

SYSTEMATIC REVIEW

Point-of-care testing in primary care: A systematic review on implementation aspects addressed in test evaluations

Deon Lingervelder¹  | Hendrik Koffijberg¹ | Ron Kusters^{1,2} | Maarten J. IJzerman^{1,3,4}

¹Health Technology and Services Research Department, Technical Medical Centre, University of Twente, Enschede, The Netherlands

²Laboratory for Clinical Chemistry and Haematology, Jeroen Bosch Hospital, Enschede, The Netherlands

³Cancer Health Services Research Unit, Faculty of Medicine, Dentistry and Health Sciences, School of Population and Global Health, University of Melbourne, Melbourne, Vic., Australia

⁴Victorian Comprehensive Cancer Centre, Melbourne, Vic., Australia

Correspondence

Maarten J. IJzerman, Health Technology and Services Research Department, Technical Medical Centre, University of Twente, P.O. Box 217, Enschede, 7500 AE, The Netherlands.

Email: m.j.ijzerman@utwente.nl

Abstract

Objectives: There are numerous point-of-care tests (POCTs) available on the market, but many of these are not used. This study reviewed literature pertaining to the evaluation/usage of POCTs in primary care, to investigate whether outcomes being reported reflect aspects previously demonstrated to be important for general practitioners (GPs) in the decision to implement a POCT in practice.

Methods: Scopus and Medline were searched to identify studies that evaluated a POCT in primary care. We identified abstracts and full-texts consisting of applied studies (eg trials, simulations, observational studies) and qualitative studies (eg interviews, surveys). Data were extracted from the included studies, such as the type of study, the extent to which manufacturers were involved in the study, and the biomarker/assay measured by the test(s). Studies were evaluated to summarise the extent to which they reported on, amongst others, clinical utility, user-friendliness, turnaround-time and technical performance (aspects previously identified as important).

Results: The initial search resulted in 1398 publications, of which 125 met the inclusion criteria. From these studies, 83 POCTs across several disease areas (including cardiovascular disease, venous thromboembolism and respiratory-tract-infections) were identified. There was an inconsistency between what is reported in the studies and what GPs consider important. GPs perceive clinical utility as the most important aspect, yet this was rarely included explicitly in test evaluations in the literature, with only 8% of evaluations incorporating it in their analysis/discussion.

Conclusions: This review showed that, despite the growing market and development of new POCTs, studies evaluating such tests fail to report on aspects that GPs find important. To ensure that an evaluation of a POCT is useful to primary care clinicians, future evaluations should not only focus on the technical performance aspects of a test, but also report on the aspects relating to the clinical utility and risks.

1 | INTRODUCTION

Diagnostic testing plays a vital part in primary healthcare, providing valuable insight to support decisions regarding treatment and referral to secondary care.¹ Patient outcomes can be greatly improved with diagnostic testing when it is used to exclude a

disease and identify those patients that will benefit the most from downstream actions, such as initiating, modifying, stopping or withholding treatment.² In primary care, the diagnostic process traditionally relies on laboratory testing. Laboratory information must therefore be accurate, reliable and reproducible. Although in some diagnostic questions rapid delivery of the test results is

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

© 2019 The Authors. *International Journal of Clinical Practice* published by John Wiley & Sons Ltd

important, traditional centralised laboratories tend to highlight the quality and reliability of tests above the turn-around-time.³ For many diseases, care providers and patients increasingly expect patient-focused, specialised diagnostic tests that can be performed quickly, easily and provide results within minutes.⁴ This has led to the development of easy-to-use analysers that can be performed at the point of care, more commonly known as point-of-care (POC) testing or near-patient testing.¹

The reason for implementing a POCT will vary according to the setting. In emergency departments or intensive care units, POCTs are used to find test results immediately to help guide life-saving decisions. In resource-limited settings, access to healthcare facilities is typically limited. In such settings, POCTs are beneficial in terms of their ease of use independent from the physical presence of a laboratory.⁵ In primary care settings, POCTs are typically used to prevent unnecessary referrals to specialised or secondary care, to guide diagnostic and treatment decisions, and to provide reassurance to patients, for example by excluding an illness. The rapid analysis can also lead to improved clinical performance, since it eliminates the potentially long intervals between the patient's initial examination and the discussion of the test results.⁴

The first major systematic review of POCTs in primary care was published more than 20 years ago by Hobbs et al,⁶ who concluded that evidence in support of the general introduction of POCTs in general practice was low. Since then, the POC diagnostic market has grown substantially and continues to do so because of the increasing development of new (supporting) technologies such as novel biomarkers, wireless connectivity, nanoparticle techniques and information sharing capabilities.⁷ It is expected that the global POC diagnostics market will reach \$40.50 billion by 2022.⁸ Despite this growing market, primary care clinicians generally are hesitant to implement POCTs in their practice. According to a study on POC blood tests by Jones et al,⁹ this is mainly because of concerns about accuracy, over-reliance on tests and limited usefulness.

A recent survey of general practitioners (GPs) in the UK,¹⁰ identified several themes regarding what GPs perceive as facilitators and barriers to the implementation of a POCT. Some of these themes were the workload, clinical utility, patient satisfaction, reimbursement, legislations, technical performance, connectivity, training and maintenance. A similar survey study in the Netherlands found comparable results, with Dutch GPs believing the proven effect on clinical management and the tests' reliability to be among the most important aspects of POCTs.¹¹ This study aims to systematically review recent literature pertaining to the evaluation and usage of POCTs in primary care and to investigate whether the outcomes and evidence reported in the literature, reflect previously established factors¹² that are important for GPs in the decision to implement a POCT.

2 | MATERIALS AND METHODS

2.1 | Literature search

The PRISMA guidelines were followed while carrying out this systematic review of available POCTs for primary care. Since this

Review criteria

- Searches were performed on Scopus and Medline for applied studies that evaluated a point-of-care test in primary care regarding its effectiveness, performance, usage or application. Studies had to focus on a specific point-of-care diagnostic being applied in a high-income country. During the full-text assessment, each test evaluation was assessed to summarise the extent to which predefined determinants were being reported on.

Message for the clinic

- There remains a gap between the aspects being addressed in point-of-care test evaluations and the aspects that clinicians find important. Clinicians should aim to collaborate and take part in test evaluations, to ensure that all the aspects that are essential to support their decision making in implementing such tests are covered during the evaluation process.

review aims to identify any POCTs that can be implemented in primary care, all types of primary research studies were included in the initial search. For this reason, it was not required that any specific outcome measure was reported in the initial search and no specific study characteristics or PICO-statement was used as part of the inclusion criteria. The review protocol for this systematic review is provided in Appendix A as a series of steps that were followed.

Two databases (Scopus and Medline) were searched for relevant English or Dutch publications between 2007 and 2017. The initial search was performed in September 2017. The search included all terms and text words related to the intervention (POC diagnostics) and the setting (Primary Care). The search query used was (Scopus format):

TITLE-ABS-KEY ("POCT" OR "Point of care" OR "Point of care testing" OR "rapid testing" OR "bedside testing" OR "laboratory-independent" OR "near patient testing") AND TITLE-ABS-KEY (diagnos*) AND ALL ("Primary Care" OR "General Pract*" OR "GP" OR "Primary Healthcare" OR "Primary Health Care").

2.2 | Study selection

Only publications that met the following inclusion criteria were selected for the review:

1. Publications should focus on POC diagnostic technologies only. Publications reporting on, for example scorecards or methodologies to diagnose patients at the point of care, decision support tools or online (cloud) systems, results sharing, electronic health records, etc were excluded.

2. Publications should focus on specific POC diagnostic technologies and not only provide a general summary of POCTs.
3. Publications should focus on primary care only. Publications focusing on secondary care or self-monitoring were excluded.
4. Publications should focus on high-income countries only. Publications that explicitly stated that their focus is on remote or rural areas were excluded, even if within a developed country.
5. Publications should be an applied study that evaluates a POCT in terms of its effectiveness, performance, usage or application. This includes qualitative studies (such as surveys and interviews) and modelling studies. Reviews were excluded.

After removing duplicate publications from the initial search results, the abstracts were screened to determine whether publications met the inclusion criteria. Publications that undoubtedly failed to meet all of the inclusion criteria, based on the abstract screening, were excluded from the full-text assessment. If there was any doubt on whether or not a publication met the inclusion criteria, it was included for full-text assessment. The abstract screening was performed by one reviewer (DL), and potential issues were discussed with a second reviewer (HK) when required. The full-text assessment of all included publications was performed by one reviewer (DL).

2.3 | Data extraction and management

The data were extracted manually by one reviewer (DL) from the studies into Microsoft Excel (version 2016) in predefined and labelled columns. The following information was extracted from each of the included publications:

1. The study design, classified according to one of three categories; namely, empirical study (trials, cohort studies, etc), qualitative study (interviews, surveys, etc) or modelling study.
2. If relevant, the country where the study was performed. For multi-country studies, each individual country was counted separately.
3. If applicable, the role that the manufacturer played in the study. This was classified in one of seven categories; namely, (a) manufacturer provided some financial support to the study, (b) manufacturer funded the study, (c) manufacturer provided the analyser/test, (d) manufacturer funded the study and provided the analyser/test, (e) one or more authors are employed by the manufacturer, (f) manufacturer played no part in the study or (g) nothing specified about funding or manufacturer involvement.
4. The name of the POC device/test that was evaluated.
5. The biomarker/assay that was measured by the POCT.

If a study evaluated more than one POCT, a separate data entry (row) was added for each individual test evaluation. During the full-text assessment, each test evaluation study was assessed to summarise the extent to which predefined determinants were being reported on. These determinants were identified previously¹² as key factors that affect the decision to implement a

POCT in primary care. All 20 of these determinants are listed in Table 1.

Some of these determinants are not applicable to a POCT specifically, but rather to the disease prevalence and the GP and his practice (Frequency of use, Room for innovation, Risks). For example Frequency of use and Room for innovation are both determinants that are associated directly with the GP's practice, while the impact and Risks of tests would differ between diseases. It is expected that these determinants will not be reported in the evaluations as frequently as some of the others. If there was any uncertainty to the first reviewer (DL) about whether a publication discussed a certain determinant, it was examined by a second reviewer (HK). On occasions when these two reviewers could not agree on a decision, a third reviewer was involved in making a final decision (either RK or MJJJ).

The data extracted from the included publications were summarised in both text and table format, before providing a descriptive synthesis of findings. Results were divided according to the biomarker/assay that the test measures.

3 | RESULTS

3.1 | Search results

A total of 1398 studies were obtained from the initial search of the Medline and Scopus database. To ensure that the search resulted in a comprehensive set of relevant publications, the selected search query was broad. This did, however, result in a large number of publications being excluded during the abstract screening, mostly because of publications focusing on something other than a (specific) POC diagnostic. After a screening of all abstracts, 286 studies were included in the full-text assessment.

After the full-text assessment, 125 studies were included in the final review. Studies were mostly excluded based on full-text assessment because they did not focus on POC diagnostics ($n = 81$), but instead described a tool, strategy or guideline to support POC testing. The PRISMA flow diagram of the search is presented in Appendix A.

3.2 | Characteristics of included publications

The 125 included studies consisted of 112 applied studies, 7 qualitative studies, 5 simulation studies and 1 study that used both applied and qualitative methods. The majority of the studies were applied in The Netherlands ($n = 25$; 20.0%), US ($n = 17$; 13.6%) and UK ($n = 13$; 10.4%), followed by Spain ($n = 6$; 4.8%), Finland ($n = 6$; 4.8%), Australia ($n = 5$; 4%) and Canada ($n = 5$; 4%). In 35 studies (28%), the manufacturer(s) of the test(s) being evaluated provided support by either funding the study in full ($n = 10$) or partially ($n = 8$), by providing the analyser(s)/test(s) ($n = 14$), or by both funding the study and providing the analyser(s)/test(s) ($n = 3$). There was a single study where one of the authors was an employee of the manufacturer. For the majority of studies ($n = 62$; 49.6%) the manufacturer(s) had no involvement, whereas in 24 (19.2%) of the studies nothing was specified about funding or manufacturer involvement.

TABLE 1 List of determinants and their description (Reproduced from Kip et al¹²)

Determinant	Description	
1	Satisfaction patient	Extent to which the use of the POC test is expected to improve service for the patient.
2	Clarity of procedure	Extent to which the procedures for using the POC test are clearly described in protocols and/or manuals.
3	User-friendliness	Extent to which the POC test is easy to perform by the layman.
4	Test interpretation	Extent to which the POC test result is easy to read and the various test results are easy to interpret.
5	Turn-around-time (TAT)	Extent to which the POC test results are instantly available.
6	Frequency of use	Extent to which the test is used sufficiently with respect to the indication and the size of the general practice.
7	Room for innovation	The extent to which the pressure of daily practice leaves room for innovation and a mind-set for change.
8	Workload	Extent to which the POC test can be implemented without dramatic changes in the current way of working and user's workload.
9	Support, training and quality control	Extent to which the introduction, maintenance and quality control of the POC test, as well as the training of personnel is sufficient and supported by a coordinator from the laboratory, manufacturer and general practice.
10	Connectivity	Extent to which the POC test results and errors are registered in an information system (HIS)
11	Clinical utility	Extent to which a correct (treatment) decision, as based on the point-of-care (POC) test result, has added value in clinical outcomes.
12	Technical performance	The extent to which the POC test is exact, precise, reliable and robust in the hands of the user.
13	Negative Predictive Value	Negative predictive value: Proportion of negative results that are true negative, which enhances the user's ability to reliably rule out a condition.
14	Positive Predictive Value	Positive predictive value: Proportion of positive results that are true positive, which enhances the user's ability to reliably diagnose a condition.
15	Risks	The impact of a (wrong) treatment/advice based on a (wrong) test result.
16	Clinical guidelines	Extent to which the POC test is implemented in national guidelines.
17	Scientific evidence	Extent to which the added value of the POC test is demonstrated (as compared with current practice) in scientific literature, in the right patient population and for a specific clinical pathway.
18	Reimbursement	Is the POC test reimbursed for the general practitioner?
19	Overall costs	Extent to which the POC test is expected to decrease costs of the healthcare system.
20	Legislations	Extent to which the innovation fits into existing legislations.

3.3 | Overall results

From the 125 studies in the synthesis set, 195 test evaluations were identified. The percentage that each determinant was reported in the test evaluations are provided in Figure 1, together with the overall weight of each determinant as found by.¹² The four determinants that were reported the most were turn-around-time (n = 105; 52.2%), technical performance (n = 97; 48.3%), positive predictive value (n = 91; 45.3%) and negative predictive value (n = 89; 44.3%). The determinants reported the least in the evaluations were room for innovation (n = 0; 0%) and risks (n = 1; 0.5%), followed by reimbursement (n = 2; 1.0%), legislations (n = 3; 1.5%) and scientific evidence (n = 3; 1.5%).

3.4 | POCTs per measurement

In 20 of the 195 evaluations (10.26%), the exact test(s) could not be recognised, since no identifiable information (such as the name of the device or the manufacturer) were provided. There were also 12 POCTs, occurring in 24 test evaluations, of which no information

could be found on the official manufacturer or partner websites. It is expected that these tests are either discontinued/recalled (such as the Clearview Simplify D-Dimer device) or that the names of these tests have been changed. In cases where it could be confirmed that a device name has been changed (eg the DCA 2000 has been renamed the DCA Vantage) the evaluations were included and categorised under the new device name. If no confirmation could be found, the device was excluded from the final list of tests. After excluding the above-mentioned 20 + 24 = 44 evaluations, a total of 83 POCTs were identified with a total of 151 test evaluations. Each of these POCTs has at least one test evaluation. The most frequently evaluated tests were those measuring HbA1c (n = 14; 16.9%), CRP (n = 6; 7.2%), D-Dimer (n = 6; 7.2%) and Influenza and/or RSV (n = 6; 7.2%).

3.4.1 | Haemoglobin A1c

A haemoglobin A1c (HbA1c) test measures glycosylated haemoglobin that gives an indication of the average blood glucose level of the

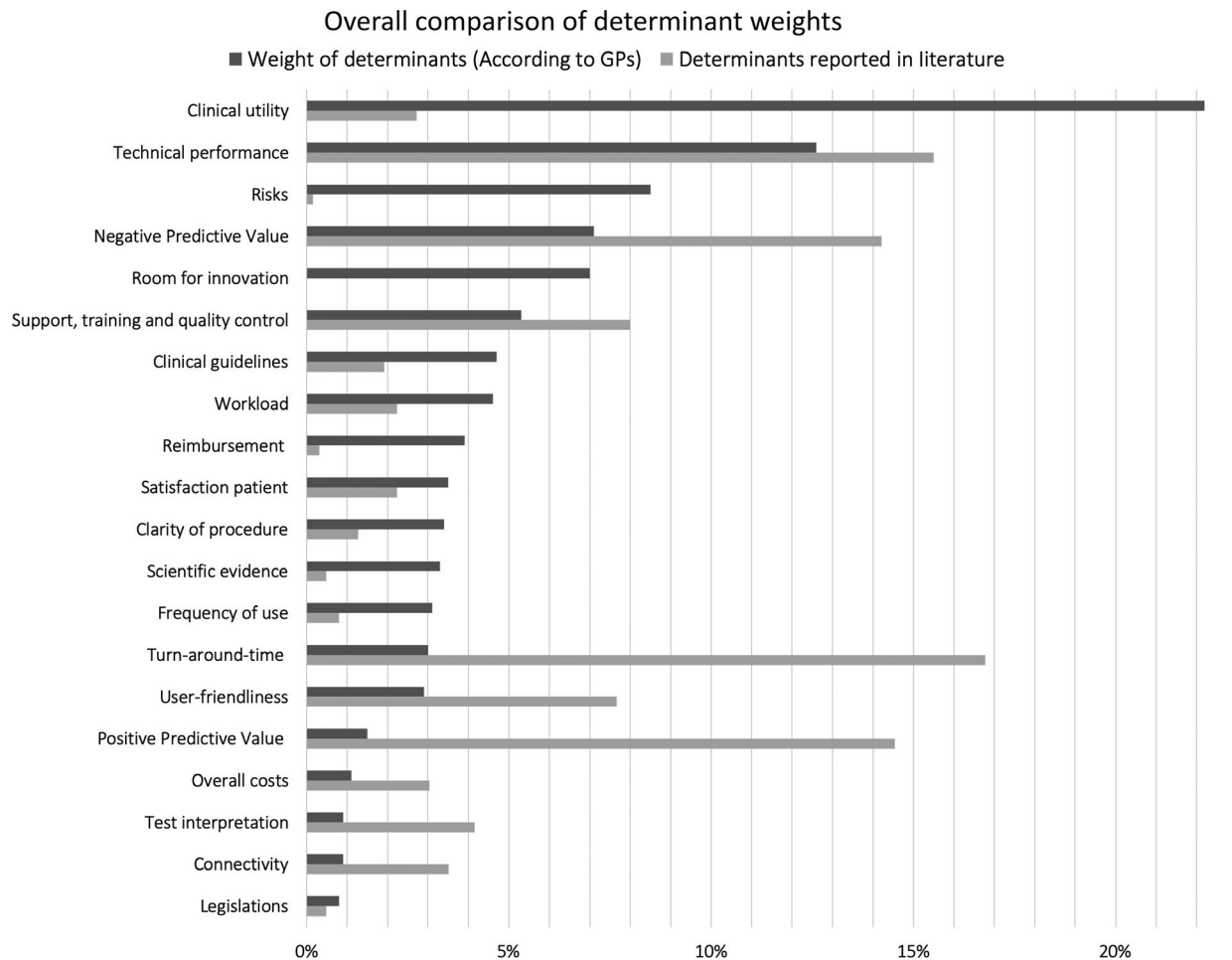


FIGURE 1 Comparison of determinant weights according to GPs and the percentage of times that each determinant was reported in the literature

past 60-120 days. Seeing as the prevalence of diabetes continues to rise each year, the timely management of HbA1c is particularly important in the primary care pathways of both patients with diabetes and those that remained undiagnosed.¹³ In Appendix B, Table B1, a list of the 14 HbA1c POCTs that were identified during the review is provided, in no particular order. The three most evaluated tests were the DCA Vantage Analyzer (n = 8), the Alere Afinion AS100 Analyzer (n = 6) and the A1CNow system (n = 5).

3.4.2 | C-reactive protein

C-reactive protein (CRP) is an acute phase protein produced by the liver when inflammation occurs. Measuring CRP levels can help identify patients that are at high risk of having respiratory tract infections, inflammatory diseases or cardiovascular disease. To support the early detection of serious infections and diseases, CRP testing is increasingly being introduced in primary care.¹⁴ A list of the 8 CRP POCTs that were identified during the review is provided in Appendix B, Table B2. The Nycocard™ Reader II (n = 7) and the Alere Afinion AS100 Analyzer (n = 6), both manufactured by Alere, had the most evaluations in the literature.

3.4.3 | D-Dimer

D-dimer is a protein fragment produced when a blood clot dissolves in the body. High levels of d-dimer are therefore typically used to assess the risk of thrombotic episodes and to exclude conditions such as deep vein thrombosis and pulmonary embolism.¹⁵ In Appendix B, Table B3, a list of the 6 D-Dimer POCTs that were identified during the review is provided.

3.4.4 | Influenza and respiratory syncytial virus

Respiratory syncytial virus (RSV) is a common virus that causes lower respiratory tract infections, especially in infants and toddlers. Since reinfection occurs throughout life, specifically during fall and winter, GPs and emergency departments are typically met with a surge of patient visits during these colder months.¹⁶ Influenza, more commonly known as the flu, is also particularly prevalent in children during winter months, causing a similar seasonal overflow of patients. Influenza is an infectious disease that causes febrile and respiratory illnesses, but typically remains undiagnosed since symptoms overlap significantly with other viral

or bacterial infections.¹⁷ POC devices for RSV and influenza can have a major positive impact on patient care by reducing both unnecessary diagnostic testing and antibiotic prescriptions.¹⁷ A list of 6 POCTs for Influenza and RSV, that were identified during the review is provided in Appendix B, Table B4.

3.4.5 | Other frequently evaluated POCTs

In addition to the above-listed POCTs, there were also tests measuring calprotectin, streptococcus pyogenes, BNP and NT-proBNP, bladder carcinoma, uric acid, INR, IgA deficiency and chlamydia, among others. The majority of these tests had only one evaluation. A list of tests that have been evaluated more than once is provided in Appendix B, Table B5.

4 | DISCUSSION

There was a clear inconsistency between what is reported on in the identified evaluations and what GPs consider important. Certain determinants of the published list used in this review are not relevant to a POCT, but rather to the disease prevalence and the GP and his practice (frequency of use, room for innovation, risks). These determinants were, as expected, underreported. None of the evaluations addressed any aspect related to room for innovation, whereas only one evaluation assessed the risk aspect of the test. Frequency of use was addressed in five of the test evaluations. Reimbursement ($n = 2$) and legislations ($n = 3$) were also rarely reported on in the evaluations. This could be since the impact of these determinants will vary between countries and were therefore purposefully excluded from the evaluations. The most relevant inconsistency was with clinical utility. Although GPs perceive clinical utility as the most important aspect when it comes to POCT, it was rarely explicitly included in the test evaluations found in the review. Only 8% of evaluations incorporated some aspect of clinical utility in their analysis and/or discussion. Although the definition of clinical utility used in this paper was broad to ensure that it encompasses all aspects of clinical utility, it could be that certain aspects described in the test evaluations were not accounted for. One reason for the clinical utility of a test only rarely being mentioned, could be the fact that clinical utility is often implied rather than being described. For example by pointing out that current testing and decision making is sub-optimal without explicitly indicating how POCT would improve this. Furthermore, the turn-around-time of the test was reported in more than half of the evaluations (52.5%) even though it is not among the ten most important determinants according to GPs. This could possibly be because of GPs expectations that user friendliness and short turn-around-time are evident properties of a POCT; which is why these properties are considered a high priority in the evaluation of POCTs. Technical performance is considered the second most important determinant among GPs and it was addressed by almost half of the evaluations (48.3%).

In a study by Huddy et al,¹⁸ clinicians stated during interviews that POC devices with the ability to perform multiple tests (such as HbA1c combined with lipids) was seen as an additional incentive for purchasing. This could explain the high number of evaluations found in this review for the Nycocard™ Reader II (Seven evaluations for CRP, two for HbA1c and one for D-Dimer) and the Alere Afininion AS100 Analyzer (Six evaluations for CRP and six for HbA1c). However, not all of the multiple-test devices had a high amount of evaluations. For example the AQT90 FLEX immunoassay analyser can perform six tests (D-dimer, Procalcitonin, CRP, NT-proBNP, Troponin T and Troponin I), yet only one evaluation, in this case of its D-Dimer test, was identified in the review. However, since this instrument requires a large volume of blood, and therefore a venipuncture instead of a fingerpick, it may not be considered as a POCT.¹⁹ Therefore, studies investigating this multiple-test device (or similar devices) without using POCT terminology may have been missed.

Care should be taken when interpreting the absolute number of evaluations per test, as some tests may have been available on the market longer than others, and could, therefore, have been evaluated more over the years. With respect to the aforementioned tests, the earliest year that information regarding the AQT90 FLEX was found, was in 2010, with the one test evaluation in this review being from 2015. For the Nycocard™ Reader II, the earliest information about the test is from 2008, with the 11 test evaluations in this review being from 2009 ($n = 2$), 2010 ($n = 2$), 2011 ($n = 1$), 2013 ($n = 3$), 2015 ($n = 2$).

There are some POCTs that did not have as many evaluations in this review, for example INR testing. Although POC INR testing is used in some outpatient labs and anticoagulation clinics, the reference standard remains clinical laboratory testing.²⁰ The use of POC INR testing has become popular for at-home testing, where patients can easily use the device to monitor their INR and report their results to a clinician (either in person or via telephone) who would then adjust their anticoagulant dose, if necessary. Another use is for patient self-management, where patients not only tests their INR themselves but can self-adjust their dose using a predetermined algorithm or protocol.^{21,22} While some of the POCTs may also be applied by patients themselves, the focus of this review was related to the application of these tests in general practice. If an evaluation was on self-testing, it was not included.

It is worth mentioning, that a large number ($n = 33$; 39.2%) of the 84 identified tests are manufactured by only four companies, namely Alere ($n = 13$), Roche ($n = 11$), Quidel ($n = 5$) and pts Diagnostics ($n = 4$), whereas the remainder of the tests ($n = 51$) are manufactured by a total of 44 different companies. The POCTs manufactured by these four companies, also have the most test evaluations. In total, almost half ($n = 71$; 47.0%) of the 151 evaluations in this review were of tests manufactured by them, with 34, 19, 9 and 9 evaluations of tests manufactured by Alere, Roche, Quidel and pts Diagnostics, respectively. Although test evaluation studies are, in most cases, performed to collect (additional) evidence on test performance and added value, they may also serve the purpose to increase awareness of test availability amongst care professionals.

The biggest limitation of this review was missing studies because of not reporting the names or manufacturer of the POCT being

evaluated. Furthermore, devices that have been discontinued or re-named provided further reduced the evidence base. Both of these factors could cause bias in the conclusions. Additional bias could also be caused because of the limited test selection (only applied studies in primary care). It is possible that by excluding evaluations of devices in secondary care, some tests applicable to primary as well were missed. However, if a POCT is truly relevant to primary care, it is expected that at least one study evaluating it in a primary care setting would have been found. Some of the identified tests have, presumably, been available on the market for a longer period of time than others. This makes the absolute number of evaluations per test hard to interpret. The determinants investigated in this review was identified by¹² based on a review of existing literature. The relative importance of each determinant, however, could be specific to Dutch GPs and two specific POCTs were used as reference when assigning weights. It is therefore uncertain whether the determinants and their relative importance can be transferred to other POCTs and settings.

This review showed that, despite the growing market and rapid development of new POCTs, studies evaluating such tests fail to report on some of the key factors in the adoption of important innovative diagnostics in primary care. To ensure that an evaluation of a point-of-care test is useful to primary care clinicians, future evaluations should not only focus on the technical performance aspects of a test, but also report on the aspects relating to the clinical utility and risks.

ACKNOWLEDGEMENTS

None.

DISCLOSURES

None.

AUTHOR CONTRIBUTIONS

All authors contributed to the design of the study. DL and HK developed the search strategy. DL performed the data extraction and synthesis. All authors contributed to the selection procedure, data interpretation, data analysis, result interpretation, discussions, drafting of the manuscript and approved the final version of the manuscript for submission.

ORCID

Deon Lingervelder  <https://orcid.org/0000-0002-6529-2564>

REFERENCES

- Howick J, Cals JW, Jones C. Current and future use of point-of-care tests in primary care: an international survey in Australia, Belgium, The Netherlands, the UK and the USA. *BMJ Open*. 2014;4:e005611.
- Bossuyt P, Reitsma JB, Linnert K, Moons K. Beyond diagnostic accuracy: the clinical utility of diagnostic tests. *Clin Chem*. 2012;58:1636-1643.

- Drenck N-E. Point of care testing in Critical Care Medicine: the clinician's view. *Clin Chim Acta*. 2001;307:3-7.
- Mor M, Waisman Y. Point-of-care testing: a critical review. *Pediatr Emerg Care*. 2000;16:45-48.
- Drain PK, Hyle EP, Noubary F, et al. Diagnostic point-of-care tests in resource-limited settings. *Lancet Infect Dis*. 2014;14:239-249.
- Hobbs F, Delaney B, Fitzmaurice DA, et al. A review of near patient testing in primary care. *Health Technol Assess (Rockv)*. 1997;1:i-v.
- Luppa PB, Müller C, Schlichtiger A, Schlebusch H. Point-of-care testing (POCT): current techniques and future perspectives. *Trends Anal Chem*. 2011;30:887-898.
- Zion Market Research. *Point Of Care Diagnostics Market by Products, by Prescription Mode (Prescription-Based Testing Kits and Over-the-Counter Testing Kits) Market for Hospitals*. Clinics and Ambulatory Care Settings: Global Industry Perspective, Comprehensive Analysis and Forecast; 2017:2016-2022.
- Jones C, Howick J, Roberts NW, et al. Primary care clinicians' attitudes towards point-of-care blood testing: a systematic review of qualitative studies. *BMC Fam Pract*. 2013;14:117.
- Turner PJ, Van den Bruel A, Jones C, et al. Point-of-care testing in UK primary care: a survey to establish clinical needs. *Fam Pract*. 2016;33:388-394.
- Cals J, Schols A, van Weert H, et al. Sneltesten in de huisartspraktijk: Huidig gebruik en behoefte aan testen in de toekomst. *Ned Tijdschr Geneesk*. 2014;158:A8210.
- Kip MA, Hummel J, Eppink E, et al. Understanding the adoption and use of point-of-care tests in Dutch general practices using multi-criteria decision analysis. *BMC Fam Pract*. 2019;20:8.
- Kristensen T, Waldorff FB, Nexøe J, Skovsgaard CV, Olsen KR. Variation in point-of-care testing of HbA1c in diabetes care in general practice. *Int J Environ Res Public Health*. 2017;14:1363.
- Minnaard MC, van de Pol AC, Hopstaken RM, et al. C-reactive protein point-of-care testing and associated antibiotic prescribing. *Fam Pract*. 2016;33:408-413.
- Greenberg CS. The role of D-dimer testing in Clinical Hematology and Oncology. *Clin Adv Hematol Oncol*. 2017;15:580-583.
- Leonardi GP, Wilson AM, Daus M, Zuretti AR. Evaluation of respiratory syncytial virus (RSV) direct antigen detection assays for use in point-of-care testing. *J Virol Methods*. 2015;213:131-134.
- Poehling KA, Zhu Y, Tang YW, Edwards K. Accuracy and impact of a point-of-care rapid influenza test in young children with respiratory illnesses. *Arch Pediatr Adolesc Med*. 2006;160:713-718.
- Huddy JR, Ni MZ, Barlow J, Majeed A, Hanna GB. Point-of-care C reactive protein for the diagnosis of lower respiratory tract infection in NHS primary care: a qualitative study of barriers and facilitators to adoption. *BMJ Open*. 2016;6:1-10.
- Schols A, Dinant GJ, Hopstaken R, Price CP, Kusters R, Cals J. International definition of a point-of-care test in family practice: a modified e-Delphi procedure. *Fam Pract*. 2018;35:475-480.
- Johnson SA. Point-of-care or clinical lab INR for anticoagulation monitoring: which to believe? *Clin Lab New*. 2019.
- Barcellona D, Fenu L, Marongiu F. Point-of-care testing INR: an overview. *Clin Chem Lab Med*. 2017;55:800-805.
- Canadian Agency for Drugs and Technologies in Health. Point-of-care INR testing compared with lab INR testing: what does the evidence say? 2015.

How to cite this article: Lingervelder D, Koffijberg H, Kusters R, IJzerman MJ. Point-of-care testing in primary care: A systematic review on implementation aspects addressed in test evaluations. *Int J Clin Pract*. 2019;73:e13392. <https://doi.org/10.1111/ijcp.13392>

APPENDIX A

REVIEW PROTOCOL AND PRISMA FLOW DIAGRAM

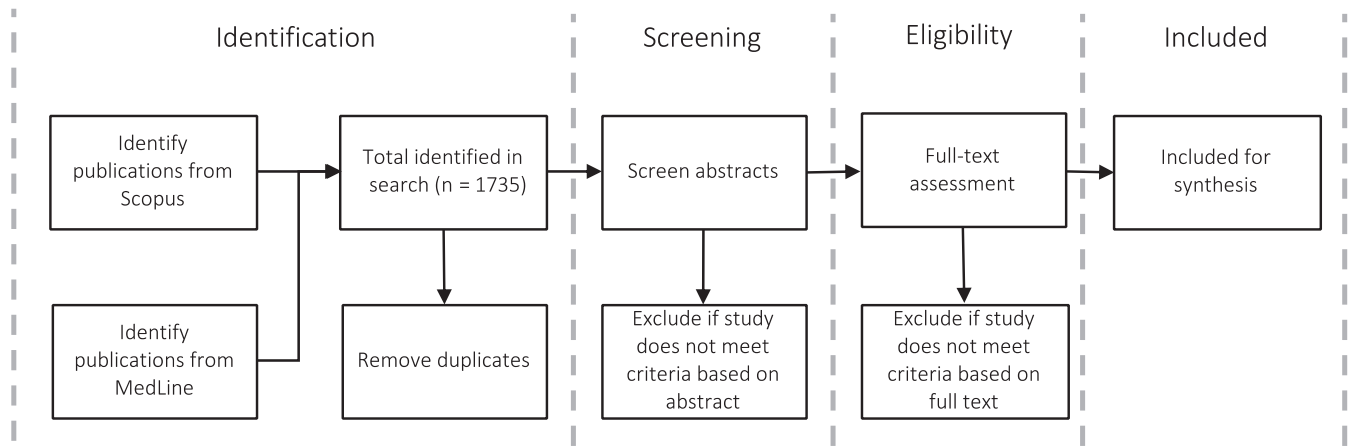


FIGURE A1 Review protocol

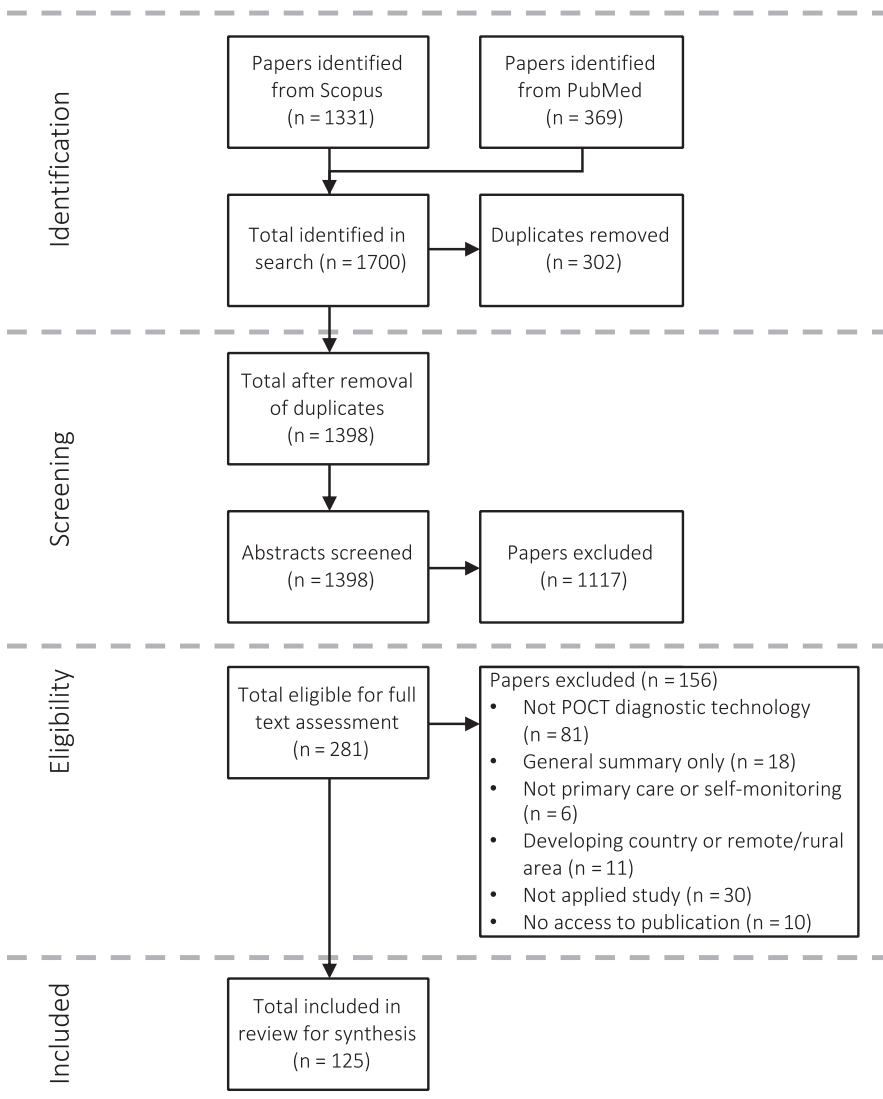


FIGURE A2 PRISMA flow diagram

APPENDIX B

TABLE B1 List of HbA1c POCTs identified from the review

Name of Device/ Analyzer/Test	Number of studies	Manufacturer	Link to official site	Measure- ment used in study	Other available measurements
A1CNow System	5	pts Diagnostics	http://www.ptsdiagnostics.com/a1cnow-systems-overview.html	HbA1c	N/A
Cobas b 101 POC system	1	Roche	http://www.cobas.com/home/product/point-of-care-testing/cobas-b-101-poc-system.html	HbA1c	HbA1c and Lipid Panel
Cobas b 101 POC system	1	Roche	http://www.cobas.com/home/product/point-of-care-testing/cobas-b-101-poc-system.html	HbA1c and Lipid Panel	HbA1c
Nycocard™ Reader II	2	Abbott/Alere	https://www.alere.com/en/home/product-details/nycocard-reader.html	HbA1c	D-Dimer, U-Albumin, CRP
B-analyst	1	Menarini diagnostics	http://www.menarinidiag.co.uk/Products/Haemoglobin-Analyser/B-analyst	HbA1c	hsCRP, CRP
A1c EZ 2.0	1	BioHermes	http://en.biohermes.com/artic le.php?xml:id=17	HbA1c	N/A
SAKAE's A1c Gear	1	SAKAE Corporation	http://www.sakaecorp.com/english/a1c.html	HbA1c	N/A
Alere Afininion AS100 Analyzer	6	Abbott/Alere	https://www.alere.com/en/home/product-details/afinion-as100-analyzer.html	HbA1c	Albumin/Creatinine Ratio, CRP, Lipid Panel
DCA Vantage Analyzer	8 ^a	Siemens	https://usa.healthcare.siemens.com/point-of-care/diabetes/dca-vantage-analyzer	HbA1c	Albumin/Creatinine Ratio
Quo-Test® HbA1c Analyzer	1	EKF Diagnostics Holdings	https://www.ekfdiagnostics.com/quo-test.html	HbA1c	N/A
Clover A1c Analyser	1	EuroMedix	https://www.euromedix.com/en/product?item=22	HbA1c	N/A
in2it™ A1C	2	Bio Rad	http://www.bio-rad.com/webroot/web/pdf/cdg/literature/A-243_in2it_%20A1C_brochure_DG09-0324.pdf	HbA1c	N/A
InnovaStar®	1	DiaSys Diagnostic Systems	https://www.diasys-diagnostics.com/products/poct-systems/innovastar/#tab-state-3284-3287	HbA1c	CRP, Glucose
LABGEO PT10	2	Samsung	https://www.avant-medical.com/portfolio-item/samsung-labgeo-pt-10-analyzer/	HbA1c	Several

^aThree of the eight studies used the DCA 2000 + device, the predecessor of DCA Vantage.

TABLE B2 List of CRP POCTs identified from the review

Name of Device/ Analyzer/Test	Number of studies	Manufacturer	Link to official site	Measure-ment used in study	Other available measurements
ABX Micros CRP 200	1	ABX Diagnostics (Horiba Medical)	http://www.horiba.com/us/en/medical/products/hematology/abx-micros/abx-micros-crp-200-details/abx-micros-crp-200-907/	CRP	N/A
Alere Afininion AS100 Analyzer	6	Abbott/Alere	https://www.alere.com/en/home/product-details/afinion-as100-analyzer.html	CRP	Albumin/Creatinine Ratio, HbA1c, Lipid Panel
Nycocard™ Reader II	7	Abbott/Alere	https://www.alere.com/en/home/product-details/nycocard-reader.html	CRP	D-Dimer, U-Albumin, HbA1c
QuikRead 101	4	Orion Diagnostica	http://www.oriondiagnostica.com/Products/QuikRead/	CRP	Faecal Occult Blood, U-Albumin
QuikRead Go	3	Orion Diagnostica	http://www.oriondiagnostica.com/Products/QuikRead-go/	CRP	CRP and HbA1c, Streptococcus pyogenes
Eurolyser Smart 700 340	2	Eurolyser Diagnostika	https://www.eurolyser.com/medical-diagnostics/point-of-care/smart/smart-700-340/	CRP	15 of them

TABLE B3 List of D-Dimer POCTs identified from the review

Name of Device/ Analyzer/Test	Number of studies	Manufacturer	Link to official site	Measure-ment used in study	Other available measurements
Roche CARDIAC® D-Dimer (D-Dimer assay) on the cobas h 232 POC system	2	Roche	http://www.cobas.com/home/product/point-of-care-testing/cobas-h-232.html	D-Dimer	CK-MB, Troponin T, Myoglobin, NT-proBNP
Nycocard™ Reader II	1	Abbott/Alere	https://www.alere.com/en/home/product-details/nycocard-reader.html	D-Dimer	D-Dimer, U-Albumin, CRP
AQT90 FLEX immunoassay analyzer	1	Radiometer	https://www.radiometer.com/en/products/immunoassay-testing/aqt90-flex-immunoassay-analyzer/d-dimer-test-on-the-aqt90-flex-immunoassay-analyzer	D-dimer	Procalcitonin (PCT), CRP, NT-proBNP, Troponin T, Troponin I
Triage D-Dimer Test	2	Quidel	https://www.quidel.com/immunoassays/triage-test-kits/triage-d-dimer-test	D-Dimer	N/A
PATHFAST	2	Mitsubishi Chemical Europe GmbH	http://www.pathfast.eu/emergency-marker	D-Dimer	Troponin I, NT-proBNP, hsCRP, Myoglobin, HCG and CK-MB mass
LABGEO IB10	1	Samsung	https://www.tecom-as.com/en/samsung-labgeo/ib10/	D-Dimer	Troponin I, NT-ProBNP, Troponin I and NT-ProBNP, Troponin I and CK-MB and myoglobin, Troponin I and NT-ProBNP and D-Dimer, beta-hCG, Thyroid-stimulating hormone, Procalcitonin (PCT)

TABLE B4 List of Influenza and RSV POCTs identified from the review

Name of Device/ Analyzer/Test	Number of Studies	Manufacturer	Link to official site	Measure-ment used in study	Other available measurements
cobas® Liat® PCR System	1	Roche	https://www.cobasliat.com/	Influenza A and Influenza B	Streptococcus pyogenes group A, Influenza A and Influenza B and RSV, Cdiff, MRSA/SA
cobas® Liat® PCR System	1	Roche	https://www.cobasliat.com/	Influenza A and Influenza B and RSV	Streptococcus pyogenes group A, Influenza A and Influenza B, Cdiff, MRSA/SA
mariPOC® (Respi test)	4	ArcDia	http://www.arcadia.com/eng/maripoc/introduction/	Influenza A and Influenza B	Influenza A virus and Influenza B virus and Respiratory syncytial virus and Human Coronavirus OC43 and Human metapneumovirus and Human bocavirus and Parainfluenza virus type 1 and Parainfluenza virus type 2 and Parainfluenza virus type 3 and Adenovirus and Streptococcus pneumoniae
Alere™ i	1	Abbott/Alere	https://www.alere.com/en/home/product-details/alere-i.html	Influenza A and Influenza B	RSV, Streptococcus pyogenes group A
BD Veritor™ Plus system	1	Becton, Dickinson and Company (BD)	https://www.bd.com/en-us/offers/capabilities/microbiology-solutions/point-of-care-testing/veritor-plus-system	RSV	Influenza A and Influenza B
QuickVue Influenza A + B Test	2	Quidel	https://www.quidel.com/immunoassays/rapid-influenza-tests/quickvue-influenza-test	Influenza A + B	N/A

TABLE B5 List of other frequently evaluated POCTs identified from the review

Name of Device/ Analyzer/Test	Number of studies	Manufacturer	Link to official site	Measure-ment used in study	Other available measurements
AUTION ELEVEN AE-4020	3	Arkray/A. Menarini Diagnostics	http://www.arkray.eu/english/products/laboratory/analyzers/ae-4020.html	Urine analysis	N/A
Urisys 1100®	2	Roche	http://www.cobas.com/home/product/urinalysis-testing/urisyys-1100-urine-analyzer.html	Urine analysis	N/A
Quantum Blue® fCAL	3	Buhlmann Labs	https://www.buhlmannlabs.ch/products-solutions/quantum-blue/calprotectin/	fCAL	Adalimumab, CRP, Infliximab
Triage BNP Test used with the Quidel Triage MeterPro	3	Quidel	https://www.quidel.com/immunoassays/triage-test-kits/triage-bnp-test	BNP	CK-MB and Myoglobin and Troponin I, Troponin I and BNP, CK-MB and Troponin I and BNP, Troponin I and CK-MB and myoglobin and BNP and D-dimer, Troponin I
CoaguChek® XS system	5	Roche	http://www.coaguheck.com/coaguheck_patient/en/home/products/xs-system.html	INR	N/A
Alere Cholestech LDX® Analyzer	5	Abbott/Alere	https://www.alere.com/en/home/product-details/cholestech-ldx-system.html	Lipid Panel	N/A
CardioChek® PA Analyzer	2	pts Diagnostics	http://www.ptsdiagnostics.com/cardiocheck-pa.html	High density lipoprotein (HDL)	Glucose, Total Cholesterol, Triglycerides
Biocard™ Celiac Test	3	Labsystems Diagnostics	https://www.labsystemsdx.com/products/gastroenterology/biocard-celiac-test	IgA deficiency	N/A
Xpert® MTB/RIF	2	Cepheid	http://www.cepheid.com/en/cepheid-solutions/clinical-ivd-tests/critical-infectious-diseases/xpert-mtb-rif	MTB and Rifampin-Resistance Mutations	N/A
CardioDetect med	2	rennesens GmbH	https://rennesens.en.ecplaza.net/products/cardiodeTECT-med-fabp-rapid-test_261655	Fatty-Acid-Binding Proteins	N/A
Roche CARDIAC® POC Troponin T (Troponin T assay) on the cobas h 232 POC system	3	Roche	http://www.cobas.com/home/product/point-of-care-testing/cobas-h-232.html	Troponin T	CK-MB, D-Dimer, Myoglobin, NT-proBNP