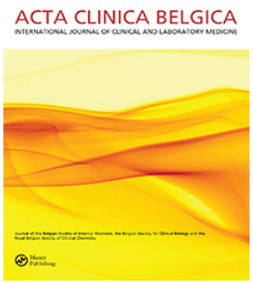
Taylor & Francis
Taylor & Francis Group



Acta Clinica Belgica
International Journal of Clinical and Laboratory Medicine

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/yacb20

Organisation and quality monitoring for point-of-care testing (POCT) in Belgium: proposal for an expansion of the legal framework for POCT into primary health care

Viviane Van Hoof , Dragos Barglazan , Laurent Blairon , Bob Braekevelt , Regis Debois , Nathalie Véronique J. De Vos , Damien Gruson , Jef Jonckheere , Katrien Lanckmans , Marc Moens , Bart Peeters , Joris Penders , Alain Roman , Lieve Van Hoovels , Florent Vanstapel , Jan Y. Verbakel , Ann Verdonck & Alain G. Verstraete

To cite this article: Viviane Van Hoof , Dragos Barglazan , Laurent Blairon , Bob Braekevelt , Regis Debois , Nathalie Véronique J. De Vos , Damien Gruson , Jef Jonckheere , Katrien Lanckmans , Marc Moens , Bart Peeters , Joris Penders , Alain Roman , Lieve Van Hoovels , Florent Vanstapel , Jan Y. Verbakel , Ann Verdonck & Alain G. Verstraete (2021): Organisation and quality monitoring for point-of-care testing (POCT) in Belgium: proposal for an expansion of the legal framework for POCT into primary health care, Acta Clinica Belgica, DOI: 10.1080/17843286.2020.1868906

To link to this article: https://doi.org/10.1080/17843286.2020.1868906

Published online: 06 Jan 2021.

ACTA CLINICA BELGICA
https://doi.org/10.1080/17843286.2020.1868906

Organisation and quality monitoring for point-of-care testing (POCT) in Belgium: proposal for an expansion of the legal framework for POCT into primary health care

Viviane Van Hoof[a*], Dragos Barglazan[b#], Laurent Blairon[c#], Bob Braekevelt[d#], Regis Debois[e#], Nathalie Véronique J. De Vos[b#], Damien Gruson[f#], Jef Jonckheere[d,g#], Katrien Lanckmans[h#], Marc Moens[i#], Bart Peeters[j#], Joris Penders[k,l#], Alain Roman[m,n#], Lieve Van Hoovels[o#], Florent Vanstapel[p#], Jan Y. Verbakel[q,r#], Ann Verdonck[s#] and Alain G. Verstraete[t#]

[a]Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium; [b]Laboratoire Hospitalier Universitaire de Bruxelles, Universitair Laboratorium Brussel (LHUB-ULB), Brussels, Belgium; [c]Laboratory Medicine, Iris Hospitals South, Brussels, Belgium; [d] Belgische Vereniging Apothekers Specialisten Klinische Biologie (BVASKB), Brussels, Belgium; [e]CHU UCL Namur Ste Elisabeth, Namur, Belgium; [f]Medical Biochemistry, Clinique Saint-Luc, UCLouvain, Woluwe-Saint-Lambert, Belgium; [g]Algemeen Medisch Laboratorium (AML), Antwerp, Belgium; [h]Dept of Clinical Biology, UZ Brussel, Jette, Belgium; [i]Belgische Beroepsvereniging Van Artsen-Specialisten in Medische Biopathologie, Union Professionnelle de Biopathologie Médicale; [j]Department of Clinical Biology, Antwerp University Hospital, Edegem, Belgium; [k]Clinical Biology Ziekenhuis Oost Limburg, Genk, Belgium; [l]Faculty of Medicine and Life Sciences, UHasselt, Belgium; [m]Intensive Care Unit, CHU Saint-Pierre, Brussels, Belgium; [n]ULB - Université Libre de Bruxelles, Brussels, Belgium; [o]Department of Laboratory Medicine, OLV Hospital, Aalst, Belgium; [p]KULeuven, Leuven, Belgium; [q]EPI-Centre, Academisch Centrum Huisartsgeneeskunde, KU Leuven, Leuven, Belgium; [r]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK; [s]Department of Clinical Biology, UZ Leuven, Leuven, Belgium; [t]Laboratory Medicine, Ghent University Hospital, Ghent, Belgium

ABSTRACT

Background: There is a trend towards decentralisation of laboratory tests by means of Point-of-Care testing (POCT). Within hospitals, Belgian law requires a POCT policy, coordinated by the clinical laboratory. There is however no legal framework for POCT performed outside the hospital: no reimbursement, no compulsory quality monitoring and no limits nor control on the prices charged to the patient. Uncontrolled use of POCT can have negative consequences for individual and public health.

Proposal: We propose that POCT outside hospitals would only be reimbursed for tests carried out within a legal framework, requiring evidence-based testing and collaboration with a clinical laboratory, because clinical laboratories have procedures for test validation and quality monitoring, are equipped for electronic data transfer, are familiar with logistical processes, can provide support when technical issues arise and can organise and certify training. Under these conditions the government investment will be offset by health benefits, e.g. fall in antibiotic consumption with POCT for CRP in primary care, quick response to SARS-CoV2-positive cases in COVID-19 triage centres.

Priorities:1° extension of the Belgian decree on certification of clinical laboratories to decentralised tests in primary care; 2° introduction of a separate reimbursement category for POCT; 3° introduction of reimbursement for a limited number of specified POCT; 4° setup of a Multidisciplinary POCT Advisory Council, the purpose of which is to draw up a model for reimbursement of POCT, to select tests eligible for reimbursement and to make proposals to the National Institute for Health and Disability Insurance (*RIZIV/INAMI*).

KEYWORDS
Point-of-care testing; POCT; primary care; legal framework; quality

Introduction

Small mobile devices are increasingly used to perform tests on blood or other bodily fluids. These tests are referred to as near-patient testing (NPT), rapid diagnostic testing (RDT), bedside testing, decentralised testing or point-of-care testing (POCT),[1] the latter will be used throughout this document. Examples include POCT for C-reactive protein (CRP), blood gases, glucose, Influenza A and B, Group A streptococcus, Respiratory Syncytial Virus (RSV), Human Immunodeficiency Virus (HIV) and recently also Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Training required for POCT should be limited and performing the test should not require specific technical laboratory skills.

Key reason for using POCT is the rapid availability of results, allowing for prompt medical decision-making, without the need to send samples to a central laboratory. It is obvious that POCT results should be absolutely reliable.

Small mobile POCT instruments are lower throughput (i.e., process fewer samples in a specified timeframe) than automated instruments in the central laboratory and

CONTACT Viviane Van Hoof vivianeom.vanhoof@uantwerpen.be; viv.van.hoof@outlook.com Faculty of Medicine and Health Sciences, University of Antwerp, 2610 Wilrijk (Antwerpen), Belgium

*President of the Working Group POCT of the National Commission Clinical Biology.
#Members of the Working Group POCT of the National Commission Clinical Biology.

typically run one sample at a time in 5 to 30 minutes. Larger POC platforms have a higher throughput as compared to the small mobile platforms and most of them return results in less than 60 minutes.

POCT technology is already well established in hospitals in Belgium, e.g. in emergency and intensive care departments. Within hospitals, Belgian law requires a POCT policy that is coordinated by the clinical laboratory, which implies that the laboratory director is responsible for all POCT within the institution, together with the hospital direction. There is however no legal framework for POCT performed outside the hospital.

To improve the health of its citizens, the Belgian government has set a target to build a high-quality health care system that is accessible to everyone. Primary health care is the backbone of this health care system and key to the integration and continuity between and throughout the various levels of care.

There is evidence in the literature that the quality of patient care increases through evidence-based use of specific POCT in hospitals and in primary care [1]. On the other hand, there is also evidence that uncontrolled use of POCT can have far-reaching negative consequences for individual as well as for public health [2]. Incorrect use of POCT can affect the accuracy of results and lead to variations in quality, causing both false positive and false negative results [1].

Stakeholders for POCT in primary care are patients, the government, primary care physicians, clinical biologists/pathologists, clinical laboratories, residential and nursing homes, pharmacists, sexual health clinics, manufacturers, importers, authorized representatives and distributors of POCT.

Several difficulties are associated with the implementation of POCT outside hospitals:

- Availability of large numbers of POCT devices and tests: how to choose?
- Quality of POCT assays: how can it be monitored?
- Justifiable use of POCT: how evidence-based /guideline-based do the tests have to be, and how can the government monitor this?
- Traceability of patient results: how can it be ensured that POCT results end up correctly in the electronic patient record?
- Logistical challenges: how should POCT be organised? This includes ordering, lot monitoring, evaluation of new lots, etc.
- Technical challenges: what to do when problems arise?
- Training: how should training be organised and certified?
- Health economics, i.e. pricing and reimbursement, since the cost of POCT is usually higher as compared to central laboratory tests: who should pay for it?
- CE-IVDR label (Requirements of European Directive - In Vitro Diagnostics Regulation): conform the European regulation?
- An appropriate policy on POCT should cover all these different aspects.

Organisation of POCT in primary care in Belgium

Current situation with regard to POCT outside hospitals in Belgium

POCT outside hospitals are currently unregulated and not reimbursed. Results of this (lack of) policy are that:

- The user has to choose from a large range of devices and reagents (often obtained via the internet) in a rapidly growing market, involving the risk that the chosen devices are of doubtful quality and not state of the art.
- The user has to organise training. Lack of training or erroneous training comes with a risk of errors that may influence results (false positives and false negatives).
- Incorrect use cannot be traced.
- The user is assumed to organise quality monitoring.
- Due to the lack of coordinated quality monitoring, quality deviations become apparent at a late stage only, if at all.
- The government (Sciensano) could be involved in external quality control of POCT. However, due to the large number of potential users and the many different types of devices and reagents, this is practically impossible to organise.
- It cannot be checked whether POCT patient results are sent to the electronic patient record.
- Overuse is not traceable, neither is underuse.
- The patient pays and there are no limits and no controls on the prices charged, resulting in a two-tier health care system.

Options for the organisation of POCT use in primary care in Belgium

The Working Group on POCT of the Belgian National Commission Clinical Biology sees three possible options for organizing POCT:

Option 1: POCT outside hospitals remains largely unregulated: only some specific tests are reimbursed, but reimbursement is free of obligations and without commitment.

In this scenario, the government pays for certain types of POCT but has absolutely no control over implementation or quality of the tests. Most of the consequences mentioned above in relation to the existing situation apply to this option.

Option 2: a separate body is created to organise POCT in Belgium ('British model').

The Belgian Federal Agency for Medicines and Health Products (FAGG/AFMPS) and Sciensano are supervised by the Federal Minister of Social Affairs and Public Health and are the competent authorities responsible for the quality of the IVD (in vitro diagnostics) introduced on the Belgian market and the correct use of these products according to the applicable quality standards (ISO 15189) (Sciensano). In that capacity, Sciensano is responsible for the inspection and certification of medical laboratories in Belgium. Certification can only be granted if the laboratory meets all legal requirements that are specified in the Royal Decree of 30 December 1999 on certification of clinical biology laboratories. Sciensano also organizes the external quality control for all certified medical laboratories. FAGG/AFMPS and Sciensano would be the most appropriate government institutions for creating a separate body for the organisation of POCT in Belgium. This option appears unrealistic in view of the current economic situation, as this would require a large and continuous investment and a considerable increase in manpower for these institutions.

Option 3: POCT outside hospitals is only reimbursed for tests that are carried out within a legal framework, requiring evidence-based testing and collaboration with a clinical laboratory ('Scandinavian model').

The consequences of option 3 are that:

- The user can profit from the existing infrastructure, logistics and expertise of the clinical laboratory.
- Since the user is guided by the laboratory in the choice of POCT equipment and reagents, there is a guarantee that the chosen devices and reagents are state of the art.
- Since user training is organised and monitored by the laboratory, the risk of pre-analytic errors is lower and results will be more reliable.
- The quality of the test results is guaranteed by the laboratory.
- Since quality controls are organized* and monitored by the clinical laboratory (*quality checks are performed by the user by means of materials provided by the laboratory and results are sent electronically to the laboratory), quality deviations will come to light quickly, and appropriate action can be taken. Gross quality deviations are rare, but they can block the POCT instrument and prevent further measurement. In this case the laboratory can provide new testing material or a back-up instrument. Monitoring of quality check results over time by the laboratory can pick up more subtle quality deviations that also need attention.
- Since the number of clinical laboratories is very limited as compared to the number of potential users, Sciensano can play a significant role in inspection and external quality control.
- Incorrect use can be avoided through evidence-based/guideline-based requirements, appropriate training and follow-up by the laboratory.
- Since this option links POCT to reimbursement, the government can easily check the electronic transmission of patient results via existing platforms.
- Since this option links POCT to reimbursement, the government can identify overconsumption.
- The laboratory can play a part in monitoring appropriate and evidence-based use of POCT.
- Under these conditions it is to be expected that the government investment will be offset by health benefits, as outlined below.

Proposed organisation of POCT in primary care in Belgium

Following the recommendations of its working groups on POCT and Legislation, the National Commission for Clinical Biology considered option 3 as the best way forward. To this end, a letter was sent by the Commission to the Minister of Social Affairs and Public Health on 31 July 2017 with a detailed proposal to amend the Royal Decree of 30 December 1999 on certification of clinical biology laboratories by including POCT outside the hospital.

This amendment implies that POCT outside hospitals is only reimbursed for specific tests that are carried out within the proposed legal framework. This proposal complies with the legislation on good clinical practice in health care (March 2019) [3], in which the same quality standards apply both within and outside hospitals.

Additional arguments in favour of this solution are that:

- This proposal complies with the Dutch Guidelines on Point-of-Care testing in GP care [4] and is inspired by the Scandinavian model, which has proven its effectiveness [5,6].
- Clinical laboratories have experience in evaluating devices and reagents and can offer advice to the user based on their evaluations, on the relevant literature, on cost/benefit analyses and on evaluations carried out by approved bodies, for example, SKUP in Scandinavia [7] and EPI-Centre in Leuven [8]. This guarantees an evidence-based and economically justified choice of tests, devices and software, in consultation with users.
- The majority of hospital laboratories already have experience with POCT.

- Clinical laboratories have compulsory procedures for monitoring the quality of diagnostic tests.
- State of the art POCT hardware is equipped for identification of the patient and the user, and for electronic data transfer of patient results to POCT middleware (which is already available in most hospital laboratories), to the lab information system (LIS) and to the electronic health record (EHR). This way POCT results are made fully traceable in the LIS, available in the EHR and consultable via the existing e-health platforms such as CoZo [9]. *
- The laboratory has expertise with regard to processing quality control results and is familiar with the actions that must be taken in case of deviations.
- The laboratory is familiar with logistical processes and procedures with regard to ordering, distribution and storage of reagents, monitoring lot numbers, evaluation of new lots etc.
- The laboratory can provide support when technical issues arise (e.g. provision of back-up equipment) and can arrange for contacts with manufacturers/distributors.
- The laboratory can organise and certify training (state of the art POCT equipment only works if the user is identified and certified).

** Some POCT, e.g. lateral flow tests, are performed on individual cassettes and produce a result that is visually read. This can be problematic for traceability and documentation of patient results and hampers the use of this type of tests within the proposed legal framework. To solve this issue, a lateral flow reader with connectivity (WiFi, Bluetooth, cloud connection) and supported by the LIS can be used.*

Priorities

Priority 1 = Amendment of the decree on certification of clinical laboratories, with extension to include decentralised tests in primary care

The same organisation and multidisciplinary collaboration are proposed for POCT outside hospitals as for POCT within hospitals.

Priority 2 = Introduction of a separate reimbursement category for POCT

At present POCT within Belgian hospitals is subject to tariffs based on the same nomenclature as tests performed in the central laboratory. As a result, the government has no idea which tests were carried out on a decentralised basis. Reimbursement of IVD tests in Belgium is based on a specific Nomenclature of Health Benefits, including the benefits – with specific hospital and ambulatory codes – that are partially or totally reimbursed by the Belgian health care insurance (National Institute for Health and Disability Insurance, RIZIV/INAMI).

Articles 24 and 24bis of the Nomenclature concern 'clinical biology' tests. The situation is complicated by the distribution of the refund over a fixed fee (lump sum, 'forfait') and a payment per performance. A separate nomenclature for POCT – using an article such as 24ter – which would be billed by the laboratories on a 100% basis and not as part of a fixed fee – was proposed by the Working Group Clinical Biology of the Medical Technical Council (TGR/CTM) of the RIZIV/INAMI. This would allow the government to monitor decentralized testing and would create the opportunity to develop a national POCT policy.

- The greatest advantages of this model are:
- The encouragement of evidence-based/guideline-based implementation of POCT in primary care; which can be further promoted by the availability of decision support software.
- A quality guarantee provided by the laboratory for both patients and doctors.
- A clear structure, which has already demonstrated its value in hospitals and in other countries.
- The physician/user does not need to be concerned about practical and logistical aspects.
- A strong position in dealings with POCT manufacturers and distributors, e.g. for price negotiations and quality issues.
- Traceability and transparency.
- A separate reimbursement scheme that permits monitoring and control by the government.

Priority 3 = Introduction of reimbursement for a small, non-limitative range of POCT

The following tests have been put forward by the working group on POCT:

(1) POCT for CRP

CRP, a marker of infection, was mentioned in a recent report by the Belgian Health Care Knowledge Centre (KCE) as one of the ways to reduce the use of antibiotics in Belgium and to combat antibiotic resistance [10].

Improved awareness of the fact that bacterial resistance to antibiotics is partly due to overuse of antibiotics has led to an understanding that empirical prescription of antibiotics for respiratory infections needs to be replaced by a targeted prescription. To achieve this, it is necessary to identify the most probable cause of the patient's symptoms quickly and correctly. As part of the efforts towards evidence-based medicine and the pursuit

of approved guidelines, POCT CRP has been included in the NICE guidelines 'Pneumonia in adults: diagnosis and management' in the UK [11] and in the NHG standard on 'acute cough' in the Netherlands [12].

We quote from the KCE Reports 311A and 311As [10]: 'Inappropriate use of antibiotics in both human beings and animals is causing bacteria to become resistant more and more quickly. This is resulting in deaths, more hospital admissions and people remaining sick for longer. In Belgium the use of antibiotics in outpatient care (where GPs are the main prescribers), in residential and nursing homes and in stock farming is higher than the European average. At the request of the Public Health FPS, the KCE has investigated the causes of this and set out 21 recommendations to improve the situation.'

Recommendation 5.12 of this report concerns point-of-care testing for diagnosis of infectious diseases in the Belgian outpatient context: 'Point-of-care tests such as measurement of C-reactive protein (CRP) or procalcitonin can help clinicians to determine in a few minutes how probable it is that a patient has a serious or less serious bacterial infection or a viral infection. In clinical studies these tests have resulted to antibiotics being prescribed much less readily.' 'Within the One Health AMR (antimicrobial resistance) action plan there is a need to ensure that a cost-effectiveness study is carried out on point-of-care tests to diagnose infectious diseases in the outpatient care sector in Belgium. It will then be necessary to ascertain whether it is desirable to reimburse these tests.'

However, as multiple studies have already demonstrated the cost-effectiveness of POCT CRP in adults [13–20], new cost-effectiveness studies, as proposed in KCE Report 311A, will create additional costs and delay the potential benefits, and are actually unnecessary for adults. Additional studies are only needed in children [21]. A report from the European Network of Health Technology Assessment agencies (EUNetHTA) views POCT CRP as useful and safe in reducing antibiotic prescribing for respiratory tract infections [20]. Existing scientifically proven guidelines, such as the NICE guidelines 'Pneumonia in adults: diagnosis and management' and the NHG standard on 'Acute cough' can be used to implement an appropriate use of POCT CRP [11,12].

Within the proposed legal framework, permission to carry out the tests would only be granted to primary care centres* and laboratories* that meet predefined criteria and carry out the tests in accordance with the guidelines. Real-world data could then be collected, which can form a basis for a health technology assessment. The literature that is already available on the costs and benefits of POCT CRP for acute cough in adults can be included as a secondary outcome measure to confirm these findings in the Belgian context. To improve compliance with the guidelines, requests for these POCT tests could be guided by decision support software.

*There are already a number of trial projects undertaken in collaboration with several Belgian academic centres that apply the basic principles of the proposed legal framework, including support from a medical laboratory, proper training for end-users, appointment of a point-of-care test manager in each practice, traceability of the operator and patient in the point-of-care device, IT connectivity between point-of-care devices in the various practices and the central laboratory IT infrastructure, guarantees of quality control (both internal and external), validation of test results and communication with the electronic medical record.

(2) POCT for infectious diseases: influenza, group A streptococcus, RSV and SARS-CoV-2.

Infections with influenza virus A and B, group A streptococcal bacteria, RSV and SARS-CoV-2 can currently be diagnosed with a high degree of sensitivity and specificity using POCT based on molecular diagnostics (polymerase chain reaction tests, PCR). Sensitivity and specificity of the older Rapid Antigen Detection Tests (RADTs) for influenza and RSV were less good as compared to the molecular diagnostic tests [22]. The performance of recently developed RADTs for SARS-CoV-2 is not as yet fully known [23].

Influenza (flu) is a seasonal disease that can result in hospitalisation and death, particularly in high-risk groups such as children, the elderly and people with chronic diseases [24]. Flu is characterised by a sudden occurrence of symptoms that overlap with respiratory tract infections, which makes diagnosis difficult. Rapid differentiation between influenza and other flu-like conditions is essential to ensure that patients are treated correctly. A POCT based on molecular diagnosis can quickly and reliably confirm or exclude influenza [25]. There is evidence in the literature that POCT for influenza can save costs due to reduced empirical prescribing and more targeted prescribing of antibiotics and antiviral agents [26]. In view of the current *SARS-CoV-2* pandemic, it is of great importance to effectively differentiate between influenza and SARS-CoV-2. Several companies have developed or are in the course of developing combined tests for both viral diseases, some of which will be available as POCT and some will also include RSV (press release Cepheid http://cepheid.mediaroom.com/2020-06-09-Cepheid-Announces-Development-of-Four-in-One-Combination-Test-for-SARS-CoV-2-Flu-A-Flu-B-and-RSV).

Group A streptococcus (Streptococcus pyogenes, group A beta-haemolytic streptococcus, GAS) infection causes acute pharyngitis. If untreated, this can lead to serious complications such as acute glomerulonephritis (kidney inflammation) and acute rheumatic fever. Antibiotics are very effective in treatment of GAS. As

acute pharyngitis may be caused by other bacterial infections or viral infections, some clinical guidelines recommend that antibiotics should only be used in proven GAS infections [27]. Nevertheless about 60% of patients with a sore throat are prescribed antibiotics, while GAS is the cause of the pharyngitis in only 5–30% of the cases. A recent study has shown that in real-world circumstances RADT results and laboratory cultures were less specific and sensitive than the literature has suggested, which has led to inappropriate antibiotic use. POCT based on NAATs (nucleic acid amplification techniques) on the other hand combines high sensitivity and specificity resulting in more efficient use of antibiotics in primary care settings in a US study [28]. However, like RADTs and throat culture, NAATs cannot by themselves discriminate between an infection and a carrier state. Therefore, they must be supplemented with a physical examination to avoid negatively affecting antimicrobial stewardship efforts [29].

RSV (respiratory syncytial virus), is a frequent cause of respiratory tract infections in infants, but it can occur at any age. RSV is very infectious and the virus can survive for several hours outside the human body. RSV infection starts in the upper respiratory tract (nose and throat) but can evolve into a lower respiratory tract infection, particularly in infants and in the elderly, in whom it can cause bronchiolitis or pneumonia [30]. For serious infections, it is recommended to carry out an RSV test in order to take the appropriate measures (isolation, infection prevention). POCT molecular diagnostics tests for RSV can facilitate patient triage for prompt implementation of infection control measures [31].

The *corona viral disease (COVID-19) pandemic* urged the quick development of PCR tests to detect the causal agent, *SARS-CoV-2*. Initially, these tests were performed in central laboratories, but meanwhile POCT tests, both PCR-based and RADT, were developed for COVID-19 [32,33]. Their sensitivity and specificity in real life is still under study, although some POCT molecular diagnostic tests for SARS-CoV-2 appear to perform as well as PCR carried out in the central laboratory [32].

Due to the low throughput of POCT, it may not be feasible to test, for example, an entire facility of thousands of employees for COVID-19 with a POCT platform. On the other hand, implementation of POCT for SARS-CoV-2 according to the proposed legal framework could be a very useful asset for selective testing of high-risk patients in Covid-19 triage centres, as would be combined testing for Influenza and SARS-CoV-2 in flu season.

A small subgroup of COVID-19 patients develops very severe disease, requiring ICU treatment, ventilation, and ECMO (extracorporeal membrane oxygenation) therapy. It has been demonstrated that higher levels of CRP are associated with increased severity, lack of improvement and bacterial superinfections. Apart from POCT CRP, arterial blood gases also proved to be useful to identify COVID-19 patients with respiratory failure as a result of SARS-CoV-2 induced microvascular injury [34]. Implementing these two POCT tests in COVID-19 triage centres according to the proposed legal framework would be a great help to decide which patients need urgent care.

The working group on POCT proposes the introduction of POCT for SARS-CoV-2, CRP, blood gases and Influenza in the COVID-19 triage centres and the introduction of POCT for Influenza, group A streptococcus and RSV as pilot projects in primary care.

As for POCT CRP, reimbursement would be conditional on compliance with the guidelines within the proposed legal framework and, consistent with the proposal for POCT CRP, real-world data could be collected to form the basis for a health technology assessment.

(3) POCT Glucose

Glucose is an important tool for monitoring diabetes patients [35]. If the patient is no longer capable of carrying out glucose self-testing, glucose POCT is used, mainly in hospitals and in residential and nursing homes [36]. There is currently no specific reimbursement for POCT glucose in the hospital and, under the existing legislation, there is no reimbursement for glucose POCT in residential and nursing homes, even if their quality is monitored by a laboratory.

The working group proposes to reimburse POCT glucose under a time-limited (e.g. 3 years) renewable agreement, incorporating compliance with the guidelines within the proposed legal framework.

Priority 4 = Establishment of a POCT advisory council

The working group proposes the creation of a Multidisciplinary POCT Advisory Council including general practice (GP) clinicians, clinical biologists/pathologists, clinical laboratories and, depending on the POCT in question, also relevant advisory members on an ad-hoc basis (e.g. emergency physicians, cardiologists, infectious diseases specialists, etc.).

The purpose of this Advisory Council is:

- to draw up a general model for reimbursement of POCT tests

- to research which POCT could be eligible for reimbursement in primary care
- to make proposals in this area to the National Institute for Health and Disability Insurance (RIZIV/INAMI).

Note

1. Self-testing (PST, Patient Self Testing or Personal Self Testing) is outside the scope of this proposal.

Disclosure statement

All authors are members of the Roche POCT Advisory Board. VVH is also member of the BD EU Scientific Advisory Board on POCT.

Funding

No funding was received for this work. Meetings of the members of the Working Group POCT with external experts on POCT were facilitated by Roche Diagnostics Belgium (Machelen, Belgium).

ORCID

Viviane Van Hoof http://orcid.org/0000-0002-6054-3053
Dragos Barglazan http://orcid.org/0000-0002-7092-8790
Laurent Blairon http://orcid.org/0000-0003-0304-7624
Damien Gruson http://orcid.org/0000-0001-5987-4376
Katrien Lanckmans http://orcid.org/0000-0001-7992-6364
Alain Roman http://orcid.org/0000-0003-0561-1890
Florent Vanstapel http://orcid.org/0000-0001-6273-856X
Jan Y. Verbakel http://orcid.org/0000-0002-7166-7211

References

[1] Florkowski C, Don-Wauchope A, Gimenez N, et al. Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM) – does it leverage any advantage in clinical decision making? Crit Rev Clin Lab Sci. 2017;54(7–8):471–494.
[2] Cohen D. Rivaroxaban: can we trust the evidence? BMJ. 2016;352:i575.
[3] Wetgeving inzake de kwaliteitsvolle praktijkvoering in de gezondheidszorg. [Legislation on high-quality practice in healthcare]. http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2019042220&table_name=wet
[4] Nederlandse Richtlijn point-of-care testing in de huisartsenzorg. [Dutch guideline on point-of-care testing in GP services]. https://www.nhg.org/sites/default/files/content/nhg_org/uploads/final_richtlijnpoct_2015lmlres.pdf
[5] Stavelin A, Sandberg S. Harmonization activities of Noklus – a quality improvement organization for point-of-care laboratory examinations. Clin Chem Lab Med. 2019;57(1):106–114.
[6] Bukve T, Anne Stavelin A, Sandberg S. Effect of participating in a quality improvement system over time for point-of-care C-reactive protein, glucose, and hemoglobin testing. Clin Chem. 2016;62 (11):1474–1481. http://clinchem.aaccjnls.org/content/clinchem/62/11/1474.full.pdf
[7] SKUP Scandinavian co-operation for evaluation of near patient laboratory equipment. https://skup.org/
[8] EPI-Centre, Evaluating Primary Care Innovations. Academisch Centrum voor Huisartsgeneeskunde Leuven. https://www.epi-centre.be
[9] Collaboratief Zorgplatform (CoZo). https://www.cozo.be
[10] KCE Rapport 311A en 311A synthese: voorstellen voor een effectiever antibioticabeleid in België – 2019. [KCR Report 311A and 311A synthesis: propositions for a more effective management of antibiotic treatments in Belgium – 2019]. https://kce.fgov.be/sites/default/files/atoms/files/KCE_311R_Antibiotics_politics_Report_0.pdf;https://kce.fgov.be/sites/default/files/atoms/files/KCE_311A_Antibioticabeleid_Synthese.pdf
[11] NICE Guidelines Pneumonia in adults: diagnosis and management. https://www.guidelines.co.uk/nice-pneumonia-guideline/455006.article
[12] NHG standaard "acuut hoesten" [NHG standard "acute coughing"]: https://www.nhg.org/standaarden/volledig/nhg-standaard-acuut-hoesten
[13] JWL C, AJHA A, Hood K, et al. C-reactive protein point of care testing and physician communication skills training for lower respiratory tract infections in general practice: economic evaluation of a cluster randomized trial. J Eval Clin Pract. 2011;17(6):1059–1069.
[14] Hunter R. Cost–effectiveness of point-of-care C-reactive protein tests for respiratory tract infection in primary care in England. Adv Ther. 2015;32 (1):69–85. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4311066/
[15] Oppong R, Jit M, RD S, et al. Cost–effectiveness of point-of-care C-reactive protein testing to inform antibiotic prescribing decisions. Br J Gen Pract. 2013;63 (612):e465–471.
[16] Dahler-Eriksen BS, Lauritzen T, Lassen JF, et al. Near patient test for C-reactive protein in general practice: assessment of clinical, organizational and economic outcomes. Clin.Chem. 1999;45(4):478–485.
[17] Johnson M, Cross L, Sandison N, et al. Funding and policy incentives to encourage implementation of point-of-care C-reactive protein testing for lower respiratory tract infection in NHS primary care: a mixed methods evaluation. BMJ Open. 2018;8(10): e024558.
[18] West of England Academic Health Science Network. Evaluation case study: near-patient-testing in Swindon CCG urgent care GP service. https://arc-w.nihr.ac.uk/Wordpress/wp-content/uploads/2017/04/CLAHRC-Evaluation-Case-Study-Near-patient-CRP-testing-v.4-stylednccropped.pdf
[19] Health technology assessment of C-reactive protein point-of-care testing to guide antibiotic prescribing for acute respiratory tract infections in primary care settings. 2019. https://www.hiqa.ie/reports-and-publications/health-technology-assessment/hta-c-reactive-protein-point-care-testing
[20] O'Brien K, Gloeckner I, Jordan K et al. C-reactive protein point-of-care testing (CRP POCT) to guide antibiotic prescribing in primary care settings for acute respiratory tract infections (RTIs). Rapid assessment on other health technologies using the HTA core model for rapid relative effectiveness assessment. EUnetHTA Project ID: OTCA012. 2019. https://www.eunethta.eu/

wp-content/uploads/2019/02/EUnetHTA_OTCA012_CRP-POCT_31012019.pdf
[21] Verbakel JY, Lemiengre MB, De Burghgraeve T, et al. Should all acutely ill children in primary care be tested with point-of-care CRP: a cluster randomised trial. BMC Med. 2016;14(1):131.
[22] Azar MM, Landry ML, Kraft CS. Detection of influenza A and B viruses and respiratory syncytial virus by use of clinical laboratory improvement amendments of 1988 (CLIA)-waived point-of-care assays: a paradigm shift to molecular tests. J Clin Microbiol. 2018;56(7):e00367–18.
[23] Dohla M, Boesecke C, Schulte B, et al. Rapid point-of-care testing for SARS-CoV-2 in a community screening setting shows low sensitivity. Public Health. 2020;182:170–172.
[24] WHO. Influenza (seasonal) factsheet. 2018. http://www.who.int/mediacentre/factsheets/fs211/en/
[25] Nolte FS, Gauld L, Barrett SB. Direct comparison of Alere i and cobas Liat influenza A and B tests for rapid detection of influenza virus infection. J Clin Microbiol. 2016;54(11):2763–2766. https://jcm.asm.org/content/jcm/54/11/2763.full.pdf
[26] Mason J. Point-of-care testing for influenza in: CADTH issues in emerging health technologies. 2016. https://www.ncbi.nlm.nih.gov/books/NBK401783/
[27] Matthys J, De Meyere M, van Driel ML, et al. Differences among international pharyngitis guidelines: not just academic. Ann Fam Med. 2007;5(5):436–443. https://www.annfammed.org/content/5/5/436.long
[28] Rao A, Berg B, Quezada T, et al. Diagnosis and antibiotic treatment of group a streptococcal pharyngitis in children in a primary care setting: impact of point-of-care polymerase chain reaction. l. BMC Pediatr. 2019;19(1):24.
[29] Mustafa Z, Ghaffari M. Diagnostic methods, clinical guidelines, and antibiotic treatment for group A streptococcal pharyngitis: a narrative review. Front Cell Infect Microbiol. 2020 October 15;10. https://www.frontiersin.org/articles/10.3389/fcimb.2020.563627/full
[30] Sciensano website. https://www.sciensano.be/nl/gezondheidsonderwerpen/respiratoir-syncytieel-virus-rsv/risicos-en-gevaren
[31] Ho YII, Wong AH, Lai RWM. Comparison of the cepheid xpert xpress flu/RSV assay to in-house flu/RSV triplex real-time RT-PCR for rapid molecular detection of influenza A, influenza B and respiratory syncytial virus in respiratory specimens. J Med Microbiol. 2018;67(11):1576–1580. https://dl.uswr.ac.ir/bitstream/Hannan/66109/1/JoMM%202018%20Volume%2067%20Issue%2011%20November%20%287%29.pdf
[32] Smithgall MC, Scherberkova I, Whittier S, et al. Comparison of cepheid xpert xpress and Abbott ID now to roche cobas for the rapid detection of SARS-CoV-2. J Clin Virol. 2020;128:104428.
[33] Mertens P, De Vos N, Martiny D, et al. Development and potential usefulness of the COVID-19 Ag RESPI-STRIP diagnostic assay in a pandemic context. Front Med. 2020;7. article 225. DOI:10.3389/fmed.2020.00225
[34] Skevaki C, Fragkou PC, Cheng C, et al. Laboratory characteristics of patients infected with the novel SARS-CoV-2 virus. J Infect. 2020 Aug;81(2):205–212. Published online 2020 Jun 21.
[35] American Diabetes Association. Diabetes care in the hospital, nursing home, and skilled nursing facility. Position statement. Diabetes Care. 2015;38(Supplement 1):S80–kS85.
[36] van Kerkhof LWM, et al. Point-of-care testing in nursing homes in the Netherlands. Management of patient safety related aspects. RIVM Report 2014-0060/2014. https://www.rivm.nl/bibliotheek/rapporten/2014-0060.pdf