current therapy.

These standards outline the minimum requirements for the

provision of outpatient pharmacy services:

- review all medicine orders, new or repeat, for legality and clinical appropriateness to ensure that therapy is safe, rational and cost-effective before dispensing;
- identify and resolve medicine-related problems with the prescriber before processing the medication order;
- accurately dispense and label medicines, in adequate packaging, to ensure safe and appropriate use according to legal requirements;
- dispense medication in line with local formulary and/or Pharmaceutical Benefits Scheme requirements;
- counsel or offer to counsel all patients or carers to ensure that the patient understands all information required for the safe and proper use of the medicine;
- provide consumer medicines information where appropriate to reinforce oral communications;
- ensure methods for payment have been arranged;
- maintain medication history and relevant records;
- interface with community practitioners, such as general practitioners and pharmacists, to ensure continuity of care;<sup>7</sup> and
- where the dispensary is in a tertiary hospital, ensure that appropriate levels of education are given to medical and nursing staff where required.

## **EXTENT AND OPERATION**

Pharmacy outpatient services are provided to outpatient clinics, emergency departments, and primary care clinics. In some settings, an outpatient pharmacy service will discharge patients and provide primary health care and over-the-counter medicines to hospital staff. Pharmacy outpatient services should be available whenever outpatient clinics are operating. Emergency departments should have access to medicines for patients to take home outside pharmacy hours.

Outpatient services should issue sufficient supply of medicines to the patient until their next appointment. If this is not possible, an explanation for ongoing access to medicines should be provided, for example, repeat prescription, local general practitioner or community pharmacy.

## **POLICIES AND PROCEDURES**

### **Medicines Procurement and Materials Management**

#### *Hospital Formulary and Policy*

The pharmacist in charge of outpatient pharmacy services should be actively involved in establishing a hospital formulary and related policies. Hospital formularies and policies should be maintained and followed. A process should exist to obtain non-formulary medicines when necessary.

A policies and procedures manual which governs the scope of outpatient pharmacy services should be available and properly maintained. All personnel should be familiar with the contents of the manual and comply with the policies and procedures.

#### *Procurement*

Policies for the procurement of medicines must include:

- efficient and prompt systems for ordering and maintaining adequate supplies of medicines;
- regular review of stock and quantities held;
- expiry date monitoring;
- records of usage for individual medicines and groups of medicines;
- regular and routine stock takes;
- appropriate rotation of stock; and
- recall procedures, and when the recall is to the patients' level, a process for notifying patients who have received recalled medicines and for replacing their supplies.

#### *Storage*

Appropriate storage conditions (e.g. temperature monitored refrigeration, freezing facilities) must be available.

#### **Issue of Medicine**

Dispensing should be carried out in accordance with the PSA Dispensing Practice Guidelines and all relevant legislative requirements.<sup>9</sup>

#### *Labels*

Labels should be computer generated and must comply with applicable state and other regulatory requirements. Labels must be clearly printed and legible and include: the name of the patient; date of dispensing; the name, address, and telephone number of the pharmacy; directions for the correct use of the medication; the generic and brand name, strength and form of the medication; name of the prescriber; and the expiry date and or, directions for storage of the medicines where appropriate; and any other information that may be required by state regulation.

Appropriate cautionary and advisory labels must be applied to medicine containers where applicable (according to *Australian Pharmaceutical Formulary* recommendations) and used as an aid when counselling patients.

Labels should be placed on containers of dispensed medicines in such a way as to leave visible all relevant information contained on the manufacturer's label which may be of importance to the patient, e.g. batch number, expiry date, preservative. Use of scanner technology may require that the medicine barcode is left unobscured. Where more than one container is required each immediate container should be labelled.

Use of extra labels printed in languages other than English may need to be considered in areas where there is a concentration of patients with a non-English speaking background.

#### *Pharmaceutical Benefits Scheme*

Where the Pharmaceutical Benefits Scheme is used to provide supply of medicine to outpatients, all requirements of the scheme should be followed. All staff must remain up to date with the Pharmaceutical Benefits Scheme Schedule (yellow book or web site) and be appropriately trained and competent in using the relevant hardware and software to administer this scheme.

#### *Scanner*

Barcode scanners can aid in the detection of the incorrect selection of medicines and are required to be used as part of the dispensing procedures in some states. Effective use of barcode scanners requires the dispensed product to be scanned towards the end of the dispensing process just prior to supply to the patient. The use of scanner technology is encouraged where its use is not required by legislation

#### *Clinical Trials Medicines*

Accurate accountability records of all clinical trial medicines should be maintained as per the SHPA Standards of Practice for Pharmacy Investigational Drugs Services.<sup>11</sup> Clinical trial medicines should be kept in a secure place under suitable storage conditions and distributed only by authorised personnel. If a separate area and staffing is used for clinical trial medicines there should be adequate liaison between services to provide optimal patient services.

#### *Narcotic Drugs*

Proper security and auditing processes must be in place in the

outpatient services to ensure that all regulatory and legal requirements are adhered to. This may also require contact with the patient's community medical and pharmacy practitioners.

#### *Special Access Scheme*

The Special Access Scheme (SAS) allows individual patients to access unapproved therapeutic medicines.<sup>12</sup> Pharmacists should be familiar with the conditions and their institution's policy for the use of SAS medicines. Procedures and adequate staff must be in place to deal with SAS medicine requests and their follow-up. Refer also to the SHPA Standards of Practice for Pharmacy Investigational Drugs Services.<sup>11</sup>

Procedures should be documented for the completion of SAS Category A or B forms by a doctor responsible for the care of the patient prior to the order and/or dispensing of the SAS medicines. The institution may also require internal approval, consent to treatment, and indemnity for use of products derived from biological tissues, including human blood or plasma (if appropriate).

#### **Accurate Medication History**

An accurate medication history should be taken and regularly updated by the pharmacist to include details of where appropriate:

- name (age and weight where relevant);
- unit medical record number;
- allergies and adverse drug reactions;
- disease state;
- current medication including over-the-counter and non-prescription items;
- where possible, reference to results of relevant clinical investigations should be consulted;
- any information relevant to the patient's medicines should become a part of the patient profile, e.g. therapeutic drug monitoring, biochemistry results;
- if access to a patient's record is not available by computer, the hard copy should be readily accessible by pharmacists;
- use of computers should enable simultaneous updating of patient profiles; and
- development of patient medication lists that can be printed and given to patients (or carers, other pharmacies, medical staff) should be encouraged.

A Medication Action Plan may be developed in the outpatient clinic or in the ward. The outpatient pharmacist should have access to and be involved in the continuing development of these plans.

#### **Provision of Medicines Information to Consumers**

All patients (or carers) should be counselled by a pharmacist. The pharmacist must ensure that the patient understands all information required for the safe and proper use of the medicines and devices, as applicable. A designated area for counselling should be available to ensure privacy during communication with a patient. A pharmacist must ensure that counselling is given or offered to the following groups of patients:

- patients with new medicines;
- patients with acute illness;
- patients on drugs with a narrow therapeutic range, patients on multiple drug regimens or with multiple chronic disease states;
- elderly patients;
- psychiatric patients;
- carers for paediatric patients;
- patients with a history of poor compliance;
- patients from a non-English speaking background;

- patients on a harm minimisation program (e.g. methadone); and
- patients on drugs which may affect driving or ability to operate machinery.

Consumer medicine information leaflets and aids to compliance should be used when appropriate.<sup>9,10</sup> Access to interpreter services, either within the hospital or external services, should be available.

#### **Information for Ongoing Care**

Follow-up of some patients may be necessary, e.g. patients who:

- have blood taken to determine a drug level;
- have had microbiology tests undertaken;
- have had relevant biochemistry tests;
- have questionable compliance; and
- are elderly and whose medicines or dosage has changed.

Follow-up may be by telephone, home visit or liaison with community pharmacists, community nurses, other health professionals and/or general practitioners.

#### **Distribution of Medicines**

##### *Services to Other Healthcare Facilities*

Base hospitals may offer an outreach service to smaller sites without a pharmacist. Many smaller hospitals/clinics provide medication via an outpatient clinic where dispensing is provided by other authorised providers, e.g. endorsed rural nurse. Base hospitals should conduct regular visits to these hospitals to provide:

- an assessment of services;
- training of nursing staff;
- review of stock held including levels, expiry date, rotation of stock and conditions; and
- review of records.

##### *Dispensing at a Distance*

The routine provision of prescribed medicines by a delivery service including mail order is discouraged. If such service is provided, procedures must be put in place to ensure the compliance of all legislation, adherence to guidelines for good dispensing practice and requirement for the supply of dispensed medicines set by Medicare Australia.

The supply of dispensed medicines by mail must comply with postal requirements, including use of appropriate and secure packaging, and the prohibition of certain types of products, such as flammable or cytotoxic substances. The package should not be labelled to indicate that it may contain scheduled drugs. A procedure should be in place for investigating, replacing, and reporting, as required, any medications lost during delivery.

#### **RESOURCES**

The design and location of any outpatient pharmacy department will affect the quality and the efficiency of the service and the potential for future development (Appendix). Occupational Health Safety and Welfare Acts in each state require the employer, so far as it is reasonably practicable, to provide and maintain a safe working environment in which employees are not exposed to hazards. These requirements include attention to the following:

- safe ergonomic practice with regard to seating arrangements and time spent at visual display units;
- staff standing for long periods of time;
- bending, lifting and reaching;
- security of staff counselling patients must be considered;
- hazards of stock or equipment blocking exits or aisles;
- fire and security knowledge;
- hazardous chemical storage and handling;

- noise, including continuous low level noise; and
  - appropriate and adequate lighting.
- Access to current editions of standard pharmacy references such as the *Australian Pharmaceutical Formulary*, *Australian Medicines Handbook*, Therapeutic Guidelines series and a compendium of available medicines such as *MIMS Annual* together with bimonthly addenda or *MIMS CD* or *APPGuide* is essential. This may be either via electronic means or hard copy.

### STAFFING LEVELS

Adequate staffing levels, with appropriate levels of seniority, should be available so that:

- services are provided without undue delay (not more than 60 minutes);
- initial receipt and review of prescriptions is carried out by an experienced pharmacist;
- all patients receive adequate counselling and education by a pharmacist;
- dispensing and checking process is free from other distractions, e.g. telephones, patient collection area; and
- there is sufficient time and resources for other outpatient and management-related activities, e.g. responding to drug information queries, maintenance of patient medication profiles, inventory control, participation in outpatient clinics, coordination of and participation in clinical drug trials, Pharmaceutical Benefits Scheme claim processing, liaison with and education of doctors, nurses, other health professionals and pharmacy staff.

Staffing should be arranged to meet patient care needs. Workload should be monitored and evaluated on an ongoing basis. A systematic plan should be established for adjusting the mix and number of pharmacists and pharmacy technicians. Most recommendations indicate pharmacists should not be required to dispense more than 16 to 20 prescription items per hour.<sup>13-15</sup> Skills and knowledge necessary for staff in outpatient services must include:

- excellent communication and counselling skills;
- dispensing skills and knowledge necessary to provide prompt and accurate service;
- up-to-date clinical knowledge and the ability to compare, analyse and interpret health and medicines information;
- ability to use available information to ensure optimal therapy; and
- relief staff must have experience or be trained in the necessary skills.

Appropriately trained technical or support staff should be available to assist in the dispensing process but a pharmacist must review the initial prescription against the patient's medication history and counsel the patient about their medication. The ratio of pharmacists to pharmacy technicians must not exceed the level currently acceptable to the registering authority of the state in which the pharmacy is situated. Where no registering guidelines exist, a ratio of two pharmacy technicians to one pharmacist should not be exceeded.<sup>16</sup> Duties that may be performed by technical or support staff are outlined in Table 1.

Periodic evaluations for performance should take place for pharmacy personnel. All personnel should be evaluated on their demonstrated competence in meeting the criteria on each component of the job description.

### TRAINING AND EDUCATION

All new personnel must be orientated to their position responsibilities, the pharmacy and organisation policies and procedures. Training should be competency based. To enable pharmacists to maintain up-to-date and useful knowledge it is

**Table 1. Role of pharmacy technicians**

Suitably trained and supervised pharmacy technicians can assist the outpatient pharmacist. They should be familiar with the SHPA Code of Ethics and with relevant privacy legislation. Pharmacy technician training may require recognition by the regulatory authority.

Roles suitable for pharmacy technicians include:

- perform routine maintenance procedures on computer
- assist in dispensary stock control including stocktake, order, unpack and put away of stock
- check expiry dates and rotate stock
- pre-pack stock
- assist in dispensary administration in the dispensing process including: label preparation, gathering consumer medicine information leaflets, gathering medication, affixing labels to medication, and gather non-clinical information.

Roles not suitable for pharmacy technicians include:

- performing medication history review;
- interviewing patient/carer to obtain medication history or to determine allergies;
- checking the medicine order is written in accordance with legal and local requirements;
- ensuring appropriateness of medicine order;
- counselling patients and providing consumer medicine information leaflets to patients;
- investigating medicine related problems; and
- providing drug information.

essential that all pharmacists should be encouraged to participate in continuing professional development programs. This can be in many forms including:

- formal postgraduate studies;
- in-house clinical meetings;
- regular outpatient departmental meetings;
- journal review;
- hospital medical presentations; and
- seminar and conference attendance.

Pharmacy dispensary technicians should preferably complete an accredited training program and possess the training necessary to fulfil their responsibilities. Hospital pharmacy departments should have a training and assessment program in place to orientate, train, assess, mentor and educate pharmacy technicians working in outpatient pharmacy settings.

### RESEARCH

Pharmacists practising in the outpatient pharmacy department settings should support, initiate and participate in research projects whenever possible. Pharmacists involved in research activities should adhere to the principles and procedures outlined in the Declaration of Helsinki, the Therapeutic Goods Administration 'Note for Guidance on Good Clinical Research Practice in Australia', relevant SHPA guidelines and those of individual institutional research and ethics committees.<sup>11,17-19</sup> Funding to support research can be obtained from direct operational sources or through application and submission to various professional organisations.

### QUALITY

A quality assurance program for the provision of services to outpatients must be developed and maintained. The SHPA Standards of Practice for Clinical Pharmacy provide measures of quality performance for clinical activities.<sup>2</sup> In addition the following performance indicators may also be considered.

### Medication Errors

There should be an ongoing program to minimise dispensing errors and near-miss errors, including reporting, analysis, monitoring and implementing corrective actions. Medication

error rates, reported and those uncovered during periodic observer studies, should be measured.

### Data Collection and Reporting

Some examples of data that may be collected and reported for audit review of quality and safety are:

- number of products standardised on hospital formulary (reduction in range of products held on inventory within a pharmacological group);
- non-formulary medicine use;
- in tertiary hospitals the pharmacy may be involved in doctor training and therefore regular assessment of junior medical officer prescribing is important for their development and that of future education programs;
- percentage of patients attending the pharmacy who wait longer than the agreed acceptable time;
- incidence of omitted medications due to unavailability;
- percentage of prescriptions prepared by support personnel;
- patient satisfaction surveys; and
- doctor and nursing views of outpatient service provided.

### DOCUMENTATION

All documentation that is legally required must be maintained. The SHPA Standards of Practice for Clinical Pharmacy and relevant guidelines should be consulted.<sup>3,6,20</sup> Documentation should include:

- accurate medication history as detailed under Policies and Procedures;
- adverse drug reaction management;
- clinical pharmacy interventions;
- therapeutic drug monitoring;
- provision of medicines information to health professionals;
- orientation procedures;
- provision of consumer medicines information to patients or carers;
- comprehensive policy and procedure manuals for pharmacist staff and technical staff;
- where appropriate, procedures for obtaining approvals for non-formulary medications;
- Medicare Australia claims;
- Section 100 and SAS forms;
- efficient retrieval system to locate copies of previously dispensed prescriptions; and
- record of orientation, training and competency assessments of pharmacists and dispensary technicians.

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### Appendix. Outpatient layout and resources

#### Location

- ease of patient access
- ease of stock delivery
- adequate space allowed for all functions
- appropriate signage
- close proximity to clinics

#### Security

- maintain staff safety while still allowing effective patient counselling to occur
- glass barrier or other protective devices should be available
- easy access of alert to a designated system in the event of a breach of security
- a 24-hour monitoring intrusion alarm system must be installed

#### Layout

- consider workflow movements including review of prescriptions and direct supervision of pharmacy technicians
- location of dispensing and checking area should provide minimal interruptions
- an area should be set aside for preparation of extemporaneous products where necessary
- the environment must be conducive to the comfort and safety of both the patient and pharmacist
- an area should be set aside for counselling without any distraction
- storage space must be adequate and readily accessible, particularly for high usage stock items

#### Equipment

- bench space must be adequate for safe dispensing
- all equipment must be accurate and maintained in a clean manner so as to prevent contamination
- separate equipment must be available for the dispensing of oral cytotoxic drugs
- an accurate record should be kept of the location of equipment
- equipment should be maintained according to manufacturers' specifications
- conditions of temperature, humidity and light suitable for the storage of all medications must be maintained
- facilities must be adequate to meet all legal and good manufacturing practice requirements as required by the Therapeutic Goods Administration
- an appropriate library should be maintained and include texts required by law
- other drug information resources should be readily accessible
- telephones should be connected to allow ease of access; the number should not be sufficient to remove all staff from the dispensing process
- appropriate computer and printer equipment