Pharmaceutical Practitioner

South African Association of Community Pharmacists

Guidance Document for Point-of-Care Testing (POCT) in Community Pharmacies in South Africa

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Introduction

Community pharmacists are strategically positioned within the healthcare system to deliver Point-of-Care Testing (POCT), leveraging their accessibility and frequent patient interactions to provide timely diagnostic services. Evidence has consistently demonstrated that integrating POCT into community pharmacy practice significantly enhances patient access to essential diagnostic services, particularly in underserved or resource-limited settings. By offering POCT, community pharmacists contribute to reducing the burden on other healthcare facilities and contribute to improving the health outcomes of their patients.[1]

POCT is the performance of a diagnostic screening test for a medical condition outside of a laboratory setting. Furthermore, it is completed in a single encounter, at the patient's side, often leading to a change in the care of the patient.

This document offers a guideline for pharmacists in South Africa, which is compliant with the Good Pharmacy Practice (GPP) Guidelines and SAPC Board Notice 539. It aims to provide a comprehensive guide to ensure that pharmacists deliver safe, ethical, and reimbursable POCT services in community pharmacies. Board Notice 539 of 2023, clarifies the rules relating to the services for which a pharmacist may levy a fee.

Compliance with SAPC regulations (Board Notice 539)

The integration of POCT into pharmacy practice requires a controlled and professional approach to ensure patient safety and service quality. Pharmacists are advised to implement POCT services in compliance with Good Pharmacy Practice (GPP) standards, maintaining accurate documentation, ensuring proper waste disposal, and always upholding patient confidentiality. POCT must be conducted under supervision of a pharmacist. In addition, only SAHPRA-approved POCT devices may be used. Pharmacists must also be able to show competency through training.

As per the SAPC Board Notice 539 of 2023, the following POCT services, which fall under the screening and testing of biological and physical parameters, are currently approved for implementation within the scope of pharmacy practice:

- Lipid Profile Testing (procedure code 0013): Including total cholesterol, LDL, HDL, and triglyceride measurement (Used for cardiovascular risk assessment and lipid management)
- Urinary Tract Infection (procedure code 0014) Testing: Dipstick tests for nitrites, leukocyte esterase, and other urinary markers (Assists in the preliminary diagnosis of UTIs)
- Pregnancy Screening (procedure code 0018): Qualitative urine HCG detection (For early pregnancy confirmation)
- Rapid HIV Testing (procedure code 0017): Immunoassay-based testing for the detection of HIV antibodies and/or antigens (Requires pre- and post-test counselling in line with national HIV testing protocols)
- Glucose Testing (procedure code 0012): Capillary blood glucose testing for screening or monitoring of hyperglycaemia or hypoglycaemia (Of relevance in diabetes care).[2]

Additional POCT services beyond Board Notice 539

While Board Notice 539 does not list all available POCT services, it does offer guidance to pharmacists, who can show competency, to perform additional tests within their scope of practice.

These additional tests, include HbA1c, Hepatitis B and C rapid tests, Prothrombin Time/INR for warfarin monitoring, C-reactive protein (CRP) for infection screening, and faecal occult blood tests for colorectal cancer screening. The concept of screening in pharmacies indicates the importance of POCT as a primary healthcare initiative, aligning with the pharmacists' scope of practice, and enhance patient care accessibility. A study done by the SAACP in 2023 in response to a South African Pharmacy Council (SAPC) request, indicated that there are far more POCT being performed in pharmacies, which are not specifically listed in the board notice. Pharmacists, particularly those with Primary Care Drug Therapy (PCDT) certification, possess expanded prescribing authority, enabling them to integrate broader POCT services into their practice. This approach is further supported by international guidelines from the International Pharmaceutical Federation (FIP), which advocate for pharmacist-led POCT to improve healthcare access and outcomes.[3]

Informed Consent and Confidentiality

As community pharmacists increasingly deliver POCT services, it is essential to uphold ethical standards and patient rights by ensuring proper informed consent. The following principles should be integrated into POCT services:

From the onset, there must be compliance with POPIA (Protection of Personal Information Act). Patients have the right to make informed choices about their healthcare. Pharmacists must ensure that each patient understands the purpose, benefits, risks, and limitations of the POCT before proceeding. Information about the test should be delivered in clear, simple language, considering the patient's literacy level and cultural background. Pharmacists must explain what the test does, how it is performed, and how the results will be used in their patient care.

Consent must be voluntary, with patients given the freedom to decline or withdraw at any time without any negative consequences. For certain tests, particularly those with significant clinical impact, pharmacists should ensure that consent is documented, in accordance with legal requirements, including POPIA. Patients must be assured that their test results and personal information will remain confidential and only be shared with authorised healthcare.

Consent processes must be inclusive and respectful of diverse backgrounds, ensuring that no patient is disadvantaged due to language, culture, or literacy barriers. It is recommended that pharmacies incorporate a standard informed consent protocol into their standard operating procedures (SOPs) for POCT services.[4]

Testing procedure

A standardised and well documented process provides precise and accurate testing, as well as options for counselling or referrals when necessary. Best practices recommend a structured and reproducible approach to POCT that can be incorporated into regular healthcare procedures within pharmacies. The procedural framework for POCT involves three distinct phases to ensure accuracy and compliance. The following is an overview of the steps to follow within these three phases, when performing a POCT:

1. Pre-test

The pre-test phase prioritises patient identification and the communication of the test procedure, its objectives, and limitations. Additionally, informed consent is obtained, adhering to ethical and legal standards compliant with POPIA. POPIA is South Africa's data protection law, which outlines conditions for the lawful processing of personal information. It is recommended to use language that is clear and appropriate to the patient's literacy level.

2. Test procedures

Prior to initiating a POCT, pre-test readiness must be ensured by preparing a clean, private testing area and verifying the availability of all necessary equipment and materials. The patient's relevant history and indications for testing should be documented when applicable. During the test, strict adherence to the manufacturer's instructions for use is essential to maintain test accuracy and reliability. Infection control protocols must be rigorously followed, including proper hand hygiene, the use of appropriate personal protective equipment (PPE), and preparation of the testing area using single-use items where indicated. The test must be performed with correctly labelled materials to avoid cross-contamination, and all steps, including timing and monitoring should comply with the specified guidelines. This structured approach ensures both the clinical integrity of the POCT and the safety of the patient and testing personnel.

3. Post-test procedure

Following the completion of a POCT, results must be interpreted within the manufacturer's recommended time to ensure accuracy. The presence of control lines should be verified to confirm the validity and reliability of the test being performed. Accurate documentation is essential and must include recording the test results manually or electronically. Additionally, patient consent, any counselling provided, and referrals made must be clearly documented. All personal health information should be managed with strict confidentiality and stored securely in compliance with POPIA. These procedures are critical to maintaining clinical accuracy, legal compliance, and patient trust in pharmacy-based POCT services.[5]

Documentation and record-keeping

The FIP policy statement (5238) on POCT underscores the significance of comprehensive documentation systems within pharmacies. These systems are crucial for ensuring traceability of tests and results, facilitating communication with other healthcare workers, supporting quality control, and auditing processes, meeting regulatory and legal obligations, and safeguarding patient confidentiality and data integrity. Essential cautionary criteria include the maintenance of confidential electronic and physical records, complying with SAPC and POPIA regulations, reporting notifiable diseases like Tuberculosis (TB), as per the National Health Act. It furthermore includes recording POCT activity on your dispensing programme or appropriate clinic software programme. Records management is a critical component of POCT processes, requiring the meticulous documentation of test-related information. This includes obtaining and preserving patient consent forms, recording the test type, date, and result, noting the lot number and expiry date of the test kit, and identifying the pharmacist who conducted the test. Additionally, any referrals or follow-up actions must be recorded. These records are mandated to be retained for a minimum duration, ensuring compliance and supporting accountability.

Quality Assurance (QA)

Regular calibration directly affects both the accuracy and precision of results. Without it, systematic errors may accumulate, potentially leading to clinically significant misinterpretations. It serves as an internal quality control check in POCT. It is advisable to maintain a QA logbook for audit purposes.

Patient management and referral

POCT provides rapid results that enable immediate clinical decisions. However, test results should not be interpreted in isolation. Pharmacists need to consider the patient's symptoms, medical history, and other

relevant factors to make informed decisions to manage patient care efficiently. When results indicate complex or severe conditions beyond a pharmacist's scope, a timely referral to an appropriate healthcare professional is necessary to ensure comprehensive care.[6]

Remuneration for POCT

Certain POCT services are eligible for reimbursement under selected medical aid schemes in South Africa. For example, Discovery Health provides coverage for specific tests such as HIV rapid tests, HbA1c testing for diabetic patients, lipid profile assessments when clinically indicated, glucose monitoring, and total cholesterol measurements. To facilitate reimbursement, pharmacists must use the appropriate billing codes, approved NAPPI codes, and submit claims through the designated online portals. Accurate patient records should be maintained to support verification during audits or claims processing. For POCT services that are not reimbursed, pharmacies should implement a clear and transparent fee structure to ensure patient understanding. Additionally, offering bundled screening packages, such as comprehensive diabetes screening can enhance service delivery and promote preventive care.[7]

Continuous Professional Development (CPD) and competency

Whilst not compulsory, it is recommended that pharmacists complete accredited POCT training to show competency. This includes training and competency in test performance, infection control practices, patient communication and counselling, and legal and ethical obligations which include informed consent and data privacy. An example of this would be the training offered by the manufacturer, when performing POCT on the Lumira-Dx® platform. They provide training, and certification for SARS-CoV-2 Ag testing, HbA1c testing and C-Reactive Protein testing, as provided for by the manufacturer.

Community pharmacists must stay abreast of new POCT technologies, updated clinical guidelines, and reimbursement policies to deliver high-quality, sustainable diagnostic services. Keeping up with advancements ensures better patient outcomes, allows for alignment with improved standards, and contributes to the development of financially viable models. This in turn will improve access to care.[8]

The importance of Standard Operating Procedures

According to the SAPC, a Standard Operating Procedure (SOP) is a set of detailed instructions that must be followed to complete a specific task safely, without harming the environment, and in a manner that optimises operational efficiency and productivity. SOPs can be developed for most tasks performed in a pharmacy that requires a consistent and standardised approach, like POCT. The responsible pharmacist is accountable for ensuring that SOPs are in place and followed within the pharmacy. They must also be actively involved in the creation, review, and distribution of SOPs to all pharmacy personnel.

Establishing SOPs for POCT in pharmacies is crucial for maintaining accuracy, consistency, and adherence to regulatory standards. These procedures provide clear guidelines for conducting POCT functions. SOPs enhance patient trust and facilitate staff training. In addition, staying up to date on advancements, pharmacists can deliver reliable and efficient diagnostic services while maintaining ethical and professional care standards.

Conclusion

POCT represents a significant opportunity for community pharmacists in South Africa to advance their role within the healthcare system. By enabling the rapid identification of both acute and chronic conditions, POCT supports early diagnosis and prompt intervention, thereby enhancing the scope of community pharmacy practice. This in turn enables pharmacists to contribute more actively to the management and continuity of patient care. In a country where many communities face limited access to healthcare, this shift can lead to improved patient outcomes and reduced pressure on overburdened clinics.

However, it is essential that pharmacists adopt these services responsibly. Strict adherence to Good Pharmacy Practice (GPP) standards and SAPC regulations, is non-negotiable to ensure patient safety, professional integrity, and consistency in service delivery. Equally important are clear and standardised POCT protocols, which guide pharmacists through safe and effective testing, interpretation, and referral practices.

Sustainable implementation also requires the co-operation of medical schemes to ensure fair remuneration models. Additionally, investment in adequate IT infrastructure and clinic software is vital to support data management, reporting, and integration with broader healthcare systems. By aligning clinical practice with regulatory standards and fostering strong partnerships with medical schemes, community pharmacists can effectively implement POCT and contribute meaningfully to strengthening the country's primary healthcare environment.

Review

This guidance document will be subject to review in accordance with any current or future regulatory changes.

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