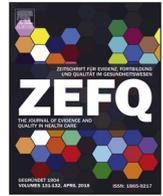




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Research on point-of-care tests in outpatient care in Germany: A scoping review and definition of relevant endpoints in evaluation studies

Forschung zu Point-of-Care-Tests in der ambulanten Versorgung in Deutschland: Scoping-Review und Definition relevanter Endpunkte für Evaluationsstudien

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ABSTRACT

Background: The fast turnaround time and user-friendliness of point-of-care tests (POCTs) offer a great potential to improve outpatient health care where clinical decisions have to be made during the physician-patient encounter and time resources are limited. The aim of this scoping review is to describe the extent and nature as well as gaps in German research activities on POCT in outpatient care. In addition, we define research endpoints that should be addressed in the comprehensive evaluation of POCTs targeted for outpatient care.

Methods: We performed a scoping review with a systematic literature search in Medline (via PubMed), Scopus, Web of Science, Cochrane library and Google Scholar for German publications on POCT with relevance to German outpatient care published from January 2005 to November 2020.

Results: Our literature search identified 2,200 unique records. After literature selection 117 articles were included in this scoping review. Just over half of the articles (67/117, 57.3%) were primary research studies with original data, while one third of all the studies (33.3%) were secondary research articles (e.g., review articles). The remaining articles were clinical recommendations / position papers (7/117, 6.0%) and other types of articles (3.4%). The majority of articles focused on POCT use in infectious diseases (44/117, 37.6%), diabetic syndromes (15.4%), cardiac disease (12.0%) or coagulopathies and thrombosis (10.3%), while the remaining articles did not specify the disease (13.7%) or investigated other diseases (11.1%). Similar to international studies, most primary research studies investigated the diagnostic performance of POCT (e.g., sensitivity, specificity). Evidence beyond diagnostic accuracy remains scarce, such as the impact on therapeutic decisions and practice routines, clinical effectiveness, and user perspectives. In line with this, interventional studies (such as RCTs) on the effectiveness of POCT use in German outpatient care are limited. We define six endpoint domains that should be addressed in the evaluation of POCTs targeted for outpatient care: (i) diagnostic performance, (ii) clinical performance, (iii) time and costs, (iv) impact on clinical routines / processes, (v) perspectives of medical professionals and patients, and (vi) broader aspects.

Conclusion: There is considerable research activity on POCTs targeted for use in outpatient care in Germany. Data on their potential benefits beyond diagnostic accuracy is often lacking and should be addressed in future POCT research studies.

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ZUSAMMENFASSUNG

Hintergrund: Aufgrund ihrer Schnelligkeit und Anwenderfreundlichkeit besitzen Point-of-Care-Tests (POCT) großes Potenzial, die Patientenversorgung im ambulanten Versorgungsbereich zu verbessern, da dort klinische Entscheidungen direkt während des Arzt-Patient-Kontakts getroffen werden müssen und Zeitressourcen knapp sind. Ziel dieses Scoping-Reviews ist es, den Umfang, die Art sowie potenzielle

Abbreviations: CRP, C-reactive protein; POCT, point-of-care tests; RCT, randomized controlled clinical trials

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Schlüsselwörter:
 Point-of-care-Tests
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 Ambulante Versorgung
 Deutschland

Lücken der deutschen Forschungsaktivitäten hinsichtlich POCT für die ambulante Versorgung zu beschreiben. Darüber hinaus werden Endpunkte definiert, die bei der Evaluation von POCT adressiert werden sollten.

Methoden: Ein Scoping-Review mit systematischer Literaturrecherche in Medline (via PubMed), Scopus, Web of Science, Cochrane Library und Google Scholar nach deutschen wissenschaftlichen Publikationen zu POCT für die ambulante Versorgung wurde durchgeführt (Publikationsdatum: Jan. 2005 bis Nov. 2020).

Ergebnisse: In der Literaturrecherche wurden 2200 Artikel identifiziert, von denen nach der Literatúrauswahl 117 Artikel in dieses Scoping-Review eingeschlossen wurden. Knapp über die Hälfte der Artikel (67/117; 57,3%) stellten Primärstudien mit Originaldaten dar, während ein Drittel (33,3%) Sekundärstudien (z. B. Literaturreviews) waren. Darüber hinaus wurden sieben (6,0%) klinische Empfehlungen / Positionspapiere und vier sonstige Artikeltypen identifiziert.

Die überwiegende Anzahl der Artikel untersuchte POCT bei Infektionskrankheiten (44/117; 37,6%), Diabeteserkrankungen (15,4%), Herzerkrankungen (12,0%) sowie Koagulopathien und Thrombosen (10,3%). 16 Artikel (13,7%) fokussierten auf keine spezielle Erkrankung, und 13 Artikel (11,1%) untersuchten POCTs bei sonstigen Erkrankungen.

Vergleichbar mit internationalen POCT-Studien untersuchten auch deutsche POCT-Primärstudien überwiegend die Testgüte von POCT (z. B. Sensitivität, Spezifität). Selten wurden Outcomes untersucht, die über die Testgüte hinausgehen, wie z. B. Einfluss von POCT auf therapeutische Entscheidungen, patientenrelevante Outcomes und Anwenderperspektiven. Wie in der internationalen POCT-Forschung werden auch in Deutschland nur vereinzelt Interventionsstudien (z. B. RCTs) zum Nutzen des POCT-Einsatzes in der ambulanten Versorgung durchgeführt.

Wir definieren sechs Endpunktdomänen, die bei der Evaluation von POCT in der ambulanten Versorgung adressiert werden sollten: (i) diagnostische Performance, (ii) klinische Performance, (iii) Zeit und Kosten, (iv) Einfluss auf klinische Routinen / Prozessabläufe, (v) Perspektiven und Einstellungen des medizinischen Personals und von Patient:innen sowie (vi) weitergehende Aspekte.

Schlussfolgerungen: In Deutschland gibt es umfangreiche Forschungsaktivitäten im Bereich POCT für den ambulanten Versorgungsbereich. Über die Testgüte hinausgehende Evidenz zum potenziellen Nutzen von POCT fehlt aber überwiegend und sollte in zukünftigen Studien stärker adressiert werden.

Introduction

Point-of-care-tests (POCTs), also referred to as rapid tests, are in-vitro laboratory procedures that are performed in close proximity to patients and are characterized by their fast turnaround time as they typically yield results within 15 min [1,2]. Examples for POCTs typically used in outpatient care include tests for plasma glucose, Troponin and urine dip sticks (pH-value, leucocyte count, protein level, etc.). In contrast to standard laboratory tests carried out in external laboratories, POCT have the potential to directly impact therapeutic and/or diagnostic decision making at the index consultation. This is particularly important in the management of patients in outpatient care where rapid clinical decisions have to be made and time resources are limited. In the last decade, many novel POCT have been developed and the size of the POCT market has steadily increased and is expected to further increase in the future [3]. Although a relatively large number of POCT are now available for diagnostic use in Germany and other countries, many of them are not routinely used in outpatient care [4,5]. This can be explained by several factors, such as concerns about accuracy, over-reliance on tests and limited usefulness [6] as well as structural barriers including a lack of reimbursement.

POCT use in routine outpatient healthcare should be based on the principles of evidence-based medicine. Clinical studies that investigate the effects of POCT diagnostics are therefore necessary. However, while there are often sufficient data on the diagnostic accuracy of POCT (e.g. sensitivity, specificity), the impact of POCT on other relevant outcomes, such as patient health or broader impact, is rarely addressed in clinical studies [7]. Since the clinical performance of healthcare interventions might be significantly influenced by the study setting and location [8,9], study results may not be transferable to settings and regions in other countries. In order to evaluate the diagnostic and clinical value of POCT in outpatient care in Germany, it is therefore necessary that such studies are conducted in the German outpatient healthcare setting.

The aim of our scoping review [10] is to describe the extent and nature as well as gaps of POCT research in outpatient care in Germany. In particular, we describe the studied endpoints of research articles on POCT use and define endpoints that should be addressed in the comprehensive evaluation of POCT targeted for outpatient care.

Methods

This scoping review was conducted according to recognised guidelines on the methodology of scoping reviews [10–12]. The methodology of a scoping review was chosen, because it allows to identify knowledge gaps, scope a body of literature, and to investigate research conduct [13].

Search strategy and study selection criteria

We systematically searched Medline (via PubMed), Scopus, Web of Science, Cochrane library and Google Scholar for publications published from January 2005 to November 2nd 2020 (date of last search). The detailed search strategy, including search strings and applied filters, is provided in [Supplementary Material](#). An abstract and title screening of all search results was performed and potentially relevant articles were retrieved for full-text review. The study selection was independently performed by two investigators (AM, RM) using the Rayyan software [14]. Rayyan is a professional software application which helps expediting and organising the literature screening process and was developed by the Qatar Computing Research Institute and Cochrane Bahrain. Discordances were solved by discussion.

Studies were included if they met all of the following criteria:

- Publication type: Full research articles (primary or secondary literature), clinical recommendations and guidelines,

conference abstracts and academic theses (master's theses, PhD theses, habilitations). Studies must be published after 2004.

- Focus on POCTs: The publication's focus is on POCT or the publication provides substantial information on POC diagnostics. In our study POCT encompass laboratory tests that can be performed in close proximity to patients (i.e. in the physicians' office) without extensive laboratory equipment or manual procedures. Although most POCTs yield results within 15min, we accepted a maximum of 60min turnaround time.
- Setting: The clinical setting encompasses outpatient care, including ambulatory emergency care. Studies with clear focus on POCT use in a hospital setting were excluded.
- Focus on Germany: Studies were included if they were conducted in Germany or involved authors with an affiliation of a German institution (academia or industry). Clinical recommendations and guidelines were included if they were specifically tailored for Germany.

Data extraction

Data of all eligible studies were independently extracted by two authors (AM, RM) using standardized forms. All disagreements were resolved through discussion. The following study characteristics and data were extracted: Title, first author, year of publication, study period, publication type, main topics in regard to POCT, setting in outpatient care (e.g. general medicine, emergency medicine, etc.), study population (e.g. patients, medical professional staff, POCT stakeholder, etc.), disease (e.g. respiratory disease, cardio-vascular disease, etc.), characteristics of POCT, overall conclusion of study authors in regard to POCT use (i.e. favourable or not favourable in the context of the study).

Results and data synthesis

In the systematic literature search we identified 2200 unique records. After title and abstract screening, 808 studies were assessed in full-text review. In total, we identified 117 articles [15–131] on POCT use in outpatient care in Germany published between 2004 and 2020 (Figure 1).

Publication characteristics

The majority (72.6%, 85/117) of articles were full research articles. Conference abstracts / posters and academic theses accounted for 10.3% and 11.1% of all articles, respectively. Seven clinical recommendations / position papers (6.0%) with primary focus on POCT application in outpatient care were found.

Just over half of the articles (67/117, 57.3%) were primary studies that collected original data on POCT use or development (Table 1). Among these 67 primary studies, the great majority (62/67, 92.5%) were non-interventional studies, while only five (7.5%) provided results from interventional clinical studies. Out of these, one was a randomized controlled trial (RCT) and four were either non-randomized controlled trials (n = 2) or uncontrolled trials (n = 2).

Out of all included studies, one-third (39/117, 33.3%) were secondary research articles, with most of them (87.2%) being narrative reviews / expert opinions and the remaining five articles being systematic reviews and scoping reviews. The majority of articles were published in English (74/117, 63.2%) but over one third (36.7%) of all identified articles were exclusively published in German with English abstract available in most cases. The remaining articles were clinical recommendations/ position papers (7/117, 6.0%) and articles of other types (4/117, 3.4%)

The majority of articles focused on POCT use in infectious diseases (44/117, 37.6%), diabetic syndromes (15.4%), cardiac diseases (12.0%) or coagulopathies and thrombosis (10.3%) (Table 2). Sixteen out of 117 studies (13.7%) did not specify the disease and 13 studies (11.1%) focused on other diseases, such as cancer or allergic diseases. Among the 44 studies on POCT use in infectious diseases, most studies (61.4%, 27/44) investigated POCT for the detection of pathogens, while seven (15.9%) focused on POCT measurements of inflammatory markers, such as C-reactive protein or procalcitonin. Articles on POCT use in diabetic syndromes (n = 18) predominantly investigated POCT glucose measurement (77.8%, 14/18) while the remaining four studies (22.2%) evaluated POCT for glycosylated hemoglobin (HbA1c). Among the 14 studies on POCT use in cardiac diseases (e.g. cardiac infarction or insufficiency), eight studies (57.1%, 8/14) investigated natriuretic

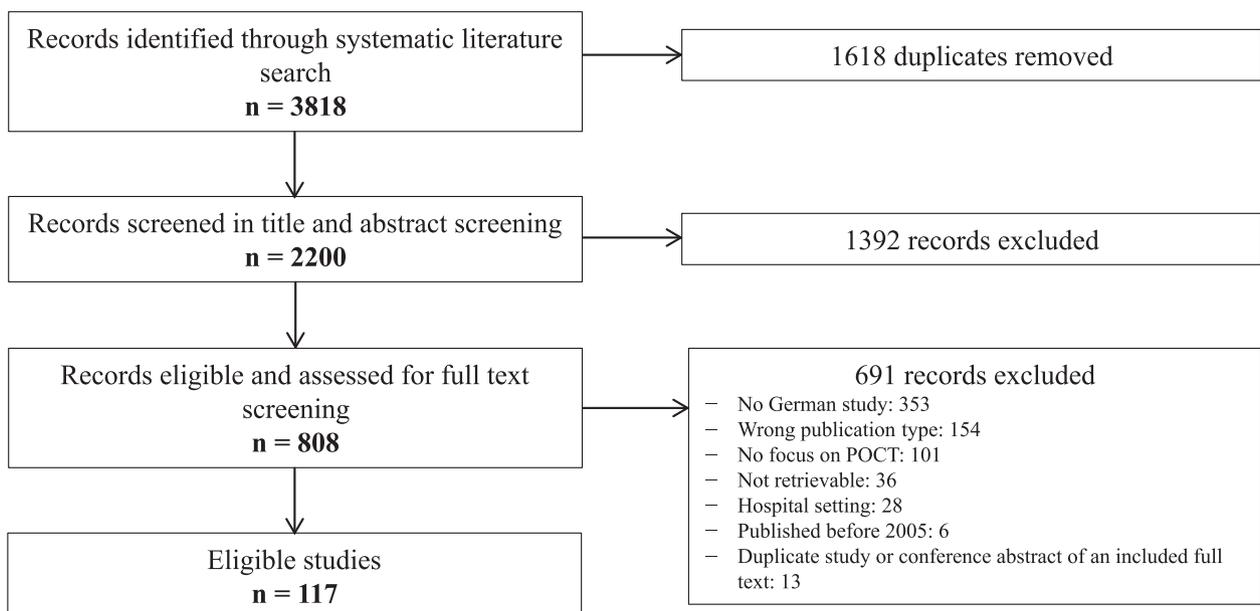


Figure 1. Flow chart of study selection.

Table 1
Articles types of articles on POCT use in German outpatient care published between 2005 and 2020.

Article type	Total number	(%)	References
Primary research studies	67	(57.3)	
Randomized controlled interventional study (RCTs)	1	(1.5)	[1]
Non-randomized controlled interventional studies	2	(3.0)	[2,3]
Uncontrolled interventional studies (i.e. pre-post studies)	2	(3.0)	[4,5]
Non-interventional studies	62	(92.5)	[6–67]
Secondary research articles (review articles / experts opinions)	39	(33.3)	[68–106]
Clinical guidelines / recommendations and positions papers	7	(6.0)	[107–113]
Others	4	(3.4)	[114–117]
Total	117	(100)	

Table 2
Disease focus in articles on POCT use in German outpatient care published between 2005 and 2020.

	Total number	(%)	References
Total number of studies	117		
Infectious diseases	44	(36.7)	[1–44]
Diabetic syndromes	18	(15.4)	[45–62]
Cardiac syndromes (e.g. cardiac infarction or insufficiency, etc.)	14	(12.0)	[63–76]
Coagulopathies and thrombosis	12	(10.3)	[77–88]
Unspecified diseases	16	(13.7)	[89–104]
Others	13	(11.1)	[105–117]
Total	117	(100)	

Table 3
Research focus and studied outcomes in primary research studies on POCT use in German outpatient care published between 2005 and 2020*.

	Total number	(%)	References
Total number of primary studies	67*	(100)	
Preclinical research			
Technical development/preclinical basic research	9	(13.4)	[1–9]
Diagnostic performance			
Technical and clinical diagnostic test performance	40	(59.7)	[10–49]
Clinical performance			
Impact on therapeutic decisions	4	(5.9)	[15,50–52]
Clinical effectiveness (patient health outcomes)	2	(3.0)	[13,50]
Time and costs			
Time-related aspects (e.g. time to result, time saving, etc.)	6	(9.0)	[31,45,50,53–55]
Costs (e.g. total costs, cost effectiveness, etc.)	2	(3.0)	[13,56]
Impact on clinical routines / processes			
Implementation (e.g. training, quality assurance, etc.)	11	(16.4)	[31,36,37,45,50,53–55,57–59]
Perspectives of medical professionals and patients			
Medical professionals	4	(6.0)	[3,53,55,58]
Patients*	2	(3.0)	[55,58]
Broader aspects			
Frequency of use in routine healthcare and/or availability	9	(13.4)	[50,52,53,60–65]
Reimbursement	1	(1.5)	[62]
Others	3	(4.59)	[57,66,67]

* Some studies investigated more than one outcome and therefore the numbers of outcomes exceeds the number of studies.

peptides (e.g. BNP, NT-proBNP), while the remaining six studies (42.9%) included POCT measurements of troponin.

Research focus and studied outcomes in primary studies on the use of POCT in outpatient care in Germany

Considering the primary studies, we identified nine pre-clinical studies (9/67, 13.4%) which provide data on the technical development of novel POCT (Table 3); among these six studies on POCT targeted for outpatient testing of infectious diseases, such as respiratory tract infections and malaria. However, these studies do not provide any data on the clinical utility of POCTs. Our systematic literature search shows that the majority (40/67, 56.7%) of primary research studies in Germany focus on the analytical and diagnostic performance of POCTs. A typical diagnostic accuracy study includes

testing of target patient samples using the POCT and the established reference method (gold standard) which defines the “true” disease status for each patient. By using predefined diagnostic thresholds for the POCT, the diagnostic accuracy can be calculated in comparison to the reference method. Most of these studies found that the diagnostic performance of POCT is sufficient for clinical routine use and is often not significantly inferior to established laboratory tests.

Going beyond test accuracy, eleven studies (16.4%) presented data on implementation aspects of POCT in outpatient care, including quality assurance and user training. Nine studies (13.4%) focused on data on the frequency of use and availability of POCT in German outpatient care.

Importantly, our results show that only few POCT primary research studies provide data on the therapeutic impact (4/67, 5.9%)

and clinical effectiveness (2/67, 3.0%). Among those, Deichmann et al. [31] and Jennings et al. [64] reported results from the same non-randomized interventional study and found that the use of point-of-care influenza testing decreased the number of antibiotic prescriptions and impacts the initiation of antiviral therapy compared to the control group (no influenza POCT) in outpatient pediatric practices. Two observational studies in emergency medical services reported that POCT measurements of vitality markers (such as pH, K⁺, lactate, glucose) impacts acute therapeutic interventions [55,56], but did not result in statistical significant differences in health outcomes between patients with preclinical vs. patients without preclinical POCT measurements [55]. One RCT comparing POCT measurement of BNP vs. standard assessment without BNP did not find differences in health outcomes of patients presenting with dyspnea in primary care practices in Switzerland and Germany [28]. However, BNP-POCT decreased the need for further diagnostic procedures and accelerated the initiation of the appropriate treatment.

In addition to therapeutic impact and clinical effectiveness, economic aspects (e.g. cost effectiveness and reimbursement) as well as user and patient perspectives are key elements for successful implementation of POCT in routine outpatient healthcare. However, our literature search shows that these endpoints are rarely addressed in German primary research studies (Table 2).

German clinical recommendations and consensus papers with focus on the use of POCT in outpatient care

Among the seven clinical recommendations / position papers, three articles summarize requirements for measurement quality and quality assurance of POCT systems in the measurement of blood glucose for diagnosing diabetes manifested in pregnancy [92,93,122]. In 2009, the *POCT Working Group of the German Society for Clinical Chemistry and Laboratory Medicine* published suggestions on standardized POCT measurements of blood glucose [76]. One joint position paper on POCT for sexual transmitted diseases (STI) published in 2017 emphasizes the potential of POC-testing to lower the barrier of testing and improving access to testing [88]. This position paper concludes that POCT for HIV, HCV and syphilis are well suited for POC-testing. In contrast, sufficient diagnostic accuracy for detection of *C. trachomatis* and *N. gonorrhoeae* can only be achieved by PCR-based POCTs. In a clinical recommendation, Betz et al. [19] describe the diagnostic value and routine use of preclinical POC-testing of blood gas analysis in emergency care. In a clinical guideline on patient self-management of oral anticoagulation from 2009, the authors highlight the diagnostic potential of patient self-testing of oral anticoagulation as it improves therapies and decreases the risk for thromboembolic events and bleedings [26]. However, this guideline was not updated and therefore may not reflect the current state of scientific evidence.

Discussion

Given their low turnaround time and user-friendliness, POC laboratory tests offer great potential in the management of patients in outpatient care, including primary care practices or outpatient emergency care. In order to ensure an evidence-based use of POCT in German outpatient care, robust scientific evidence is needed, preferably derived from studies conducted in German outpatient healthcare facilities to increase the external validity. Our scoping review identified and analysed 117 articles on POCT use in outpatient care published by German researchers.

A systemic overview on international POCTs studies concluded that evidence generation tends to focus on accuracy and overlooks other test attributes such as impact, implementation and cost-

effectiveness [7]. In line with these findings, our results show that also most German primary research studies focused on the diagnostic accuracy of POCTs, while evidence for other critical aspects, such as therapeutic impact, (comparative) clinical and cost effectiveness as well as user and patient perspectives is relatively rare. Even less evidence is available for the feasibility of POCT in routine outpatient healthcare and the organisational consequences of POCT use, such as improved patient flows or optimized practice routines. Importantly, rapid and sufficient diagnostic performance of POCT does not necessarily translate into improved patient outcomes [134] and results from diagnostic accuracy studies provide limited or no evidence on the therapeutic impact or broader implications of POCT use in routine healthcare practice.

According to Horvath et al. [135] the evaluation of in-vitro diagnostic tests, including POCTs, encompasses (i) analytical performance (e.g. precision), (ii) diagnostic performance (e.g. sensitivity, specificity), (iii) (comparative) clinical effectiveness (improvement of patient outcomes), (iv) cost-effectiveness and (v) broader impact, such as acceptance and organizational consequences. In addition, Fryback and Thornbury [136] defined the impact of diagnostics on diagnostic thinking and therapy decisions as further relevant endpoints that go beyond analytical and diagnostic performance. Based on these studies, our own research activity and this literature review, we define six domains of endpoints that should be addressed in the evaluation of a given POCT to comprehensively understand its potential benefits in outpatient care: (i) diagnostic performance, (ii) clinical performance, (iii) time and costs, (iv) impact on clinical routines / processes, (v) perspectives of medical professionals and patients, and (vi) broader aspects (see Figure 2). Based on our results from German POCT studies, POCTs for outpatient care are typically well characterized in their diagnostic performance (domain i) but evidence for all other endpoint domains is usually lacking. In accordance with the principles of evidence-based medicine, the effectiveness of POCT use in outpatient care should be assessed in interventional studies, preferably in randomized controlled clinical trials (RCTs), which are the gold standard in clinical research [137–139]. For POCT interventions in outpatient practices, cluster-randomised interventional studies may be preferable over patient-randomised trials as test operators cannot be trained / untrained between individual patients or outcomes are collected on the level of physicians (e.g. prescription behaviour). However, RCTs are often time and resource consuming, especially in the decentralised outpatient care setting. Therefore, other interventional study designs, such as non-controlled studies (e.g. pre-post studies) or non-randomized controlled trials as well implementation studies [140], may also offer valuable data on the effectiveness of POCT when RCTs are not feasible.

Importantly, as indicated by our spectrum of different research endpoints, the added value of POCT (or any other diagnostic procedure) should not be solely judged by their impact on patient health outcomes as it is the case in therapeutic interventions. Given their upstream role in patient management and the context of all other factors influencing patient outcomes, the independent effect (if any) of POCT to health outcomes may be small and therefore very large sample sizes may be required in appropriate clinical trials [141]. Even if POCT do not improve patient health outcomes compared to standard (laboratory) diagnostic procedures, their routine application in outpatient care may be beneficial as they might improve patient flows, therapeutic decisions, communication with patients, patient satisfaction and can be associated with time and cost savings in primary care. For example, there is robust evidence that POCT measurements of C-reactive protein (CRP) result in decreased prescriptions of antibiotics in primary care [142,143] and are cost-effective [144,145]. Although these studies show that patient health outcomes are not improved by CRP-POCTs, their use

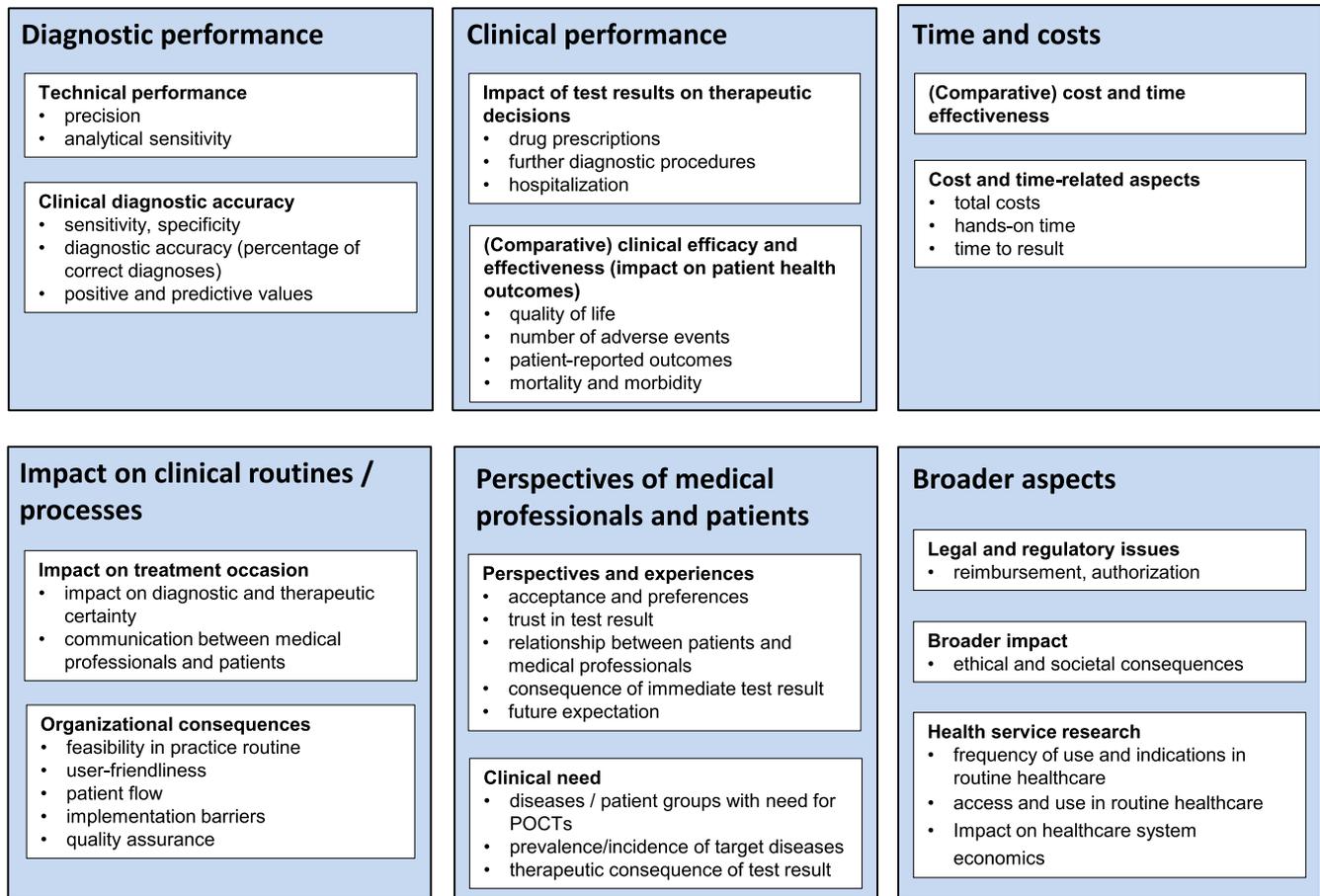


Figure 2. Research endpoints for the evaluation of POCT used in outpatient and adapted and modified from Verbakel et al. [7], Horvath et al. [135] and Fryback and Thornbury [136].

is recommended in clinical guidelines to reduce diagnostic uncertainty and to aid prescribing decisions [146,147].

Depending on the diagnostic goal, target disease and user requirements, different POCT require various evidence on their potential clinical value for routine application [141]. A recent systematic review on POCTs in primary care showed that POCT evaluation studies do often not investigate aspects that are relevant for general physicians in the decision to implement a POCT in practice [148]. It is therefore desirable to involve outpatient medical professionals (physicians and medical assistants) in the definition of relevant clinical endpoints. Moreover, the involvement of patients has recently gained significance as their perspectives provide valuable input in the planning and interpretation of clinical studies [149]. The evaluation of POCT use may include both quantitative clinical studies as well as qualitative approaches which can provide valuable data on attitudes, implementation barriers and acceptance among users (medical professionals) and patients.

In addition to relevant endpoints, it is also important that studies on POCT use are conducted in the target setting in order to provide robust data that are representative to the “real-life” outpatient care context. Recruiting outpatient practices for research projects often is challenging [150] since resources and, in some cases research interest, are limited among outpatient physicians. Consequently, many studies on healthcare intervention, including in-vitro diagnostics, are carried out at university hospitals which have dedicated research personnel and resources. However, patient characteristics, medical infrastructure and legal obligations are fundamentally different in the hospital setting compared to outpatient settings. In order to recruit outpatient practices for research projects, research approaches should be tailored to the context of

outpatient care settings, which includes the involvement of outpatient medical professionals in all steps of the research project, definition of endpoint relevant for outpatient physicians and may also include appropriate financial compensation.

Importantly, our scoping review indicates that there might be a publication bias in primary POCT research studies since only four studies interpreted the obtained data as not favorable for the POCT in question. As known for decades, publication bias is a serious problem in clinical research [151–153] and also has been described for diagnostic accuracy studies [132,133]. It is therefore important to implement strategies to prevent publication bias towards favourable results, such mandatory publication of study protocols or journal policies to accept and publish “negative results”.

Strengths and limitations

To our knowledge, no scoping review on research activity on POCT use in German outpatient care has been conducted yet. Based on 117 included scientific articles, our study provides a comprehensive overview on publication types, studied POCT and diseases as well as outcomes addressed in recent POCT research in Germany. However, our scoping review has some limitations. Firstly, we designed a systematic literature search to specifically identify POCT articles with focus on outpatient care in Germany. However, it might be possible that our search did not cover all articles on potentially relevant POCT research, especially in cases where studies did not specifically mention outpatient care settings. This is most likely true for technical development (“proof-of-principle”) studies that do not specify any particular clinical setting. Secondly, grey literature, such as academic theses, may not be fully covered

with our search strategy and used electronic databases. Despite the potentially limited sensitivity of our systematic literature search, our scoping review is a representative snapshot of the German research activity on POCT use in outpatient care.

Conclusion

There is considerable research activity on POCT use in German primary care. The majority of primary research studies focuses on the diagnostic performance of POCTs. Similar to international POCT studies, evidence beyond diagnostic accuracy remains scarce, such as impact on therapeutic decisions and practice routines / processes, clinical effectiveness, and user and patient perspectives. We defined six research domains of endpoints that should be addressed in POCT evaluation to comprehensively understand potential benefits and challenges of POCT use in primary care.

Data statement

All data are available on reasonable request from the authors.

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Conflict of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Anni Matthes, Robby Markwart report financial support was provided by German Federal Ministry of Education and Research.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.zefq.2022.06.002>.

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