

# Point-of-care testing in primary care in Europe: Improving pathways and patient outcomes

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### Summary

- Point-of-care (POC) testing technologies offer a means of improving access to diagnostic and monitoring decision-making in the community setting
- Primary care physicians can benefit from the implementation of POC tests across a number of patient pathways to deliver improved outcomes and improve patient access to care and satisfaction
- There is a wide variation in the access to POC testing in primary care across Europe
- This review highlights the access to POC testing in Europe, the evidence for benefits in specific patient pathways, the challenges of broader implementation and the opportunities for new technologies

#### Trends in healthcare provision across Europe

Healthcare systems around the world are rapidly changing, with an overall aim to improve healthcare delivery and reduce costs. Specific discussions focus on healthcare access, quality, diagnosis and treatment, and subsequently increasing clinical outcomes, Indeed, there is a move to delivery of a more integrated approach to health and social care, and a shift in healthcare management away from a focus on activity to an emphasis on outcomes.<sup>1</sup> There is a strong drive to prevent patients being hospitalised unnecessarily and a general trend towards consolidating networks of hospitals and improving primary care.<sup>2,3</sup> However, these changes bring about challenges and pressures regarding adoption of new practices, such as utilising POC testing and potential lack of incentives for general practitioners (GPs) in providing this service. This pressure stems from increasing demands and expectations from patients, an aging population, an increase in long-term complex conditions, understaffing and the transition from secondary to primary care.<sup>4</sup>

A more integrated approach to healthcare has a special focus on delivering care closer to home, which may improve patient satisfaction and encourage more patient self-care.<sup>5</sup> Primary care physicians in particular have expressed a desire for POC testing for use in the patient pathway, in order to aid diagnosis and manage long-term conditions more efficiently.<sup>6</sup> POC testing can transform patient care, enabling early and on-site detection of biomarkers, leading to reduced turnaround times by giving the clinician access to rapid and actionable test results.<sup>7</sup> The portability of POC devices allows for testing to be performed in multiple venues of care such as in primary care clinics, emergency departments, out-

patient rooms, care homes, patient's homes and pharmacies.<sup>8</sup> Using capillary blood samples negates the need for venepuncture and on-site requirements for phlebotomists, and is more convenient for the patients.<sup>9</sup> In addition to enabling faster diagnosis and more efficient therapy management, using POC tests in primary care can also help to reduce the amount of referrals to secondary care and can help the patient and physician decide upon the best-suited approach of management.<sup>8,9</sup>

Concerns have been expressed about access to healthcare in rural areas. The use of POC testing in rural communities of Australia and Norway have demonstrated how access, and healthcare outcomes, can be improved.<sup>9,10,11</sup> Overall, POC testing in a primary care or community setting can provide both clinical and economic benefits.

### POC testing can benefit specific patient pathways and improve clinical outcomes

There is a wealth of evidence demonstrating that POC testing shows benefits in clinical pathways typical of primary care presentation when used alongside clinical decision tools and with approved clinical guidelines. For patients on oral vitamin K antagonist therapy, regular monitoring of the international normalised ratio (INR) is necessary. One of the advantages of POC INR testing systems is the ability to perform the test at home or in the primary care clinical environment. Self-testing and self-management strategies in particular have been shown to provide better anticoagulation control, and improve the quality of life for patients and their families.<sup>12,13,14</sup> Furthermore, device training programmes can aid patients on oral anticoagulation treatment, to optimise their

LumiraDx UK Ltd: Unit 1, Block 5, Dumyat Business Park, Bond Street, Alloa, FK10 2PB, UK LumiraDx inc: 221 Crescent Street, Waltham, MA 02453, USA INR self-measurements.<sup>15</sup> Frequent INR testing is seen to improve time in therapeutic range and can be delivered in primary care.<sup>16,17</sup>

POC testing in diabetes improves glycaemic control in patients.<sup>9</sup> HbA1c POC testing can improve patients' quality of life and clinical outcomes, and contribute to cost and time savings for both patients and healthcare professionals (HCPs).<sup>18</sup> A recent German primary care study demonstrated a reduction in required visits to the GP by 80% and a reduction in venous blood draws by 75%, compared to before implementation of the POC test system.<sup>19</sup> Improvements were also seen in clinic workflow and patient satisfaction.

One of the main presentations in primary care is acute cough. POC C-reactive protein (CRP) testing can be used to differentiate bacterial pneumonia requiring an antibiotic from a non-serious lower respiratory tract infection in primary care, and has been shown to reduce antibiotic use in general practice across Europe.<sup>20-24</sup> In addition, POC tests for upper respiratory tract infections due to streptococcus A have a fast turnaround time compared with laboratory culture of throat swabs, providing immediate results and preventing unnecessary use of antibiotics.<sup>25,26</sup>

POC D-dimer testing, used with clinical decision tools such as the Wells score, helps to rule out patients who present with symptoms of venous thromboembolism, such as deep vein thrombosis or pulmonary embolism. Patients with low D-dimer levels and no other concerning symptoms may be managed without the need to refer the patient for conventional lab-based testing or secondary care ultrasonography referral.<sup>27</sup> One study showed that age-adjusted cut-off values for D-dimer tests improve overall testing in patients over 50 years.<sup>28</sup>

In cardiology, POC brain natriuretic peptide (BNP) testing has been shown to improve the diagnosis of heart failure (HF).<sup>29</sup> Similar results have been shown for primary care, where it aids in the management of difficult-to-diagnose causes of dyspnoea and congestive HF.<sup>30</sup> In addition to this, home monitoring of BNP linked to primary assessment and monitoring has been shown to be a feasible testing approach in managing discharged HF patients.<sup>31</sup>

Sexual health services have used community-based POC testing for human immunodeficiency virus. The direct availability of results has been especially useful in situations where it is difficult to give people their results at a later stage: for example, if they are unwilling to leave their contact details or to come forward to a sexual health clinic for privacy reasons.<sup>32,33</sup>

As well as the pathways identified above, many other POC tests are used routinely in primary care, including tests for glucose, urinalysis, human chorionic gonadotrophin and creatinine.<sup>1,34</sup>

#### POC testing in the UK - where are we now?

Although GPs in England and the rest of the UK have expressed a desire for more access to POC testing in practices, they are still aware that system-level changes must be made in order to aid the wider adoption of POC testing.<sup>4,35</sup> The NHS sustainability and transformation plans offer a broad opportunity to transform care delivery closer to home, and propose that care should be organised around GP clusters while also encouraging patients to take more responsibly, resulting in a reduction in hospitalisations.<sup>35</sup> Widespread implementation of POC testing could deliver significant benefits within this NHS strategy. A higher level of POC testing services is reported in Scotland compared with other parts of the UK, which may be due in part to the more remote location of a significant proportion of the population.<sup>1</sup>

#### POC testing in Germany and Switzerland

In Germany there is a diagnosis-related group (DRG) hospital care reimbursement system for medical devices, adopted following the high degree of accurateness of the Australian DRG system. Testing is conducted in general practice and also in the more specialist physician office sector. POC testing with troponin, D-dimer and BNP in ambulatory care and in primary care surgeries has proved to be very successful in Germany.<sup>36,37,38</sup> Additionally, the implementation of HbA1c POC testing in German medical practices has shown improved practice workflow and increased satisfaction among physicians, staff members and patients.<sup>19</sup> POC testing is widely used in Switzerland where many POC tests are found in the list of 'Rapid Analyses', consisting of drugs that are effective, efficacious, appropriate and cost-effective, of the Swiss Federal Office of Public Health, which are carried out in primary care and are reimbursed by the patients' insurance companies.

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### The case of the Netherlands – POC testing from the future

The implementation of CRP POC testing in physicians' offices in the Netherlands has been shown to improve the quality of care of patients with lower respiratory tract infections and the decision to prescribe antibiotics for patients with acute cough.<sup>39</sup> A initiative of HCPs and clinical chemistry joint microbiology laboratory professionals was and responsible for the successful implementation of CRP quality-assured POC testing in the Netherlands, and there is now a high demand for it among GPs.<sup>6</sup> One of the major factors contributing to the broad and sustainable uptake of CRP POC tests in primary care has been the introduction of national guidelines for GPs, which ensured that GPs are able to perform POC tests rationally.40,41 Other success factors include free training at dedicated websites, advocacy for rational use, good consultation skills, connections with insurance companies regarding reimbursements, face-to-face contact with thousands of GPs in the Netherlands and collaboration with laboratories to deliver a highquality service to GPs.<sup>39</sup>

#### **POC in Norway**

In Norway, POC testing is well developed and there is a large range of routinely offered tests. Out-ofhours services utilise the rapid results which can be delivered across a range of illnesses and, critically, to remote settings.<sup>1</sup>

### What are the key barriers to POC testing adoption across Europe and how could they be overcome?

Some barriers that have been identified with POC testing within primary care are the impact on clinical decision making, patient experience and cost-related issues. Findings from the literature have identified the major barrier at present to be the absence of funding and reimbursement models for most European countries. The quality of POC results as well as the clinical governance are concerns for managing diagnostic results in primary care. It is therefore important that a clinical governance framework is put in place and the ideal features of a POC test device are specified.

There are a number of features POC test devices should possess in order for them to be more widely adopted. These include having laboratory-level accuracy and a broad test menu to avoid requiring many small systems. Additionally, they require the ability to utilise small sample sizes (preferably capillary blood where it is used), produce fast results near to the patient in many settings, be used and stored at room temperature, and should be very simple to use. Costeffectiveness, digital transfer of results to the patient health record, and central management of quality procedures are desirable features for successful adoption, with patient care and satisfaction being the most important considerations.

## Improving technologies are delivering a better experience for patients and their HCPs

POC testing has the potential to revolutionise patient services in primary care, improving overall quality of care and limiting health costs. Small, portable POC devices that allow for easier use and portability would be especially beneficial, allowing use not only in primary care clinics, but also in care homes, patient homes and by paramedics.<sup>42</sup> Using a capillary blood sample rather than venous blood is more patientfriendly and requires no phlebotomist. Being able to receive the result quickly, in a few minutes, would improve clinical decision making. Technology has now improved such that it is possible to bring two-way smart connectivity to primary care POC testing. This has the ability to send the result from different venues of care to the patient's electronic health record, which should comply with strict European data security legislation can be immediately transferred. Remote connectivity via quality management systems mean that a central hospital laboratory POC coordinator could oversee instruments in the community and ensure quality and governance policies are implemented. This would be a solution to overcoming some barriers such as insufficient training of POC device users and insufficient quality assurance.<sup>9,43</sup> Finally, there is a lack of available POC devices that have extensive multiple test capability in order to have one system for many parameters. Using multiple separate instruments has issues due to requiring different training and quality management protocols, and increased storage and inventory monitoring. This would ultimately improve patients' and HCPs' experiences.44

#### Conclusion

POC testing in the primary care setting across Europe is growing, but its uptake today differs between countries and institutions. There have been many studies confirming evidence for the useful clinical and patient benefits in primary care; however, there are still several challenges that exist for widespread adoption. There is a clear need for new POC test solutions that are adaptable to the needs of a busy primary care practice and able to deliver the technology to meet the users' needs, such as multiple parameter testing, simplicity of use, capillary blood sample use, state-of-the-art two-way smart connectivity, small size and portability, and lab-quality control at the POC.

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