Pathology AUSTRALIA

Guidelines for establishing on-site pathology collection centres for pharmacists

Introduction

Pathology Australia (PA) has been asked to provide advice relating to Approved Pathology Collection Centres (ACCs) located within pharmacies.

The purpose of the brochure is to provide Pharmacists with a guide relating to the issues they need to consider in the process of agreeing to establish a Collection Centre located within a pharmacy.
The information provided in this brochure relates to:

1. Standards for Establishing Collection Centres
2. Shared Staff Arrangements.

Please note the advice provided cannot and should not be construed as legal advice. It is intended as a guide only. Pharmacists are strongly encouraged to seek their own legal advice before entering any arrangements with pathology providers.

In addition to the information contained within this brochure, more information is available from PA. Pharmacists are encouraged to contact the authority responsible for registering pharmacy premises in their state when establishing a collection centre in their pharmacy.

Pharmacists should be aware pathology providers are bound by regulations relating to establishing and operating collection centres. Collection centres need to meet the standards to be accredited so that specimens collected in the centre are eligible for Medicare Benefits Schedule rebates.

Whilst in the main the standards apply to pathology providers, pharmacists need to be aware of the standards as they will significantly impact upon the pharmacists store layout and design. In addition, with regard to pharmacy staff undertaking pathology specimen collection duties, pharmacists must be aware of the standards applicable to those duties such as dealing with medical emergencies, performance reviews and ongoing training.

The following information has been summarised from the National Pathology Accreditation Advisory Council, (NPAAC) standards. All pathology providers must ensure that these standards are adhered to in all of their collection facilities. The standards are grouped into the areas listed below

Premises

- Staffing
- Equipment
- Documentation and Instruction
- Collection Procedures
- Safety
- Transport and Storage

There are a number of applicable standards relating to the collection premises. Premises must comply with all applicable laws and regulations.

The size and location of collection areas must be appropriate for purpose and there should be reasonable access provided for ill and dis- abled patients, including wheelchair access. Hours of operation should be displayed.

There must be appropriately designated areas for reception, waiting and collection, which must not compromise patient privacy and confidentiality of information. These areas do not have to be separate rooms.

Unauthorised persons must not enter collection rooms and there should be provision to accommodate carers as required.

Ventilation, lighting, plumbing, communication systems and temperature control must be adequate and appropriate for the safe and comfortable functioning of the collection premises.

Appropriate hand-washing facilities must be conveniently available to collection staff and adequate toilet facilities must be available for patients, staff and accompanying persons in, or conveniently adjacent to, the collection centre.

Additionally, toilet doors should be lockable from the inside and unlockable from the outside in case of an emergency. The doors should be removable or open outward for access.

Easily cleanable surfaces must be available for clerical work, specimen collection and specimen handling. Suitable tables and a secure storage area for supplies must be available and accessible to staff only.

Finally, there must be easily cleaned floor coverings appropriate to the use of that area. For example, floor coverings in the immediate collection and storage areas must have a non-porous surface.

Staffing

Staff numbers must be appropriate to the throughput of the centre. Appropriate identification must be worn by all staff displaying a first or last name and an organisation name as a minimum.

Appropriate attire must be worn by staff. Attire should be in accordance with the pathology provider's policies.

Continuing education and training and ongoing performance reviews must be relevant to the job being performed and relevant standard (AS ISO 151892).

Staff must be aware of existing policies regarding privacy, confidentiality and informed consent and comply with the policies. The specimen must be collected in accordance with these policies also.

Staff must be trained to ensure knowledge of basic first aid to deal with situations likely to be encountered in the course of collection. Evidence of such training should be documented for each trained staff member.

Equipment

It is essential to provide and maintain all equipment listed below (materials must not be used past their expiry date):

- a suitable collection chair and couch for patients
- materials required for adequate specimen collection
- basic first aid equipment
- approved receptacles for sharps and for contaminated waste
- materials required for management of biohazard spills.

Appropriate resuscitation equipment must also be available for use by trained personnel when complicated procedures are performed, for example, the injection or infusion of any substance.

There must also be dedicated specimen storage areas, including suit- able, securely-placed refrigerators and appropriate, secure, room temperature storage. Specimens must not be stored with food, drink or pharmaceuticals and should be stored for the least possible time prior to transport.

If a centrifuge is required, it must be compliant with AS/NZS 2243.33. Maintenance and service records for centrifuges must be available on request, including a report of an annual check.

Some collection centres perform more than just collections. All equipment used for other procedures, for example ECG, must comply with the appropriate standards.

Documentation and Instruction

Collection instructions must be available for all procedures including those where patients collect their own specimens. Manuals can be in electronic form or hard copy and should conform to AS ISO 151892.

Documented procedures for handling emergencies must be under- stood and available for immediate reference and a protocol for management of biohazard exposure, including spills, must also be avail- able.

In addition, maximum allowable storage time should be specified in the collection instruction manual.

Collection Procedures

The collection centre must have written procedures for the identification of patients and labelling of specimens.

Prior to collection, the patient must be informed of the procedure about to take place. Patient comfort and safety with the full procedure should be assured.

Collection procedures must be in accordance with the laboratory's procedures manual.

For blood collection, specimens must be labelled immediately following collection while still in the presence of the patient. The patient should be asked to confirm that the name on the label is correct.

Patients must be instructed on post-procedure care in accordance with the laboratory's instruction manual.

Safety

The collection centre must conform to OH&S legislative requirements. Further safety requirements are summarised in the four key points below:

- minimisation of infection risk should be clearly demonstrated
- collection centre staff must use personal protective equipment where appropriate
- APAs must have a vaccination policy
- transport and disposal of waste must be carried out in accordance with laboratory policy and applicable regulatory requirements.

Transport and Storage

Collection centres must comply with the current NPAAC requirements for transport and storage. Further information can be found in the *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials*).

If specimens are to be retained within the collection centre, safety, specimen stability and security requirements must be addressed and appropriately documented. The security procedures specified must ensure that the specimens are not accessible to members of the public.

Shared Staff Arrangements

Shared staff arrangements relate to the delineation of employment between the pharmacist employer and the pathology provider employer when the pharmacy employee undertakes collection duties.

There are potential risks for pharmacists when entering into an arrangement relating to the staffing of ACC's.

The Health Insurance Act requires staff who collect pathology specimens for testing to be employed by the pathology provider. A risk for the pharmacist employer exists if it is determined there is no legally recognised employment relationship between the pathology provider and the person collecting the specimen.

As a logistical and practical matter, it may be difficult to legally deter- mine when an individual ceases to be an employee providing services to one employer and commences providing services to another.

From the point of view of the pharmacist, if there is uncertainty as to who the employer is there will be considerable risk exposure and potential liability for the pharmacist.

It is our understanding that some of the proposed arrangements mean the pharmacist will encourage its own staff to become collectors. In addition the pharmacist will choose the staff and determine the availability of staff to provide collection services. If that is so, the pharmacist may be perceived as being involved in the pathology provider's business and bring into question who the actual employer of the collection staff is.

The issue is whether, in these circumstances, there is a transfer of employment from the pharmacist to the pathology provider when the pharmacy employee is engaged with pathology patients.

Additionally, if the pharmacist holds directive control over the daily activities and the timing of leave of an employee and the pharmacist is also responsible for ensuring that key pathology performance

measures are met, the pharmacist may be perceived as being the employer for all of the activities, both pharmacy and pathology duties, under- taken by that particular staff member.

Despite the fact that the collectors are employed by the pathology provider, there is a risk that the collector might claim he or she is employed by the pharmacist. This will further confuse the issue as to who, for practical purposes, is the employer.

There may be issues relating to termination of employment, occupational health and safety and workers' compensation matters. The pharmacist may find him/herself in a position of inadequate protection with regard to potential liability.

If it is determined that there is no employee/employer relationship between the pathology provider and the employee who would other- wise be engaged by the pharmacist, the services provided by the pathology provider are ineligible for benefit payments made by Medicare Australia. Whilst this is an issue for pathology providers, pharmacists should be aware of it as it may well effect the financial viability of the ACC lease.

Bibliography

1. Health Insurance Act 1973, Commonwealth of Australia, Australian Government, Canberra, viewed 21 November 2008,

   http://www.comlaw.gov.au

2. AS ISO 15189 – 2009 Medical Laboratories - Particular Requirements for Quality and Competence, Standards Australia

3. AS/NZS 2243.3:2002/Amdt 1:2003 – Safety in laboratories - Microbiological aspects and containment facilities, SAI Global

4. NPAAC (2007), Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials, Commonwealth of Australia, Australian Government Department of Health and Ageing, Canberra

   http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-PackTransPathSpecimens.htm