

## FIP STATEMENT OF POLICY

# The role of pharmacy professionals in point-of-care testing

### INTRODUCTION

#### *The importance of providing health screening services through point-of-care tests*

Pharmacy professionals are fully committed to an interprofessional and person-centred approach to healthcare. This includes a firm commitment to accessible and effective primary healthcare services, as demonstrated through FIP's endorsement of the World Health Organization's (WHO) Declaration of Astana on Primary Healthcare (2018).<sup>1</sup> Pharmacy professionals' multiple contributions to primary healthcare include the provision of health education and the improvement of health literacy (including public health and medicines use awareness), the primary and secondary prevention of diseases (both communicable and non-communicable), the identification of signs and symptoms of disease and referral to other healthcare professionals where appropriate, and screening for disease or health indicators in the community. These services are valuable not only for the individual patients who receive them, but also from a public health point of view. They greatly contribute to the efficiency and sustainability of healthcare systems and are, therefore, an important stepping-stone towards universal health coverage.

A critical element in the provision of health screening services through point-of-care (POC) tests is to leverage the knowledge, skills and accessibility of pharmacy professionals, particularly in community pharmacies. The definition of POC testing of the International Organization for Standardization (ISO) is "testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient".<sup>2</sup> Where the regulatory framework permits, a broad range of POC tests can be performed at community pharmacies in the presence or absence of any symptoms of disease, as long as necessary measures are in place to ensure the safety and protection of the pharmacy team, other patients and other pharmacy customers. Pharmacy POC tests can provide valuable information to support health-related decision making and reduce unnecessary presentations to general practitioners or emergency departments. POC tests may also be provided as part of a disease state management service to monitor the outcomes of treatment in people with chronic non-communicable diseases, for example, treatment with cholesterol-lowering or diabetes control medicines.<sup>3</sup> In addition, pharmacy professionals can use POC tests to intervene and provide safe and quick pharmaceutical care in acute situations. This leads to faster and more appropriate pharmaceutical care, less disease worsening and savings in healthcare costs.

#### *The health and economic benefits of pharmacy-based testing services*

Studies have demonstrated the potential health and economic benefits of performing POC tests in pharmacies.<sup>4,5</sup> The maintenance of good health and the early detection of disease significantly reduce the need for expenditure on healthcare and expand the capacity of healthcare systems to respond to the needs of populations. Although this is important for countries and territories



at all income levels, it is acutely important in low- and middle-income countries to ensure access to affordable healthcare services where there may be insufficient workforce capacity across other healthcare professions, and access to healthcare services or clinical laboratories may be limited.<sup>6</sup> Despite the difficulties and constraints in the implementation of POC tests in low-resource settings, the WHO encourages their continued development and use, particularly as an integral part of the WHO Global Health Sector Strategy for the control and prevention of sexually transmitted infections.<sup>7</sup>

Early detection of health conditions and monitoring of treatment outcomes when illness occurs will also ensure that maximal therapeutic benefit is achieved as economically as possible. Substantial benefits will, therefore, accrue if pharmacy-based testing services are incorporated in publicly funded and insurance-funded healthcare schemes, as well as being available for purchase by individuals.

Moreover, health screening services (for acute and chronic conditions) in pharmacies or clinical biology laboratories (where many pharmacists practise in several parts of the world) contribute to increasing the awareness among patients that clinical laboratory results are relevant for medication safety, and to inform the responsible use of medicines (e.g., combating antimicrobial resistance by reducing inappropriate use of antibiotics).<sup>8, 9</sup>

POC tests are also a valuable tool to triage patients and to identify those that may require further medical attention. Health screening services also expand the role of pharmacy professionals as healthcare professionals insofar as they may enable and inform the initiation, adjustment or discontinuation of certain medicines and the provision of health information and advice.

Pharmacy professionals should also consider the appropriateness of POC tests and any situations where POC testing should not be performed. Reasons for withholding POC testing may include when test results will not guide referral, treatment or self-care advice.

The range of POC tests to be provided by pharmacies should be appropriate for the specific epidemiological and healthcare needs of each country or local community, and should be defined at the level of the relevant jurisdiction, and in line with the applicable regulatory framework. The same applies to the funding of such tests and their performance by qualified healthcare professionals through public or private health insurance programmes. Funding for such tests and their being free of charge for patients at the point of delivery is encouraged, at least for diseases with a significant epidemiological burden at local level, or for which an early screening may avoid subsequent higher expenditure by healthcare systems.

### ***Requirements and procedures for conducting point-of-care tests at pharmacies***

Pharmacy professionals must consider all relevant patient factors in a holistic manner, and discuss the test with the person in an appropriate setting that ensures the privacy of the conversation, explaining the conditions, procedure, consequences and implications of the test, using a form of language that ensures the person understands the information.

The result of a POC test should not be used in isolation when making a clinical decision. POC tests should be used to provide an objective measure in conjunction with pharmacy professionals' routine assessment through systematic questioning and observation. This includes patient case presentation such as signs, symptoms and duration or progression of the illness, as well as other factors such as social and demographic characteristics, medical history and comorbidities. Pharmacy professionals should elicit all necessary information prior to making an informed clinical decision within their level of competence and regulated scope of practice. For example, although hyperlipidaemia detected by an appropriate series of tests is certainly a risk factor associated with coronary heart disease (CHD), it must be considered



alongside other modifiable CHD risk factors such as smoking, diet, excessive alcohol consumption, lack of exercise, obesity and hypertension, as well as blood glucose control in people living with diabetes.

Modern equipment for POC testing, including testing of bodily fluids, is generally compact in size, allowing for its use in pharmacies. This equipment requires appropriate location and storage at the pharmacy, careful maintenance and, in some cases, calibration or control validation on a regular basis. POC testing equipment must be approved by regulatory agencies and operated by competent, authorised and adequately trained members of the pharmacy staff. When each of these factors is present, safe, reliable and accurate POC testing services can be successfully provided in a pharmacy.

The purchase and proper maintenance of equipment represents only part of the resources that must be devoted to providing a testing service safely and effectively. Other important resource factors to be considered include: the allocation of time for training and keeping knowledge up to date on the use of tests, the interpretation of results and the actions that should follow; assurance that technical support for the equipment is available; and time and means for carrying out the tests, providing appropriate patient support, accurately documenting the test and its result as appropriate, and communicating the results to other members of the patient's healthcare team.

The selection of POC testing devices is critical and must be based on independently demonstrated and quality-assured analytical and clinical performance criteria, as certified or approved by an appropriate regulatory agency. The WHO asserts that POC tests can be used in different healthcare settings and that, when they are adequately performed, they improve quality of care. To ensure this, it is required that every POC testing device must meet seven characteristics under the acronym "ASSURED": Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, and Deliverable.<sup>10</sup>

A further crucial factor for the provision of POC testing services to ensure optimal impact in terms of patient outcomes and health system efficiency is the need to work in close co-operation with other healthcare professionals attending to the same person, particularly general practitioners and relevant local healthcare facilities. There should be agreement on the criteria for patient referral for further investigation and on the appropriate referral pathway, and it is essential to advance towards pharmacy professionals having read-and-write access to adequately designed and secure shared (electronic) health records, in order to register POC test results and ensuing clinical decisions, and that this information is accessible to the rest of the healthcare team. This will be critical for the integration of healthcare provision, the demonstration of value and, ultimately, for claiming appropriate remuneration for the performance of POC tests by pharmacies.

### ***Education and training needs for conducting POC tests***

The use of POC tests in pharmacies and the subsequent actions that they might enable should be framed within national or local regulations defining the scope of practice of pharmacy professionals. They should also be supported by appropriate education and training at undergraduate and continuous professional development level to ensure pharmacy professionals' competence to understand, select and perform tests, to document and communicate test results, to interpret their results and to make appropriate clinical decisions.

It is essential for pharmacy professionals providing POC testing services to possess up-to-date knowledge, demonstrable practical skills, competence in interpreting clinical findings and proficiency in clinical decision-making, including on the appropriateness of performing POC tests.



**This FIP Statement of Policy** is intended to support governments and policymakers, FIP member organisations, pharmacy academic institutions and individual pharmacy professionals wishing to promote the provision of POC screening and testing services in pharmacies.

## **AGAINST THIS BACKGROUND, FIP RECOMMENDS THAT:**

### **Governments and policymakers should:**

1. Acknowledge that POC testing is within pharmacy professionals' scope of practice and ensure that they are supported by appropriate legislation and regulations to perform such roles.
2. Develop policies and remove regulatory barriers to enable pharmacy professionals, as appropriate, to play a broader role in POC testing for health screening, patient assessment and medication management purposes in pharmacies.
3. Consider and include pharmacy professionals as part of the solution for screening strategies at national and local levels.
4. Collaborate with pharmacy professional organisations in developing a suitable framework for the provision of POC tests in pharmacies.
5. Develop suitable and fair remuneration models to ensure the sustainability of such services by pharmacies.
6. Enable access to adequately designed and secured shared (electronic or otherwise) health records, in order to document POC test results and ensuing clinical decisions, and that this information is accessible to the rest of the healthcare team.

### **FIP member organisations should:**

1. Where necessary, promote and advocate the revision of legislation to facilitate the involvement of pharmacy in POC tests for health screening, patient assessment and medication management purposes, as essential and valuable components of comprehensive person-centred care.
2. Encourage governments, health authorities, healthcare insurers and others who fund healthcare to recognise the quality of life and economic benefits that will accrue from incorporating pharmacy-based POC testing for disease screening, patient assessment and medication management services in the health care services they fund.
3. Where appropriate, set the necessary requirements, standards and guidelines and providing the necessary tools and resources to ensure the quality of the services provided.
4. Facilitate and promote research designed to demonstrate the benefits to healthcare services of appropriate POC testing in pharmacies, and to improve the standards of practice.
5. Encourage their members to offer high quality health screening, patient assessment and medication management services.
6. Develop practice-support guidance and resources for their members, in accordance with their codes of ethics, on POC testing in pharmacies covering the following elements:
  - a. The training of pharmacy professionals to ensure continuing competence in the choice and use of equipment, standard operating procedures to be followed, validation and calibration of equipment, risk minimisation, interpretation of results (including the possibility of false positive or false negative results and their implications in terms of false reassurance or unnecessary treatment) and the limitations of various tests and appropriate waste management.
  - b. The training of pharmacy professionals to take biological samples, and the implications this may have on the relevance and quality of the results obtained.
  - c. The need for the institution and diligent operation of a quality assurance programme covering equipment, procedures and competence, to ensure the accuracy of results and their interpretation.

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- d. The need to create and maintain accurate, appropriate and timely documentation, including full patient details, the results of tests, and any professional decisions arising from the results of the test and the rationale for the decisions, complying with all relevant data protection legislation and the profession's code of professional standards in relation to confidentiality.<sup>11</sup>
- e. The need to document and report any adverse reactions that may be experienced by the patient following the test.
- f. The need to provide suitable facilities for every aspect of the performance of the tests, for the segregation, storage and disposal of clinical waste and for dealing with spillages (as per biomedical waste handling guidelines of the state/country) and needle-stick injuries.
- g. The need to ensure that information about the outcome of tests, and appropriate counselling of individuals can be conducted in a location that provides privacy.
- h. The need to work in collaboration and in a timely manner with physicians, laboratory medicine specialists and other professionals providing healthcare to those utilising the testing services provided in the pharmacy, not least to seek to agree relevant referral criteria, especially when results may require further confirmation by laboratory medicine specialists
- i. Guidelines regarding minimum space and equipment requirements for the types of POC tests provided.
- j. Guidelines to ensure the safety of all pharmacy professionals, the person receiving the POC test, and other people present at the pharmacy, especially when testing for potentially infectious diseases or when the test itself may increase the risk of transmission.
- k. The need to explain the purpose of conducting any POC test to the person receiving it or their caregiver before providing the service, and to receive their consent, and to explain the implications of the potential outcomes of the test, by presenting and advising the patient on the options available for follow-up. The follow-up after the POC test is a shared decision between the patient and the pharmacist.
- l. The need to obtain consent to test from the person being tested or their caregiver. Such consent should indicate where the results of the test will be transmitted, including to the individual's physician or other health care provider or health authority.
- m. The need to ensure that the professional indemnity insurance held for pharmacy professionals covers all aspects of the provision of the testing service provided.
- n. The need to participate in collaborative practice and in research with other healthcare providers to confirm the appropriate interpretation and use of results of tests conducted in the pharmacy and update the appropriate practice guidelines accordingly.
- o. The need, when conducting POC tests linked to the monitoring or treatment of patients with chronic diseases, to inform them when follow-up tests are required, in compliance with any relevant local jurisdictional legislation or regulations.

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**Pharmacy academic institutions and providers of continuing professional development training courses should:**

1. Provide pharmacy students with basic education and training in their curricula on both the practical steps related to testing such as the taking of biological samples, the use of equipment, the interpretation of results and the procedures to be followed when conducting tests for health screening, patient assessment and medication management purposes, as well as the necessary communication skills involved in seeking consent for testing procedures and explaining to the patient what the test results mean for them.
2. Include these topics in continuing education for pharmacy professionals.
3. Produce appropriate guidance on how to utilise reference materials.



4. Cooperate with pharmacy professional organisations to demonstrate the clinical and economic benefits of appropriate POC testing in pharmacies, and to improve the standards of practice.

**Individual pharmacy professionals should:**

1. Follow guidelines issued by the pharmacy professional body they are affiliated to and ensure they meet any legislative requirements issued by the local health authorities or regulatory agencies.
2. Ensure they have standard operating procedures in place covering all aspects of POC testing, including training, scope of practice, equipment, patient identification, patient consent and confidentiality, and appropriate record keeping.
3. Be able to identify and implement Good Pharmacy Practice standards where applicable in performing POC tests.
4. Ensure they only utilise medical devices authorised by the local health authorities for POC tests.
5. Commit to their professional obligation and duty to maintain and upskill competence, including knowledge and skills, in undertaking POC tests.



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This Statement replaces the following previous FIP Statements	:	FIP Statement of Policy on Point of Care Testing in Pharmacies. New Orleans, 2004
This Statement can be quoted by stating:	:	International Pharmaceutical Federation. Title: FIP statement of policy on the role of pharmacy in point of care testing. The Hague: FIP, 2022. Available at: <a href="https://www.fip.org/file/5238">https://www.fip.org/file/5238</a>
This Statement references the following FIP Statements and documents:	:	International Pharmaceutical Federation. FIP Statement of Professional Standards – Code of ethics for pharmacists. The Hague: International Pharmaceutical Federation [Internet]. 2014. [accessed: 28 March 2022]. Available at: <a href="https://www.fip.org/file/1586">https://www.fip.org/file/1586</a> .

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