The Pharmacy Guild of Australia

POLICY

Health Screening and Condition Management in Community Pharmacy

Position

The Pharmacy Guild of Australia (the Guild) believes that health screening and condition management through community pharmacies can facilitate early diagnosis and intervention, enhance the monitoring of chronic conditions, improve therapeutic control and Quality Use of Medicines (QUM), and improve patient self-management. This will contribute to better health outcomes and quality of life for patients.

Community pharmacy is ideally placed to assist in the screening for conditions including, but not limited to, cardiovascular disease (CVD), asthma, chronic obstructive pulmonary disease (COPD), diabetes, sleep apnoea and transmissible diseases including chlamydia, respiratory borne diseases such as influenza and SARS CoV2 (COVID) and blood borne diseases such as human immunodeficiency virus (HIV) and hepatitis C.

Community pharmacy is also the optimal environment to provide patient education and support in the ongoing self-management of diagnosed conditions that can be assisted by the monitoring of health markers such as blood pressure, blood lipids, blood glucose/HbA1c, lung function and International Normalised Ratio (INR) for anticoagulant therapy.

The Guild supports the use of point of care testing (PoCT) technologies, including in-vitro diagnostic (IVD) medical devices, to enhance health screening and condition management within a community pharmacy setting. Having been available for many years in Australia in the tertiary health setting and increasingly within general practice[1], PoC Testing technology offers patients convenient access to fast, reliable and evidence-based testing.

The Guild believes that community pharmacy should only utilise, or supply to the patient for home use, products that have been approved as an in-vitro diagnostic (IVD) medical device by the Therapeutic Goods Administration, assuring that such a device is appropriate, accurate, reliable and included in the Australian Register of Therapeutic Goods (ARTG) as a basis for legal supply.[2]

The Guild also believes that the preferred outlet for IVD medical devices for use in the community setting should be able to provide the opportunity for counselling with a health professional, such as a community pharmacist. Community pharmacies or other health centres should be the primary outlet for such devices in preference to internet supply and the Guild does not believe such devices should be supplied from a non-health retail outlet such as grocery stores or service stations.

The Guild supports the availability of genetic testing kits within community pharmacy for home use or assessment by a pharmacist or external specialist if the testing kits are quality assured and listed on the ARTG or registered with the relevant authority. In addition, the Guild highlights the importance of appropriate training for pharmacy staff or the availability of a health professional with expertise in the area to reinforce the application of the testing and pre and post-test counselling.

[1] St John. A (2010) 'The Evidence to Support Point of Care Testing' Clin Biochem Rev Vol.31(3):111-119 [accessed online 27 September 2012]

[2] Therapeutic Goods Administration 'Overview of the regulatory framework for in-vitro diagnostic medical devices' (July 2011)

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The Guild believes that with the correct infection control and cold chain processes in place, community pharmacy could be utilised as a drop-off point for specimens intended for laboratory-based analysis. The use of community pharmacy as a site for venepuncture utilising suitably qualified providers should also be considered. This may be of particular use in rural and remote areas and other under-serviced communities where access to services is impeding patient health.

Service models and considerations

There are several models of providing these services within a community pharmacy setting, and the Guild believes that each allow convenient access to healthcare, including to underserviced communities:

- screening/monitoring functions performed by the pharmacist or appropriately trained staff (for example, blood pressure, INR monitoring, lung function, HbA1c or point-of-care testing) for assessment by a pharmacist or external specialist;
- contracted health professionals perform the screening/monitoring functions in the pharmacy (for example bone density testing and venepuncture);
- the supply of a test from the pharmacy for patient self-screening with assessment via external professional arrangements (for example bowel cancel screening).
- the supply of a test or monitoring device from the pharmacy for patient self-screening/monitoring and assessment (for example HIV self-test kits, blood glucose and blood pressure monitors); and
- genetic testing (for example personalised health or pharmacogenomic tests) for self-use or assessment by a pharmacist or external specialist.

The Guild believes that any health screening or condition management service offered through community pharmacy should be within scope of practice, evidence-based, and focused on an improved outcome for the patient. It is important to clearly explain to the patient the difference between an indicative **screening test** (which requires further testing or advice) and a **diagnostic test** (which confirms whether the disease is present).

The Guild recommends that during the development of health screening or condition management professional services, consideration should be given to:

- access to a health professional to ensure that the patient is able to address any results that may be of concern, including appropriate referral pathways;
- the use of data collection and information management software, and the privacy consideration of patient data;
- clinical governance and quality management, including implementation of standard processes and evaluation frameworks;
- obligations for recording and documenting provisions of service;
- the availability of and requirements for an appropriate consultation/testing area;
- the importance of appropriate training of staff involved in each service;
- ensuring equipment used is evidence-based and meets regulatory requirements;
- appropriate waste disposal of testing consumables;
- infection control procedures;
- researching and identifying local service gaps and level of patient demand; and
- pharmacist counselling and ongoing patient support.

Background

The benefits of community pharmacy-based health screening and condition management include earlier disease detection, improved health outcomes for patients and potential financial savings for the health system. These benefits have strong evidence supported by research, which has found community pharmacy screening to be highly effective in detecting and referring individuals at risk of chronic disease, and that this model of care was highly cost effective.[3]

Community pharmacies are often the first point of contact for patients and are therefore well placed to assist in identifying possible risk of disease through robust screening services, provide appropriate health education, assist in the monitoring and management of disease and improve QUM. The delivery of such professional services is addressed within the Quality Care Pharmacy Program (QCPP)[4].

Recent years have highlighted many communities around Australia are underserviced with reduced or delayed access to health services[5]. People in regional, rural and remote areas have a higher incidence of health risk factors, a greater prevalence of chronic conditions and a greater burden of disease.[6] People living in rural and remote areas face barriers to accessing health care, due to challenges of geographic spread, low population density, limited infrastructure, and the higher costs of delivering rural and remote health care.[7] Other groups who would benefit from improved access to health screening and condition management services in community pharmacy include First Nations people as well as people with a disability, culturally and linguistically diverse people and people from lower socioeconomic households.

Point of Care Testing and use of In-vitro diagnostic medical devices (IVDs)

Point of care testing is defined as a test that is performed outside of a laboratory, where healthcare is provided close to or near a patient.[8,9] It is focused on the location where the test happens, rather than the type of test, and includes tests performed in community pharmacy as well as those performed at home.

A number of PoCTs utilise in-vitro diagnostic (IVDs) medical devices, which are defined as any test performed on human samples that provides results at the time of testing, which enables a clinical decision to be made and an action taken that leads to an improved health outcome.[10] As more community pharmacies choose to supply Therapeutic Goods Administration (TGA) approved IVDs for PoC testing or home test use, health screening and condition management for Australian patients is becoming increasingly robust.

Until 1 July 2010, the level of IVD regulation in Australia was limited, where most IVDs were not subject to appropriate regulatory control. The potential for inadequate protection of public and personal health was recognised, and a new regulatory framework commenced on 1 July 2010 that ensures all IVDs will undergo a level of regulatory scrutiny that is commensurate with the risks associated with their use, aligning Australia with international best practice.

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[3] Peterson GM, Fitzmaurice KD, Kruup H, Jackson SL, Rasiah RL. Cardiovascular risk screening program in Australian community pharmacies. Pharm World Sci. 2010 Jun;32(3):373-80. doi: 10.1007/s11096-010-9379-8. Epub 2010 Mar 10. PMID: 20217476.

[4] www.qcpp.com

[5] Patient Experiences in Australia: Summary of Findings, 2020-21 financial year | Australian Bureau of Statistics (abs.gov.au)

[6] https://www.aihw.gov.au/reports/rural-remote-australians/rural-and-remote-health

[7] ibid

[8] Department of Health | Definitions - Point-of-care testing

[9] Point-of-Care Testing - Testing.com

[10] Therapeutic Goods Administration 'Overview of the regulatory framework for in-vitro diagnostic medical devices' (July 2011)

Under the framework IVDs are regulated as a subset of medical devices. *The Therapeutic Goods Regulations (Medical Devices) 2002* has been amended to include IVDs under Part 3, Division 3.2. The legislation incorporates accepted best practice relating to safety, quality and risk management procedures, and provides the flexibility and capacity to regulate new and changing technology and emerging diseases.

Examples of IVDs include HIV self-test kits that have been approved for community pharmacy supply, pregnancy tests, urinalysis sticks, and blood glucose meters and testing strips. The TGA approved changes in late 2021 to enable the supply of HIV self-tests from community pharmacy.[11] Community pharmacies have been a significant provider of COVID rapid antigen tests as part of the management response for COVID-19 and were the provider of choice for the Australia Government's COVID-19 Rapid Test Concessional Access (CRTCA) Program[12] in the first half of 2022 to ensure Australians with concession cards had free access to these tests. IVDs do not include products that are not intended for therapeutic use, including tests for parentage and kinship, drug tests used in sport, and most tests for alcohol or the detection of illicit drugs.

Internationally, tests for hepatitis C[13] and sexually transmitted infections such as chlamydia[14], gonorrhoea, syphilis and HIV are available through community pharmacy, either by using in-pharmacy testing or self-tests purchased in-store or online.[15] Evidence shows that such services are feasible, accessible, convenient and accepted by the public[16].

Whether supplied as a supervised PoC test or sold over the counter for home use, the community pharmacy setting provides an opportunity for patients to seek advice on correct test use, and counselling on what to do if the test returns a reactive result.

Pharmacogenomics testing for condition management

Pharmacogenomic testing at community pharmacies is a growing area with enormous potential to improve medicine efficacy through personalised treatment. Traditionally medicines have been prescribed to treat a condition without the ability to know whether that medicine will be effective for an individual patient. Pharmacogenomic testing offers the means of prescribing and dispensing medicine at doses appropriate to individual patients' genetic profile. To identify the right treatments for individual patients and minimise the risk of adverse drug reactions, pharmacogenomic testing can be carried out prior to initiation of treatment or during treatment in response to adverse effects being experienced. Commonly used medications with 'risk' gene variants include allopurinol, amitriptyline, azathioprine, carbamazepine, citalopram, clopidogrel, codeine, escitalopram, ondansetron, oxycodone, paroxetine, simvastatin, tamoxifen, tramadol and warfarin[17].

[11] HIV self-tests available in Australia | Therapeutic Goods Administration (TGA)
[12] COVID-19 Rapid Test Concessional Access (CRTCA) Program - Pharmacy Programs Administrator (ppaonline.com.au)
[13] London Drugs Launches Potentially Life-Saving Hepatitis C Screening at Pharmacies - London Drugs Blog
[14] A pharmacy-based private chlamydia screening programme: results from the first 2 years of screening and treatment - PubMed (nih.gov)
[15] https://onlinedoctor.lloydspharmacy.com/uk/sti-tests
[16] (PDF) Chlamydia screening interventions from community pharmacies: A systematic review (researchgate.net)
[17] RACGP - Pharmacogenomics in general practice

Digital Health Records

Digital health records will be a crucial element to effective pharmacogenomic condition management. In time we might expect patients to have pharmacogenomic profile when interacting with the health system. This profile could be stored in a digital health record and accessed via the Electronic Prescription Service to assist prescribers in choosing quality medicines. Pharmacists use of technology will ensure that patient information is correctly recorded in the digital health record.

Related Policies

COVID-19 Point of Care Testing (2021)

Authority

Endorsed

National Council – November 2022
National Council – November 2012 (*Disease Screening and Condition Management in Community Pharmacy)*

Review

Policy and Regulation Sub-Committee – November 2022
Policy and Regulatory Affairs Committee – October 2012 (*Disease Screening and Condition Management in Community Pharmacy)*