

Point-of-care testing in the community pharmacy: Improving access to care

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Summary

- The evolution of community pharmacies into convenient and accessible care providers using point-of-care (POC) testing has become more prominent in Europe and the USA in the last decade
- A wide range of benefits can now be delivered utilising the convenience of access to community
 pharmacies in a number of patient pathways that cover disease screening, case finding, chronic
 disease management and minor illness testing
- This evidence review provides examples of care delivered by pharmacies where POC testing is offered, and the patient satisfaction, convenience and cost benefits that result

Current trends in the delivery of healthcare

Today's ageing population, with a higher incidence of chronic health problems and the resulting demands on medical and social services, calls for a more integrated approach to healthcare. This is reflected in the need for advances in patient-centred care, improved access to care and care closer to home, reduced consultations and hospital admissions, and finding means of cost containment. Such progress in healthcare delivery systems will enhance both patient and provider satisfaction and improve clinical management. Such progress in healthcare delivery systems will enhance both patient and provider satisfaction and improve clinical management.

As part of delivering integrated care, there is an ongoing drive to provide diagnostic test results quickly and conveniently to patients in primary care settings.² Care closer to home can be improved by providing diagnostic services using point-of-care (POC) testing in the community setting. Patients can benefit from more immediate clinical decision making as such services reduce delays incurred as a result of sending samples to a central laboratory and the need for repeat visits or referrals once results are available.² In addition, healthcare systems could benefit from the potential cost-savings achieved by having more patients assessed and treated in the community setting.⁴

The evolving role of the community pharmacists

In the United Kingdom (UK), there is a government push to transform healthcare services to deliver care closer to home by encouraging and training pharmacists to take on a wider role in the provision of healthcare. ⁵ Access to care can be improved by extending the clinical services provided by community pharmacies to include patient consultation, diagnostic testing and the prescribing of medicines. Placed in convenient locations, pharmacies are easily accessible, with long opening hours that extend to weekends. ⁶ Examples

of such services can already be found in countries such as in the United States of America (USA) where some pharmacists already diagnose and prescribe medications for minor illnesses.⁶

Rapidly emerging technologies in POC testing enable the use of smart, portable, efficient, reliable and easy-to-use devices.4 POC devices are well suited for diagnostic testing in community pharmacies as they allow patients more flexible access to care.6 Research among patients in the UK showed that pharmacists are considered to be highly trusted members of the community who are highly trained and have good interpersonal communication skills, placing them in an ideal position to provide POC testing where it is needed.⁷ In order to offer these high-level care services, it is important that pharmacists are well trained in the use of POC testing and interpretation of the results, besides being able to effectively communicate the test results to patients and other healthcare professionals (HCPs).8

In the USA, it has been recognised that broad uptake of POC testing in community pharmacies offers the potential to help deliver the goals in The Institute for Healthcare Improvement's Triple Aim Initiative framework by improving patient satisfaction, extending access to care, expediting initiation of treatment and lowering costs by reducing primary care appointments and laboratory tests.9 Pharmacies with improved access and delivery of care are already available in the USA; there are, for example, retail clinics that offer walk-in consultation services, diagnostic testing and treatment of minor illnesses. 10 Another example is the integration of a non-dispensing pharmacist (NDP) located in primary care practices around the world (e.g. USA, Australia, Canada, Sweden and UK). NDPs conduct foremost clinical pharmacy services that focus on

chronic disease management, such as diabetes and cardiovascular (CV) diseases, and can add value to patient-centred care.¹¹

The landscape of POC testing in community pharmacies in different countries

In the USA, community pharmacy-provided care services using POC testing fall into three broad models. In the simplest model, the pharmacy serves as a convenient site for sample collection, with a central laboratory processing the samples. In the second model, a Clinical Laboratory Improvement Amendments (CLIA)-waived pharmacy or retail clinic has an HCP working on site, such as a nurse practitioner, who conducts POC testing as part of the patient care services.⁶ An example of a convenience care clinic is CVS Health, the largest pharmacy healthcare provider in the USA, which includes the retail clinic division MinuteClinic. The MinuteClinic is staffed by nurse practitioners and physician assistants who can evaluate, diagnose and treat minor illnesses.¹² Physician assistants, referred to as physician associates in the UK, are HCPs who work under the supervision of a licensed doctor. A similar example of a large pharmacy retail chain that provides care services using selected POC tests is Walgreens healthcare clinic, based in the USA. 13

'Waived' POC test procedures available in retail pharmacies across the USA

- HbA1c and blood glucose tests for diabetes screening and monitoring
- Cholesterol test for screening and monitoring
- Urine albumin test for kidney function
- Strep test for sore throat
- Mononucleosis test
- Urinary tract infections test
- Tuberculosis purified protein derivative test
- Common sexually transmitted infections tests (chlamydia, gonorrhoea, hepatitis A, B and C, HIV, genital herpes, syphilis, trichomoniasis and genital warts)

Box1: POC test procedures that are available in selected retail pharmacies in the USA providing convenience care services. 12,13

The third and most comprehensive model is where pharmacists provide complete disease-management services, which include POC testing and provision of

care based on the outcome of the results.⁶ This model is possible through collaborative agreements set by the Practice Advisory on Collaborative Drug Therapy Management (CDTM), which is a collaborative practice agreement between pharmacist(s) and physician(s) on the management of patients' drug therapies. Pharmacists are allowed to provide clinical services under formal agreements with physicians and this model has been demonstrated to increase the satisfaction of the patient, physician and pharmacist, as well as the quality of therapy while decreasing costs. 14 However, not all states in the USA have laws that allow for collaborative practice agreements. Certain states allow for direct prescribing of medicines by pharmacists without the need for agreements. Community pharmacies in the USA are the leading providers of adult vaccinations, and over the years have been increasing their services by aiding the management of acute and chronic health issues. Such services now include POC testing for CV disease (cholesterol or lipid profile monitoring), oral anticoagulation management (measurement of the international normalised ratio (INR)), diabetes (glucose and HbA1c testing) and acute respiratory infections (influenza, Strep A testing). 12,13,15

POC testing in a pharmacy setting is enabled in the USA by the availability of POC tests that are 'waived' under the CLIA of 1988 (Box 1). CLIA-waived tests are defined as simple-to-conduct procedures that are cleared by the US Food and Drug Administration, which should have minimal risk of error and cannot result in significant harm to patients if performed incorrectly.¹⁵

The clinical care services in European community pharmacies have also evolved. The Pharmaceutical Group of the European Union (PGEU) is the European association of community pharmacists aims to advance the contribution of community pharmacists to European healthcare systems, society and individual patients. 16 In 2017, the PGEU conducted a survey of its members to understand the extent and variety of community pharmacy services available across Europe. The main services offered by pharmacies include the supply of medicines, promotion of rational use of medicines, disease-management services and measurement and testing services. Of the latter, the survey revealed that 90% of the pharmacies provided blood pressure monitoring, 90% provided 77% weight measurements, provided

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glucose testing and 73% provided cholesterol measurement services.¹⁷

The UK is one of the front-runners in Europe when it comes to pharmacy-led clinical care services. The National Health Service (NHS) England – Five Year Forward View highlighted that patients should understand that for minor ailments, they can visit pharmacies instead of seeing a general practitioner (GP) or going to the Accident and Emergency (A&E) department.¹⁸

Clinical care services in community pharmacies offering POC testing for screening and diagnosis are not yet widely available in all European countries. However, feasibility studies, such as creatinine POC testing in Dutch pharmacies, diagnosis of diabetes using HbA1c POC testing in Norwegian community pharmacies and screening for CV disease in Austrian pharmacies, show positive outcomes for pharmacy-led clinical care services in European pharmacies. ¹⁹⁻²²

POC testing has rapidly evolved in the last decade in community settings in Australia. This is driven by the movement towards patient-centred care, the change from secondary to primary care for patients with chronic disease, and especially the geographic isolation of many rural and remote communities. Following the introduction of POC testing in the community, both patients and POC users have reported significantly improved satisfaction levels. The community-based POC testing is generally performed by nurses, aboriginal health workers and pharmacists.²³

Expanding screening programmes using POC testing

The uptake of CLIA-waived POC screening tests by pharmacies is still expanding in the USA, with new assays being tested on a regular basis. A CLIA-waived POC test for the screening of hepatitis C virus antibody (HCV-Ab) has recently been piloted in a community pharmacy-based programme in California, in collaboration with the US Department of Health and Human Services. The study showed that trained pharmacists could perform rapid HCV-Ab POC screening procedures for undiagnosed potentially high-risk patients.²⁴ HCV infection is the leading cause of liver transplantation in the USA, and having a POC screening programme conveniently accessible in community pharmacies could identify a large proportion of people with high risk of HCV infections.¹⁵ Moreover, the Public Health England guidelines stipulate that human immunodeficiency virus (HIV) testing is recommended in community pharmacies in areas with high prevalence of HIV.²⁵

One of the best examples of the use of POC testing in community pharmacies is the NHS Health Check in the UK. This is one of the largest public health prevention programmes in the world where screening of risk factors for CV disease, stroke, Type 2 diabetes mellitus (T2DM), kidney disease and dementia are conducted.²⁶ The Department of Health and Social Care has included community pharmacies as a provider of the NHS Health Check in order to broaden public access and increase uptake of the tests.²⁷ The NHS Health Check includes a symptom questionnaire combined with tests of blood pressure, cholesterol and HbA1c or glucose levels where diabetes is suspected. The health check could be further expanded to include tests for kidney damage (blood creatinine) and heart failure (BNP/ NT-proBNP), and be managed by a pharmacist. The benefits of a pharmacy-led CV risk-screening programme was demonstrated in a study performed in Austria, which identified CV risk factors in 30% of participants.²²

It is widely accepted that early screening of T2DM could reduce the risk of hyperglycaemic and CV complications by facilitating management of the relevant risk factors. 28 It is therefore not surprising that pharmacy-based screening using POC testing has been successful in identifying a significant proportion of individuals with undiagnosed T2DM in countries such as the UK and Switzerland. 29 Screening has not been routinely implemented in all European countries, but initiatives for future implementation are being undertaken. 29 For example, a recent study showed the feasibility of diabetes diagnosis using HbA1c POC testing in community pharmacies in Norway. 21

POC opportunities for clinical diagnosis and disease monitoring

POC testing in community pharmacies could play an important role in the diagnosis of common diseases and the monitoring and management of chronic diseases. In recent years, self-testing for HIV has gained popularity since the first over-the-counter test was approved for commercial sale in the USA in 2012. The predominant benefit is that HIV self-testing allows for increased access to testing and

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therefore increases the number of patients who can be screened.³⁰ However, the uptake of this particular POC test has also raised critical questions regarding the provision of counselling and healthcare advice, test accuracy and the risk of abuse.30 In response to these concerns, a US research group developed a model for rapid HIV testing in community pharmacies that work in close collaboration with specialist doctors.³¹ Moreover, pharmacy-led HIV pre-exposure prophylaxis (PrEP) programmes have been recently introduced, such as the One-Step PrEP® clinic at Kelley-Ross Pharmacy where the pharmacist performs a risk assessment, tests for HIV, and then prescribes and dispenses PrEP in a single appointment to reduce HIV risk for at-risk people. When using PrEP daily, the risk of HIV infection could be reduced by up to 92%. 32,33

Several pharmacy-based HIV testing programmes implemented in Spain have identified a large population of undiagnosed individuals, especially in remote regions that lack easy access to HIV diagnostic services.³⁴ The major advantage of using an in-pharmacy HIV POC testing model in close collaboration with HCPs is that it addresses most of the concerns raised with self-testing; for example, patients can be counselled or referred to an infectious disease specialist if tested positive, rather than being lost to follow-up.

The use of POC blood coagulometers has made it possible for patients who are on long-term anticoagulation therapy to monitor and manage their blood-clotting time. Patients can either self-manage their anticoagulation therapy by adjusting their own medication, or self-monitor and visit a clinic or pharmacy to have their medication adjusted. Both models of POC testing have been adopted in most countries across Europe and shown to improve quality of therapy. Furthermore, patient satisfaction with community-based anticoagulation clinics has been associated with improved access to testing, reduced waiting times and more personalised services. Self-monitor and more in the patients and services.

Patients who are being treated for diabetes and/ or CV disease require regular monitoring of renal function by frequent testing of their urine albumin. Impaired function may entail dosage adjustments as failure to adjust drug dosage could lead to drug accumulation and toxicity, which could result in hospitalisation.³⁷ However, adherence of primary care to guidelines that recommend regular monitoring of renal function varies.¹⁹ A research group in the Netherlands tested the feasibility of creatinine POC testing combined with clinical decision support in community pharmacies and the findings showed improved drug therapy management and monitoring in elderly patients in this setting.^{19,20}

Indigenous Australians living in remote areas are twice as likely to develop diabetes compared with their counterparts living in urban areas. POC testing offers a practical solution for monitoring diabetes in such populations.³⁸ The Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) programme is Australia's largest national POC testing programme that has been running since 2008. The programme supports HbA1c and urine albumincreatinine ratio POC testing to assist diabetes screening and management.²³

Evidence of clinical effectiveness

A study by Robson et al. investigated the effectiveness of the NHS Health Check programme in its first four years in 214,295 attending patients. Of the eligible population who attended the programme, 12.9% were found to have high CV disease risk, 7844 attendees were diagnosed with hypertension, 1934 with diabetes and 807 with chronic kidney disease. These patients may have gone undiagnosed without the implementation of the NHS Health Check.³⁹

POC screening in community pharmacies could also play a part in reducing antibiotic prescriptions, thus limiting the development of antimicrobial resistance.40 A study based in England showed that diagnosis of group A streptococci using POC testing by pharmacists across England has the potential to reduce unnecessary antibiotic prescriptions in a large segment of the population. The authors found that the POC testing service in question reduced by two thirds the number of patients who would have otherwise seen their GP; as a result, consultations for sore throats in England were reduced by an estimated 800,000 per year.41 Another feasibility study found a reduction in antibiotic use in patients who were referred by their GP to the pharmacy to carry out a C-reactive protein (CRP) test, which could contribute to the UK antimicrobial resistance strategy.42

Evidence of cost effectiveness

Two key drivers in the transformation of healthcare

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systems are the improvements in cost containment and the delivery of value-for-money. An One important economic burden is adverse drug effects arising from medication errors. A budget impact study performed by Gout-Zwart et al. analysed the effects of POC testing for renal function in Dutch community pharmacies. By using a POC test, the number of patients with available renal function values increases, enabling dose adjustments to be made when necessary. The analyses estimated that the introduction of POC testing in the community pharmacy would provide annual cost-savings of €86 per patient through the availability of renal function values in Dutch community pharmacies. Savings were mostly due to avoided hospitalisations.

Another study investigating the potential cost-savings in performing POC testing, instead of the traditional laboratory pathway in delivering the NHS Health Check in primary care, showed a potential saving of £29 per 100 patients. In the analysis, the researchers assumed that a health check would require a minimum time of 20 minutes and can take up to 40 minutes. 45 Additional cost-savings could be made by reducing primary care consultations by performing the NHS Health Check in community pharmacies. Overall, more studies need to be carried out to provide evidence on the costeffectiveness of POC testing in community pharmacies. Several considerations would need to be taken into account including the costs of POC testing versus central laboratory testing, primary care consultation fees versus pharmacy costs and the impact on the pharmacists' practice.⁵

Barriers and challenges for the uptake of POC testing in the community pharmacy

Perceived barriers, such as lack of pharmacist training, quality control (QC), inclusion of test results in patients' electronic heath record (EHR) and inadequate reimbursement schemes, have limited the widespread uptake of POC testing in community pharmacies. 46 Resources for e-learning are, however, becoming more available, and technological advances in the development of easy-to-use portable POC testing devices means that testing can be performed by individuals with little training. 8 Issues of compliance and QC are increasingly complex as clinical testing becomes integrated in pharmacy-provided care services. Connectivity of POC devices can simplify the managerial aspect by providing smart solutions for QC and assuring direct

incorporation of patient details and test results into a patient's EHR.⁴⁷ These barriers can be managed by developing close collaborations between GPs and pharmacists (i.e. the CDTM agreements), appropriate training schemes and close oversight to promote safe practice in pharmacies.

Reimbursement incentives for POC testing must be financially worthwhile for pharmacists to provide care services using POC testing. On a unit base, POC tests may appear to cost more than a laboratoryperformed test, but the real cost of a laboratory test is hidden by fixed costs and silo budgets. The real value of POC testing is in the overall improved outcomes in healthcare. A streamlined referral process, earlier rule-out, decreased GP consultations or emergency department presentations, and improved patient satisfaction should all be taken into account when assessing the true value of POC testing. California and Washington have set examples through the implementation of laws requiring insurance companies to recognise pharmacists as providers and include them in medical benefit networks.

Opportunities in pharmacy POC testing

Across Europe, there is a drive to provide healthcare closer to home. A greater involvement of community pharmacists in care services, with the ability to diagnose using POC testing and prescribe treatment based on the results, could improve access to healthcare while providing care closer to home, as well as reduce the burden on primary care practices.²

A study performed in the UK showed that GPs believe POC testing will be most beneficial for the diagnosis of certain conditions (e.g. urinary tract infections, diabetes and acute cardiac disease), for reducing referrals (e.g. pulmonary embolism / deep vein thrombosis and chronic obstructive pulmonary disease / asthma) and for helping them monitor or manage patients' conditions (e.g. INR for anticoagulation therapy management).² Certain POC tests are already routinely performed by GPs (e.g. blood glucose, haemoglobin tests and urinalysis) and additional uptake of these by pharmacists could potentially improve health outcomes, be more convenient for patients and reduce visits to GP clinics.48 Pharmacy-led CRP POC services are also developing complementary service for patients presenting with symptoms of respiratory tract infection who

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may require antibiotics.49

Timely access to laboratory test results and followup appointments for patients to initiate treatment is very challenging for rural areas. A study by Spaeth et al. showed that the mean turnaround time for laboratory testing of HbA1c in remote health centres in the rural parts of Australia was 2.3 days, while POC testing only took 6 minutes. Another important finding was that when patients were required to have a follow-up visit, the mean time to consultation was 24 days in these remote communities compared with an immediate consultation after POC testing. The ability to see the patient and initiate treatment or change the management of chronic diseases in the same consultation improves clinical care.³⁸ This study highlights the importance of POC testing in providing care closer to home in remote areas. Uptake could be further enhanced by the implementation of POC testing services in community pharmacies.

The care services of pharmacies could be further expanded by having pharmacists perform patient drug monitoring. Patients on drugs such as digoxin, lithium and theophylline require routine monitoring to maintain the narrow therapeutic drug ranges and to check for drug toxicity.⁵⁰ Drug adherence is also important in the case of chronic diseases and for the maintenance of long-term health.⁵⁰

Conclusion

The evolution of community pharmacies into convenient and accessible care providers utilising POC testing has become more prominent in Europe during the last decade. The benefits of community pharmacies, such as easy access to skilled and trusted healthcare providers, convenient location and extended hours of operation, are being recognised by patients and HCPs. Studies performed across Europe using a range of different POC tests have demonstrated the feasibility of utilising community pharmacies to provide care services; the associated benefits, such as improved patient satisfaction and cost-savings have been highlighted. POC devices with two-way connectivity could further improve clinical workflows by having test results directly transferred to patients' EHR, built-in QC alerts and checks, and quality assurance (e.g. restricted access for trained personnel only and a track record of the testing personnel). With POC technologies rapidly evolving to become more convenient and accessible with greater connectivity and improved performance,

more POC tests can be safely and accurately performed in community pharmacies, leading to a new era in pharmacy-led POC testing providing care closer to home.

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