Pharmacy-based point-of-care testing

A global intelligence report

2023

FIP Development Goals

International Pharmaceutical Federation

Colophon

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Executive summary

Point-of-care testing (POCT) services performed in pharmacies or clinical biology laboratories (where many pharmacists practise in several parts of the world) for screening, monitoring or assessing acute or chronic diseases, contribute to increasing patient awareness of the importance of such tests for the early detection of disease and appropriate referral, to improve medication safety and to informing responsible use of medicines (e.g., combating antimicrobial resistance by reducing inappropriate use of antibiotics). These tests serve as an invaluable tool for triaging patients and identifying those who may need further medical attention. POCT services can also expand the role of pharmacy professionals as healthcare professionals by enabling and informing the initiation, adjustment or discontinuation of certain medicines, and the provision of health information and advice.[1] This provides an opportunity for pharmacists to become more directly engaged with patients in terms of monitoring and managing their care.[2]

This report aims to provide a comprehensive overview of the key role of pharmacists in POCT and how this contributes to timely patient care and to health system efficiency through interprofessional care teams. The report also shares global best practices to advance pharmacy practice and international standards of patient care.

The basis for this report was established through a review of existing literature. In addition, a short survey and a compilation of case studies specifically tailored to engage FIP member organisations (MOs) were conducted. An insight board (focus group) discussion was then convened with subject matter experts from selected MOs to provide valuable insights.

Our literature review suggests that POCT services are strongly correlated with health outcomes, economic savings, increased health system efficiency and reduced burden on other healthcare sectors. It also identified barriers that prevent pharmacists and their team members from providing these services effectively. Evidence from 22 countries, 11 case studies and inputs from the insight board identify the range of services currently provided in different countries/regions, explain the remuneration models available and reinforce the valuable role of pharmacists in providing these services. The data collected indicate that while most countries supporting the implementation of POCT services have professional standards in place, the specifics of these standards and the supporting remuneration frameworks vary considerably. In addition, the data highlight the challenges faced by pharmacists wishing to implement POCT services and show that fostering a collaborative ethos between other members of the primary healthcare team and pharmacists remains crucial.

Key findings and recommendations:

- Several studies included in the literature review in this report suggest that the provision of POCTs is becoming more common in community pharmacies.
- Inadequate practice models for POCTs, lack of understanding of good laboratory practice and inadequate training in how to perform or interpret some tests, legislative and regulatory barriers, and bureaucracy in referral or continuity of care in other healthcare settings were identified in the reviewed articles as potential challenges that could hinder the role of pharmacists in this area.
- The survey highlights the global variation in the adoption and practice of community pharmacy-based POCT services, with an increasing number of countries having implemented legislation to allow the provision of such services by pharmacists and pharmacies.
- Our findings show that while pharmacy professionals can make little to no clinical decisions with the results of the tests they perform in several parts of the world, some interesting experiences exist where POCT services have been linked to prescribing authority by pharmacists, contributing to reducing the pressure on general practice and emergency departments.
- Lack of adequate reimbursement and varying levels of national legislation to provide POCT services are the main recurring challenges to pharmacists' scopes of practice.
- Data from pharmacy-based services, as well as the visibility of practice gained through the role of pharmacy during the COVID-19 pandemic, should be used in advocacy discussions with governments, third-party funders, other healthcare professions, pharmacy associations and the public.

- For member organisations considering the initiation and/or implementation of pharmacy-based POCT services, it is important to lead stakeholder discussions on the implementation of pharmacist scope to adjust medication dosages as an actionable response to POCT results to further improve access and timeliness of care for patients.
- The evidence from this report shows that by providing POCT services to the communities they serve, pharmacies and their teams can have an impact on the healthcare system by providing access to medicines and services for all populations, engaging in collaborative disease management programmes for person-centred care, promoting antimicrobial stewardship, providing patient education and improving the ability to monitor community exposure to infectious agents.

Foreword

Point-of-care tests include a wide range of near-patient tests to identify, diagnose, assess or monitor indicators of health conditions or bodily functions, used in non-communicable diseases (e.g., blood pressure, blood cholesterol levels, glycaemia, etc.,) infectious diseases (including sexually transmitted infections, human immunodeficiency virus, hepatitis C, influenza, etc.), and pregnancy. Some of these tests have the potential to improve the detection and management of infectious diseases by reducing the time between testing and diagnosis of an infection. Early diagnosis of infection benefits patients by facilitating timely access to care and initiation of treatment, and it also benefits the community at large and health systems by reducing the likelihood of disease transmission.[3, 4]

Due to their accessibility, convenience and expert health workforce, community pharmacies are ideal places for the provision of primary healthcare services, including preventive interventions, POCT, referral and the provision of healthcare advice, and pharmacists are continually sought out for recommendations of over-the-counter medicines and prescription treatments.[4] Therefore, community pharmacists have the knowledge and training to assess, triage and treat or refer these health conditions appropriately.

With at least 400 million people worldwide lacking access to essential health services, with every year 100 million people being pushed further into disadvantage because they must pay for health care out of their own pockets, extensive pharmacy-based tests can be an important component for every country and economic setting on the path to reaching universal health coverage (UHC), promoting health, keeping the world safe and serving the vulnerable.[5]

Considering the global significance of the role of pharmacies, which intensified during the COVID-19 pandemic, it is paramount that pharmacists can perform these tests, receive the necessary training and reimbursement for the provision of these valuable services, and be involved in collaboration with governments, non-governmental organisations, and third-party payers for service provision and public policies implementation. In addition, it is essential that professional pharmacy organisations at global, regional and national levels support practitioners in the implementation and delivery of services in this area.

FIP's statement of policy on the role of pharmacy professionals in point-of-care testing, published in 2022, emphasised and resolved to support government and policymakers, FIP member organisations, pharmacy academic institutions and individual pharmacy professionals who wish to promote the provision of point-of-care screening and testing services in pharmacies.[1] By leveraging the expertise of pharmacists and the accessibility of pharmacies, the integration of POCT improves patients' outcomes and, from a public view, contributes to stronger health systems.

Through an extensive consultation process with member organisations, this FIP report provides insights into pharmacy-based POCT services globally, identifies the challenges in the provision of these services, and encourages regional and country-level integration of pharmacy-based tests in healthcare programmes.

This report brings together the results of a literature review, a global survey, a compilation of case studies and an insight board discussion to provide examples of evidence-based POCT interventions by pharmacists around the world and the positive health and economic outcomes for patients and the wider community. I trust you will find the report valuable and inspiring. FIP looks forward to working with its member organisations and all individual pharmacists around the world to ensure the optimisation and expansion of pharmacists' scope of practice in POCT to better serve patients and health systems and improve the well-being of our communities.

Paul Sinclair
President
International Pharmaceutical Federation (FIP)

1 Introduction

Community pharmacies are ideal places for a wide range of point-of-care (POC) tests in the presence or absence of any symptoms of disease, as long as necessary measures are taken to ensure the safety and protection of pharmacy staff, patients, and other pharmacy customers. According to the International Organization for Standardization (ISO), POC testing is "testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient".[6] Thus, where the regulatory framework permits, community pharmacies offer access to these services that are valuable not only for the individual patients who receive them but also from a public health point of view.[1]

Pharmacies are convenient settings for patients to have POC testing since they are widely spread and easily accessible, usually require no appointment scheduling, and test results are more quickly available than laboratory tests. POC tests have been offered in pharmacies for some time; for instance, many pharmacies offer blood glucose and cholesterol measurements. Other POC tests have been accessible in the community pharmacy setting more recently, such as tests for streptococcus A pharyngitis, coeliac disease, influenza, hepatitis C, or human immunodeficiency virus (HIV) infections. Such tests can only be helpful in the considered setting if they meet the stated attributes, are performed correctly, and will yield high-quality results.[7] Under the "ASSURED" acronym, the World Health Organization (WHO) defines seven characteristics that POC tests should have. They should be: Affordable, Sensitive (avoid false negative results), Specific (avoid false positive results), User-friendly (simple to perform, uses non-invasive specimens), Rapid and robust, Equipment-free, and Deliverable (accessible to end-users).[8]

Health screening services in pharmacies can provide valuable information to support health-related decisions and reduce visits and appointments at general practitioners or emergency departments. People with chronic non-communicable diseases (NCD) can also be offered POC testing as part of a disease state management programme to monitor treatment outcomes, such as cholesterol-lowering therapy or diabetes management. Similarly, pharmacy professionals can use POC tests to intervene and provide safe and rapid pharmaceutical care in acute situations. This all leads to faster and more appropriate pharmaceutical care, less disease exacerbation and savings in healthcare costs.[1, 9] Assessing POCTs in a community pharmacy can also lead to pharmacists offering self-care recommendations. In addition, pharmacist-provided POC testing can play a key role in complementing community disease surveillance, and regular follow-up and rapid test results can enable pharmacists to tailor patient education and optimise therapy through recommendations to physicians and collaborative primary care.[10, 11]

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.[1, 9]

POCT can also raise awareness of infectious or chronic diseases and their risk factors. Performing POCT for common infectious diseases in community pharmacies could also have a significant societal benefit by reducing inappropriate antimicrobial use, reducing community transmission of these pathogens, and improving the ability to monitor community exposure to an infectious agent.[3]

From a public health perspective, early and rapid point-of-care diagnostics will achieve their greatest impact on disease prevalence (and, in time, incidence) if they are used in well-planned and coordinated screening programmes.[8] On an individual case management basis, their use would improve quality of care (and reduce the risk of both under-diagnosis and over-diagnosis) for infected individuals, and reduce the likelihood of complications, including HIV transmission.[8, 10, 12]

There is evidence of barriers to undertaking these roles, including legal and regulatory restrictions, lack of access to clinical training and poor community awareness, lack of standardised guidelines on how to act on POCT results and manage disease states, lack of uniformity in training and variation in time, cost, curriculum and assessment processes, limited training for community pharmacy staff, fragmentation of care, lack of private consultation areas in pharmacies and reimbursement for service provision.[13, 14]

The success of POCT in community pharmacy practice depends on leveraging resources, partnering with other healthcare professions, selecting meaningful tests for patients, and analysing finances and workflow to deliver personalised care and convenience to patients.

The availability of a collaborative practice agreements and corresponding POC testing models that are flexible enough to evolve as practice and technology changes will provide a clear framework to support the expansion and integration of pharmacist-provided services into a collaborative effort that will be key to advancing patient care.[9]

POCT and screening services provided by pharmacists and community pharmacies are interconnected with broader healthcare systems and practices. Patients have general practitioners (GPs) and other specialists involved in their health care, and with concerns about the fragmentation of care, it is considered essential that community pharmacy POCT is integrated with a patient's overall health care.[15] Increasing the involvement of community pharmacists in care services can improve access to health care and reduce the burden on primary care practices. To provide these services, pharmacists must be legally authorised to perform POCT, to interpret test results and act on the test results.[16] Therefore, the availability of collaborative practice agreements and corresponding POC testing models that are flexible enough to evolve with changes in practice and technology will provide a clear framework to support the expansion and integration of pharmacist-provided services into a collaborative effort that will be key to advancing patient care.[9] In addition, this broader framework would allow pharmacists to fully engage as part of the healthcare team as public health needs change over time, while maintaining accountability to take disciplinary action against professional misconduct.[16] This will encourage a sense of ownership in community pharmacists, enhance the prospect of utilising this protocol to guide their management of various ailments and contribute to building a workforce capable of offering efficient POCT services.

Overall, the healthcare landscape is changing and pharmacists, as highly competent and accessible healthcare providers, are perfectly positioned to make a significant contribution to primary health care and preventive patient care.[10] For POCT to reach its full potential and provide maximum benefit to patients, more work is needed by policy makers, educators and researchers to ensure that such services are of high quality, patient-centred and consistent. Pharmacists involved in these activities need to document and share best practice through publications, so that their colleagues can readily adopt these best practices.[9]

The future of healthcare will benefit from the expansion and implementation of POCT services by pharmacies in all regions, contributing to sustainable health systems and the achievement of quality health for all. As such, this publication explores and describes the role of community pharmacies in the provision of POCT for the screening and management of infectious and non-communicable diseases, with the goal of supporting health-related decision making and reducing unnecessary presentations to GPs or emergency departments. Utilising information obtained from FIP member organisations and territories, FIP evaluated the current understanding of pharmacy-based POCT within this context, and consolidated international best practices, makes recommendations, and promotes national, regional and global advocacy for POCT services.

Data and intelligence for this report was collated through a mixed-methods approach including a literature review of relevant publications, a brief survey to FIP MOs as detailed in Chapter 3, a collection of case studies by FIP MOs based on a structured template (see Chapter 4), and a full discussion that was conducted with participants from various FIP MOs in an insight board, as detailed in Chapter 5.

2 Review of the literature and existing data

A quasi-scoping review of the recent literature was conducted to collate the evidence on the provision of POC testing in community pharmacies. This review helped to identify the value of POC testing in community pharmacies in terms of health outcomes, economic savings, increased health system efficiency and reduced burden on other healthcare sectors. Barriers to the provision of POC testing by pharmacists have also been identified.

2.1 Search strategy and inclusion criteria

The review inclusion criteria were:

- Population: Studies which involved pharmacists or pharmacies within primary healthcare settings;
- Phenomena of interest: Pharmacist's and/or pharmacy role, practice standards and remuneration mechanisms;
- Context: Point-of-care testing services in the community pharmacy;
- Study types: Recent literature (2010–2023) with full-texts available via open-access; and
- Studies published in English.

The search was conducted in June 2023, utilising two comprehensive databases: PubMed and SCOPUS. Various keywords were searched using the e-databases; however, controlled vocabulary and key words were modified when there were zero results. The details of the search strategies are outlined in Table 1. Only articles published in English were included due to resource constraints for all-language translation. All study types, including primary studies, reviews, and meta-analyses, were incorporated where full texts were available via open access.

Table 1. Search strategies

Database (up to 15 June 2023)	Search terms and key words	Citations retrieved	Articles included in this review
PubMed	(((community pharmacy[MeSH Terms]) OR (community pharmacy services[MeSH Terms]) OR ("pharmacy") OR ("pharmacies") OR (pharmacist*)) AND ((point of care test*)))	34	After excluding duplicates: 540 After title and abstract screening: 23 After reviewing the content in detail: 17 articles were included
	(("point of care test*") AND ("econom*") AND ("pharmac*"))	94	
	(((community pharmacy[MeSH Terms]) OR (community pharmacy services[MeSH Terms]) OR ("pharmacy") OR ("pharmacies") OR (pharmacist*)) AND ((point of care test*)))	159	
	(((community pharmacy[MeSH Terms]) OR (community pharmacy services[MeSH Terms]) OR ("pharmacy") OR ("pharmacies") OR (pharmacist*)) AND ((point of care test*)) AND (("role")))	164	
	((("pharmac*"[Title])) AND (("econom*"[Title]) OR ("saving"[Title]) OR ("budget"[Title])) AND ((point of care test[Title] OR (test*[Title]) OR (screening[Title]))))	27	
SCOPUS	(TITLE ("pharmac*")) AND (TITLE ("point of care test*"))	65	

We identified 543 articles in our initial search and three articles were excluded due to duplication. The remaining 540 articles were screened for inclusion criteria and were reviewed for relevant titles or abstracts, and 517 were excluded. The remaining 23 studies were closely reviewed, and a final 17 articles were included in the literature review. The screening process is presented in Figure 1 along with the summary of included studies in Table 2.

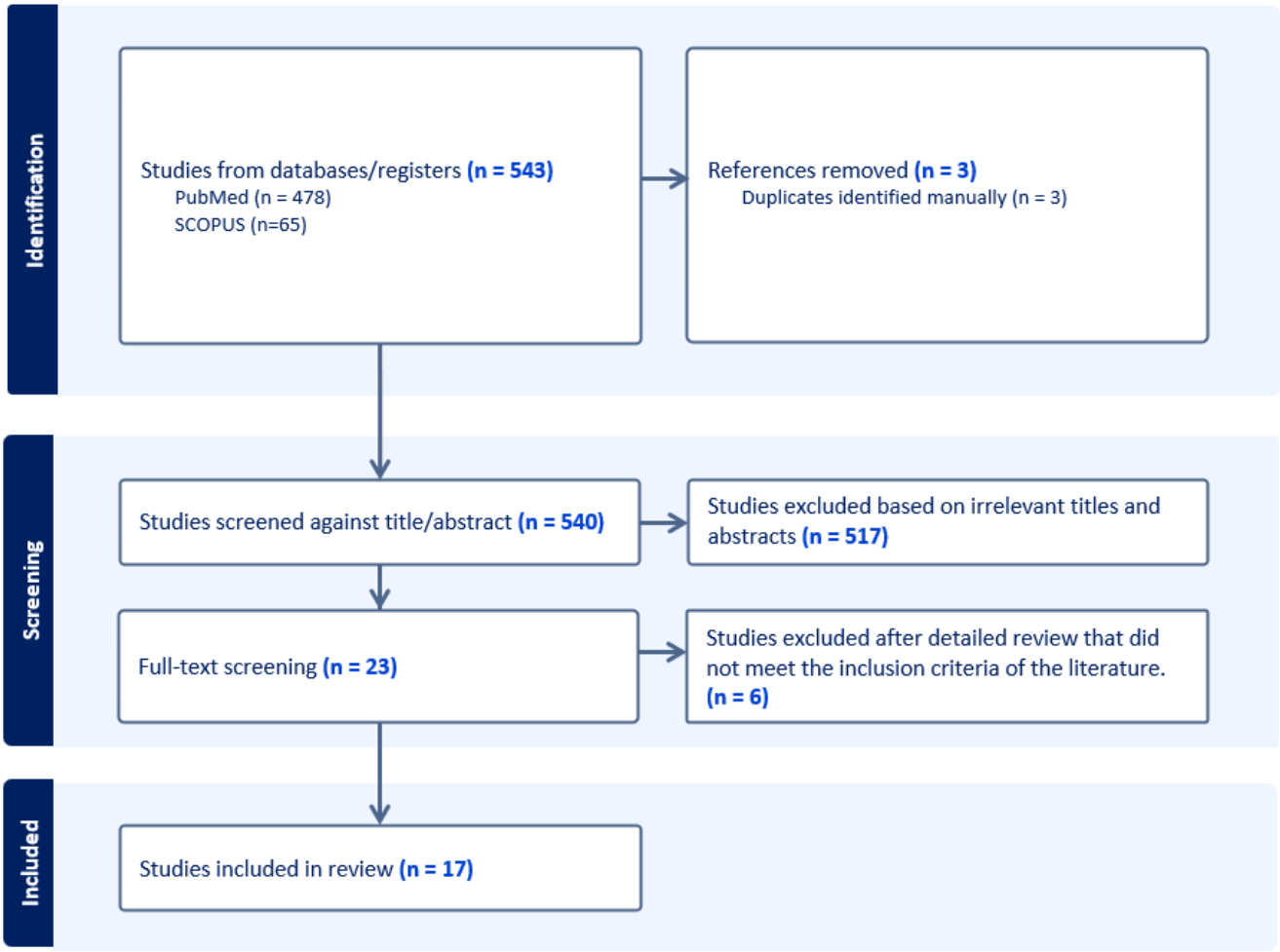

Figure 1. Screening process mapped to the PRISMA Flowchart.[17]

Table 2. Summary of included literature

Author, year and country	Aim/objectives	Study type	Relevant key findings	Impacts on addressing health challenges	Workforce trends and services
Buss VH *et al,* 2019, Cross countries.[7]	To evaluate the effectiveness and analytical quality of POC tests performed in the community pharmacy in comparison with other healthcare settings or the laboratory reference standard.	Systematic literature review	Eleven studies which focused on blood glucose, cholesterol, creatinine, uric acid, liver enzymes, international normalised ratio for anticoagulation therapy, bone mineral density for osteoporosis, forced expiratory volume for chronic obstructive pulmonary disease, and infection with human immunodeficiency virus showed that point-of-care tests that were conducted and analysed in community pharmacies had satisfactory analytical quality and that the interventions applying these tests were effective overall.	Patients with chronic diseases may be earlier diagnosed and treated with a potential decrease in societal costs and other healthcare practitioners could prioritise different aspects of their workload if community pharmacists conducted POCT services such as anticoagulation management.	The evidence of satisfactory quality and effective POC tests should encourage policy makers to provide funding in this area to establish effective pilot programmes in community pharmacies allowing a wider range of screenings for various risk factors and diseases.
Weber NC *et al*, 2016, United States.[18]	To review POC testing in community pharmacies, availability, and specifications of CLIA-waived infectious disease POC tests and provide recommendations for future community pharmacy POC models to improve patient outcomes while reducing antibiotic resistance.	Literature review	POC testing provides a unique opportunity for community pharmacists to implement collaborative disease management programmes for infectious diseases and reduce over-prescribing of antibiotics and improve patient outcomes through early detection, treatment and/or referral to a specialist.	Patient satisfaction with pharmacy-based care models is high.	Accreditation standards require each entry-level pharmacist to be knowledgeable and competent with some basic assessment techniques. Refresher courses and training on these clinical skills are available for continuous professional development.
Gout-Zwart JJ *et al*, 2019, Netherlands.[19]	To determine the budget impact of obtaining and evaluating renal	Research article	The budget impact analysis showed annual cost-savings of EUR 86 per patient through the availability of renal function values in Dutch	Accurate results and follow-up ensure only required medication therapy is started.	There is a likelihood for pharmacists to implement the use of a renal POCT to improve pharmaceutical care because the

Author, year and country	Aim/objectives	Study type	Relevant key findings	Impacts on addressing health challenges	Workforce trends and services
	function in community pharmacies in the Netherlands to prevent antibiotic-related hospitalisations.		community pharmacies. Savings were mostly due to avoided hospitalisations.		provision of this service provides a quick and accurate result.
Haggerty L *et al*, 2017, Cross countries.[20]	To summarise the literature on cholesterol POC tests and serve as a resource to assist community pharmacists in developing cholesterol POC pharmacy services.	Review	Information from 36 reviewed articles was summarised under: devices, pharmacists' impact, and operational cost for the pharmacy. The article suggested that POCTs in community pharmacies assist with patient outcomes by providing screenings and referring patients with dyslipidaemia for further evaluation.	Screenings offered at a community pharmacy are often more effective than in non-healthcare settings because of the trusting relationship pharmacists have with their patients, resulting in higher adherence to recommendations including lifestyle modifications and follow-ups with their primary care provider.	Post-screening education may further assist patients with understanding their disease state, increase medication adherence and improve lifestyle habits such as diet and exercise.
Klepser DG *et al*, 2021, United States.[21]	To discuss the ramifications that the COVID-19 pandemic had on the common barriers to pharmacy-based POC testing.	Report	Relaxation of regulatory restrictions on the ability of pharmacies to provide testing led to a significant increase in the number of pharmacy-based labs.	The COVID-19 pandemic has, at least, temporarily removed several of the barriers to pharmacy-based testing in the United States. Pharmacy-based POCT improve access to timely testing.	Some states acted before the federal government to ensure pharmacists could conduct COVID-19 tests; waived restrictions concerning a pharmacist's ability to practice outside of the pharmacy setting to allow for drive-through testing.
Lathia N *et al*, 2018, Canada.[22]	To conduct an economic evaluation of treating severe sore throat through POCT service in the selected population.	Research article	Five separate cost-minimisation analyses for the provinces of Alberta, British Columbia, Nova Scotia, Ontario and Saskatchewan, from the public payer perspective, showed that strep throat POC testing in pharmacies was cost saving compared with physician-based care. Approximate total cost savings ranged from CAD 1.3 million to CAD 2.6 million per year across the five provinces.	Pharmacist-based care for sore throat could potentially result in quicker identification of strep throat cases, more appropriate antibiotic use and improved outcomes for patients.	Most severe sore throat cases that were assessed by a pharmacist and not suspected of being strep throat resulted in the pharmacist making a recommendation for self-care, for which the healthcare system does not incur any incremental costs.

Author, year and country	Aim/objectives	Study type	Relevant key findings	Impacts on addressing health challenges	Workforce trends and services
Gubbins PO *et al*, 2014, United States.[3]	To identify opportunities to perform POC testing and/or screening for infectious diseases in community pharmacies, provide an overview of such tests and their use in current practice, and discuss barriers and provide recommendations.	Research article	POC testing for infectious diseases could benefit patients and society and represents an opportunity to expand pharmacy services in community pharmacies. Existing barriers to the implementation of such services in community pharmacies, including deficits in pharmacist training and education along with state regulatory and legislative variance and vagueness in statutes governing pharmacy, are not insurmountable.	Data demonstrate that community pharmacists and pharmacies can significantly improve the prevention and management of infectious diseases, such as influenza, herpes zoster, and streptococcal pharyngitis; produce a significant societal benefit by lessening inappropriate antimicrobial use, reducing transmission of these pathogens in the community, and improving the capacity to monitor population exposure to an infectious agent (e.g., influenza).	The number of pharmacies with a certificate to offer CLIA-waived laboratory services has greatly increased in the past two decades.
Gubbins PO *et al*, 2017, United States.[23]	To provide a comprehensive literature review that explores the potential for pharmacists to collaborate with public health professionals and prescribers using pharmacy-based CLIA-waived POCT services for infectious diseases.	Literature review	Evidence demonstrates that pharmacists in collaboration with other healthcare professionals can leverage their knowledge and accessibility to provide CLIA-waived POCT services for infectious diseases. Services for HIV infection raise infection status awareness, increase access to health care, and facilitate linkage to appropriate care.	Through these tests community pharmacists can promote antimicrobial stewardship in the community, enhance screening for communicable diseases of public health interest, and develop collaborative infectious disease management programmes.	Some pharmacy programmes have begun integrating POC testing, specific to infectious diseases, into their curricula. A national accredited certificate training programme was launched to update pharmacists on how to perform CLIA-waived POCT services for infectious disease and highlight best practices in offering such services in a community pharmacy.
Figueira I *et al*, 2022, Portugal.[24]	To characterise the individuals choosing to have POC testing or screening for HIV, hepatitis C and hepatitis B virus infections in community pharmacies, their risk behaviours and motivations to perform the tests, as well as to understand the facilitators and barriers	Research article	Knowing the perspectives of main stakeholders is valuable to help define priorities and strategies to overcome main barriers to the service implementation and to increase access to tests, and could also encourage policymakers to provide funding to extend the screening more broadly.	The counselling provided by pharmacists and the relationship with users seems to increase the receptivity to the information transmitted and positively influence the way users manage the test results. Counselling reduces the anxiety of the diagnosis by demystifying ideas and educating users about prevention, diagnosis, treatment and quality of life for patients with these infections.	Interventions such as destigmatising infection screenings with routine testing, creating community partnerships with doctors and key informants from the least-adhering groups, reinforcing the project's visibility and the possibility of scheduling tests could contribute to the elimination of some of the barriers identified, thereby increasing tests' uptake.

Author, year and country	Aim/objectives	Study type	Relevant key findings	Impacts on addressing health challenges	Workforce trends and services
	from the perspective of pharmacists.				
Lingervelder D *et al*, 2021, Cross countries.[25]	To review the available evidence on the health economic impact of introducing POCT to assess if poor POCT uptake may be related to lacking evidence.	Systematic review	The uptake of POCT in many countries remains low, and the lack of evidence on POCT does not appear to be the primary barrier to its implementation. Even though the evaluations included in the review did not always include the full long-term benefits of POCT, it is clear that health economic evidence across a few dimensions of value already indicate the benefits of POCT.	POC tests allow early diagnosis, a decrease in the number of hospitalisations and referrals to specialised care, reduced risks of infection and antibiotic prescription, and a decrease in additional burden and costs associated with referrals and additional testing.	This review showed that high-quality health economic evaluations on POCT are limited. The implementation and utilisation of POC tests is reliant on technical advancements alone, changes in costing systems and reimbursement practices.
Heringa M *et al*, 2017, Netherlands.[26]	To investigate the management of medicine therapy alerts on the safe use of antibiotics in elderly patients with (potential) renal impairment and the contribution of optional creatinine POC testing in community pharmacy practice.	Research article	A total of 351 pharmacists registered the management of 88,391 alerts for 64,763 patients. For 68,721 alerts (77.7%), the pharmacist retrieved a renal function above the threshold for intervention, of which 1.7% of the alerts (n=1,532) led to a prescription modification because of renal impairment.	The routine use of a clinical decision support system (CDSS) can contribute to better documentation of renal function. POCT can be useful when information on renal function is urgently needed, when the intended drug needs dose adjustment or replacement even in the case of mild or moderate impaired renal function, and when the prescribed medicine has a narrow therapeutic window.	For this study, all pharmacists were trained in performing POCT, interpretation of renal function measures, and registration in the CDSS by attending three half-day meetings (before the start, after three months and after six months) and by e-learning.
Kuhn CH, 2015, United States.[27]	To inform the members of the American Pharmaceutical Association about the opportunities for pharmacists to provide patient care through point-of-care testing.	Association report	POC test screening results may serve as a preliminary means for screening for chronic disease states and potential diagnosis. The addition of lipid screenings and extensive counselling present both a clinical and business opportunity for pharmacists.	Convenient, inexpensive, and quick POC tests may serve as a valuable tool for pharmacist-provided disease state management of patients diagnosed with chronic disease(s), enable pharmacists to deliver necessary recommendations and interventions to help patients manage their disease states in a timely and convenient manner. Pharmacists are an accessible and convenient patient resource, and their roles	New training education programmes are being offered across the nation that help pharmacists identify and overcome barriers to testing. While some legislative restrictions may exist, pharmacist-administered POC testing has already proven valuable in the evaluation and management of acute and chronic diseases.

Author, year and country	Aim/objectives	Study type	Relevant key findings	Impacts on addressing health challenges	Workforce trends and services
				in rapid screening could have a significant impact on public health.	
Essack S *et al*, 2020, Cross countries.[14]	To identify opportunities to perform POC testing and/or screening for infectious diseases in community pharmacies, provide an overview of such tests and their use in current practice, and discuss barriers and provide recommendations.	Perspective	POC testing for pharyngitis has become widely available in pharmacies in some countries. Where the results are available within minutes, they can distinguish between viral and GAS pharyngitis and can therefore guide treatment in primary healthcare settings such as community pharmacies, which are often the first point of contact with the healthcare system.	POC testing in the community pharmacy setting represent a strategy to contain antibiotic resistance and contribute to antimicrobial stewardship. It can be cost-saving from a public funding perspective. It may lead to cost-savings in comparison with physician-based care within publicly funded healthcare systems.	Pharmacists in many states are able to apply for a CLIA waiver, which allows them to carry out POC testing in the community pharmacy setting. Pharmacists providing POC testing services in the USA are able to charge patients directly, or in some cases, a third-party insurance company is willing to pay for the test.
Herbin SR *et al*, 2020, United States.[13]	To discuss the rationale behind incorporating CLIA-waived POC tests into disease screening and management programmes offered in the pharmacy.	Mini review	Pharmacy-based POCT has resulted in a dramatic improvement in appropriate antimicrobial use and has become a means to promote outpatient antimicrobial stewardship. Pharmacists should communicate with a laboratorian or public health entity to discuss potential uses and limitations of given tests.	Owing to a high level of patient interaction and the manner in which patients' frequent pharmacies, community pharmacies provide a unique opportunity for the implementation of disease management programmes for various infectious diseases and other conditions of public concern.	All pharmacy graduates are trained to evaluate patient function and dysfunction through the systematic gathering of objective (physical assessment and laboratory data) and subjective (patient interview) data important to the provision of care. A nation-wide 20-hour certificate programme has been developed by the National Association of Chain Drug Stores aimed at educating pharmacists on the appropriate use of CLIA-waived POCT.
Kehrer JP *et al*, 2016, Cross countries.[2]	To describe some of the issues surrounding POCT, particularly POCT performed outside traditional health care settings and make the case for pharmacists to embrace this technology as a means	Statement	Training for POCT done in an institutional setting (including schools of pharmacy) should include an increased emphasis on the details about the technology employed and the advantages and challenges associated with POCT. At the same time, in jurisdictions where necessary, efforts should be made to	Provision of POCT services in community and institutional pharmacy settings can enhance disease state and medication management programmes and include an emphasis on preventive care.	Resources for practising pharmacists to learn about POCT are increasing rapidly. There are professional development and certificate programmes. More programmes are likely to be developed, and incorporating aspects of these programmes into pharmacy school curricula should be considered.

Author, year and country	Aim/objectives	Study type	Relevant key findings	Impacts on addressing health challenges	Workforce trends and services
	to enhance patient care.		change regulations to optimise the use of POCT in terms of patient care.		
Hutchings L *et al*, 2022, Canada.[28]	To use the available information on the usage of POCT services in pharmacy settings to develop policy that protects and promotes the health and well-being of New Brunswickers.	Communication	A literature review, an environmental scan of nine Canadian provinces, and stakeholder consultations identified the use of pharmacy-based POCT in chronic disease management and infectious disease screening. This provided the evidence base for a POCT policy aimed at enhancing pharmacists' ability to provide patient care and take action on outcomes through medication management.	Community pharmacist POCT removed the need for patients to receive a laboratory requisition, attend a facility for sample collection and wait for results.	Due to operators not being laboratory-trained, the National Academy of Clinical Biochemistry strongly recommends training programmes that cover pre-analytical through to post-analytical stages.
Albasri A *et al*, 2020, Cross country.[29]	To summarise the literature regarding the use of POC tests POCT in pharmacies versus control/usual care.	Review	POCT in pharmacies reduced the risk of receiving antimalarial treatment when not clinically indicated (risk-ratio 0.34, 95% CI 0.31–0.37).	Pharmacy-based POCT may be useful in guiding appropriate antimalaria prescribing, particularly in low resource settings.	Given the current strain on primary healthcare services, the provision of POCTs has become more commonplace in UK community pharmacies, with particular emphasis on the potential for POCTs to aid both acute condition diagnosis and long-term condition management.

2.2 Data extraction and analysis

2.2.1 Health related-outcomes

There is strong evidence of positive health outcomes from the use of POCT in community pharmacies for acute infectious diseases. A systematic review and meta-analysis of the impact of POC testing in community pharmacies found that there was a reduced risk of inappropriate antimalarial treatment, particularly in low-resource settings, when pharmacies provided POC malaria testing.[29] Several studies have shown that POC testing for infectious diseases in community pharmacies has the potential to reduce inappropriate antibiotic prescribing for viral illnesses and subsequent rates of antibiotic resistance.[3, 13, 14, 18] At the population level, POC tests for infectious diseases also reduce the transmission of pathogens in the community through efficient identification and improve a country's ability to monitor population exposure to diseases such as influenza.[3, 23]

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In addition, community pharmacies are improving health outcomes through POCT for chronic diseases. A study on renal function POC testing for safe use of antibiotics in elderly patients found that creatinine POC testing may improve health outcomes through decreased adverse events.[26] In this study, pharmacists performed creatinine POC testing on 2.2% of their clinical decision support messages, and 0.8% of those tests led to prescription modifications. Antibiotic prescriptions for the elderly are a large source of medication adverse events and hospitalisations if renal function cannot support the dosage.[26] Moreover, a review of POCT for cholesterol confirmed that community pharmacies contribute to patient outcomes by providing screening and referring patients with dyslipidaemia for further assessment.[20] Screenings in community pharmacies offer a uniquely effective and accessible approach that leverages the trusted relationships pharmacists have with their patients, creating a comfortable and convenient environment for proactive health monitoring and intervention. This personalised setting not only encourages regular screening, but also facilitates tailored health guidance, improving overall patient engagement and promoting a holistic approach to wellness within the community. This can result in higher medication adherence rates and/or more recommendations for lifestyle changes such as healthy eating and exercise.[20] In addition, community pharmacists are more likely to reach at-risk patients who may not have an established GP through community outreach events. They are generally more accessible to advise patients on understanding disease states and on both prescription and over-the-counter medicines.[20, 24]

2.2.2 Economic related-outcomes

A systematic review of POC testing identified several factors that lead to health economic savings. It concluded that POC testing reduces overall economic costs by allowing earlier diagnosis of disease, reducing hospitalisations and specialist referrals, reducing the risk of infection and subsequent antibiotic prescriptions, and reducing the need for additional testing.[25]

POC testing reduces overall economic costs by allowing earlier diagnosis of disease, reducing hospitalisations and specialist referrals, reducing the risk of infection and subsequent antibiotic prescriptions, and reducing the need for additional testing.[25]

One of the articles included in the review by Herbin SR *et al*[13] reported the experience of a community pharmacist-led Group A Streptococcus (GAS) management programme in Canada. Of 7,050 retrospectively identified patients, 25.5% tested positive for GAS using rapid antigen detection tests. Notably, nearly 70% of these individuals received antibiotics directly from the pharmacy. Most of the patients surveyed reported they would have gone to a clinic, doctor or emergency department if the pharmacy service had not been available. Therefore, the increased accessibility of this service did not lead to an increase in testing, but rather optimised the delivery of cost-effective care.[30]

Two of the studies found highlight the exact monetary savings of pharmacy-based POC testing. A Dutch study looked at the cost savings of implementing renal POC testing in patients aged 65 years or older with antibiotic prescriptions. The budget impact analysis showed annual savings of EUR 86 per patient. Most of the direct savings were due to the pharmacist's ability to adjust antibiotic doses to avoid adverse events and hospitalisations.[19] The second study was a cost-minimisation analysis of community pharmacy-based POCT for strep throat in five Canadian provinces.[22] According

to this study, strep throat POCT in pharmacies was cost saving compared with physician-based care, and funding strep throat POCT in community pharmacies in these five provinces would lead to public health system cost savings and potentially improve patients' access to care for severe sore throat. This study estimates that in a scenario where 60% of patients with severe sore throats seek care from a community pharmacy, compared with a scenario where all patients with severe sore throats seek care from a family physician, walk-in clinic or emergency department, the health care system in the five Canadian provinces saves a mean of CAD 12.47 to CAD 24.36 per patient. The estimated economic savings for all five of the Canadian provinces studied were between CAD 1.3 million to CAD 2.6 million per year. This estimate was only for direct cost savings; the estimate may have been higher if indirect costs like timely access to care or reducing inappropriate antibiotic prescribing had been included. The two main reasons for cost savings were many sore throat cases being viral in origin and the fact that over-the-counter medicines do not incur the health system any incremental costs.[22]

2.2.3 Increased health system efficiency

A systematic review of CLIA-waived* POC testing for infectious diseases in community pharmacies in the United States confirmed that pharmacists can improve the timely and accurate identification of infections and guide treatment decisions through POC testing. Several of the studies included in this review demonstrated successful collaborative disease management for a variety of infectious diseases including influenza, Group A Streptococcus pharyngitis, *Helicobacter pylori*, HIV and hepatitis C virus (HCV).[18] The improvement in patient access to care through these practice agreements and POC testing at pharmacies allow the health system to function more efficiently. Another review of CLIA-waived POC testing showed that POC testing for influenza, Group A Streptococcal pharyngitis, urinary tract infections, HIV and HCV in community pharmacies also increases the efficiency of the healthcare system by improving patient access to care.[13] Two of the articles included in the Herbin *et al* review highlighted that offering HCV screening in community pharmacies has been proposed as a means of increasing access to the test for individuals who may not otherwise be screened, such as patients without a regular GP, homeless or living in non-traditional locations without access to multi-day laboratory results.[13, 31, 32]

A statement from the *American Journal of Pharmaceutical Education* on the role of pharmacists in POC testing noted that pharmacists are well positioned to provide POC testing to improve patient access to clinical data and to enhance disease state and medication management programmes.[2] Both of these factors increase the efficiency of the healthcare system. A similar report from the American Pharmacists Association stated that expanding pharmacists' scope of practice to include POC testing would help improve access, quality and value in an already overburdened system.[27] Moreover, the New Brunswick College of Pharmacists evaluated Canadian POC testing in pharmacies to inform policy writing. It stated that chronic disease POC tests remove the need for patients to find a laboratory, travel to the facility for the sample collection, and then wait for results. When POC tests are used to screen for infectious diseases, faster results can help detect infections and improve the efficiency of disease management.[28]

Pharmacists are well positioned to provide POC testing to improve patient access to clinical data and to enhance disease state and medication management programmes.[2]

* The Clinical Laboratory Improvement Amendments of 1988 (CLIA) are federal standards enacted to establish quality standards for laboratory testing of clinical specimens for the diagnosis and treatment of patients (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/). The goal of CLIA was to ensure the accuracy, reliability, and timeliness of diagnostic test results regardless of where they are performed. CLIA empowered three federal agencies: the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Centers for Disease Control and Prevention.

2.2.4 Reduced burden on other healthcare sectors

Healthcare sectors that provide POC testing will have directly lower patient volume when more POC testing occurs at community pharmacies.[14] Additionally, there will be an indirect reduced burden for disease progression that was prevented via early detection. A systematic review on POC testing in community pharmacies found no difference in effectiveness or analytical quality of POC tests performed in community pharmacies versus other healthcare settings. A variety of POC tests were studied such as blood glucose, cholesterol, creatinine, uric acid, liver enzymes, international normalised ratio, bone mineral density, forced expiratory volume and HIV.[7] Thus, expanding POC testing in community pharmacies can reduce the burden on other healthcare sectors by decreasing laboratory visits and allowing other healthcare providers to spend more time on other aspects of their workload. Increasing the number of patient care access points would help lower the burden on the existing providers.[27] A specific example of this is from an international review looking at pharyngitis POC testing in community pharmacies that found potential to reduce the need for general practitioner consultations.[14]

Expanding POC testing in community pharmacies can reduce the burden on other healthcare sectors by decreasing laboratory visits and allowing other healthcare providers to spend more time on other aspects of their workload.[27]

2.2.5 Drivers and barriers to pharmacists' roles on point-of-care testing

Several articles identified common barriers to expanding community pharmacists' scope of practice through POC testing. In many countries, there are legal and regulatory barriers to pharmacists' scope of practice and recognition as providers of POC testing.[3, 13, 14, 21, 27] In some countries, the COVID-19 pandemic has increased POC testing through COVID tests and increased political advocacy for similar pharmacy services.[14, 21, 28] It is also likely that many patients are not aware of all the POC testing options available to them at the pharmacy.[21, 27] While many countries have different health insurance schemes, there is a common barrier regarding billing and reimbursement for the POC tests, even in countries with national health services.[14, 21, 27] Some countries allow pharmacists to perform POC tests on their own, while others require collaboration with a provider.[13, 20, 28] Another major barrier is clinician awareness and acceptance. This can be particularly problematic for pharmacies which are not chain pharmacies, where clinicians may be reluctant to collaborate.[13, 14, 21] Stemming from these relationships, there is also concern that pharmacy records fragment care with providers. Clinicians prefer to have complete medical records and to have these test results shared with them. To address this concern, there is evidence that community pharmacies have successfully sent medical records of the POC test visit to clinicians if the patient provides one.[2, 13, 27] Another barrier is the lack of education and training of pharmacy staff.[13, 24, 29] This may include pharmacy technicians, depending on the country. In response, there is evidence of the success of training programmes where pharmacy staff have been able to perform POC tests safely and accurately.[2, 3, 14, 27]

In many countries, there are legal and regulatory barriers to pharmacists' scope of practice and recognition as providers of POC testing. Other barriers include billing and reimbursement for POC testing, pharmacy staff training, clinician awareness and acceptance, the cost and time required to implement a new POC testing service, biohazard concerns when handling human bodily fluids, the logistics of having adequate space in the pharmacy to perform the test, and ensuring that the pharmacy has liability insurance for POC testing.[3, 13, 14, 21, 27]

A number of other barriers to implementing POC testing in pharmacies were also identified, such as staffing requirements to allow a pharmacist to step away and spend time with a patient, the cost and time required to implement a new POC testing service, the logistics of having adequate space in the pharmacy to perform the test, and ensuring that the pharmacy has liability insurance for POC testing.[14] The lack of data on POC testing for chronic conditions compared with acute condition, and the biohazard concerns associated with handling human bodily fluids were also identified.[13, 29] In response to the biohazard concerns, pharmacists have safely administered vaccines and have ample practice with proper handling.[13] Some articles also raised concerns about the lack of focused impact within pharmacy curricula to address the educational needs in the face of the expansion of POCT in the pharmacy environment.[2, 14, 23, 29]

3 Assessing the pharmacy team's involvement and needs in supporting POCT — findings from a brief international survey

The literature review presented in Chapter 2 provided insights into the inherent value that pharmacies provide through the provision of point-of-care testing, as well as highlighting several barriers to the integration of this service in practice. Following these findings, FIP conducted a brief survey of its members organisations. The aim of the survey was to gather data on the range of services provided by pharmacists and their teams, and their level of authority in interpreting POC test results. The overall aim was to carefully assess the prevailing legal and policy frameworks, funding mechanisms and overall cost-effectiveness of these services, and to provide recommendations for member organisations wishing to prioritise and incorporate this service into their practice.

3.1 Method

An 11-question survey was sent to FIP member organisations (see Appendix 1 — Survey questionnaire). The questions highlighted different aspects of point-of-care testing and served as a first step to understanding which countries could have these practices in place. Data collected from the online survey was automatically coded and entered into MS Excel, and only completed responses were considered for analysis. A completed response was considered "valid" if the respondent progressed through the survey and submitted their responses. Respondents could stop the survey if pharmacists weren't allowed to provide POC testing services in their country. Responses to the survey questions were collected and summarised using descriptive analysis.

3.2 Results

3.2.1 Geographical distribution of responses

Twenty-five responses were received from Australia, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Canada, Cape Verde, Denmark, Fiji, Finland, France, Germany, Ireland, Israel, Nigeria, North Macedonia, Norway, Portugal, Romania, Slovenia, South Africa, Spain, Switzerland, Uruguay and the United States. Based on the sample of 25 countries and territories surveyed, a higher percentage of countries from Europe (64%) returned completed surveys compared to other WHO regions (Africa 12%, Americas 12%, Western Pacific 8%, Eastern Mediterranean 4%). No responses were received from South-East Asian countries.

3.2.2 Authorisation for pharmacists to provide POCT services

As seen in Table 3 and Figure 2, 72% of the member organisations (n=18) reported that pharmacists were authorised to carry out point-of-care testing in their country/territory; 48% (n=12) of the positive responses were from European countries. While 16% of respondents (n=4; Canada, Cape Verde, Spain, Switzerland) stated that POCT services were offered depending on permissive laws in their countries, 12% of respondents (Finland, Denmark, and Bulgaria) reported that pharmacists are not allowed by law to perform POCT services in their countries, and they provided no further answers to the survey questions.

To analyse the results of the survey, 22 countries in which pharmacists are authorised to perform POCT were considered (Australia, Austria, Belgium, Bosnia and Herzegovina, Canada, Cape Verde, Fiji, France, Germany, Ireland, Israel, Nigeria, North Macedonia, Norway, Portugal, Romania, Slovenia, South Africa, Spain, Switzerland, Uruguay and the United States). This finding marks the global progress in pharmaceutical service delivery and indicates which regions may benefit from stakeholder engagement and policies for substantial impact.

Table 3. List of countries that responded to the survey and an overview of responses to questions 1 and 2.

Country	Are pharmacists allowed by law to perform POCT?	In addition to pharmacists, are other pharmacy workforce members (e.g., pharmacy technicians) allowed by law to perform POCT?
Australia	Yes	Yes
Austria	Yes	No
Belgium	Yes	Yes
Bosnia and Herzegovina	Yes	Varies
Bulgaria	No	—
Canada	Varies	No
Cape Verde	Varies	Varies
Danmark	No	—
Fiji	Yes	Varies
Finland	No	—
France	Yes	Yes
Germany	Yes	Yes
Ireland	Yes	Yes
Israel	Yes	No
Nigeria	Yes	No
North Macedonia	Yes	Yes
Norway	Yes	Yes
Portugal	Yes	Yes
Romania	Yes	No
Slovenia	Yes	Yes
South Africa	Yes	No
Spain	Varies	No
Switzerland	Varies	Varies
Uruguay	Yes	Yes
United States	Yes	Varies

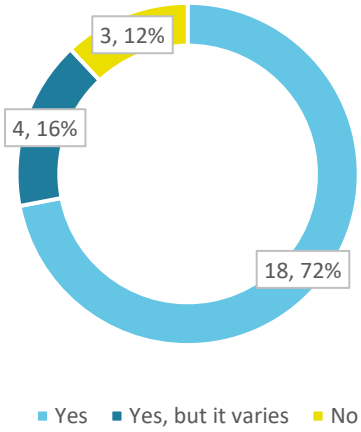

Figure 2. Are pharmacists allowed by law to perform POCT? (n=25)

3.2.3 Authorisation for other members of the pharmacy workforce to provide POCT service

While 45% (n=10; Australia, Belgium, France, Germany, Ireland, North Macedonia, Norway, Portugal, Slovenia, and Uruguay) of respondents affirmed that other pharmacy workforce members (e.g., pharmacy technicians) were authorised to provide POCT services in their countries, the provision of these services by pharmacy technicians was non-existent in 32% (n=7; Austria, Canada, Israel, Nigeria, Romania, South Africa, and Spain) of respondent countries. However, in 23% (n=5; Bosnia and Herzegovina, Cape Verde, Fiji, Switzerland, and USA), there was a variation in the extent to which pharmacy technicians could provide these services (see Figure 3). With positive responses from close to half of the participants, the finding is representative of the collaborative efforts within the pharmacy workforce, to delivery health services. On the other hand, the practice variation in some countries many indicate areas for improvement, and the absence of authorisation might mean that the pharmacy workforce is not recognised or trusted with these capabilities in the countries concerned.

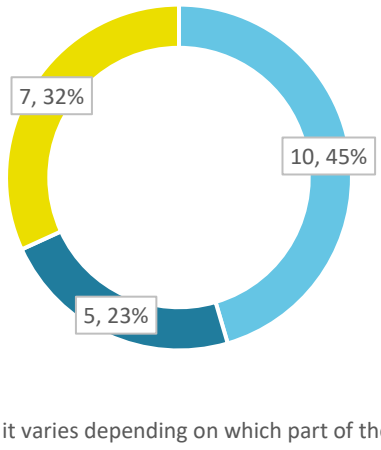

Figure 3. Are other members of the pharmacy workforce (e.g., pharmacy technicians) allowed by law to perform POCT? (n=22)

3.2.4 Types of point-of-care tests provided by pharmacies

In more than 68% (n=15) of the countries surveyed, blood pressure, mean pulse rate and SARS-CoV-2 were reported as the most provided pharmacy-based testing services. Plasma glucose two hours after a 75g oral glucose load (oral glucose tolerance test, OGTT), respiratory syncytial virus (RSV) and procalcitonin tests were the least common services provided by only 18% (n=4) of respondents. Canada, Portugal and Switzerland reported the highest levels of service provision, while Belgium, North Macedonia and Romania reported the lowest (see Table 4 and Figure 4).

Table 4. Community pharmacy-based POCT services offered in each country. (n=22)

Type of test	Countries
Blood glucose and diabetes	
Fasting plasma glucose (FPG)	Bosnia and Herzegovina, Canada, Fiji, Germany, Nigeria, Portugal, South Africa, Spain, Switzerland, Uruguay
Random plasma glucose (RPG)	Australia, Bosnia and Herzegovina, Canada, Cape Verde, Fiji, Germany, Israel, Nigeria, North Macedonia, Portugal, Slovenia, South Africa, Switzerland, USA
Plasma glucose 2 hours after a 75g oral glucose load (oral glucose tolerance test, OGTT)	Canada, Nigeria, South Africa
Glycated haemoglobin A1C (HbA1C)	Canada, Israel, Portugal, South Africa, Spain, Switzerland, Uruguay
Lipid testing	
Total cholesterol	Australia, Canada, Cape Verde, Fiji, Germany, Ireland, Israel, Nigeria, Portugal, Slovenia, South Africa, Spain, Switzerland, Uruguay, USA
HDL cholesterol	Canada, Germany, Ireland, Nigeria, Portugal, South Africa, Spain, Switzerland, Uruguay, USA
Triglycerides	Canada, Germany, Ireland, Nigeria, Portugal, South Africa, Spain, Switzerland, Uruguay, USA
Cardiovascular health indicators	
Blood pressure	Australia, Austria, Bosnia and Herzegovina, Canada, Cape Verde, Fiji, France, Germany, Ireland, Israel, Nigeria, Norway, Portugal, Romania, Slovenia, South Africa, Spain, Switzerland, Uruguay, USA
Mean pulse rate	Australia, Austria, Bosnia and Herzegovina, Canada, Fiji, Germany, Ireland, Israel, Nigeria, Portugal, Romania, South Africa, Spain, Switzerland, USA
Respiratory function testing	
Spirometry	Australia, Bosnia and Herzegovina, France, Ireland, Nigeria, Portugal, South Africa, Spain, Switzerland
Haematology testing or indicators	
Haemoglobin	Canada, Ireland, Portugal, South Africa, Spain, Uruguay
Infectious disease testing	
Flu tests	Australia, Canada, Portugal, Switzerland, USA
Strep throat tests	Canada, Ireland, Israel, Portugal, Switzerland, USA
Respiratory syncytial virus (RSV) tests	Australia, Canada, USA
HIV testing	Australia, Austria, Canada, France, , Nigeria, Portugal, South Africa, Spain, Switzerland, USA
SARS-CoV-2 tests	Australia, Austria, Belgium, Bosnia and Herzegovina, Canada, France, Germany, Ireland, Israel, Portugal, Romania, Slovenia, South Africa, Switzerland, Uruguay, USA

Type of test	Countries
Hepatitis C antibody test	Australia, Nigeria, Portugal, Switzerland
Sexually transmitted infections screening tests	Canada, Nigeria, Portugal, South Africa, Spain, Switzerland
C-reactive protein	Germany, Portugal, South Africa, Switzerland
Procalcitonin	Switzerland
Urine testing	
Pregnancy tests	Australia, Bosnia and Herzegovina, Fiji, France, Germany, Nigeria, Portugal, Slovenia, South Africa, Spain, Switzerland
Microscopic panel (erythrocytes, leukocytes, casts, crystals, bacteria, epithelial cells)	Portugal, Spain
Macroscopic panel (dipstick) (colour, bilirubin, occult blood, macroscopic blood, glucose, ketones, leukocytes esterase, nitrite, pH, protein, gravity, urobilinogen)	France, Nigeria, Portugal, South Africa, Switzerland

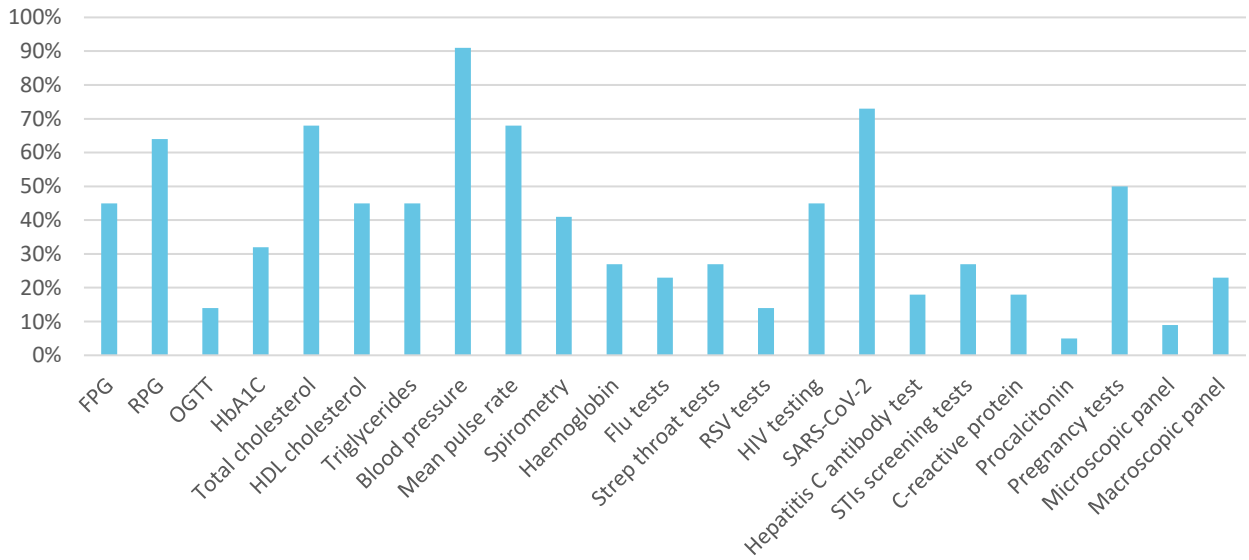

Figure 4. Which types of POC tests are provided by pharmacies in your country/territory? (n=22)

Some countries provided services that were not captured in the survey; respondents from Australia indicated that other services may be provided that the member organisation was not aware of and therefore not included in their responses. This was attributed to the absence of legal barriers to testing and the availability of tests that could be administered by the individual. In Norway, some pharmacies have provided HbA1c, total cholesterol, RPG and strep throat tests, but only on a project basis. Respondents from Portugal highlighted other tests such as 48-hour ambulatory blood pressure monitoring (ABPM), other blood tests — PSA (prostate specific antigen), erythrocytes, haematocrit, uric acid, FORT (free oxygen radicals test), FORD (free oxygen radicals defence), ALT (alanine transaminase) and AST (aspartate transaminase) — offered in community pharmacies in their country. Spain noted that the SARS-CoV-2 tests performed in the pharmacy

during the pandemic were currently stopped due to the end of the public health emergency declared by the WHO. Of all respondents, only community pharmacies in Uruguay offered POCT services for coeliac disease. The wide array of tests provided in community pharmacies across the regions are indicative of community pharmacies' ability to conduct and provide this valuable service.

3.2.5 Legal provisions to sell self-tests

Of the respondents, 95% (n=21) had legislation that allowed pharmacies to sell self-tests for use by consumers in their homes (see Figure 5) Only Romania did not allow pharmacies to sell these kits. It is clear from this sample that there is a relationship between legislation and the accessibility of self-test kits by consumers. Favourable legislation can impact access to necessary health products.

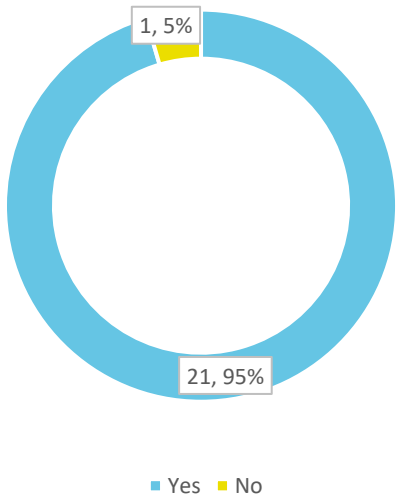

Figure 5. Are pharmacists allowed by law to sell self-tests for use by the consumer in their home? (n=22)

3.2.6 Renumeration models

Participants were asked how pharmacists are remunerated for POCT services. This was divided into four payments categories: by public health system/third-party payers; private health insurance companies/third-party payers, patient/customer out-of-pocket; and no remuneration for POC tests, as indicated in Table 5.

In Ireland and North Macedonia, pharmacies received no payment at all for these services. Germany reported that SARS-CoV-2 tests were the only test paid for by the government and in the USA, payment depended on a patient's insurance coverage. For countries such as Austria, Australia, Canada, France, South Africa, Spain which reported multiple remuneration models, reimbursement varied by jurisdiction.

The result showed a variety in remuneration models. The finding that in more than half of the cases, patients paid out-of-pocket payment, shows lack of recognition by policymakers, lack of support from government and/or the unwillingness to fund these services through third-party payers. Repeated payments by patients impacts negatively on the sustainability of this service provision. This highlights an important area to be improved upon.

Table 5. How are pharmacies remunerated for POCT in your country/territory? (n=22)

Remuneration for services	Countries
They are reimbursed by public health systems /third-party payers	Austria, Belgium (as at time of survey, June 2023), Canada, France, Spain
They are reimbursed by private health insurance companies/third-party payers	Bosnia and Herzegovina, Canada, South Africa
They are paid by the patient/customer out of pocket	Austria, Australia, Canada, Cape Verde, Fiji, France, Germany, Israel, Nigeria, Norway, Portugal, Romania, Slovenia, South Africa, Spain, Switzerland, Uruguay
They receive no remuneration for POC tests	Australia, Ireland, North Macedonia, South Africa
Other	Germany, United States

3.2.7 Result documentation in internal system

From surveyed participants, France was the only country that reported the existence of a unified nationwide documentation system which enabled patient management and follow-up. Of the respondents, 55% (n=12) confirmed the presence of result documentation in a system shared across pharmacies in the same network. There were 41% (n=9) of respondents who stated that pharmacies were not obligated to document their results in any system (see Table 6). The presence of a "same network documentation" in more than half of the countries is indicative of strong basis for patient management. This shows room for improvement in countries where such documentation is non-existent, and the need for cross-pharmacies documentation to ensure patients can visit any pharmacy and still have access to their records.

Table 6. Are pharmacists authorised to store the results of POCT and other health data in an internal system that supports patient management and follow-up? (n=22)

Authorisation to store results	N	%	Countries that offer this service
Yes (in a system shared across all pharmacies in the country)	1	4	France
Yes (in a system shared across all pharmacies of the same network/owner, or individual pharmacies)	12	55	Australia, Austria, Belgium, Canada, Cape Verde, Norway, Portugal, South Africa, Spain, Switzerland, Uruguay, USA
No	9	41	Bosnia and Herzegovina, Fiji, Germany, Ireland, Israel, Nigeria, North Macedonia, Romania, Slovenia

3.2.8 Result sharing with other professionals

More than 70% of respondents (n=16; Australia, Austria, Bosnia and Herzegovina, Canada, Cape Verde, Fiji, Germany, Ireland, Nigeria, North Macedonia, Norway, Portugal, Slovenia, Spain, Switzerland, Uruguay) reported that pharmacies are not able to register the results of POCT in a shared health record accessible to other healthcare professionals. However, 27% (n=6) reported that they can register the results of POCT in a shared health record accessible to other healthcare professionals (Belgium, France, Israel, Romania, South Africa, and the United States), which could facilitate collaboration between healthcare professionals (see Figure 6). It is noteworthy that this finding is indicative of a barrier in the execution of pharmacy-based POCT. The inability to share POCT results with other healthcare practitioners hinders patient-centred collaborations and can affect patient care. This is an area to be highlighted to the government and necessary agencies for improvement.

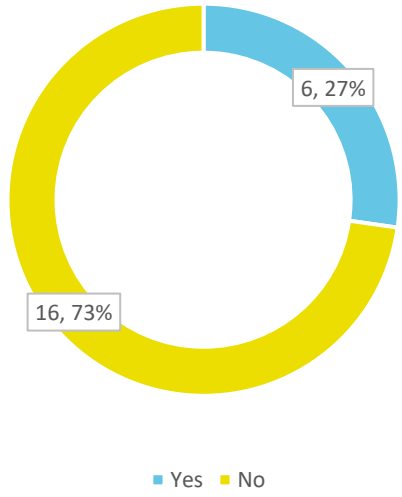

Figure 6. Are pharmacists able to register the results of POCT in a shared health record accessible to other healthcare professionals? (n=22)

3.2.9 Specific professional regulations

Specific professional regulations, standards, or requirements for conducting POCT services at pharmacies, including a standard operating procedure for each device are required in 12 countries (Australia, Belgium, Canada, France, Germany, Ireland, Israel, Norway, Romania, Slovenia, South Africa, Switzerland). Eight countries (Austria, Bosnia and Herzegovina, Cape Verde, Fiji, Nigeria, North Macedonia, Portugal, Uruguay) mentioned that these professional requirements did not exist, and two countries reported the existence of regulatory differences within the country (Spain and the USA) (see Figure 7). The existence of professional regulations, standards or requirements is essential to ensure the quality of POC testing and increase the likelihood that these services will be sustainable in a long-term perspective.

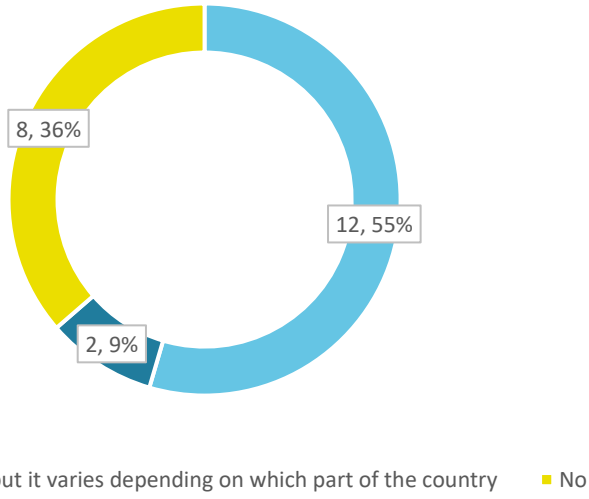

Figure 7. Are there specific professional regulations, standards, or requirements for conducting POCT services at pharmacies, including a standard operating procedure for each device? (n=22)

3.2.10 Workspace specifications

The presence of a separate private area for the provision of POCT services was a requirement in 68% of countries (n=15; Austria, Belgium, Canada, Cape Verde, France, Germany, Ireland, Israel, Norway, Portugal, Romania, Slovenia, South Africa, Switzerland, Uruguay). Austria, Bosnia and Herzegovina, Nigeria and North Macedonia did not highlight that pharmacies had to meet any requirements regarding the facilities for conducting POC tests. However, 14% (n=3; Fiji, Spain, USA) reported that the enforcement of these requirements varied in different parts of the country (see Figure 8).

According to the results, it appears that in some countries the existing pharmacy layout is not fully designed to encourage patient involvement in professional care within this healthcare setting. This is surprising given that patient confidentiality and privacy is one of the priorities in retail settings. Nevertheless, with more than half of respondents reporting a workspace specification requirement, this evidence supports the fact that community pharmacies providing POCT services should have a separate private area in which to provide this service.

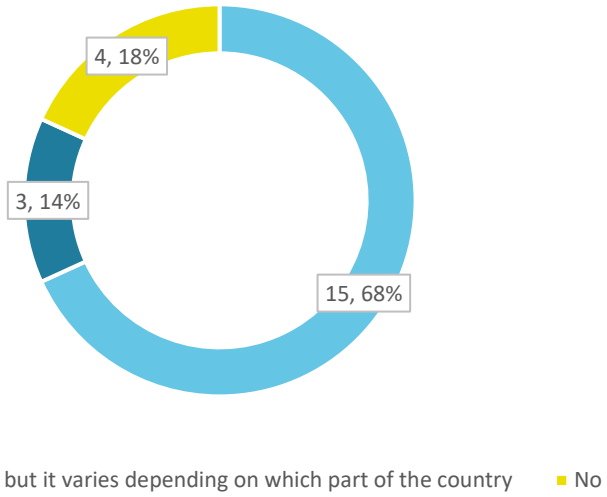

Figure 8. Do pharmacies have to meet any requirements regarding the facilities for conducting POC tests (e.g., separate private area? (n=22)

3.2.11 Clinical decision making

Authorisation for pharmacists to make clinical decisions based on POCT results is less common, with only 9% (n=2, South Africa, Switzerland) of respondents reporting this. In Canada, France and the USA, the authorisation to make clinical decisions based on test results depends on the region where the community pharmacy is located. However, 77% (n=17; Australia, Austria, Belgium, Bosnia and Herzegovina, Cape Verde, Fiji, Germany, Ireland, Israel, Nigeria, Northern Macedonia, Norway, Portugal, Romania, Slovenia, Spain, Uruguay) reported that there was no legislation in their country that would allow them to make clinical decisions based on POCT results, such as prescribing antibiotics for strep throat and adjusting or renewing prescribed treatments for certain chronic non-communicable diseases (see Figure 9).

With only two countries being able to make clinical decisions on POCT results, this finding shows that authorisation to make clinical decisions based on the results of POC tests remains a major issue in many countries. Hesitancy from other professionals or lack of policy implementation might be a possible explanation. However, the provision of POCT services by community pharmacies is increasingly accepted as an accessible healthcare option and can be used to contribute to primary healthcare services.

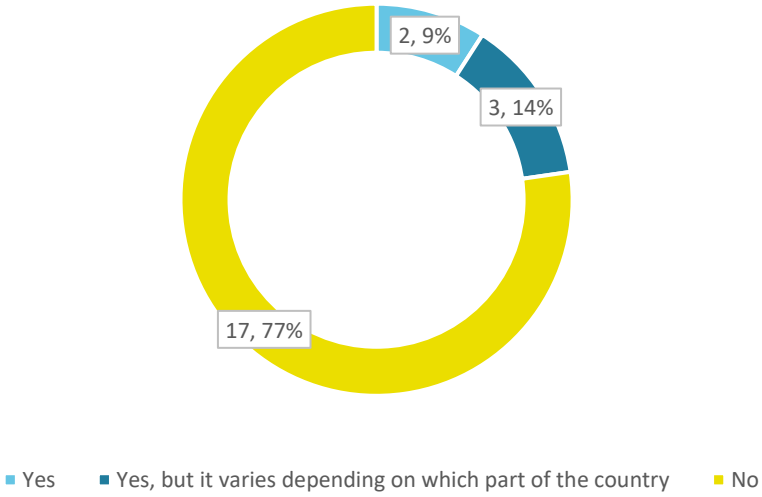

Figure 9. Are pharmacists authorised to make clinical decisions based on the results of POC tests (e.g., prescribe antibiotics for strep throat, adjust, or renew prescribed treatments for certain chronic non-communicable diseases, etc.)? (n=22)

3.2.12 Workforce training

In 41% of countries (n=9, Australia, Austria, Bosnia and Herzegovina, Cape Verde, Germany, Israel, South Africa, Uruguay, USA), no additional education or training is required for pharmacy professionals to provide POC testing services, although in 36% of countries additional training is required for specific POC tests (n=8, Canada, Fiji, Ireland, North Macedonia, Portugal, Slovenia, Spain, Switzerland). Additional education or training for pharmacy professionals is required in 23% of countries (n=5, Belgium, France, Nigeria, Norway, Romania), (see Figure 10).

This shows some reliance on pre-registration training to provide knowledge of these tests and provides scope for reviewing how POCT training in pharmacy school curricula contributes to overall professional performance post-registration.

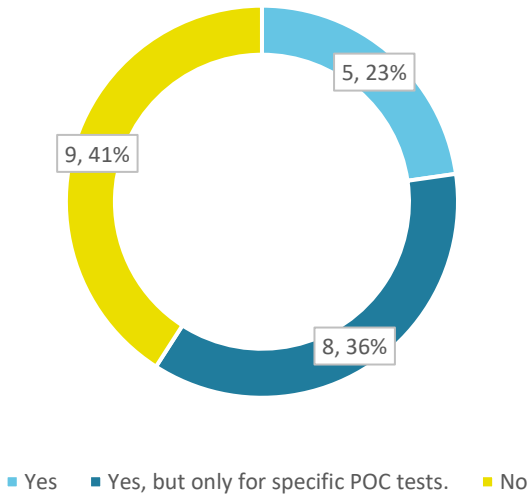

Figure 10. Are pharmacy professionals providing POCT required to undergo additional education or training? (n=22)

3.3 Summary and conclusion

The delivery of public health services has been influenced by the continuing evolution of the pharmacy profession in the healthcare system and the continuing trust between pharmacy professionals and patients. Due to the high level of patient interaction and the way in which patients frequent pharmacies, community pharmacies offer a unique opportunity for the implementation of POC testing for various conditions of public concern, ranging from infectious diseases to chronic diseases.

This survey highlights the global variance in the adoption and practice of community pharmacy-based POC testing services, with an increasing number of countries having implemented legislation to allow the provision of such services by pharmacists and pharmacies. This survey explored the range of services provided in community pharmacies in different countries and provides evidence on how the sale of consumer test kits in pharmacies can improve the range of testing services provided. Our sample shows that in most pharmacies providing POC testing services, the service is paid by the patient or customer out of pocket. This health expenditure can be avoided by implementing strategies to strengthen the financing of screening tests and, more generally, to promote the affordability of accessible health services. Although documentation of results is practised in most countries, the inability to share this information with other healthcare professionals who may be treating the patient is detrimental to professional collaboration and may expose patients to more unnecessary testing.

Furthermore, professional standards such as an operating procedure for each POC testing device, as well as workspace specifications are required. This ensures that the community pharmacy establishes what is already available in the premises, what would be required to deliver the patient service and improve the management of relevant aspects of health and safety and infection control in the community pharmacy.[33]

The results of our survey indicate that pharmacists in most countries do not have the authority to make clinical decisions based on the results of the POC tests they perform. Being able to make such clinical decisions is beneficial in terms of labelling, communication, and tailoring prescriptions to patients' physiological functions. Notably, pharmacists' educational knowledge post-registration was seen as sufficient to support POCT service provision in most countries. Given the increasing prevalence of POC testing in pharmacy practice, there is a need for educators to make a conscious effort to both improve the knowledge of students and provide professional development opportunities on POC testing for pharmacists already in practice.[2]

In Chapter 4, case studies offer a more comprehensive understanding of key elements of POC testing services such as professional standards, remuneration models and details of implementation processes.

4 Case studies

FIP invited FIP member organisations from countries or territories where pharmacists are allowed by law to perform POCT to submit a case study. The case studies contained similar topics to the short survey but had open-ended questions where participants could detail the information about the case studies and include links for further reading. We received 11 case studies from 10 countries:

- Austria
- Belgium
- Canada
- France
- Ireland
- Portugal
- Scotland and England
- South Africa
- Spain
- Switzerland
- Wales

4.1 Austria

Member organisation	Austrian Chamber of Pharmacists
Author	Franz Ferrari

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**	
• Covid-19 screening • Blood pressure testing • Blood sugar testing • Vitamin testing • HIV infection testing • Other health tests	
2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**	
There is no regulation on that. Pharmacies decide on the procedure on their own.	

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**	
a. Practice guidelines and quality assurance	None that are regulatory. The Austrian Chamber of Pharmacists occasionally sent out short guidelines to their members.
b. Education and qualification(s)	Currently not required, but the Austrian Chamber of Pharmacists offered courses and trainings.

c. Requirements for POCT procedure(s)	Currently none.

4. Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.

Only COVID-19-tests were remunerated during the pandemic (EUR 25 per test)
Currently, none of them are remunerated, so they have to be paid for privately by the customer/patient.

[Section C] Details of the implementation process

5. What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).

Not applicable

6. Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).

Date	Events
	Tests listed above apart from COVID-19 have been offered by pharmacists for a long time.
December 2020	First pharmacies started to offer COVID antigen tests on a privately paid basis.
March 2021	Ministry of health decided to make pharmacy COVID-19 tests remunerated.
August 2021	POC PCR tests were added.

7. What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).

This information was not provided by the MO.

8. Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.

☒ Yes
☐ No

If yes	URL: This information was not provided by the MO.

[Section D] Partnership and mobilisation

9. Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.

With/from other healthcare professional groups	This information was not provided by the MO.
With/from policymakers	This information was not provided by the MO.
With/from the public	This information was not provided by the MO.
With/from pharmacists	This information was not provided by the MO.

10. Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?

This information was not provided by the MO.

4.2 Belgium

Member organisation	Association of Pharmacists Belgium (APB)
Author	Jan Saevels

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

SARS-COV-2 rapid antigen tests. Implementation territory is the whole country. In reality this type of POCT is performed by nearly 70% of all Belgian community pharmacies.

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

Target population/workflow/structure
Symptomatic citizens with up to five days of symptoms and asymptomatic (returning and departing travellers) citizens. Patients with severe symptoms or high-risk patients as described by the Belgian authorities are always referred to a physician for further follow-up, regardless of the test result. Children under six years of age cannot be tested at the pharmacy.
Testing is performed using a European approved rapid antigen test that meets sensitivity and specificity requirements. These tests are less expensive than PCR tests and give a rapid result allowing faster clinical decisions. Infected patients can thus be detected and isolated very quickly.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	Testing is performed using a European approved rapid antigen test that meets sensitivity and specificity requirements.
Education and qualification(s)	The pharmacist performing the test is trained for this purpose by following a webinar made available by APB, followed by a hands-on session on the practice of nasopharyngeal swab sampling, led by a physician. Pharmacy technicians who have followed the same training and work under supervision of a pharmacist, are also allowed to perform the tests.
Requirements for POCT procedure(s)	A pharmacy that performs tests must meet specific quality requirements. For example, the test must be conducted with respect to privacy, and there must always be sufficient distance between citizens. The room should be ventilated or have a proper ventilation system. In addition, the room must be easy to clean according to the set rules (manner and frequency) and easily accessible. The pharmacist must always wear the necessary personal protective equipment. Each pharmacy decides individually whether the testing should be done or not or by appointment and within or outside the conventional opening hours of the pharmacy.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

When responding to the initial survey (early June 2023), most of the tests were reimbursed (if they were performed on symptomatic patients). This was abolished on 30 June 2023, meaning that patients needed to pay out-of-pocket since 1 July 2023.

[Section C] Details of the implementation process

5. What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).

- Rapid antigen tests are less expensive than PCR tests and give a rapid result allowing faster clinical decisions. Infected patients can thus be detected and isolated very quickly.
- In case of negative result: Production of European certificate allowing patients to travel.
- If the test result is positive, it means that the patient must adhere to the measures in place to prevent further infection of others. Like the certificates, the positive test result is visible through the federal platforms. After 12 days the patient automatically receives a European recovery certificate which can be found through the same federal platforms.

6. Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).

Date	Events
March 2021	Pilot project eight pharmacies in one city (Brussels)
July 2021	Federal authorities allow pharmacists in pharmacies to perform tests on asymptomatic citizens/travellers
September 2021	300 pharmacies perform tests
November 2021	All pharmacies are allowed to test all patients/citizens (symptomatic and asymptomatic)

7. What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).

Testing guidelines change depending on the pandemic. This makes sense but sometimes led to public confusion. For example, at certain times high-risk contacts should be tested and at other times they should not. On the other hand, pharmacies were never allowed to test these high-risk contacts while they were allowed to test other citizens with symptoms or who returned from or left on a trip.

Reimbursement is crucial.

Training and supporting documentation as this type of POCT was brand new, e.g., training documents, process models, example reports, data sets, etc.

E-learning, manual, information sheets on the safe using and removal of personal protective equipment, information sheet on how to handle with waste, guide on how to use the so-called e-form correctly, posters to communicate that a pharmacy does or does not offer this service and for which patients, clear notices for the pharmacists when testing policy changes, flyers on how to download certificates, etc.

Finally, the possibility to link directly from the pharmacy dispensing software to the “official national” testing databases was conditional for success. This link was made through the e-form

8. Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.

☒ Yes

☐ No

If yes	URL: https://ijic.org/articles/10.5334/ijic.ICIC22376

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**	
With/from other healthcare professional groups	The implementation was strongly driven by pandemic situation. Little resistance or engagement from or with other HCPs.
With/from policymakers	Strong collaboration with the Belgian authorities which developed testing policies.
With/from the public	Use of our public portal www.pharmacie.be to make the service known, and even to allow citizens to search for nearest pharmacy that offers the service.
With/from pharmacists	E-learning, manual, information sheets on the safe using and removal of personal protective equipment, information sheet on how to handle waste, guide on how to use the e-form correctly, posters to communicate that a pharmacy does or does not offer this service and for which patients, clear notices for the pharmacists when testing policy changes, flyers on how to download certificates, etc.
10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**	
This information was not provided by the MO.	

4.3 Canada

Member organisation	Canadian Pharmacists Association
Authors	Lindsay Rodwell, Kelsey Skromeda

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

Pharmacists in Canada are governed by their respective provincial regulatory authority and as such have different scopes of practice across the country. Due to this, specific provinces have been highlighted in this case study. Links to all available provincial pharmacy regulations on POCT have been provided in this first section, with the focus on Alberta and Ontario thereafter.

Helpful resource: Pharmacy | Free Full-Text | Evaluation of Point-of-Care Testing in Pharmacy to Inform Policy Writing by the New Brunswick College of Pharmacists (mdpi.com) – Table 1 describes POCT Scope across Canadian provinces.

Alberta:

- Pharmacists may conduct a POCT to identify or manage a disease state or chronic condition, with rationale including but not limited to: (i) ensuring that the drug and the dose ordered is appropriate for the individual patient; (ii) monitoring patients' responses to therapy to ensure optimal outcomes; (iii) monitoring for adverse effects to ensure patient safety; and (iv) screening of patients with preliminary indicators for untreated health conditions.
- Guidance_Lab_POCT.pdf (abpharmacy.ca)
- Standards_Lab_POCT.pdf (abpharmacy.ca)

Ontario:

- Point-of-Care Testing | Ontario Pharmacists Association (opatoday.com)
- Point of Care Tests - OCPInfo.com
- Update_to_Executive_Officer_Notice:_Publicly_Funded_COVID-19_Testing_Services_in_Ontario_Pharmacies (gov.on.ca)
- Glucose
- Hemoglobin A1C (HbA1C)
- Lipids
- Prothrombin time and International Normalized Ratio (PT/INR)
- COVID-19

British Columbia:

- Community-based point-of-care testing policy - Province of British Columbia (gov.bc.ca)

Saskatchewan:

- REF_Laboratory_Tests_and_Medical_Devices.pdf (saskpharm.ca)
- REF_Disease_State_Monitoring_20161026.pdf (saskpharm.ca)

Manitoba:

- Guide to Pharmacy Practice (cphm.ca)
- College-of-Pharmacists-of-Manitoba-Spring2020.pdf (cphm.ca)
- The Manitoba Pharmaceutical Association (cphm.ca)

Nova Scotia:

- Standards of Practice: Testing (nspharmacists.ca)

New Brunswick:

- GM-PP-POCT-01POLICY-ADMINISTERING-AND-INTERPRETING-POINT-OF-CARE-TESTS.pdf (nbpharmacists.ca)

Newfoundland and Labrador:

- Guidelines-POCT-March2022.pdf (nlpb.ca)

Prince Edward Island:

- Pharmacist and Pharmacy Technician Regulations (princeedwardisland.ca)

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

Alberta (Standards_Lab_POCT.pdf (abpharmacy.ca)**):**

1. Pharmacist conducts patient assessment.
2. Pharmacist to obtain informed consent from patient to conduct POCT.
3. Pharmacist or pharmacy technician conducts POCT.
4. Pharmacist interprets results of POCT.
5. Document encounter and decision made from POCT data within patient profile.
6. Charge patient for service.
7. Communicate results to primary healthcare provider.

Ontario (Lipids Point-of-Care Testing Clinical Tool | Ontario Pharmacists Association (opatoday.com); Point-of-Care Testing (POCT) Services Suggested Fee Guide | Ontario Pharmacists Association (opatoday.com)**):**

1. Pharmacist assesses patient or patient asks about POCT.
2. Pharmacist explains significance of test and obtains informed consent from patient.
3. Pharmacist, pharmacy technician or pharmacy student/intern conducts POCT.
4. Pharmacist interprets results.
5. Pharmacist communicates results to patient and counsels on actions/next steps.
6. Charge patient for service.
7. Pharmacist documents encounter and relays results to the rest of the patient's care team (i.e., family physician, nurse practitioner, etc.).

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	**Alberta:** Standards_Lab_POCT.pdf (abpharmacy.ca) • Alberta pharmacists with additional prescribing authority may prescribe for any Schedule I drug, and as such can independently adjust therapy and/or prescribe based on results of a POCT conducted in the pharmacy. • Pharmacist must consider if a laboratory test would be more appropriate. • Test must be undertaken for a purpose within the "practice of pharmacists" (i.e., promotion of health, prevention or treatment of diseases, dysfunctions and disorders through proper drug therapy and non-drug therapy decisions). • Test must be required for pharmacist to identify or manage a disease state or chronic condition. • Pharmacist/pharmacy technician has a professional relationship with the patient.

	• Laboratory test data is not otherwise available (e.g., on electronic health record). • POCT is appropriate after considering clinical suitability, effectiveness, and the patient's best interests. • Test is low-risk and is either non-invasive or minimally invasive. • Test provides rapid results. • Pharmacist has adequate knowledge of the POCT being performed, when testing is appropriate considering patient-specific factors, which POCT to select, how results should be interpreted and what action should be taken based on results. **Ontario:** • Point-of-Care Testing (POCT) References Chart | Ontario Pharmacists Association (opatoday.com) • Piercing the Dermis for Demonstration and Point-of-Care Tests - OCPInfo.com • The pharmacy professional will only perform POCT if assessment of patient confirms the test is appropriate. • Informed consent may be expressed or implied. • Documentation must include the test results and the decision arising from them, and the patient's primary care provider must be notified of this within a reasonable time. • Pharmacy professionals do not have the authority to perform the controlled act of "communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis". • Pharmacists cannot prescribe for any Schedule I drug, but they may adjust the dose of a medication as an adaptation of an original prescription from another healthcare provider (e.g., warfarin).
Education and qualification(s)	**Alberta:** • There are no required/accredited courses or training necessary to complete in order to provide POCT services for Alberta pharmacists or pharmacy technicians. The Alberta College of Pharmacy has compiled a list of 11 resources to improve POCT know-how located here: 11 resources to improve your point-of-care testing know-how | Alberta College of Pharmacy (abpharmacy.ca). • Pharmacists and pharmacy technicians who conduct tests must be "trained, competent and follow standard operating procedures and manufacturer standards". • Must be aware of the following documents: Standards_Lab_POCT.pdf (abpharmacy.ca) Guidance_Lab_POCT.pdf (abpharmacy.ca) **Ontario:** • There are no required/accredited courses or training necessary to complete in order to provide POCT services in Ontario. • Included in pharmacy school curriculum.

	• The Ontario Pharmacists Association provides a variety of resources for pharmacy professionals to conduct POCT (for members only): • Lipids Point-of-Care Testing Clinical Tool | Ontario Pharmacists Association (opatoday.com) • HbA1C/Glucose Point-of-Care Testing Clinical Tool | Ontario Pharmacists Association (opatoday.com) • PT/INR Point-of-Care Testing Clinical Tool | Ontario Pharmacists Association (opatoday.com)
Requirements for POCT procedure(s)	**Alberta:** • Standards_Lab_POCT.pdf (abpharmacy.ca) • Device is intended for single use or certified for multi-patient use. • Tests conducted in a clean, safe, private and appropriate environment. • Quality assurance process for POCT must be considered. • Apply routine practices to prevent transmission of infection. **Ontario:** • Point of Care Tests — OCPInfo.com • Must be conducted in an appropriate setting with evidence-based infection prevention and control measures in place. • Devices and supplies must be received and stored according to manufacturer's directions. • Follow infection prevention and control procedures (i.e., hand washing, personal protective equipment, disinfect POCT devices used for multiple patients).

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

POCT is not publicly funded anywhere in Canada. Patients must pay for the service out of pocket.
Alberta: POCT is not covered publicly and must be billed directly to the patient. 83443_compensation_guide.pdf (bluecross.ca)

Ontario: POCT is not covered publicly and must be billed directly to the patient. A suggested fee guide is provided by the Ontario Pharmacists Association with a recommended fee of CAD 35+ (CAD 35 professional service fee + cost of materials). Point-of-Care Testing (POCT) Services Suggested Fee Guide | Ontario Pharmacists Association (opatoday.com)

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

Alberta: Point of Care Testing Whitepaper.pdf (abpharmacy.ca)

1. Current unsustainable models of health care and the need for cost containment while assuring access.
2. Public's demand for more involvement, control and convenience in their care.
3. The emergence of disruptive testing technologies that are entering new and "unregulated" consumer and community healthcare markets.
4. Pressures in health systems aimed at decreasing costs and increasing access to health services (i.e. POCT shortens turn around time for test results, reduction in subsequent health encounters).

Ontario: OPA's Submission on OCP Scope of Practice Consultation | Ontario Pharmacists Association (opatoday.com)

1. Expanding scope of pharmacists to better collaborate with other healthcare providers.
2. Enables pharmacists to conduct risk assessments, monitor health outcomes of current pharmacotherapy, and facilitates increased patient engagement in the self-management of their medical conditions.
3. More accessible than laboratory testing (especially for those in remote locations, are homebound or reside in an area where traditional lab testing is unavailable) and reduces processing delays.
4. Cost savings and uses fewer resources.
5. Pharmacists are able to make real-time decisions based on test results.

6. Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).

Date	Events
Alberta	
May 2016	White paper developed to inform guidelines and standards of practice for Alberta pharmacists by the Alberta College of Pharmacy and the Alberta Pharmacists Association. (Point of Care Testing Whitepaper.pdf (abpharmacy.ca))
Apr 2017	A framework was outlined for the safe, effective and appropriate use of POCT in pharmacy practice in the province of Alberta. (Framework for Point of Care Testing.pdf (abpharmacy.ca))
2019	Alberta College of Pharmacy develops new Standards of Practice for Laboratory and Point of Care Testing. (Enhancing patient care with point-of-care testing | Alberta College of Pharmacy (abpharmacy.ca))
January 2022	Alberta College of Pharmacy last updated Standards of Practice Laboratory and Point of Care Testing document.
Ontario	
May 2019	The Ontario College of Pharmacists received a letter from the ministry of health asking for collaboration to begin to allow pharmacists to independently perform POCT to support pharmacists' role in medication management and treatment of patients. (August22_2019_Council_Materials_For_Website.pdf (ocpinfo.com))
October 2019	At the time, pharmacists had been able to perform the controlled act of piercing a patient's dermis with a lancet-type device to obtain blood for the purpose of patient education and demonstration. The Ontario Pharmacists Association submitted comments and recommendations to the Ontario College of Pharmacists in support of expanding this act past the purpose of patient education and demonstration. (OPA's Submission on OCP Scope of Practice Consultation | Ontario Pharmacists Association (opatoday.com))
November 2019	Draft regulations sent to the ministry of health by OCP. (Expanded Scope of Practice: Consultation on Draft Regulations Now Open — Pharmacy Connection)
March 2021	Amendments were made to the Laboratory and Specimen Collection Centre Licensing Act to allow pharmacists to perform antigen POCT for COVID-19 in pharmacies across the province for eligible patients. (COVID-19: Information for Pharmacy Professionals - OCPInfo.com)
July 2022	Amendments made to regulations under the Pharmacy Act to authorise pharmacy professionals to perform the controlled act of piercing a patient's dermis with a lancet-type device to obtain blood for purposes beyond patient demonstration and self-monitoring of chronic diseases. Regulations were also made under the Laboratory and Specimen Collection Centre Licensing Act to enable a pharmacist, an intern, a registered pharmacy student or a pharmacy technician to perform certain POCT (glucose, HbA1C, lipids, PT/INR). (Point-of-Care Testing | Ontario Pharmacists Association (opatoday.com))

7. What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).

Alberta: POCT: opportunities and risks | Alberta College of Pharmacy (abpharmacy.ca)
These risks/challenges are not all necessarily directed towards the implementation process, but further information on implementation is not publicly available.

- Clinical and analytical validity of tests.
- Workflow requirements when working with biological samples, space issues and regulatory requirements.
- Data sharing with healthcare providers due to digital connections lacking with some providers.
- Misinterpretation of results.
- Not financially covered by the provincial government, therefore patients have to pay out of pocket.

Ontario: Proposed Amendments to Regulations 682 and 683 made under the Laboratory and Specimen Collection Centre Licensing Act. (ontariocanada.com)

- Initial proposed changes to scope of practice regarding POCT focused on management of chronic conditions, which were assessed as part of the 2019 Ontario budget.
- The Ontario Pharmacists Association believed this could be expanded to offer other tests.
- There are still only four POCT authorised (as well as COVID-19 POCT) in the current guidelines as of July 2023.
- A provincial clinical viewer (ConnectingOntario ClinicalViewer and ClinicalConnect) is available for pharmacists to access, however this resource only displays publicly funded drugs (not covered by private insurance), and only shows information from regional health authority (not necessarily province wide, and no data from outside of the province). Expansion of this would allow for more information for pharmacists to make clinical decisions after considering POCT results. (Patient ClinicalConnect Brochure.pdf).
- Not financially covered by the provincial government, therefore patients have to pay out of pocket.

8. Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.

☒ Yes

☐ No

If yes

URL:
Alberta:

Pharmacist intervention for glycaemic control in the community (the RxING study)
RxING study showed a decrease in HbA1C after pharmacists conducted POCT to screen for patients not currently taking insulin that would benefit from insulin therapy. 51% of patients achieved the target HbA1C of ≤7%, with the HbA1C decreasing by an absolute value of 1.8%.

A Randomized Trial of the Effect of Community Pharmacist Intervention on Cholesterol Risk Management: The Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP)
SCRIP study (performed in Alberta and Saskatchewan) showed that a comprehensive pharmacist intervention in patients at risk for cardiovascular events, including using POCT, resulted in a significant number of patients (57% in intervention vs 31% in usual care) subsequently receiving a fasting cholesterol panel by their physician and/or increased dose in their cholesterol-lowering medication. Conclusion made that pharmacist-led community programme improved cholesterol management in high-risk patients.

Expanding access to HIV testing through Canadian community pharmacies: findings from the APPROACH study
APPROACH pilot study (performed in Newfoundland and Labrador, and Alberta) showed a pharmacist-led community programme to screen for HIV using POCT was feasible for scale-up with a high degree of client acceptability and pharmacist confidence in providing the service.

	Ontario: Community pharmacist identification of chronic kidney disease using point-of-care technology: A pilot study. Pilot study investigating community pharmacist identification of chronic kidney disease (CKD) using POCT of SCr and eGFR showed that screening for CKD with community pharmacy based POCT was feasible, and highlighted that a full scale trial could be completed; 11% of participants had CKD, with 90% of those having previously unrecognised CKD.

[Section D] Partnership and mobilisation

9. Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.	
With/from other healthcare professional groups	**Alberta:** From the White Paper (Point of Care Testing Whitepaper.pdf (abpharmacy.ca)): The POCT Advisory Committee chose to identify federal, provincial and professional policies, guidelines and standards of practice that may guide or govern the delivery of POCT. Standards of practice from the provincial governing bodies for pharmacy professionals were reviewed. Standards of practice from the College of Physicians and Surgeons of Alberta were also reviewed and Alberta Health Services' Laboratory POCT Network leads were consulted. **Ontario:** Event led by medical microbiologist at Public Health Ontario for providers performing POCT outside of a laboratory setting: PHO Microbiology Rounds: Quality Framework for Point-of-Care Testing in Ontario | Public Health Ontario Position statement from Canadian Society for Medical Laboratory Science: ads016e_point_of_care_testing.doc (csmls.org)
With/from policymakers	**Alberta:** White Paper and framework reports outlined by the Alberta College of Pharmacists and Alberta Pharmacists Association to develop policy on POCT for pharmacists and pharmacy technicians. **Ontario:** Provincial government reached out to the college to begin conversations on POCT as part of the 2019 budget, aligned with the goal of the current "Premier's Council on Improving Healthcare and Ending Hallway Medicine".
With/from the public	**Ontario:** The ministry of health posted the proposed regulatory changes to allow pharmacists to conduct POCT on the government of Ontario's public registry for a 45-day consultation period.
With/from pharmacists	**Ontario:** The Ontario Pharmacists Association developed resources for pharmacists conducting POCT. The Ontario College of Pharmacists held a 60-day public consultation from 22 August 2019 to 26 October 2019 for pharmacy professionals to comment.

10. Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?

- Ensure training and comprehensive guidelines are provided to pharmacists for them to follow in practice.
- Integrate results of POCT through electronic health records for other providers to have access to this information.
- Consider implementing pharmacist scope to adjust medication dosages as an actionable response to POCT results to further increase access and timeliness to care for patients.

4.4 France

Member organisation	French Community Pharmacists Union (USPO)
Author	Auge-Caumon Marie-Josée

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

Community pharmacists are allowed to test for COVID-19 and sore throat. They are also allowed to test for diabetes (capillary blood glucose screening). These three tests are authorised by the state and can be initiated by every community pharmacy.

On the other hand, pilot experiments are beginning to test for HIV in community pharmacy. These pilots are limited to a few towns.

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

COVID-19
Since the beginning of the COVID-19 crisis, community pharmacists have been allowed to test for COVID-19. Training for this is mandatory. The standard workflow is simple: a patient arrives with symptoms and the community pharmacist is allowed to test for COVID-19. Until recently, every test was recording on to a specific platform organised by the French government. This platform automatically sent the test result to the patient and was used to monitor the COVID-19 epidemic. Until recently, every test was covered by French health insurance.

Sore throat
Community pharmacists have been allowed to test for sore throat since 2019. This authorisation was suspended during the COVID-19 pandemic until 2022. Community pharmacists are paid EUR 16.50.
There are three different workflows:

- Patient arrives with a prescription for antibiotics to be given if the test is positive. In that case, community pharmacists are paid EUR 6 if the test is positive and EUR 7 if the test is negative.
- Patients arrives without a prescription. Community pharmacists are allowed to test for sore throat. In that case, community pharmacists are paid EUR 6. If positive, they must advise the patient to consult a doctor.
- Patients arrives without a prescription. Community pharmacists are allowed to test for sore throat. If positive, pharmacists are allowed to provide antibiotics. In that workflow, community pharmacists belong to a specific health professional community (territorial professional health community, CPTS, or multi-professional health centre, MSP). In that case, the CPTS or MSP is paid EUR 25 and a part of it is given to community pharmacists. A specific protocol is provided by health authorities.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	For sore throat provided by a community pharmacists in a specific structure, a protocol must be followed.
Education and qualification(s)	For COVID-19, community pharmacists must be trained by peers. For sore throat, specific training is required.
Requirements for POCT procedure(s)	For every test, the community pharmacist must have a specific room.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

See section 2.

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

- Availability of tests, since community pharmacy are well implanted in France.
- Easy and rapid access for patients: community pharmacies are open every day without any appointment needed.
- Strong expectations from patients,
- Security: tests are carried out by health professionals.
- In case of sore throat test: justified use of antibiotics. Community pharmacists can therefore act against antibiotic resistance.

6. **Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).**

This information was not provided by the MO.

7. **What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).**

- Strong opposition from biology laboratories and from doctors.
- For sore throat, pricing strategy does not compensate for the community pharmacy costs.

8. **Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.**

☐ Yes
☒ No

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**

With/from other healthcare professional groups	Working with patients associations.
With/from policymakers	Addressing notes and specific arguments to health ministry and both chambers of Parliament.
With/from the public	Posters in community pharmacies to raise awareness.
With/from pharmacists	Formation, information, communication's tools, etc.

10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**

This information was not provided by the MO.

4.5 Ireland

Member organisation	Irish Pharmacy Union
Authors	Susan O Donnell, Susan O Dwyer

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

There is currently no national, structured POCT service that has been supported with national funding at pharmacy level in Ireland.

Individual pharmacies offer some POCT services to their patients on a private pay basis.

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

Not applicable for a national funded service.

Where POCT is offered privately the pharmacy advertises the service and the patient can then choose to pay for it. The pharmacy team would assess the patient against the inclusion and exclusion criteria they devised for the service, and where the patient is eligible advise the patient of what is involved in the service and seek their informed consent to proceed. Standard operating procedures would be followed for the POCT offered and decisions on next steps made with reference to clinical history taking and results obtained. Where appropriate, patients are referred to their general practitioner. Patient records are maintained in the community pharmacy and billing is direct to the patient at the point of service delivery.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	The Pharmaceutical Society of Ireland's Core Competency Framework for Pharmacists in the Public Health Domain notes that pharmacists should identify the need for, plan and implement new services according to patients' needs. https://www.thepsi.ie/gns/Pharmacy_Practice/core-competency-framework.aspx There are several guidance documents available in relation to point-of-care testing: • The Royal College of Physicians has produced guidelines for patient testing. • The Health Products Regulatory Authority has produced guidelines on point of care testing in primary and community care. • The Pharmaceutical Society of Ireland has produced guidance on providing testing services in pharmacies.
Education and qualification(s)	Inclusion of point-of-care testing in the undergraduate programme. Self-directed learning based on the type of testing the pharmacist intends to provide.

Requirements for POCT procedure(s)	The procedure should take place in a consultation room as per PSI Guidance. The service should be delivered in line with PSI guidance on the Provision of Testing Services in Pharmacies. Appropriate clinical governance arrangements should be in place, staff should receive appropriate training and the pharmacy should have in place all relevant and, where appropriate, validated equipment and facilities necessary to deliver the service. Appropriate systems of internal and external quality assurance should be in place.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

Patients pay privately for this service.

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

When considering implementing a POCT service in their pharmacy pharmacists consider:

- Public health benefits;
- Individual patient needs;
- Early identification of risk factors and/or disease leading to better outcomes;
- Cost effectiveness;
- Improved access; and
- Equity of access.

6. **Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).**

Date	Events
July 2022	Community pharmacies were recognised as providers of antigen tests (lateral flow) for COVID-19 and were able to issue EU Digital COVID-19 Certificates (but were not publicly funded for providing such services). As of July 2023, testing is no longer routinely offered as infection control measures have been relaxed in relation to COVID-19.

7. **What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).**

At present there is no national structured POCT service available in Ireland. Challenges relate to financial resources within the health service as well as the lack of a national strategy for the delivery of pharmaceutical care/pharmacy services.

8. **Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.**

☐ Yes

☒ No

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**	
With/from other healthcare professional groups	Not applicable as no national service exists
With/from policymakers	Not applicable as no national service exists
With/from the public	Not applicable as no national service exists
With/from pharmacists	Not applicable as no national service exists

10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**
A multidisciplinary approach. Focus on citizens' health needs. Access to shared learning between organisations.

4.6 Portugal

Member organisation	National Association of Pharmacies (ANF)
Author	Maria Mendes

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

Currently, Portuguese pharmacies can carry out the following point-of-care tests:

- Rapid tests for biochemical parameters — blood glucose, HbA1c, lipid profile, total cholesterol, uric acid, INR;
- Group A streptococcus test (sore throat);
- Point-of-care testing for urinary tract infections;
- COVID-19 and influenza tests;
- HIV/hepatitis tests; and
- Pregnancy tests.

Some pharmacies gather biological samples (e.g., blood, urine, stool) from patients and, instead of conducting tests on-site, they send these samples to external laboratories for further analysis and diagnosis (e.g., faecal occult blood test; *Helicobacter pylori* test).

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

In Portugal, the standard workflow for point-of-care testing (POCT) in community pharmacies is as follows:

Initiation of POCT —The initiation of POCT can be triggered in three ways:
Pharmacist's recommendation — The pharmacist identifies the need for conducting a specific test based on the patient's condition. For example, this could be related to monitoring the effectiveness of chronic disease management (e.g., diabetes, hypertension, dyslipidaemia) or investigating common symptoms (e.g., sore throat, urinary tract infection, acute respiratory infection).
Patient's request — The patient directly requests to undergo a specific test.
Medical referral — A medical doctor recommends the performance of a particular test.

Evaluation of test relevance — The pharmacist evaluates the relevance and appropriateness of performing the suggested test based on the patient's condition or symptoms.

Test administration — If deemed appropriate, the pharmacist carries out the POC test following good practices and adhering to test specifications.

Interpretation of test result —If the result does not require immediate medical intervention, the pharmacist may provide appropriate advice or medication without the need for a medical referral. If the result indicates a need for further medical attention, the pharmacist refers the patient to a medical doctor, providing a referral letter and the test results.

Billing and record keeping —The pharmacy bills for the services provided during the POCT process. The test result is recorded in the pharmacy's information system for future reference and tracking of the patient's health status.

Patient follow-up —If necessary, the pharmacist may provide follow-up support and counselling to the patient based on the test result and any prescribed treatments.

In summary, the POCT workflow in Portugal involves an initial evaluation of the need for testing, the administration of the test by the pharmacist, interpretation of results, and appropriate follow-up actions. The process is designed to

ensure effective patient care, collaboration with medical professionals when required, and proper record-keeping for future reference.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**	
Practice guidelines and quality assurance	In Portugal, the provision of POCT by pharmacists or pharmacies is guided by the following professional standards and regulatory requirements: **Ordem dos Farmacêuticos (Portuguese Pharmaceutical Society):** Pharmacists are required to adhere to the "Boas Práticas" (Good Practices) guidelines issued by the Ordem dos Farmacêuticos. These guidelines outline the proper procedures and quality assurance measures to be followed when conducting POCT in community pharmacies. The guidelines ensure that the testing process is carried out accurately, safely and in compliance with professional standards. **Associação Nacional das Farmácias (ANF):** The ANF provides its own set of procedures for conducting POCT. These procedures are likely to complement the guidelines set out by the Ordem dos Farmacêuticos and may include specific protocols for different types of tests offered by pharmacies. **HIV/hepatitis and COVID-19 testing:** For specific tests, such as HIV, hepatitis, and COVID-19 testing, separate regulations and guidelines are in place to ensure compliance with national and international standards for infectious disease testing. These specific guidelines ensure that such tests are conducted with the highest level of accuracy, confidentiality, and patient safety.
Education and qualification(s)	**Biochemical tests and pregnancy tests:** Pharmacists can perform biochemical tests (e.g., blood glucose, HbA1c, lipid profile, total cholesterol, INR, uric acid) and pregnancy tests without mandatory additional training or certification. This means that they are allowed to conduct these tests with their existing pharmaceutical education and qualifications. **Streptococcus A test, COVID-19 test, and urine rapid test:** For tests such as streptococcus A, COVID-19, and rapid urine tests, additional training is recommended but not mandatory. Pharmacists can perform these tests after completing the recommended additional training, which ensures they have the necessary knowledge and skills. **HIV/hepatitis tests:** For HIV and hepatitis tests, it is mandatory for pharmacists to undergo certified additional training provided by the Ordem dos Farmacêuticos. This additional training ensures that pharmacists have the specialised knowledge required for performing these tests accurately and in compliance with relevant regulations.
Requirements for POCT procedure(s)	To conduct POCT in a pharmacy, the following requirements are necessary: **Infrastructure and equipment:** The pharmacy needs to have appropriate infrastructure, such as a designated private area for conducting tests (personalised consultation room), where patient privacy and confidentiality can be maintained. **Personal protective equipment (PPE):** Pharmacists must have access to proper PPE, including gloves and masks, to ensure safety during the testing process.

	Specific equipment for testing: The pharmacy should be equipped with specific devices and tools needed for conducting tests.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

In Portugal, POCT services conducted in pharmacies are typically paid for by the patients themselves (out of pocket), and there is no direct government reimbursement or insurance coverage. Patients are responsible for the full cost of the POCT provided by the pharmacist. However, there are some exceptions to this general rule:

Specific screening campaigns — In certain cases, there may be specific screening campaigns or public health projects where POCT services are offered free of charge to the population. For instance, during the "Fast track cities" project, HIV and hepatitis tests were made available free of charge to the public under the funding of the project. In such cases, there is no direct remuneration for the pharmacist's intervention, as the services are provided as part of a public health initiative.

COVID-19 testing during the pandemic — During the COVID-19 pandemic, some COVID-19 testing services provided by pharmacies were covered by the National Health Service. This arrangement was specific to the exceptional circumstances of the pandemic.

Partnerships with municipalities — Some municipalities finance tests in pharmacies for certain residents who meet certain requirements.

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

In Portugal, the implementation of pharmacy-based POCT services is driven by several key priority areas and important factors. The top arguments for introducing or expanding these services by pharmacists include:

Improved healthcare access and response — By offering POCT services in pharmacies, there is a significant improvement in healthcare access and response for the population. Patients can receive timely testing and immediate results, allowing for more effective monitoring and management of chronic conditions and common ailments.

Public health outcomes — Pharmacy-based POCT services contribute to better public health outcomes. Tests for infectious diseases like COVID-19, influenza, HIV, and hepatitis can help identify cases promptly, enabling early intervention and disease control measures. This plays a crucial role in managing public health emergencies and preventing disease transmission.

Rational use of antibiotics — POCT services that involve tests for streptococcus A and urine can aid in the rational use of antibiotics. By determining the need for antibiotics accurately, unnecessary antibiotic prescriptions can be avoided, which helps combat antibiotic resistance and promotes more effective treatment.

Reduced burden on primary and hospital care — By providing accessible and efficient testing services in pharmacies, there is a potential reduction in the number of people seeking primary and hospital care for non-emergency conditions. This relieves the burden on healthcare facilities, allowing them to focus on more critical cases.

Efficiency in healthcare delivery — Pharmacy-based POCT services promote efficiency in healthcare delivery. Patients can receive immediate results and appropriate interventions directly at the pharmacy, reducing the need for multiple visits and streamlining the overall health care process.

Empowering pharmacists as healthcare providers — Expanding the role of pharmacists to include POCT services empowers them to be more proactive in healthcare delivery. They can take on a broader role in patient care, providing valuable health information and support.

Overall, the implementation of pharmacy-based POCT services in Portugal is driven by the goal of meeting the health needs of the population effectively, promoting public health, enhancing healthcare efficiency, and empowering pharmacists to play a more active role in patient care. These services are recognised as valuable contributions to the healthcare system, with a focus on patient-centric and accessible healthcare solutions.

6. **Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).**

Date	Events
November 2007	The first decree-law was published, defining the services that can be provided in pharmacies, including complementary diagnostic and therapeutic methods. This decree-law established the groundwork for expanding the range of services that pharmacies can offer, which included POCT services.
April 2018	Another decree-law was published, further expanding the services that can be offered in pharmacies. This decree-law specifically included HIV and hepatitis testing among the services that pharmacies can provide.
November 2020	Publication of a decree-law defining the professionals authorised to perform COVID-19 tests. This resulted in the inclusion of pharmacists among the authorised professionals.

7. **What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).**

In the implementation process of POCT in Portugal, several main challenges and limitations were encountered:

Lack of an adequate reimbursement model — One of the primary limitations was the absence of a suitable reimbursement model for POCT services. Without proper reimbursement, pharmacists may find it financially challenging to offer these services, as the costs are borne directly by patients. The lack of government or insurance coverage for POCT can hinder the widespread adoption and accessibility of these services.

Limited acceptance by healthcare providers — The acceptance and support for POCT services by the broader medical community, including physicians and other healthcare providers, were a significant challenge. The medical community's hesitancy or reluctance to fully embrace pharmacy-based POCT may have been due to concerns about the accuracy and reliability of the tests, or it could have been due to the unfamiliarity with the expanded role of pharmacists in healthcare.

Interprofessional collaboration constraints — The successful implementation of POCT services often requires effective interprofessional collaboration between pharmacists and other healthcare professionals. Limited collaboration and communication between different healthcare providers might hinder the seamless integration of POCT services into the overall healthcare system.

Public awareness and engagement — Public awareness and engagement about the availability and benefits of POCT services in pharmacies may have been another challenge. Ensuring that patients are aware of the services offered, their accuracy, and their potential to improve health outcomes is crucial for encouraging patient participation and utilisation.

Regulatory and policy barriers — Changes in regulations and policies might have posed challenges during the implementation process. Obtaining the necessary approvals and meeting regulatory requirements for providing POCT services could be time-consuming and complex.

8. **Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.**	
☒ Yes	
☐ No	
If yes	Point-of-care HIV and hepatitis screening in community pharmacies: a quantitative and qualitative study **Outcomes**: A total of 210 questionnaires were collected (57.9% response rate). Point-of-care test users were predominantly male, mean age of 35 (± 13.0) years, the majority had higher education level, and 22.8% were born outside Portugal. Almost half of the users were first time tested and the main reason for screening was unprotected sexual intercourse. Pharmacists identified speed, confidentiality, counselling provided to users, pharmacists' initial training to perform the tests, and trust in the pharmacist as facilitators of these tests. Stigma associated with infections, the procedure, logistical conditions, and the referral process were considered as barriers. Pharmacies are a screening site with special importance for individuals who are first tested, heterosexuals, and some migrants. Nevertheless, it is necessary to understand and reduce barriers and increase the support to specific groups. Effectiveness of a collaborative diabetes screening campaign between community pharmacies and general practitioners **Outcomes**: Out of 909 screened subjects, 405 (44.6%) presented a Finnish Diabetes Risk Score (FINDRISC) ≥ 15. Of these, 94 (23.4%) had HbA1c levels that made them eligible for GP referral, of which 35 (37.2%) completed the scheduled appointments. Of the participants, 24 were diagnosed with pre-diabetes, and 11 with diabetes. The prevalence was estimated at 2.5% (CI95% 1.6–3.8%) and 7.8% (CI95% 6.2–9.8%) for diabetes and pre-diabetes, respectively. This collaborative model has proved to be effective in the early detection of diabetes and pre-diabetes. Joint initiatives between health professionals can play a pivotal role in the prevention and diagnosis of diabetes, which may lead to a reduction on the burden to health system and society.

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**	
With/from other healthcare professional groups	This information was not provided by the MO.
With/from policymakers	Professional associations and pharmacies engaged in active policy advocacy to highlight the role of pharmacists in delivering POCT services. They emphasised the potential impact of these services on healthcare accessibility, early detection, and improved patient management.
With/from the public	**Awareness campaigns** —Public awareness campaigns were conducted to educate the public about the availability and benefits of POCT services in pharmacies. These campaigns aimed to inform people about the convenience, accessibility and reliability of the tests offered, encouraging them to consider using these services. **In-pharmacy campaigns** — Pharmacies organised in-store campaigns to promote POCT services. Informational posters, brochures and displays were used to highlight the importance of early detection and timely healthcare interventions through POCT. Pharmacists engaged with customers, explaining the significance of the tests and addressing any concerns. **Social media presence** — Pharmacies leveraged social media platforms to reach a wider audience.

With/from pharmacists	The ANF offered specific and comprehensive training in POCT services. This training covered the technical aspects of conducting tests, result interpretation and counselling patients. It also emphasised the importance of adhering to professional guidelines and best practices. Continuing education and professional development opportunities were provided to pharmacists. Workshops, webinars and conferences were organised to keep them updated on the latest advancements in POCT and related healthcare fields.

10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**

Learn from successful international examples. Study and analyse successful international implementations of pharmacy-based POCT services. Understand the key factors that contributed to their success and adapt those strategies to suit your country/territory's healthcare landscape.

Demonstrate added value. Conduct studies and gather data to demonstrate the added value of pharmacy-based POCT services. Show how these services can improve patient outcomes, enhance healthcare accessibility, and contribute to public health goals.

Prioritise the availability of specialised training for pharmacists to ensure they are well-equipped to perform POCT services accurately and confidently. Proper training instils trust and professionalism in delivering these services.

Establish robust quality assurance measures to ensure the accuracy and reliability of POCT services. Maintaining high-quality standards is essential for gaining trust and credibility.

Engage in collaborative discussions with relevant stakeholders, including policymakers, healthcare providers and patient advocacy groups. Building strong partnerships will garner support and foster a coordinated approach.

4.7 Scotland and England

Member organisation	Royal Pharmaceutical Society
Author	Fiona McIntyre

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

A list of POC services is described for England and Scotland with a description of the smoking cessation service in Scotland as the example case study. This service has been established for some time and therefore historical detail on the development phases of the service are not available at this time but could be explored in more detail if necessary.

Carbon monoxide validation is a core element of the community pharmacy smoking cessation support service in Scotland; and is part of the public health service element of the community pharmacy contract. It aims to provide extended access through the NHS to smoking cessation support, including the provision of person-centred behavioural support and evidence-based pharmacotherapies where appropriate, in line with the national service standards.

In some parts of Scotland, locally enhanced services negotiated within health board areas with NHS contracted community pharmacies offer alcohol breath tests as part of a service to supply disulfiram treatment; and a chlamydia test and treat service.

In England, POC services through locally commissioned services within the NHS include hepatitis C diagnostic testing, hypertension, alcohol screening, blood-borne virus testing, anticoagulant monitoring, chlamydia testing and C-reactive protein testing.

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

The public health service is provided free of charge to patients in Scotland. Patients can either self-refer to the smoking cessation service, be approached by a member of the pharmacy team or can be referred by another healthcare professional.

Patients engaging with the service are assessed and their motivation to quit explored. The pharmacist or trained pharmacy support staff then assesses the person and records within the pharmacy care record all additional data required to complete the minimum data set, including a confirmed quit date and selection of pharmacotherapy. These data along with the initial data captured are electronically submitted to the national smoking cessation database and are used to form the basis of the timescales for the quit attempt, four-week and 12-week post-quit date follow-ups as well as activating the first remuneration payment for the service.

Carbon monoxide (CO) validation of a smoker's quit attempt is an encouraging and motivational tool as well as aiding discussion on smoking issues. CO monitoring is a requirement at the four-week and 12-week post quit follow up appointments where the reading should be recorded on the Pharmacy Care Record (PCR). Pharmacy contractors are paid on the electronic submission of a completed minimum data sets (MDS) form within the specified time frames.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	A nationally agreed service specification describes how the service should be run by community pharmacists, including training requirements and referral guidance. The service should comply with any policies and standards set by the NHS for the provision of such services regardless of setting. Up-to-date national guidance is

	available within "A guide to smoking cessation in Scotland" (2010) and a revised definition of smoking cessation services (2012) published by NHS Health Scotland. The service should be provided according to standards set by the General Pharmaceutical Council or the Royal Pharmaceutical Society. NHS England published guidance in 2022 for commissioners and community pharmacies.
Education and qualification(s)	Nationally recognised direct learning events, webinar/webcast or an e-learning resource package is available from National Education for Scotland (NES) for pharmacists and pharmacy support staff who wish to develop their knowledge and skills in the area of smoking cessation. The training must be satisfactorily completed as per NES performance indicators by completing the appropriate assessments to a satisfactory standard, to be able to deliver smoking cessation services.
Requirements for POCT procedure(s)	The service must be delivered from premises that can provide an acceptable level of confidentiality such as a consultation room (or a counselling area away from earshot of other people and customers). CO monitors should be made available by NHS boards, and used and maintained/calibrated in line with manufacturers' instructions.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

The smoking cessation service, and any POCTs that are performed as part of the service, where appropriate, are free of charge for patients and reimbursed to the provider as part of agreed fees within the community pharmacy contract. At the end of the month a claim is made via the established platform.

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

The introduction of the national pharmacy smoking cessation service in 2009 has seen community pharmacy deliver around 70% of all NHS stop smoking attempts in Scotland. The pharmacy network has made a crucial contribution towards public health targets to reduce smoking rates to below 5% by 2034, as set out in current tobacco control policy.

It should be noted that CO tests dropped markedly during the COVID-19 pandemic, which reflects the changes services made to adapt their protocols to make them COVID-19 safe. Annual updates on statistics from NHS Stop Smoking Services in Scotland are published in the public domain by Public Health Scotland.

6. **Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).**

This information was not provided by the MO.

7. **What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).**

The smoking cessation service has been established for some time. Carbon monoxide tests dropped markedly during the COVID-19 pandemic, which reflects the changes services made to adapt their protocols to make them COVID-19 safe.

8. **Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.**

This information was not provided by the MO

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**
This information was not provided by the MO.
10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**
Learning from the chlamydia test and treat service in Scotland demonstrated that a whole system approach to these public health services is required to ensure capacity of laboratory services is available in meeting anticipated demand. Pharmacists practising in communities require access to patient medical records to ensure they can practise safely within the context of care for a particular patient.

4.8 South Africa

Member organisation	Pharmaceutical Society of South Africa
Authors	Mariet Eksteen, Jameel Kariem

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

The following services are available nationally in South Africa:

- Blood glucose testing;
- Blood cholesterol and/or triglycerides testing;
- Urine analysis for measurement of, among others, leucocytes, nitrates, RBCs;
- Blood pressure measurement;
- HIV and AIDS testing and counselling can be stand alone, but is also prerequisite for PIMART, which is a treatment plan for PEP, PREP, and first-line ARV drug (criteria applicable);
- Pregnancy screening can be stand alone, but is also a prerequisite for clinic contraceptive supply;
- Peak flow measurements;
- Haemoglobin A1C (HbA1C) testing;
- Pulse rate;
- SARS-CoV-2 tests can be stand alone, but is also utilised by doctors/prescribers before issuing prescriptions for antibiotics or steroids as per COVID treatment plans;
- Haemoglobin; and
- Sexually transmitted infections screening tests.

South African Pharmacy Council (SAPC). 2023. Rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees.

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

Provision of different POCT are described in Good Pharmacy Practice Rules published by the South African Pharmacy Council. In general, the following procedure is recommended as a minimum standard:

1. Patient approaches pharmacy/pharmacist with a request or health-related issue.
2. Pharmacist takes a patient medical history including current signs and symptoms.
3. Pharmacist considers possible differential diagnoses.
4. Pharmacist asks further clarity-seeking questions, and performs appropriate screening tests with consent, in order to rule out/confirm possible diagnosis.
5. Pharmacist counsels the patient on the results of the screening tests and may recommend a symptomatic treatment plan (including over-the-counter medicines), which the patient may agree or disagree to take, or if pharmacist think the patient's need requires further investigation, refer to a general practitioner for intervention.
6. The POC test is performed, and its result is recorded in the pharmacy or clinic record keeping system (where applicable). This may be manually or electronically.
7. If applicable, the pharmacist dispenses medicines according to record-keeping legislation as included in the General Regulations (Regulation 35) to the Medicines and Related Substances Act (internal patient recordings, not full patient health records).
8. Patient signs a copy of pharmacist-initiated prescription.
9. Patient makes payment through selected payment option (third party payer, cash) for the screening service and medicines.

10. Some third-party payers require the pharmacist to submit electronically, that the test has been performed for disease/ICD10 clarification.
11. Check-up. Some tests like HIV, require a follow up test under certain criteria. It is recommended that positive COVID-19 tests be referred appropriately, and this is followed in some high risk locations.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**	
Practice guidelines and quality assurance	Access detailed minimum standards for the following POCT are included in the Good Pharmacy Practice (GPP) rules: • Minimum standards for blood pressure monitoring services • Minimum standards for the performance of peak flow tests • Minimum standards for the performance of HIV tests • Minimum standards for cholesterol monitoring service • Minimum standards for glucose monitoring • Minimum standards for pregnancy testing service • Minimum standards for urine analysis It must be noted that there are POCT not on the current list of SAPC approved tests, but more may be added once approved.
Education and qualification(s)	The listed POCT services are within the scope of practice of a pharmacist and thus included in the undergraduate Bpharm curriculum, as listed in the 2018 Competence Standards for Pharmacists in South Africa, published by the South African Pharmacy Council. Continuing professional development has been compulsory since 2020 for pharmacists in any field of the competency standards, following the publication of the regulations relating to CPD published by the National Department of Health.
Requirements for POCT procedure(s)	The GPP rules specify the minimum standards for pharmacy premises, facilities and equipment. Some POC tests like COVID-19 require specific standards like additional PPE, and this information is generally incorporated in the individual pharmacy's SOP. SOP's are a regulatory requirement.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**
There are services for which a pharmacist may levy a fee and rules relating to those fees. This is the fee for the service. However, the implementation of this fee is not compulsory, nor is it a maximum or minimum fee. The fee is not enforced to be remunerated by third party payers. More information can be found here.

[Section C] Details of the implementation process

5. What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).

Sustainable remuneration for services is the key priority area and has been for a number of years. Unfortunately, despite the publication on rules relating to services for which a pharmacist may levy a fee, and associated suggested fees, pharmacists receive remuneration at much lower rates from patients and third party payers. It will require a national approach to change the perception of patients around the value received from pharmacists when conducting these services, and advocacy work for proper remuneration of such services in a UHC system.

Both patients and the government should understand the value pharmacists bring with POCT and the actual savings to healthcare expenditure it may result in.

With the planned implementation of the National Health Insurance (NHI), it is critical that the primary health care role that POCT plays, and hence the pharmacist, is acknowledged. POCT is a primary health care intervention, and primary health care is the foundation of NHI.

6. Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).

Date	Events
2023/2024	Expansion of list of POCT services as certain testing devices are approved by the South African Health Products Regulatory Authority (SAHPRA).
2024	Engagement with government for inclusion in UHC/NHI pilot sites as part of the primary healthcare team.
2024	Continuous engagement with third party payers for recognition of POCT by pharmacists and sustainable remuneration thereof.

7. What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).

In South Africa, we have difficulty convincing payers to pay for the pharmacist's POCT service. Payers normally only pay for the medicines dispensed after the disease has been diagnosed. Pharmacists themselves are reluctant to charge for these services, which the South African Pharmacy Council has regulated.

Some wellness-orientated approaches support pharmacists' involvement, but an overall orientation towards prevention away from treatment is needed but difficult, if pharmacists traditionally made a living through dispensing of medicines only.

There is a lack of sufficient reliable data and studies from pharmacies of POCT carried out. This information will be useful to take to payers to indicate the positive interventions and cost savings to be had from POCT.

8. Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.

☐ Yes

☒ No

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**	
With/from other healthcare professional groups	No engagement.
With/from policymakers	Constant engagements with the government regarding inclusion in NHI pilot sites; with the Council of Medical Schemes and with individual medical schemes (third party payers).
With/from the public	Several health awareness days and a focus on preventive POCT, including interviews and social media campaigns.
With/from pharmacists	Regular communication with colleagues through official communication (organisation newsletters), and presentations at conferences or webinars.

10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**

- Define clearly the POC tests that your pharmacists are qualified to do, or you want pharmacists to be able to do.
- Design algorithms with scientific protocols.
- Design the basket of cost-effective POC tests to be performed.
- Get evidence-based data on possible cost savings to your health systems.
- Present to payers/government.
- Recognition by government and payers of our scope of services, including the additional training done like PIMART, immunisation for baby wellness, contraception, flu injection and others.
- Request payers to include pharmacists services in their treatment plans (especially for Prescribed Minimum Benefit (PMB) plans), e.g., for the management of diabetes, a diabetes treatment plan should include an HbA1c test performed by a pharmacist.
- Another point for pharmacy associations is to prepare a guidance document about communication. With reference to correct and accurate positive patient identification, confidentiality and Protection of Personal Information Act compliance, explaining test procedure and results in an appropriate manner, and how to effectively communicate with other healthcare professionals, where necessary

4.9 Spain

Member organisation	General Pharmaceutical Council of Spain
Authors	Tamara Peiró Zorrilla, Daniel Fernandez

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

In terms of the services provided as POCT, implementation depends on the autonomous communities (regions). Blood pressure measurement is the only service provided in nearly all pharmacies in the country. Others, such as blood glucose tests, lipid profile, cardiovascular indicators, haemoglobin, pregnancy test and microscopic panels are carried out based on whether the autonomous communities allow pharmacists to conduct them or whether they require a specialty for them to be carried out. The most widespread services in certain autonomous communities are SARS-Cov-2, HIV and faecal occult blood test for colon cancer screening.

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

The procedure to be followed would be:

1. Provision of the service (it may be provided by the pharmacist or requested by the patient. There are exceptions, such as screening for colon cancer, which is carried out at the request of the health administration according to the established criteria on how to screen a part of the population).
2. Interviewing the patient.
3. Measurement of the clinical parameter.
4. Result and reading.

Not all cases are recorded on an IT platform for monitoring, although this is becoming increasingly widespread.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	For the time being, there are no practical guidelines for the implementation of POCT.
Education and qualification(s)	There are services where specialisation will not be required and those where, depending on the autonomous community, pharmacists are required to specialise in clinical analysis.
Requirements for POCT procedure(s)	For the time being, there are no established national regulatory requirements. However, each autonomous community in its law on pharmaceutical regulation can establish requirements regarding the personnel or space in the pharmacy necessary for its implementation. They shall also comply with the provisions of the Spanish Agency of Medicines and Health Products and the good practice documents for carrying out the standard operating procedures, which will reflect the pharmacy facilities, equipment, equipment testing systems and quality systems.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

Based on the type of service, the payment is made by the patient or by the regional government where the tests are carried out. For instance, antigen tests were carried out in different regions of Spain during the COVID-19 pandemic and some regions as a service where the autonomous community financed them, such as Aragón, Comunidad Valenciana, Galicia and Murcia.

For HIV testing, all Spanish regions testing for HIV (Asturias, Cantabria, Castilla y León, Catalonia, Balearic Islands, Basque Country) are financed by the corresponding autonomous community.

For faecal occult blood tests for the prevention and screening of colon cancer, they are only financed in Catalonia.

On the other hand, clinical parameter measurement services such as blood glucose, blood pressure, lipid profile, etc., are charged to the patient. Prices are not fixed; each pharmacy sets its own price.

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

- Helping to rapidly identify a health problem or its signs, symptoms, causative agents (e.g., SARS-CoV-2, HIV).
- Enabling patients screening for certain health problems in order to propose an intervention against a risk measure.
- Relieving congestion in primary care and being able to reach more patients more quickly through public health programmes that improve health promotion and early detection.

6. **Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).**

No service plan foreseen by the Spanish Authorities

7. **What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).**

Currently, the main challenge is for the autonomous communities to legislate in a uniform manner the implementation of these POC tests. This will favour their development by all pharmacies in a homogeneous manner and give patients access regardless of their place of residence.

In addition, economic constraints are also a challenge, as these services require instruments and techniques that are often costly.

8. **Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.**

☒ Yes

☐ No

If yes	URL: https://scielo.isciii.es/pdf/gs/v27n2/original_breve3.pdf

	In 2009–2010, one of the first pilots was carried out on an HIV screening service in community pharmacies in the Basque Country. The test was positive and confirmed seven times (0.85%; 95% confidence interval: 0.34% to 1.75%) out of 819 questionnaires. Promptness and convenience (52.2%), as well as accessibility (32.5%), were the most valued reasons for testing in a pharmacy.

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**	
With/from other healthcare professional groups	It is necessary to involve other health professionals so that they can participate in the need to engage pharmacies in the development of these services so that they can then prescribe these services to their patients to be carried out in pharmacies.
With/from policymakers	It is necessary to work further at the national level with the ministry of health and at the regional level with the regional ministries to increase the role of community pharmacy in public health.
With/from the public	It is necessary to further raise awareness among patients of the need for many of these tests for the early detection of certain diseases and for the population to request that these tests can be carried out in pharmacies.
With/from pharmacists	Community pharmacists should be trained as the autonomous community implements these services in order to ensure that they are offered with a high level of quality and in accordance with procedures.
10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**	
This information was not provided by the MO.	

4.10 Switzerland

Member organisation	Swiss Pharmacists Association
Authors	Martine Ruggli, Stephen Jenkinson, Alexandra Vedana

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

The current list (June 2023) of all analyses (POCT as well as per order in an accredited laboratory) can be found here.

Common POCTs carried out in a general practitioner's office are as follows:

- C-reactive protein (CRP)
- HbA1c
- Albumin
- Creatine kinase-MB (CK-MB)
- B-type natriuretic peptide (BNP)
- Lipid Panel
- Troponin
- Myoglobin
- International Normalized Ratio (INR)
- Glucose

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

This cannot be answered, as every institute, pharmacy and general practitioner has its own workflow.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	Internal and external quality controls according to QUALAB (Swiss Association for Quality in medical laboratories): According to the guidelines, POCT devices are so-called "simple analytical devices". They are analysers with low throughput (single analysis) where a new reagent/measurement unit is used for each test. Calibration is usually done electronically.
Education and qualification(s)	Education depends on a person's function. The laboratory director must be a pharmacist. In addition to pharmacists, biomedical analysts may also carry out the analyses. See criteria for operating medical laboratories of the SULM (Swiss Union for Laboratory Medicine).
Requirements for POCT procedure(s)	See response under "Practice guidelines and quality assurance".

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

A doctor's prescription is required for coverage by the compulsory basic insurance. The analysis list, filtered according to the analyses for which the pharmacist's laboratory is approved, specifies how much the individual analyses are reimbursed. Without a prescription the POCT is not reimbursed.

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

To date there has not yet been an implementation of pharmacy-based POCT services. There exists a list of analysis where pharmacist can be reimbursed for certain analyses that have been prescribed by a physician (see answer 4). However, there is a need for a reimbursement of pharmacy-based POCT which is commissioned by the pharmacist, especially in the scope of enhancing interprofessional collaboration. This can be part of patient support programmes where a pharmacist conducts HbA1c analysis in diabetes patients. In general, conducting POCT in pharmacies should distribute to burden of work over different healthcare professionals.

Currently, the analysis list is undergoing a major revision. However it is not intended that pharmacies are reimbursed for POCT services without a prescription from a physician.

6. **Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).**

This information was not provided by the MO.

7. **What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).**

There has not been an implementation process so far.

8. **Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.**

☐ Yes

☒ No

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**

This information was not provided by the MO.

10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**

Provide a catalogue of cost-covering reimbursed analyses, that can be carried out usefully in the pharmacy as well as pragmatic quality controls.

4.11 Wales

Member organisation	Royal Pharmaceutical Society
Authors	Alwyn Fortune, Efi Mantzourani

[Section A] Coverage and workflow of POCT

1. **Please indicate all services that are currently covered as POCT or included in an equivalent scheme in your country/territory. Please also specify whether these services apply to national or state/province-specific implementation and are prerequisites for other medical services.**

The Sore Throat Test and Treat (STTT) service is part of Wales's Common Ailment Service (CAS). The CAS is a national service, and has provided advice and symptomatic treatment to patients with acute sore throat for several years. The STTT is an extension provided nationally by a growing number of pharmacies, whereby POCT is integrated in one stage of the service provision.

2. **Please describe below the standard workflow of POCT and how these are structured in your country/territory (e.g. (1) POCT initiation by patient (2) POCT counselling by pharmacist, (3) clinical decision-making by pharmacist, (4) referral, (5) patient records, (6) billing (7) check-up).**

The CAS is provided free of charge to patients in Wales. Patients can either self-refer to the service, or can be referred by another healthcare professional.

Under the STTT, patients with acute sore throat presenting to a participating pharmacy are stratified on their likelihood of having Group A Streptococcus (GAS) using FeverPAIN or CENTOR clinical scoring, after an initial assessment to exclude red flag symptoms that would mean direct referral to a more appropriate healthcare professional. If threshold clinical scores are met, an immediate POCT is offered. Patient education on the value, limitation and risks of antibiotics is part of the service. After this discussion and based on a joint decision, pharmacists are able to supply antibiotics to patients with a positive test result, based on predefined dosing schemes, without the patient having to see their GP. Symptomatic treatment is available for all patients who would benefit from it.

All consultations and any associated outcomes are recorded on "Choose pharmacy", a national IT platform that is used in community pharmacies in Wales for all services. Outcomes of the consultation are communicated to the patient's GP record via the platform. The platform is also used by pharmacists to claim reimbursement at the end of the month.

[Section B] Regulatory and remuneration frameworks for POCT

3. **Please describe the professional standards and/or regulatory requirements for pharmacists or pharmacies to provide POCT in your country/territory. Please provide the relevant URL link(s) where possible.**

Practice guidelines and quality assurance	A nationally agreed service specification describes how the service should be run by community pharmacists, including training requirements and referral guidance, and enables pharmacists to proceed to antibiotic supply without a prescription if specific criteria are met.
Education and qualification(s)	There is an accreditation pathway for the STTT service in collaboration with Health Education and Improvement Wales (HEIW). Several online training modules must be completed before being accredited to deliver the service. These include (i) a mandatory vodcast covering antimicrobial stewardship in community pharmacy; (ii) mandatory eLearning for the sore throat pathway and antimicrobial prescribing with working examples; and (iii) optional attendance at face-to-face practical training events.
Requirements for POCT procedure(s)	Consultations for all services, including the STTT, are required to take place in a consultation room in a community pharmacy, to maintain patient confidentiality. All equipment is provided by the health boards, as part of the service. Pharmacists are required to quality assure each batch number of tests.

4. **Please describe the financial reimbursement and/or billing policy in place for pharmacists who provide POCT services to eligible patients. Specifically, detail the professional tasks and roles that are remunerated for, and the relevant billing procedures.**

The STTT service, and any POCTs that are performed as part of the service, where appropriate, are free of charge to patients and reimbursed to the provider as part of agreed fees within the community pharmacy contract. At the end of the month a claim is made (via the "Choose pharmacy" platform) for all STTT consultations, and the proportion whereby a POCT was used.

[Section C] Details of the implementation process

5. **What were the most important factor(s) or key priority area(s) that your country/territory considered for the implementation of a pharmacy-based POCT service? Please list the top arguments for introducing or expanding these services by pharmacists (e.g., public health outcomes, economic factors, and support from relevant stakeholders).**

Acute sore throat is one of the commonest reasons for a consultation in GP and about two-thirds of consultations result in an antibiotic prescription. Most sore throats are caused by a virus and 80% of people recover without any treatment. However, antibiotic prescribing rates are high due to concern about Group A Streptococcus (GAS) infection which rarely leads to suppurative complications such as peritonsillar abscess (quinsy). Prognostic scores such as FeverPAIN and Centor help clinicians to identify which patients are most likely to have GAS infection, thus improving targeted antibiotic prescribing in line with the antibiotic stewardship agenda. Adding a rapid GAS POCT could optimise this pathway further.

The stepwise approach offered by a structured clinical assessment, prognostic score and POCT means this pathway could be delivered by allied health professionals other than GPs and hence reduce numbers attending practices where there is poor targeting of antibiotics. This is important for two reasons. Practice level interventions are complex and have modest effects and because GP workload is increasing, both in terms of absolute numbers of consultations, and in terms of consultation complexity. As a result, management of many common ailments is moving to community pharmacies across the UK to improve access for patients and give GPs additional capacity to manage more complex cases.

6. **Please provide a summary timeline of the process towards achieving and/or expanding the POCT services authority of pharmacists (key milestones: date and event).**

Date	Events
November 2018	In Wales, seven lhealth boards are responsible for delivering healthcare services within their respective areas. A pilot STTT service, with POCT as one stage of the multifaceted approach, was introduced with a staged implementation in 56 community pharmacies in two of the seven health boards.
December 2019	All health boards in Wales agree to commission STTT as a service in their area, following review of pilot evaluation. Sites are commissioned adopting a staged implementation based on a balance of population needs and expressions of interest from pharmacists.
March 2020	A total of 134 pharmacies are offering the service by March 2020, when it is temporarily suspended due to COVID-19. A new service delivery model is subsequently agreed to safeguard patients and pharmacists. The change still allows antibiotic supply to patients with threshold clinical scores, but removes the requirement for routine use of POCT to detect GAS.
December 2021	A comparison of the two service delivery models (with and without requirement for routine use of POCT) reveals that overall antibiotic supply rate increases when routine POCT is removed. The requirement for routine POCT is reintroduced.
September 2023	The service has continued to expand, and currently a total of 499 pharmacies are accredited to provide it across all seven health boards.

7. **What were the main challenges and/or limitations during the implementation process of the POCT in your country/territory? Please provide specific details and reasons (e.g., limited financial resources, organisational capacity, and public engagement).**

Use of POCT in the community — At the time of the pilot introduction, use of POCTs in the community was not widespread, and it was unknown whether patient acceptability or pharmacist acceptability would allow successful implementation of the service.

Patient acceptability of a clinical service — This was a service whereby pharmacists were providing a direct clinical assessment, and it was unknown whether this would be acceptable to patients.

Unknown antibiotic stewardship outcomes — One intended outcome of the service was a reduction in antibiotic provision. However, it was it unknown whether this could potentially increase, if a large number of patients were identified who were asymptomatic carriers of Group A Streptococcus.

Cost-effectiveness of the service — Another intended outcome of the service was to safely rebalance GP workload by utilising skills of pharmacists and transferring less complex work to them. It was unknown whether this strategy would be cost-effective.

8. **Did your country/territory conduct a pilot programme or a post-implementation assessment to measure the impact of POCT by pharmacists/pharmacies? Please provide the URL link(s) to the study and a short summary of the outcomes if available.**

☒ Yes

☐ No

If yes

URL:

Impact of a pilot NHS-funded sore throat test and treat service in community pharmacies on provision and quality of patient care.

Understanding the impact of a new pharmacy sore throat test and treat service on patient experience: a survey study.

Community pharmacist views on the early stages of implementation of a pathfinder sore throat test and treat service in Wales: an exploratory study.

To swab or not to swab? Using point-of-care tests to detect Group A Streptococcus infections as part of a Sore Throat Test and Treat service in community pharmacy.

Characteristics of the sore throat test and treat service in community pharmacies (STREP) in Wales: cross-sectional analysis of 11 304 consultations using anonymized electronic pharmacy records.

Also presented were outcomes of the service's response to the GAS outbreak in an international conference (publication to follow).

The service was well received by both pharmacists and patients, with patient satisfaction not found to be correlated to antibiotic supply.

Evaluation of >11,000 consultations found low antibiotic prescribing rates of ~21%. All patients were provided with safety netting, a vital part of consultations providing safe monitoring and follow-up. This is essentially a contingency plan that is conveyed and communicated with the patient so that they have a clear understanding of what to do if the progression of the diagnosed condition is not as expected. It ensures that there is a follow up if the progression of the condition takes an unusual course, where the initial diagnosis may be wrong or where initial treatment has failed. After 16 months of the service being embedded in the health system, the STTT offers a safe option for patients; it can be delivered at scale to align with a pre-specified pathway that promotes appropriate use of POCT and antibiotics.

A modified service without GAS testing during the COVID-19 pandemic led to an increase in antibiotic prescribing rates. Our analysis suggests that for every 100 STTT consultations with patients with the

	threshold clinical scores, the use of POCT may spare up to 36 courses of antibiotics. This increases to up to 47 courses spared when only those with higher clinical scores are included. This led to the national decision to reintroduce the requirement for GAS testing. Despite a significant increase in consultations, there was no significant increase in antibiotic prescribing rates during the GAS outbreak in December 2022. In a health economic evaluation of use of POCT in pharmacy settings, Health Technology Wales concluded that the STTT had a 100% probability of being cost-effective, at a threshold of GBP 20,000 per QALY.

[Section D] Partnership and mobilisation

9. **Engaging stakeholders: Please describe the strategies that were used to build collaboration, address resistance to change and secure ongoing support throughout the POCT implementation process.**	
With/from other healthcare professional groups	Interprofessional consultations and engagement of key stakeholders (e.g., Public Health Wales) were held from the point of the service's inception, in relation to the service specification and also the plans for evaluation. Service evaluation findings are regularly presented to interprofessional meetings, including national and international primary care meetings.
With/from policymakers	The service is in line with wider Welsh Government strategy. Policy documents, including the Welsh Government's vision for "A healthier Wales", place emphasis on sustainable services that are delivered closer to home, by the right healthcare professional, in line with principles of prudent healthcare. The Welsh Government was engaged from the point of the service's inception, and provided funding via a formal funding scheme to update the existing technology, to integrate the new service. Members of the Welsh Government were, and continue to be, part of the ongoing evaluation of the service. Regular service evaluation updates are fed to the National Extended Services Management Board, which has representation from Health Education and Improvement Wales, the Welsh Government and NHS Wales Shared Services Partnership.
With/from the public	The service is an extension of Wales's CAS, which has been available to the public since 2013. Patient representatives were also involved in the evaluation of patient experience.
With/from pharmacists	Community Pharmacy Wales, the body representing contractors in Wales, was involved from the point of the service's inception. Pharmacists were consulted on the service specification, and evaluation findings were communicated regularly to them via a range of fora.

10. **Additional comments: what general tips and advice would you give to other member organisations who are considering the initiation and/or implementation of pharmacy-based POCT services?**
It is key to involve a wide range of stakeholders from the start of the service development, through to implementation. Service outcomes need to be evaluated at regular points, using robust methodologies.

5 Insight board discussion

In order to gain a better understanding of the different strategies and issues faced by pharmacists and community pharmacies around the world in the area of point-of-care testing, FIP convened an insight board small group discussion meeting on 13 September 2023. Among the goals were to gather international best practices and gain qualitative insights from the individuals and organisations involved in POC testing, to identify the main barriers and enablers to the role of pharmacists and community pharmacies in POC testing, and to provide key advocacy messages to interested member organisations to explore ways to optimise the involvement and expansion of community pharmacies in the provision of POC testing.

5.1 Methods

5.1.1 Recruitment of participants

Participants were selected from a group that represents the member organisations of various eligible countries or territories. These were identified through a survey conducted earlier in the project, as detailed in Chapter 3. The eligibility criteria included any FIP member organisation that reported having implemented POCT services in their respective countries or territories.

From July to August 2023, invitation letters were emailed along with a comprehensive briefing document. This document provided detailed information about the insight board discussion and the conditions for participation. If the invited representatives were unable to participate but still wished to contribute, they were encouraged to extend the invitation to their colleagues within their organisation who might be interested.

5.1.2 Data collection and analysis

In anticipation of the insight board meeting, a thorough discussion guide was developed to ensure the seamless facilitation of the session and the strategic collection of insights. The discussion guide underwent validation to confirm question validity and ensure a coherent discussion flow. During the discussion, the following questions were asked:

1. How do you see the role of pharmacists and pharmacies in the implementation and provision of POCT in your country? What specific contributions can pharmacists make to improve access, convenience and patient outcomes?
2. Can you provide examples of successful initiatives or programmes that have used POCT in your country? What impact have they had on patient care and health outcomes?
3. Have there been any notable collaborations or partnerships between pharmacies and healthcare institutions or organisations to facilitate POCT? If so, what were the key factors that contributed to their success and what lessons can be learned from these experiences?
4. How are the results from pharmacy-based POCT communicated to other healthcare professions or health systems? Do pharmacists have writing access to patients' electronic health records?
5. How are pharmacy-based POCT funded in your country? Is funding a major barrier to the implementation of these tests in pharmacies?
6. What are the main challenges or barriers to the implementation of POCT in pharmacies in your country, and how are these being addressed or overcome?
7. What do you see as the most promising areas or applications for POCT in the future, and how do you see it changing healthcare in your country? What other avenues can be explored to expand and integrate POCT as a pharmacy-based service?
8. What are the key advocacy messages that should be communicated to policy makers, healthcare professionals and the public to highlight the value and importance of pharmacists and community pharmacies in the context of POCT? How can these messages be communicated effectively to ensure maximum impact?

Prior to the insight board, all participants were appropriately informed about the recording of the discussion, with the understanding that the collected data would be used to formulate this report. Furthermore, explicit verbal consent was obtained from each participant for the inclusion of their names and roles in the final report.

The insight board discussion was conducted exclusively through the online platform Zoom, facilitated by two moderators and supported by two note-takers. The role of the moderators was to ensure that the discussion remained focused on the designated topic, while the note-takers recorded field notes and provided technical assistance to participants encountering any issues.

It should be noted that the views expressed during the roundtable are those of the individuals based on their expertise and experience. They do not represent the views of member organisations or FIP policy or positions, although they may build on existing positions and statements.

After the meeting, participants were encouraged to provide further comments if they wished to contribute additional viewpoints. Following the session, the recording and transcript from the insight board were retrieved, and participant responses were analysed and interpreted. A total of 11 participants from 10 different countries attended the virtual meeting. The names and affiliations of the participants who engaged in the discussion are presented in Table 7.

Table 7. Participant names, roles and representing member organisations and countries

Name	Role	FIP member organisation	Country
Moderators			
Sherif Guorgui	President of the FIP Community Pharmacy Section		Canada
Dr Julien Fonsart	President of the FIP Clinical Biology Section		France
Participants			
Jocelyn Chaibva	Interim president	African Pharmaceutical Forum	Zimbabwe
Ally Dering-Anderson	Associate professor in the Department of Pharmacy Practice & Science at the University of Nebraska Medical Center		United States
Sadaf Faisal	Director of professional affairs	Canadian Pharmacists Association	Canada
Marcília Fernandes	President	Order of Pharmacists of Cabo Verde	Cape Verde
Brigid Groves	Vice president, pharmacy practice	American Pharmacists Association	United States
Jameel Kariem	Executive member Community pharmacist	Pharmaceutical Society of South Africa	South Africa
Susan O'Donnell	Professional services pharmacist	Irish Pharmacy Union	Ireland
Virginia Olmos	Vice president	Pharmacist Association of Uruguay	Uruguay
Ema Paulino	President Community pharmacist	National Association of Pharmacies	Portugal
Brett Simmonds	Chair, FIP Regulatory Advisory Group Chair, Pharmacy Board of Australia		Australia
Tamara Peiró Zorrilla	Coordinator Pharmaceutical Care Department	General Pharmaceutical Council of Spain	Spain

5.2 Results

5.2.1 Question 1: The role of pharmacists and pharmacies in the implementation and provision of POCT

The role of pharmacists and pharmacies in the implementation and provision of POC testing can be seen as multifaceted. Pharmacists have unique expertise and are a huge resource that needs to be harnessed to improve health outcomes for different categories of patients.

> *''The implementation of pharmacy-based POCT services in Portugal is driven by the goal of meeting the health needs of the population effectively, promoting public health, enhancing healthcare efficiency, and empowering pharmacists to play a more active role in patient care. These services are recognised as valuable contributions to the healthcare system, with a focus on patient-centred and accessible healthcare solutions.'*
> *— Ema Paulino, Portugal*

Feedback from insight board participants reflected the role of pharmacists and pharmacies under the following themes:

- Enhanced access to health care and convenience;
- Patient education, counselling, and medication management support;
- Contribution to public health initiatives and collaboration with healthcare providers;
- Promotion of health and wellness.

Enhanced access to health care and convenience

Enhanced access to healthcare and the convenience pharmacies provide was one of the top roles identified. The participant from Ireland noted that with an unequalled reach in terms of patient contact and access, pharmacies provide support, with a commitment to patient safety and quality. Adding to this perspective, the South African and Zimbabwean participants emphasised that due to pharmacies being open for more hours and on weekends when other services are not available and are convenient for patients to reach, pharmacies are the gateway to the primary health care system. Siting communities more in the rural areas will mitigate the common issue of overpopulation of communities in urban areas and increase the access and distribution of these services to the population. The Portuguese participants also highlighted this in line with rural coverage.

> *". . . coverage is advantageous for implementing POCT services, as it allows residents, especially those in rural areas, to access essential diagnostic tests conveniently.'*
> *— Ema Paulino, Portugal*

Patient education, counselling and medication management support

Pharmacists are also well placed to identify those tests that are not of benefit to the community, to educate and counsel patients and to prevent the development of antimicrobial resistance that occurs with empirical or symptom-based treatment. In support of this, a Spanish participant commented that "pharmacists have the necessary knowledge to manage and interpret POCT performed in settings unfamiliar to patients". Furthermore, the use of a test-to-treat model in pharmacy-based POCT, as shared by a US participant, reduces medication waste and improves healthcare costs.

> *"Screening or testing in the pharmacy for something that would otherwise carry stigma underscores that pharmacists can change access and has improved healthcare costs. Participating in antimicrobial stewardship, where only positive cases are treated, and referring when we can't treat, will improve the outcome for the patient who is tested, and impact positively on the community." — Ally Dering-Anderson, United States*

Contribution to public health initiatives and generation of data for surveillance and policy

Pharmacists are valued and respected members of their communities. They are in a great position to identify community needs for screenings and diagnostic tests. According to the Portuguese participant, the network of community pharmacies provided excellent access to screening at the community level during the COVID-19 pandemic and the data generated showed a reduction in testing distance from 12km to 600m. In addition, the South African participant highlighted how the contribution of pharmacies can facilitate policy making.

"With POCT, we can offer a valuable monitoring service and information as part of a disease state management service to monitor outcomes of treatment for non-communicable diseases. Some third-party payers fund and incentivise such programmes. In this regard, data can be made available to assist and guide payers and policy makers."
— Jameel Kariem, South Africa

Promote health and wellness
Pharmacies operate with strong ethics to provide healthy lifestyle recommendations, prevention strategies and a wellness environment for patients.

"Community pharmacy is a highly regulated profession with a commitment to patient safety and quality. Structures are in place to ensure that standards of professional competence and ethical conduct are clearly outlined, communicated to patients, and independently inspected on a regular basis." — Susan O'Donnell, Ireland

Participants agreed that these services are recognised as valuable contributions to the healthcare system, with a focus on patient-centred and accessible healthcare solutions. To improve access, convenience and patient outcomes, the role of training was highlighted by all participants. The consensus showed that training was necessary for mainly vaccine administrations and not mandatory for POCT services practice in any of the countries, as colleagues feel that they have the required education and knowledge. It is important to note that training on the use of the different technologies and skills in the clinical knowledge of interpreting POCT results will increase the level of knowledge for pharmacies, improve lab access and meet healthcare needs, and expedite effective communication with patients and other healthcare professionals. Some countries such as Portugal and the United States already offer quite a few different training programmes and education opportunities in point of care testing, to gain extra knowledge in this landscape.

"To facilitate patient access to POCT, community pharmacists are required to be trained in performing various tests, to have personal support in the community pharmacy and to have a POCT area to conduct this analysis. Tests such as blood pressure measurements require areas where the patient can remain seated and in a calm environment, to ensure accurate measurements." — Tamara Peiró Zorrilla, Spain

5.2.2 Question 2: Successful POCT initiatives or programmes with impact on patient care and health outcomes

Insight board participants shared some country-wise initiatives. This are summarised in Table 8.

Table 8. Successful initiatives/programmes shared by countries participating in the insight board

Country	Initiative
Canada	• Script study, done in community pharmacies in Alberta and Saskatchewan to offer point-of-care testing to patients at risk of cardiovascular events. • Study in Newfoundland and Labrador, Alberta and now being explored in other provinces with a focus on a pharmacist-led community screening for HIV using point-of-care testing. • A pilot study that examined the community pharmacists' identification of chronic kidney disease using POCT of serum creatinine and estimated glomerular filtration rate.
Portugal	• Community pharmacies' authorisation to provide SARS-CoV-2 professional rapid antigen detection testing service to the population during the COVID-19 pandemic. • HIV and hepatitis — The "Fast track cities" initiative is a collaboration with an international non-governmental organisation for ending the AIDS epidemic by 2023.
South Africa	• A third-party payer (Discovery Med Aid) offers reimbursement for clinic services and encourages its members to utilise pharmacy POCT services. It has a formalised list of services.

	• Some pharmacy associations (Independent Community Pharmacy Association of South Africa) have had outreach programmes with NGOs to make testing more accessible and affordable, including utilising existing public events like expos, conventions and fairs. • South Africa has clinic booking services (RecoMed) whereby patients can book a POCT online. it can cost as little as between EUR 0.10 and EUR 2 per clinic booking for the pharmacy. • PAMART, a pharmacist-initiated management of antiretroviral therapy that some pharmacists partake in, encompasses tests for certain kidney screenings and TB. It is currently being utilised in HIV pre- and post-exposure prophylaxis.
Spain	• Collaboration to access pharmacy-based tests for related infectious diseases such as HIV, syphilis and SARS-CoV-2 in the autonomous region of Castilla y León, the Basque Country and 12 autonomous regions of the country, respectively. • Access to pharmacy-based detection and management of chronic diseases (measurement of blood pressure, diabetes-related values such as blood sugar and Hb1Ac, and values related to hypercholesterolemia and hypertriglyceridemia). • Isolated blood pressure measurement in community pharmacies, regardless of their autonomous region, and ambulatory blood pressure monitoring in certain autonomous regions, e.g., Andalusia and the Canary Islands through the MAPAfarma project. • The measurement of clinical parameters through dry chemistry in several autonomous regions of the country. • Colorectal cancer screening in certain autonomous regions, such as Catalonia.
United States	• Test-to-treat for positive COVID results using a new oral drug to reduce hospitalisation.
Zimbabwe	• Malaria treatment has been based on a “test and treat” basis. This has been successfully implemented in community pharmacies and rural health centres. Treatment is initiated with positive results. A negative result is referred for further testing and management. • Community pharmacy screening and monitoring for diabetes and hypertension.

In all countries, these initiatives have been beneficial in raising screening awareness, identifying and testing patients at risk, ensuring universal health coverage for all citizens, facilitating proper medication management and promoting good health and well-being.

“These initiatives show the feasibility of easily scaling up this service due to the patient acceptability and pharmacist confidence. Comprehensive pharmacist intervention through the conduction of point-of-care testing in patients at the risk of cardiovascular events, significantly reduced the number of patients receiving a fasting cholesterol panel by their physician.” — Sadaf Faisal, Canada

“The provision of this service through community pharmacy ensured members of the public could readily access the COVID-19 Certificate required to travel within the EU.”
— Susan O’Donnell, Ireland

“This pharmacy-initiated testing, which is part of the national treatment guideline, has helped provide a differential diagnosis, reduce empirical malaria treatment, and improved the quality of care provided. Also, this has successfully encouraged evidence-based management and has been cost-effective for the country.”
— Jocelyn Chaibva, Zimbabwe

5.2.3 Question 3: Notable POCT partnerships between pharmacies and healthcare institutions and key success factors

Table 9 shows the summary of partnerships between pharmacies and health organizations to facilitate POCT in participants’ countries.

Table 9. Notable collaborations for POCT integration in participant countries

Country	Notable collaborations/partnerships
Ireland	• Regular pilot programmes with the Irish Pharmacy Union and external stakeholders such as the Irish Heart Foundation in areas such as atrial fibrillation screening, blood pressure monitoring and overall cardiovascular health, to raise awareness within the public about health risks and identify individuals with these conditions.
Portugal	• Collaboration between community pharmacies and healthcare institutions during the COVID-19 pandemic demonstrated the potential for a robust partnership to enhance healthcare accessibility and crisis response. • Since August 2018, in collaboration with the Fast-Track Cities international initiative for ending the AIDS epidemic by 2030, screening settings have been extended to clinical laboratories and community pharmacies, which started performing POC tests for these infections under a pilot initiated in October 2018 as part of the Fast-Track initiative.
South Africa	• Partnerships between the diagnostic company LumiraDx and the Independent Community Pharmacy Association of South Africa, to promote the COVID-19 rapid antigen testing and to promote HbA1c testing through various diabetes awareness events.
Spain	• Collaboration between community pharmacies and the regional government for their implementation and funding in all the autonomous regions where pharmacies perform rapid HIV and syphilis tests or colon cancer screening. • Collaboration by certain pharmaceutical distributors to finance, for example, the measurement devices used by community pharmacies (not a widespread practice).
United States	• State-sponsored collaborations to alleviate the need for pharmacists to find diagnosticians to collaborate with. • State-dependent partnership with health departments or partnering with primary care offices to do some follow-up management for INR testing for patients that are on warfarin therapies and then providing the results back to the clinic depending on the agreement that they have in place.
Zimbabwe	• The use of "HIV test kits and initiation of PrEP (pre-exposure prophylaxis)". PrEP would only be available to someone with a negative HIV test. Patients with positive result are referred for further confirmatory tests and initiation of antiretroviral therapy as required. • Quality assurance of test kits is ensured through the collaboration of suppliers, regulators and pharmacies.

One major factor that has facilitated these collaborations in the countries where they exist is the trust between pharmacies and the concerned stakeholders. Another factor is that pharmacists help to bridge health gaps. Even though they are given little recognition as regards POCT, the above-mentioned collaborations have been a success because the pharmacies bridge the health gap through these POCT services.. Community engagement, pharmacists training, public awareness and government support are other factors cited by the participants.

"Strong government support and regulatory flexibility allowed pharmacies to quickly adapt and offer essential testing services; the integration of pharmacy-based testing into the national healthcare system demonstrated the value of a coordinated healthcare approach during a pandemic." — Ema Paulino, Portugal

These collaborations, which utilise the expertise of stakeholders in delivering POCT services to the population, have shown some manufacturer involvement and indicated that third party payers would often pay for pharmacy-based point-of-care testing to enable their clients to maintain healthy physiological ranges. Pharmacists will provide advice and support to manage and reduce identified risk factors, with the aim of helping to reduce the burden of chronic disease among the citizens of each region. These partnerships have therefore also demonstrated that investment in

professional training and the use of the extensive network of community pharmacies play a vital role in ensuring access to healthcare services, particularly in underserved areas.

"Third-party payers have a formalised list of services that they offer but the drawback is their limit for the number of annual tests for certain health conditions or their budget."
— Jameel Kariem, South Africa

"So far, this experience has demonstrated the benefits of a multi-stakeholder approach, with robust support materials and guidance being produced to support the service."
— Susan O'Donnell, Ireland

5.2.4 Question 4: Communication of POCT results and writing access

Other healthcare professionals are aware of the skills, abilities and services that pharmacists and pharmacies provide, but are reluctant to support access to facilitate communication within the healthcare system. This is a typical barrier identified by several of the insight board participants.

"We see some significant barriers to having pharmacists and community-based settings to have access to those more from the legal side of things, typically at the institution that owns the electronic record (ER). They are concerned about additional individuals accessing the system and don't want to risk a potential break into the system. Getting into the ER is a real challenge and requires some additional levels of approval with more legal and regulatory departments at those institutions and facilities."
— Brigid Groves, United States

In Portugal, after performing a POCT, the pharmacist informs the patient of the result and the patient can share this information with another healthcare professional, if necessary. In South Africa, communication of POCT results to other healthcare professionals was manual and seldomly requested. A similar scenario was mentioned by the Ireland participant, noting that results are communicated to other healthcare professions manually through a healthcare email service (Healthmail), fax or letter. The scenario is different in the United States and Spain, with varying degrees of writing access and health conditions, respectively. American pharmacists communicate POCT results based on terms on a collaborative agreement and are legally permitted to write into the electronic record if they have an affiliation with the healthcare provider or institution that allows them. On the other hand, in Spain, established protocols only existed for COVID-19, and currently, are non-existent for POCT.

Greater success is achieved when pharmacists can document in the electronic records, resulting in seamless information dissemination and preventing fragmentation of care. This is illustrated by Australian practice.

". . . now we have access to the electronic health record. With the consent of the patient, the pharmacist inputs the results of the point-of-care testing for other health professionals to be able to see them. This way, there is a sharing of information and knowledge and the patient's information is up to date as well."
— Brett Simmonds, Australia

5.2.5 Question 5: Remuneration for pharmacy-based POCT services

Funding is a major barrier to the implementation and expansion of pharmacy-based POCT services. It is common practice for pharmacies to provide some POCT services free of charge.

In Zimbabwe, POCT services in community pharmacies and the private sector are typically client-funded, with clients paying out of pocket. In the public sector, however, a significant proportion of these tests are financed through donor-funded initiatives. To address the rising cost of test kits, the Pharmaceutical Society of Zimbabwe has introduced a structured tariff system to guide pharmacies on how to price these services. This is particularly important as the cost of test kits continues to rise.

In Australia, most pharmacies provide POC testing free of charge. However, the need for increased resources to provide the service on an ongoing basis necessitates a charge. It is anticipated that this will be a major cultural change for patients, but pharmacists' attitudes towards it will be a warning of the challenges of this paradigm shift.

In Canada, POCT is not publicly funded. Patients pay for the service out of pocket, or pharmacies provide it as part of their services. This can be difficult to implement in independent pharmacies, but is easier to spread across community chains.

> *"There is a reluctance within community pharmacy to claim payment for routine services provided, such as blood pressure monitoring or weight measurement. With the development of online healthcare, a challenge arises when pharmacists are presented with, for example, a repeat prescription for oral hormonal contraception written by a doctor where no face-to-face consultation has taken place. These prescriptions require the pharmacist to take the patient's blood pressure before dispensing the medication."*
> *— Susan O'Donnell, Ireland*

As highlighted by participants, in some provinces in Canada, Spain and South Africa, some tests are included as part of a broader disease programme. As such, they are funded by third-party payers with a predetermined maximum or capped amount.

> *''Some third-party payers in South Africa offer three HBA1C point of care tests in a pharmacy as part of a disease state management programme, e.g., for diabetes. It is quite expensive, so not all third-party payers offer that facility. But I think this is an exciting opportunity to be considered in the future globally and in South Africa as well."*
> *— Jameel Kariem, South Africa*

The participants agreed that charging a fee for added services is important as the out-of-pocket payments (OOP) spiral into more payments for follow-up tests. A fee for service not only validates the pharmacist's cognitive effort, but also encourages the patient to be an active participant in their health management.

5.2.6 Question 6: Challenges/barriers to POC testing implementation

Insight board participants identified several challenges and barriers to POCT implementation, including:

- Lack of adequate reimbursement model and investment by service providers and third-party payers;
- Legislative diversity and healthcare decentralisation;
- Lack of support from the government;
- Results interpretation and treatment initiation;
- Shortage of pharmacists and pharmacy workforce;
- Hesitancy and false perception of community pharmacies' role in POCT; and
- Insufficient promotion of POCT by pharmacists and pharmacy associations.

Lack of adequate reimbursement model and investment by service providers and third-party payers
The lack of an adequate reimbursement model and investment by providers and third-party payers has been identified as one of the main barriers to the expansion of pharmacy-based POCT services. Where these services are not reimbursed, the intervention is devalued for patients in need and only available to those with the financial capacity to pay.

> *''Some state Medicaid programmes have implemented coverage, but this is variable by plan type. Other locations conduct via a cash pay service and walk-in basis. Some self-insured employers have also built in this service coverage for their employees and may conduct as an incentive for employee coverage (e.g., employee receives an insurance premium discount if they complete a biometric screening with POCT for HbA1c and/or cholesterol by the pharmacist). As coverage for these services is variable across the country, the uptake by community pharmacists is also variable."*
> *— Brigid Groves, United States*

Legislative diversity and healthcare decentralisation
In some countries, the diversity of legislation in different parts of the country was highlighted as a further barrier. As a result, there is no national strategy for the provision of pharmaceutical care and related community pharmacy services. Obtaining the necessary authorisations and meeting regulatory requirements to provide POCT services can be time consuming and complex.

> *''The General Pharmaceutical Council has been working for years with the Ministry of Health and the autonomous regions to promote the alignment of the different autonomous regions to offer a consistent and equitable portfolio of services to patients. This year, for the first time, we have managed to implement a project supported by state funding. It's focused on health education for the population through pharmacies in municipalities with fewer than 1,500 inhabitants." — Tamara Peiró Zorrilla, Spain*

Lack of support from the government
An interesting variation among the participants is the case of Cape Verde and Uruguay, where there is a lack of political will and pharmacies do not receive the necessary professional support from the government to provide these valuable testing services. As a result, patients are overwhelming the capacity of existing health systems.

> *"Our healthcare systems give the population access to several benefits, for example, local payment, we have access to all the clinical tests at a very low cost. However, in the pharmacy, the point-of-care tests are very expensive because the supplies are obtained at increased amounts, amounting to high co-payments. As a result, people prefer to go to a hospital for free tests. This makes it very difficult for the pharmacy to provide POCT services." — Virginia Olmos, Uruguay*

> *"The use of POCT services in pharmacies can be seen as an action combined with public policies to expand access and improve health care, due to the high rates of underdiagnosis, hospital admissions, avoidable clinical complications and high rates of morbidity and mortality for various diseases. The consolidation of pharmacies as points of service and care contributes to greater continuity of treatment, with impacts on underdiagnosis, adherence to treatment and improved health outcomes. Therefore, we hope that our country will implement point-of-care testing soon." — Marcília Fernandes, Cape Verde*

Results interpretation and treatment initiation
A Zimbabwean participant commented on the inability of pharmacists to initiate or adjust treatment doses for some diseases irrespective of the medicines being used for that treatment falling under pharmacy initiative-based condition, e.g., diabetes. This point was also emphasised by participants from Australia, Canada, Portugal and Spain. Therefore, the inability of pharmacies to make clinical decisions based on POCT results compromises the holistic purpose of providing these services close to patients.

Shortage of pharmacists and pharmacy workforce
As highlighted by the Uruguayan participant, a reduced workforce is affecting the provision of pharmacy-based testing in the country. With only 12% of pharmacies having a pharmacist present to provide these services daily, it is anticipated that a strong political will and collaboration with the American forum will drive change in this narrative and further improve the POCT services performance in the country. This workforce shortage was also a barrier in the United States, as communicated by the participant.

Hesitancy and false perception of community pharmacies' role in POCT
Another barrier is the hesitancy and misconceptions about the role of community pharmacies in POCT. This results in pharmacists being deliberately or inadvertently excluded from national health agencies and patient information systems. Limited collaboration and communication between different healthcare providers may hinder the seamless integration of POCT services into the overall healthcare system.

> *"Pharmacists are not part of the national Healthlink (the national health messaging broker which allows the secure transmission of clinical patient information between hospitals, health care agencies and medical practitioners)." — Susan O'Donnell, Ireland*

> *"The medical community's hesitancy or reluctance to fully embrace pharmacy-based POCT may be due to concerns about the accuracy and reliability of the tests, or due to the unfamiliarity with*

the expanded role of pharmacists in healthcare."
— Ema Paulino, Portugal

Insufficient promotion of POCT by pharmacists and pharmacy associations
Public engagement and awareness of the availability and benefits of POCT services in pharmacies is important to encourage patients to demand this service from their pharmacies and their payers. Ensuring that patients are aware of the services offered, their accuracy and their potential to improve health outcomes is crucial to encourage patient participation and utilisation.

To expand the scope of practice and overcome these challenges, participants agreed that the integration of POCT services in pharmacies is becoming more valuable, and that countries will benefit from embracing the FIP recommendation to integrate reimbursement into the adoption of pharmacy-based POCT nationwide to maximise all economic benefits. In South Africa, the narrative is gradually shifting from pure home diabetes testing to the inclusion of testing in pharmacies, especially as the strips are accessible there. This will allow pharmacies to play a role in disease management. In addition, participants from Spain and Ireland highlighted ongoing projects and collaborations with their governments to promote more integrated healthcare. To address the issue of reimbursement, countries such as Portugal and South Africa are taking steps to establish a service contract with their governments or national health systems.

5.2.7 Question 7: Promising areas or applications for POC testing

Pharmacists have an important role to play in primary, secondary and tertiary disease prevention. With the unprecedented growth rate of POCT due to its wide range of applications and benefits in patient health management, the common areas that participants see as most promising include testing and management of chronic diseases (e.g., diabetes and hypertension) and infectious diseases (e.g., Lyme disease and sexually transmitted infections, and antimicrobial stewardship). The participant from Ireland noted that the use of POCT in these areas will facilitate early detection of risk factors leading to disease, support disease progression and monitoring, enable adjustment of therapies based on evidence from validated, reliable POCT programmes, and ultimately lead to a healthier population.

Another interesting view, from the Spanish participant, was that POCTs will never replace clinical laboratory tests, but will evolve as the technology evolves.

"With increasing technological advances, POCT is moving towards smart devices, which is expected to lead to a more personalised healthcare monitoring and management system, opening the way for next-generation POCT. The rising number of mobile phone users is expected to contribute significantly to the growth of POCT."
— Tamara Peiró Zorrilla, Spain

In response to strategies to ensure the integration of these tests as pharmacy-based services, participants suggested the following:

Increase in the number of legally approved pharmacy-based tests
Expanding the range of tests that pharmacies can perform will improve access to healthcare for all citizens, reduce pressure on primary care and reduce public spending.

"Recently, our regulatory authority has requested community pharmacies to indicate newer point-of-care tests, e.g., HBA1C and C reactive protein, strep throat, and iron R&D dimers. So, at the moment, we are utilising surveys to estimate a time frame for these tests. It's predominantly to indicate to our regulatory authority the duration spent on offering this value to patients and prove that a reimbursement model be calculated."
— Jameel Kariem, South Africa

Incorporation into major health schemes
POCT will become a fully community-based service when there is sufficient collaboration with government institutions to encourage most patients to go to the pharmacy when they have symptoms, as they do for minor ailments. In rural areas, this will provide better opportunities to make diagnosis and treatment of infectious diseases more accessible and

affordable. In addition, as the South African participant shared, the establishment of laboratories in or near a pharmacy will increase the scope, range and accessibility for pharmacy patients.

"Integrating these services into an insurance plan for patients and offering discounts and incentives to concerned employers will facilitate improved uptake of pharmacy-based testing." — Brigid Groves, United States

Partnership with third-party funders to increase fund allocation
Collaboration through legislation between community pharmacies and the government to expand the POCT scheme and increase budget allocation can facilitate a country-wide adoption of pharmacy-based POCT services.

"We have some legislation in process, which would allow pharmacists through Medicare to be able to provide 'test and treat' services for COVID-19 after the current authorisation and for influenza and strep. The passage of this legislature and adoption by Medicare will hopefully motivate more private and commercial insurers to adopt them as well. That would be a huge win for us." — Brigid Groves, United States

5.2.8 Question 8: Key stakeholder advocacy messages

POC testing is an entry point into the healthcare system and is typically used in disease management programmes. Participants agreed that the indispensability of the sector and the willingness of community pharmacists to support patients was most evident during the COVID-19 pandemic, when pharmacies ensured they remained open and accessible, providing an essential service at a time of great uncertainty.

Given the various constraints on healthcare systems, it is imperative to use this visibility to promote the use of pharmacies as key players in the provision of point-of-care testing services and other essential capacities. This approach can help improve accessibility, coverage and affordability of these essential healthcare services.

Participants suggested that key advocacy messages should be communicated to policy makers, healthcare professionals and the public to highlight the value and importance of pharmacists and community pharmacies in the context of POC testing.

Messages to governments, universities and regulatory authorities
POC testing undoubtedly improves access to quality treatment or evidence-based management. As an integral part of the healthcare system, pharmacists should be supported by favourable policies, political goodwill and training to work to their full scope of practice.

"Pharmacy is a unique profession and an untapped resource. The resources that pharmacy can provide need to be harnessed to improve patient care." — Susan O'Donnell, Ireland

"Test to treat saves time, money, and lives." — Ally Dering-Anderson, United States

"There is a need for pharmacists to be more involved in medication and treatment discussions. Our involvement in policy discussions about the importation, purchase or distribution of high quality and effective test kits is crucial for an independent and objective decision in patient management." — Jocelyn Chaibva, Zimbabwe

"Empowering pharmacists to perform POCT can lead to earlier detection of disease, improved patient outcomes and reduced healthcare costs." — Ema Paulino, Portugal

Messages to funders
The availability of a reimbursement model for pharmacy-based testing, or its inclusion in disease management packages, will broaden the range of services provided, ensure affordable healthcare and improve patient turnover for public and third-**party** payers.

"Offering POCT through an easily accessible provider can increase the proportion of people who are healthy at all stages of life, reduce health inequalities, protect the public from threats to health and wellbeing, and create an environment where every individual and sector of society can play their part in achieving a healthy population."
— Susan O'Donnell, Ireland

"Funders should increase the range of POCT reimbursed and incorporate its usage as part of chronic disease management programmes." — Jameel Kariem, South Africa

Messages to other healthcare professionals

A multidisciplinary approach best serves the health needs of the public and ensures that the skills of all healthcare professionals are recognised and used to benefit the health of the population. Communication with other healthcare professionals is essential, so establishing a continuous communication channel with primary care will facilitate doctors' and nurses' knowledge of POCT in community pharmacy.

"Pharmacists are knowledgeable, accessible and available. They should be recognised as primary health care providers if countries are to achieve the UHC target by 2030. More collaboration is needed to ensure that private-public collaboration or private-public partnerships are strengthened." — Jocelyn Chaibva, Zimbabwe

Messages to the public

Pharmacies can promote health awareness and preventive care by offering screenings and tests for diabetes, cardiovascular risk or other chronic diseases, as well as acute conditions. This proactive approach can lead to early detection and intervention, ultimately improving patient health outcomes.

"Ongoing awareness campaigns are needed to educate patients about the tests available in community pharmacies and how these tests can lead to faster diagnoses, disease improvement and improved quality of life. This proactive approach can demonstrate to patients the benefits of pharmacy-based POCT and encourage their active participation." — Tamara Peiró Zorrilla, Spain

Messages to pharmacy associations

Pharmacy associations should raise public awareness of pharmacy-based POCT services and put pressure on governments, academia and regulators to improve training and increase the range and scope of tests available to funders and third party payers to increase the range of accepted and reimbursed tests.

"These can be effectively communicated through pilot projects and presenting their results to governments. Sharing reports from projects already conducted in other countries, can also be instrumental in conveying the importance of collaborative efforts." — Tamara Peiró Zorrilla, Spain

"Pharmacy workforce development should be well supported to ensure that the education is relevant and addresses the gaps both in education and practice."
— Jocelyn Chaibva, Zimbabwe

To ensure maximum impact, pharmacists and pharmacy associations need to advocate involvement in POC testing, including continuing professional development competencies to improve patient care. They also need to use all available data on evidence-based practice of POCT in pharmacies to advocate favourable legislation and implementation.

"Continuing education and training for pharmacists ensure they maintain the highest standards in POC testing." — Ema Paulino, Portugal

"Data from pharmacy-based services show that the importance of these tests speaks for itself, and amplifying the voice of patients, who are the taxpayers, will lead to further progress. Pharmacists can use these health data to engage policy makers and regulators to understand what the patients we serve really want."
— Ally Dering-Anderson, United States

"Just as the role of pharmacies came to the fore during the COVID-19 pandemic, there may be pharmacies that are providing these POCTs out of their own pockets, just to provide a service to

their patients. We need to get these stories out there and advocate not only to policy makers, but also for regulatory changes so that pharmacists can have favourable regulations that favour them to provide these services and improve access."
— Sadaf Faisal, Canada

6 Conclusion

6.1 Summary of participant demographics

This report compiles survey feedback from 25 FIP member organisations (MOs), of which 22 countries authorise pharmacists to perform POCT. This was followed by 11 MO case studies and input from 11 MO participants (10 countries) in the insight board discussion. Across all stages of data collection, Canada, Ireland, Portugal, Spain, and South Africa engaged actively. A higher percentage of contribution to all three stages came from the European region, providing 16 of the 25 survey responses, eight of the 11 case studies, and three of the 11 insight board participants. The European, Americas and African regions contributed equal responses (three each) to the insight board discussion. Overall regional contributions to this report by the WHO classification are as described in Table 10.

Table 10. Number of FIP member organisations contributing to this report by the WHO classification

WHO classification of regions	Number of FIP member organisations participated*	Countries
European region	16	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Danmark, Finland, France, Germany, Ireland, North Macedonia, Norway, Portugal, Romania, Slovenia, Spain, Switzerland
African region	3	Cape Verde, Nigeria, South Africa
Americas region	3	Canada, the United States, Uruguay
West-Pacific region	2	Australia, Fiji
Eastern Mediterranean region	1	Israel
South-East Asian region	Nil	Nil

** Repeat contributions from the same country during different data collection phases were excluded from the overall counts.*

6.2 Summary of key findings

This report highlights the range of point-of-care tests offered in pharmacies, from simple tests such as blood pressure measurement to specialised tests such as procalcitonin determinations. In general, patients pay for the service out of pocket, as in most countries these tests are not funded by either public or private third-party payers. Survey findings also suggest that additional training for pharmacists to perform the tests efficiently is recommended, but not mandatory in all countries. In the majority of countries, test results are typically communicated to other healthcare professionals through manual documentation or telephone calls, as pharmacists in these countries generally do not have access to writing in patients' medical records.

Evidence from this report highlights the clinical and economic benefits of pharmacy-based POC testing. The literature review shows that pharmacy-based POCT services have improved patients' quality of life by reducing irrational use of antibiotics and detecting disease early or identifying at-risk populations. Economically, POCT was a more cost-effective option than physician-based care, resulting in greater efficiency in healthcare delivery and significant healthcare cost savings for individuals and governments. Additional tests and hospitalisations are significantly reduced and secondary and tertiary healthcare facilities are better optimised. Key benefits cited by participants include convenience and rapid access to healthcare, especially in rural and underserved areas, facilitating referrals for shared management, and promoting good health and general well-being.

The insight board participants identified the lack of reimbursement models, varying levels of legislation, lack of political support and reluctance from the medical community as some of the barriers to the expansion of pharmacy-based POCT services. Their feedback suggests that collaboration between community pharmacies and clinical biology pharmacists should be explored to promote a referral protocol for patient management. Importantly, stakeholder engagement with

information on the benefits of integrating community pharmacy POCT into healthcare systems is necessary to set priorities for this area of practice.

6.3 Limitations of the report

Some limitations were identified. Most respondents were from the European region, with limited participation from the African, Americas, and West-Pacific regions. The Eastern Mediterranean region contributed minimally (one out of 25 survey responses) and there was no representation from the South-East Asian region. This response distribution may distort the global generalisability of the report in a global context. In addition, the under-representation of regions may mean that pharmacy-based POCT is not a priority area or has not been widely implemented in those regions.

There was a slight difference in certain responses from participants from member organisations such as those in Canada, Spain and the United States in the three stages of data collection. This is due to the decentralisation of healthcare and the existence of state/provincial autonomy, which results in different practice structures for pharmacy-based POCT in these countries.

6.4 Recommendations and future implications

Supporting the integration of pharmacy-based POCT into healthcare in all countries is an important step towards achieving affordable and accessible primary healthcare worldwide. The process of prioritisation and implementation in each country could be accelerated by engaging stakeholders in favourable policies, improving public awareness, establishing multidisciplinary collaborations, establishing country-wide evidence-based protocols and frameworks, and advocating with data showing the benefits of these tests to patients, healthcare systems and economies.

To gain recognition from governments and third-party funders, it is recommended that available data on the benefits of evidence-based POCT practices in pharmacies be used to advocate favourable legislation and implementation. This will result in strong partnerships that provide a protocol for reimbursement and service delivery and ensure a coordinated, seamless approach to accessible healthcare. It is suggested that additional training for pharmacy professionals, access to patients' electronic health records and clinical decision making based on test results would be complementary to ensure that pharmacy-based POCT delivers increased value for patients.

In conclusion, this report presents current pharmacy-based POC testing and the role of pharmacy and pharmacists in providing this service. Using findings of the survey, case studies and input from the insight board discussion, this report has highlighted the global variation in the uptake and practice of community pharmacy-based POC testing services. Community pharmacists around the world provide a wide range of POC tests that improve health and economic outcomes for patients and communities. Despite barriers to reimbursement and reluctance from other healthcare professionals, the clinical and economic benefits, supported by the available evidence, are critical in communicating key advocacy messages to stakeholders for consistent practice.

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Appendix 1 — Survey questionnaire

1. **Are pharmacists allowed by law to perform POCT?**
   (1) ☐ Yes
   (2) ☐ Yes, but it varies depending on which part of the country
   (3) ☐ No [END SURVEY]

2. **In addition to pharmacists, are other pharmacy workforce members (e.g., pharmacy technicians) allowed by law to perform POCT?**
   (1) ☐ Yes
   (2) ☐ Yes, but it varies depending on which part of the country
   (3) ☐ No

3. **Which types of POC tests are provided by pharmacies in your country/territory?**

   Blood glucose and diabetes:

   ☐ Fasting plasma glucose (FPG)
   ☐ Random plasma glucose (RPG)
   ☐ Plasma glucose 2 hours after a 75g oral glucose load (oral glucose tolerance test, OGTT)
   ☐ Glycated haemoglobin A1C (HbA1C)

   Lipid testing:

   ☐ Total cholesterol
   ☐ HDL cholesterol
   ☐ Triglycerides

   Cardiovascular health indicators:

   ☐ Blood pressure
   ☐ Mean pulse rate

   Respiratory function testing:

   ☐ Spirometry

   Haematology testing or indicators:

   ☐ Haemoglobin

   Infectious disease testing:

   ☐ Flu tests
   ☐ Strep throat tests
   ☐ Respiratory syncytial virus (RSV) tests
   ☐ HIV testing
   ☐ SARS-CoV-2 tests
   ☐ Hepatitis C antibody test
   ☐ Sexually transmitted infections (STIs) screening tests
   ☐ C-reactive protein
   ☐ Procalcitonin

Urine testing:

☐ Pregnancy tests

☐ Microscopic panel (erythrocytes, leukocytes, casts, crystals, bacteria, epithelial cells)

☐ Macroscopic panel (dipstick) (colour, bilirubin, occult blood, macroscopic blood, glucose, ketones, leukocytes esterase, nitrite, pH, protein, gravity, urobilinogen)

Other:

☐ If other, please specify: _____

4. Are pharmacies allowed by law to sell self-tests for use by the consumer in their home?

(1) ☐ Yes

(2) ☐ No

5. How are pharmacies remunerated for POCT in your country/territory? (mark all that apply)

☐ They are reimbursed by public health systems /third-party payers
☐ They are reimbursed by private health insurance companies /third-party payers
☐ They are paid by the patient/customer out of pocket
☐ They receive no remuneration for POC tests
☐ If other, please specify: _____

6. Are pharmacists authorised to store the results of POCT and other health data in an internal system that supports patient management and follow-up?

(1) ☐ Yes, in a system shared across all pharmacies in the country

(2) ☐ Yes, in a system shared across all pharmacies of the same network / owner, or individual pharmacies

(3) ☐ No

7. Are pharmacists able to register the results of POCT in a shared health record accessible to other healthcare professionals?

(1) ☐ Yes

(2) ☐ No

8. Are there specific professional regulations, standards or requirements for conducting POCT services at pharmacies, including a standard operating procedures for each device?

(1) ☐ Yes

(2) ☐ Yes, but it varies depending on which part of the country

(3) ☐ No

9. Do pharmacies have to meet any requirements regarding the facilities for conducting POC tests (e.g., separate private area?

(1) ☐ Yes

(2) ☐ Yes, but it varies depending on which part of the country

(3) ☐ No

10. **Are pharmacists authorised to make clinical decisions based on the results of POC tests (e.g., prescribe antibiotics for strep throat, adjust or renew prescribed treatments for certain chronic non-communicable diseases, etc.)?**
    (1) ☐ Yes
    (2) ☐ Yes, but it varies depending on which part of the country
    (3) ☐ No

11. **Are pharmacy professionals providing POCT required to undergo additional education or training?**
    (1) ☐ Yes
    (2) ☐ Yes, but only for specific POC tests.
    (3) ☐ No

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