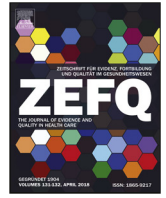




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Qualität und Sicherheit in der Gesundheitsversorgung / Quality and Safety in Health Care

Perspectives of physicians and medical assistants on the implementation of NAAT-based point-of-care testing for SARS-CoV-2 in primary care in Germany

*Perspektiven von Ärzt*innen und Medizinischen Fachangestellten zur Anwendung von NAAT-basierten Point-of-Care-Tests auf SARS-CoV-2 in der Primärversorgung in Deutschland*

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ABSTRACT

Introduction: Given their high diagnostic accuracy and fast turnaround time, rapid SARS-CoV-2 tests based on nucleic acid amplification technologies (NAAT) have great potential to expand access to testing and decrease delays in diagnosis of COVID-19.

Objectives: The aim of this study was to investigate feasibility, acceptance, organizational consequences and other implementation aspects of the use of a NAAT-based SARS-CoV-2 rapid test (ID NOW™ COVID-19, Abbott Diagnostics) for symptomatic primary care patients with a suspected SARS-CoV-2 infection.

Methods: Cross-sectional survey among primary care physicians and medical assistants from Thuringia (Germany) during the third wave of the COVID-19 pandemic in March and April 2021. The health care providers surveyed had previously used the NAAT-based SARS-CoV-2 rapid test as part of a pilot study.

Results: Eleven physicians (ten general practitioners and one paediatrician) and 22 medical assistants from Thuringia (Germany) participated in the written survey. Four physicians were additionally interviewed. The majority of the surveyed health care providers rated user-friendliness, integration into practice routine, impact on communication with patients and technical reliability of the NAAT-based SARS-CoV-2 rapid test as (very) positive. Greater workload and the costs for measuring devices were identified as disadvantages compared to PCR laboratory tests. Four out of ten physicians rated the lower sample turnover as unfavourable.

Conclusion: Our survey shows that NAAT-based point-of-care SARS-CoV-2 testing gained widespread acceptance among physicians and medical assistants, positively influences workflows, can improve patient communication and could therefore be successfully implemented into routine primary care.

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ZUSAMMENFASSUNG

Einleitung: Aufgrund ihrer hohen diagnostischen Genauigkeit und der kurzen Durchlaufzeit haben SARS-CoV-2-Schnelltests, die auf Nukleinsäureamplifikationstechnologien (NAAT) basieren, ein großes Potenzial, den Zugang zu Tests zu erweitern und Verzögerungen bei der Diagnose von COVID-19 zu verringern. Ziel dieser Studie war es, die Durchführbarkeit, die Akzeptanz, die organisatorischen Konsequenzen und andere Implementierungsaspekte des Einsatzes eines NAAT-basierten SARS-CoV-2-Schnelltests (ID NOW™ COVID-19, Abbott Diagnostics) bei symptomatischen Patienten aus der Primärversorgung mit Verdacht auf eine SARS-CoV-2-Infektion zu untersuchen.

Methoden: Querschnittsbefragung unter Hausarzt*innen und Medizinischen Fachangestellten aus Thüringen (Deutschland) während der dritten Welle der COVID-19-Pandemie im März und April 2021. Die Befragten hatten zuvor den NAAT-basierten SARS-CoV-2-Schnelltest im Rahmen einer Pilotstudie eingesetzt.

Ergebnisse: Elf Arzt*innen (zehn Allgemeinmediziner*innen und eine Kinderärztin) und 22 Medizinische Fachangestellte aus Thüringen (Deutschland) nahmen an der schriftlichen Befragung teil. Vier Ärztinnen

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wurden zusätzlich interviewt. Die Mehrheit der Befragten bewertete die Benutzerfreundlichkeit, die Integration in den Praxisalltag, den Einfluss auf die Kommunikation mit Patient*innen und die technische Zuverlässigkeit des NAAT-basierten SARS-CoV-2-Schnelltests als (sehr) positiv. Als Nachteile wurden der höhere Arbeitsaufwand sowie die Kosten für Messgeräte und Testkassetten im Vergleich zu PCR-Labortests genannt. Vier von zehn Ärzt*innen bewerteten den geringeren Probenumsatz (vier Test pro Stunde) als ungünstig.

Schlussfolgerung: Unsere Befragung zeigt, dass NAAT-basierte Point-of-Care-SARS-CoV-2-Tests eine breite Akzeptanz bei Ärzt*innen und Medizinischen Fachangestellten finden, die Arbeitsabläufe positiv beeinflussen, die Patientenkommunikation verbessern können und somit erfolgreich in die hausärztliche Routineversorgung implementiert werden könnten.

Introduction

Since March 2020 the SARS-CoV-2 pandemic has caused a significant burden on patients, the healthcare system and society in Germany and worldwide. As of July 2022, there were more than 30 million confirmed SARS-CoV-2 infections and almost 150.000 associated deaths recorded in Germany [1]. Over the course of the pandemic figures on confirmed cases, hospitalizations, critically ill patients and SARS-CoV-2-associated deaths changed dynamically, depending on virus variants, test regulations, treatment options, vaccination rates and additional protective measures, among other factors [1]. Since April 2021, the use of rapid SARS-CoV-2 antigen tests has been a cornerstone in the German national strategy to fight the pandemic [2]. Rapid antigen tests do not require extensive laboratory equipment and trained medical staff can yield reliable results within 30 minutes. Rapid SARS-CoV-2 antigen tests therefore have great potential to expand access to testing and decrease delays in diagnosis, which helps to break infection chains [3].

However, rapid antigen tests are characterized by their lower diagnostic accuracy compared to nucleic acid amplification tests (NAAT). According to the German national testing strategy, rapid antigen tests should primarily be used in asymptomatic individuals [2]. Polymerase chain reaction (PCR) tests performed in laboratories are considered as gold standard in SARS-CoV-2 diagnostics [3,4]. Due to a continuously high incidence and limited testing capacity, the national test strategy states that PCR laboratory testing should predominantly be used in patients with symptoms of SARS-CoV-2 [2]. Yet, it may take several days until results of PCR laboratory tests are available. To overcome the lower diagnostic performance of antigen tests, NAAT-based rapid tests were developed and introduced to the market [5]. Nucleic acid testing approaches generally have a better sensitivity for the detection of SARS-CoV-2 infections than rapid antigen tests. NAAT-based rapid tests therefore offer the great potential to combine the diagnostic accuracy of laboratory tests with the fast turnaround time of rapid antigen tests.

However, it has been noted that the adoption of novel healthcare technologies, including diagnostic tests, into routine care is often slow, which might be explained by a lack of evidence relevant to target clinical settings [6]. Especially in primary care settings, where physicians are challenged with time and resource constraints, aspects like feasibility, utility, organizational consequences, costs as well as acceptance among medical staff are as important as the diagnostic test performance. While there are multiple studies on the diagnostic test performance (sensitivity, specificity, etc.) of POCTs, *Verbakel et al.* noted that research often does not provide data on impact and implementation aspects [6]. To our knowledge, there are no studies on feasibility, acceptability, organizational consequences and other implementation aspects of a NAAT-based COVID-19 POC test in German primary care. Therefore, we surveyed primary care physicians and medical assistants to study the broader impact of a COVID-19 rapid test on routine

care during the third COVID-19 high incidence phase in Thuringia, Germany.

Methods

Study design

We conducted a cross-sectional survey among primary care physicians (general physicians and paediatricians) and medical assistants who participated in a pilot study on the use of a NAAT-based SARS-CoV-2 rapid test (ID NOW™ COVID-19 rapid test, Abbott Diagnostics Scarborough, Inc., USA) in symptomatic patients with a suspected SARS-CoV-2 infection. The pilot study with 13 participating medical practices (11 general practitioner's practices and 2 paediatric practices) was initiated by the *Association of Statutory Health Insurance Physicians Thuringia* in January 2021. The medical practices were selected by the *Association of Statutory Health Insurance Physicians Thuringia* with the aim to include a broad spectrum of the Thuringian practice landscape (small, large, rural and urban practices). The test kits including the analysing platform were provided by the manufacturer. Practices did not receive any fee for participating in the pilot study. All participating practice teams took part in approximately 30 minutes of training on the proper use of the NAAT-based SARS-CoV-2 rapid test instrument by an employee of the manufacturer. The cross-sectional survey was performed by members of the Institute for General Practice and Family Medicine, Jena University Hospital. The manufacturer was not involved in survey design, data collection and analysis as well as decision to publish any obtained data. The survey was approved by the institutional research ethics board of the Jena University Hospital (Registration No.: 2021-2108-Bef). We report the results in line with the STROBE standards [7].

NAAT-based SARS-CoV-2 rapid test

The ID NOW™ COVID-19 rapid test (Abbott Diagnostics Scarborough, Inc., USA) uses the isothermal nucleic acid amplification technique for the qualitative detection of SARS-CoV-2 nucleic acids [8]. According to the manufacturers' information, the diagnostic sensitivity and specificity is 95.0% and 97.9%, respectively [9]. However, an independent Cochrane review showed that the average sensitivity was 73.0%, while the specificity was 99.7% [10]. As demonstrated by several studies [11–13], the sensitivity of the ID NOW™ COVID-19 rapid test is particularly decreased in samples with low viral loads. Despite its relatively low sensitivity in samples with low genome load, the advantage of the ID NOW™ COVID-19 rapid test over other NAAT-based rapid tests is its fast turnaround time of max. 13 min.

Local health authorities in the German Federal State of Thuringia have officially approved results from ID NOW™ COVID-19 rapid tests as confirmation / non-confirmation of SARS-CoV-2 infections

in symptomatic patients without requesting a confirmatory PCR laboratory tests since January 2021 [14]. According to the German national testing strategy, a NAAT-based rapid test such as the ID NOW™ can also be performed in asymptomatic individuals but only for confirmation of an already positive rapid antigen test [2]. During the period of the pilot study (January–March 2021), rapid antigen tests were not yet widely available [2]. Therefore, the pilot study and consequently this survey primarily relate to the experience with the NAAT-based rapid testing in symptomatic patients in primary care.

Survey design

For this study we developed separate questionnaires (in German) for (i) physicians and (ii) medical assistants (Appendix A). The questionnaires included questions on implementation, experiences, acceptance and attitudes towards the use of the NAAT-based SARS-CoV-2 rapid test in clinical routine in the form of 5-point Likert scales, single and multiple selection questions as well as open questions with short free text answers. The content of the questionnaires was piloted and validated by primary care physicians and researchers with expertise in cross sectional surveys. The questionnaire for medical assistants was anonymous and completion of the questionnaire implied their consent. Physicians' written consent was obtained as they were asked for their full names in order to conduct qualitative interviews after the survey (see below). The purpose of the survey as well as information on data protection and security were explained to participants on the first page of the questionnaire. Participation was voluntary. No financial compensation was provided.

Data collection and analysis

The survey was conducted in March and April 2021 after the NAAT-based SARS-CoV-2 rapid tests had already been in use for two months. During the study time, Germany was in the midst of a SARS-Cov-2 high incidence phase. Importantly, especially high 7-days incidences (> 150 cases per 100.000 residents) were reported in Thuringia [1]. The national vaccination campaign (with initial prioritization on individuals 80 years and older or at particularly high risk of exposure) had just started and rapid antigen testing was scarce [1]. Thus, primary care practices were faced with a high number of suspected SARS-CoV-2 cases, which were predominantly unvaccinated and unselected (i.e., no rapid antigen test in advance).

All medical practices participating in the pilot study were contacted via email and by mail and asked for participation in the survey. The questionnaires were provided in written form by mail. Completed questionnaires were collected by the researchers and raw data were entered into Microsoft Excel 2010. Data were analysed using "R" [15] using descriptive statistics.

Qualitative interviews

In order to address ambiguities and unanswered questions that arose during the analysis of the quantitative survey data, we conducted qualitative interviews with certain respondents (sequential timing explanatory approach). We identified four physicians of relevance based on their survey answers and asked for participation. All four interviews took place in May 2021, were semi-structured and had a length of 10 minutes. Two interviews were conducted via telephone, two were face-to-face.

Results

A total of eleven physicians (ten general practitioners and one paediatrician) from ten different practices and 22 medical assistants from eight practices participated in the survey. An overview of the characteristics of the participants is provided in Table 1. Six of the eleven participating physicians work in practices in larger Thuringian cities (i.e. Erfurt, Jena, and Weimar with each more than 65.000 inhabitants), while the other five physicians work in rural areas in Thuringia. All participating physicians and medical assistants have frequently performed the SARS-CoV-2 rapid test in person or have delegated its execution. In our survey, ten out of eleven participating physicians and all medical assistants were female.

Qualitative interviews were conducted with four selected physicians and findings are summarized in the results for the corresponding items.

Process of performing the NAAT-based SARS-CoV-2 rapid test

The surveyed physicians and medical assistants reported that the swabbing for the rapid test was generally performed by physicians (reported by 60% of the physicians and 68.2% of the medical assistants) or in some practices by both physicians and medical assistants (reported by 30% of the physicians and 27.3% of the medical assistants). According to the physicians, the sample collection for the rapid test was predominantly (66.7%) performed in the physicians' examination room. Although medical assistants were less frequently involved in sample collection, they mainly performed the measurements on the analysing platform (reported by 66.7% of the physicians and 86.4% of the medical assistants). According to all respondents, physicians were not the principal operators of the analysing platform. The NAAT-based SARS-CoV-2 rapid test device was mainly (reported by 90% of the physicians) set up in the practice laboratory or outside the physicians' examination room.

Table 1
Baseline characteristics of participating healthcare providers.

	Physicians (n = 11)	Medical assistants (n = 22)
Profession	10 x general physician 1 x pediatrician	22 x Medical assistants
Gender	10 x female 1 x male	22 x female
Type of practice	4 x single practice 5 x group practice 2 x medical care center	not inquired
Location of practice	6 x urban area (pop. >65.000) 5 x rural areas	not inquired
Average number of performed ID NOW™ tests per physician/medical assistant	Median: 49.0 Mean: 57.2 IQR: 21.0 - 90.0	Median: 21.0 Mean: 41.8 IQR: 10.0 - 77.5
Average number of positive ID NOW™ test results per physician/medical assistant	Median: 4.0 Mean: 6.4 IQR: 4.0 - 9.0	Median: 3.0 Mean: 5.4 IQR: 2.0 - 9.0
Use of other SARS-CoV-2 tests	11 x SARS-CoV-2 PCR laboratory tests (sample shipment) 11 x SARS-CoV-2 rapid antigen tests 6 x SARS-CoV-2 rapid antibody tests	not applicable

Reasons and circumstances for performing the NAAT-based SARS-CoV-2 rapid test

Nine out of eleven (81.8%) physicians reported that the severity of the symptoms and a close contact (anamnestic) between the patient and a COVID-19 case were the main reasons for using the ID NOW™ COVID-19 rapid test instead of a SARS-CoV-2 PCR laboratory test. Moreover, the occupational background (36.4%) and the (high)-risk group (e.g. age, comorbidities) of the patients (18.2%) were indicated as reasons. In addition, the following statement was reported twice, respectively once, in the free text field: (i) ID NOW™ COVID-19 rapid test always performed if patient consented and (ii) administrative needs (discharge from quarantine, travel request).

Furthermore, the participating physicians were asked to name circumstances in which the utilization of the ID NOW™ COVID-19 rapid tests was considered particularly useful. The severity of symptoms (72.7%), a close contact of the patient with a COVID-19 case (54.5%) and the professional background of the patient (45.5%) were most frequently mentioned. Other circumstances specified in the free text field were the following: (i) situations where an immediate fast result is needed (2x), (ii) useful in all situations, (iii) patients with many contacts (e.g. supermarket cashiers), (iv) administrative needs (discharge from quarantine, travel request).

Evaluation of the test properties

The results on the evaluation of the properties and use of the studied NAAT-based SARS-CoV-2 rapid test are displayed in Figures 1 and 2.

The majority (>60%) of the surveyed physicians and medical assistants rated the user-friendliness and the technical reliability of the studied NAAT-based SARS-CoV-2 rapid test as (very) positive; a small fraction of the participants ($\leq 10\%$) judged these items as (very) negative (Figure 1). The interpretability of the test results was evaluated as (very) positive by the majority (>80%) of the physicians and medical assistants. Interestingly, the required (i) patient information and disclosure and (ii) personnel expenses associated with the use of the SARS-CoV-2 rapid test were judged more positively by the medical assistants in comparison to the physicians (Figure 1).

As reported by the majority of the surveyed medical staff (physicians: 63.5%, medical assistants: 81.8%) the NAAT-based SARS-CoV-2 rapid test was successfully integrated into the practice

routine (Figure 2). However, one physician (9.1%) and one medical assistant (4.5%) tended to disagree that the rapid test was successfully implemented. In a qualitative interview, the physician in question explained the difficulties in integrating the rapid test with the fact that only four tests could be performed per hour (given the turnaround time of up to 15 min) and that a lot of time was required for the medical assistants performing the measurements. Especially during periods with a large number of suspected COVID-19 cases, it was difficult to successfully integrate SARS-CoV-2 rapid tests into the practice routine. From this physician's point of view, it was easier to implement PCR laboratory tests in the daily practice routine due to reduced workload and a higher sample turnover. In line with this statement, only half of the surveyed medical staff (54.5% among physicians and medical assistants, respectively) agreed that the turnaround time of the studied rapid test is appropriate, while the remaining participants neither agreed nor disagreed (27.3% among physicians and medical assistants, respectively) or disagreed (18.2% of the physicians and 13.6% of the medical assistants) (Figure 2).

The vast majority of physicians (72.7%) and medical assistants (81.2%) agreed that they would wish to continue using the NAAT-based SARS-CoV-2 rapid test in the future. The great majority of the surveyed healthcare providers (90.9% of all physicians and medical assistants, respectively) agreed that they trust in the test results (Figure 2). In line with this notion, six out of ten physicians (60.0%) rated the diagnostic accuracy of the ID NOW™ COVID-19 rapid test as equivalent to a SARS-CoV-2 PCR laboratory test; one physician (10.0%) perceived the rapid test as less accurate than the PCR laboratory test. Most physicians (80.0%) rated the diagnostic accuracy of the ID NOW™ COVID-19 rapid test as better than a SARS-CoV-2 antigen test.

Moreover, the majority of physicians (63.6%) and medical assistants (77.3%) agreed that the use of a NAAT-based SARS-CoV-2 rapid test improves communication with patients, although 18.2% of the participating physicians and medical assistant disagreed with this statement (Figure 2). Importantly, nine out of eleven physicians (81.8%) agreed that the use of SARS-CoV-2 rapid tests helped to avoid further laboratory tests. These physicians reported that the use of SARS-CoV-2 PCR laboratory tests was reduced. Additionally, savings in testing for C-reactive protein and blood count were mentioned by three and two physicians, respectively.

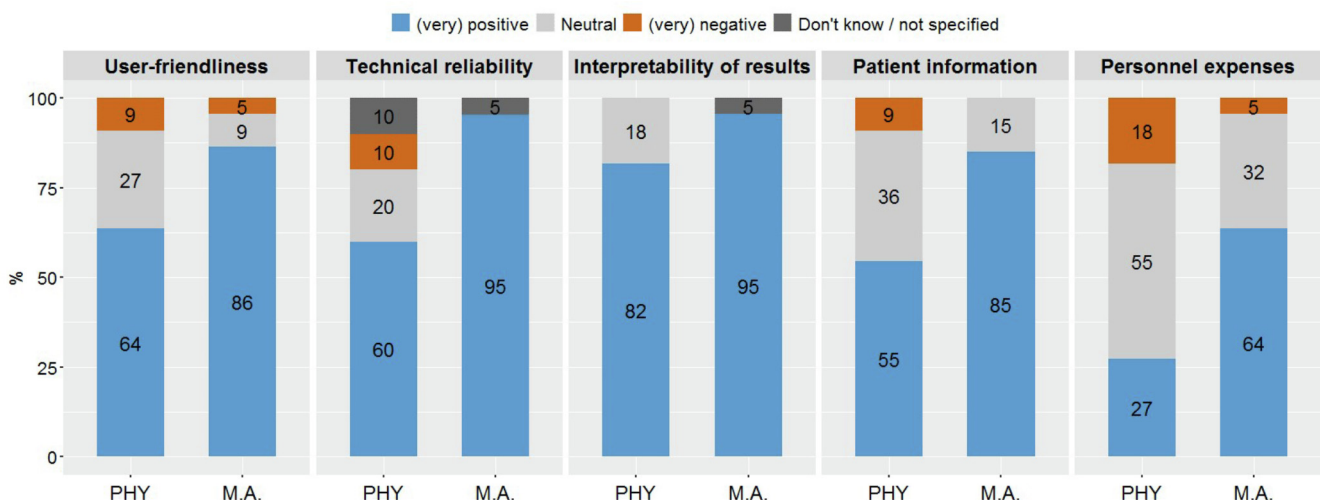


Figure 1. Judgements on aspects concerning the implementation of the NAAT-based SARS-CoV-2 rapid test by physicians (PHY) and medical assistants (M.A.).

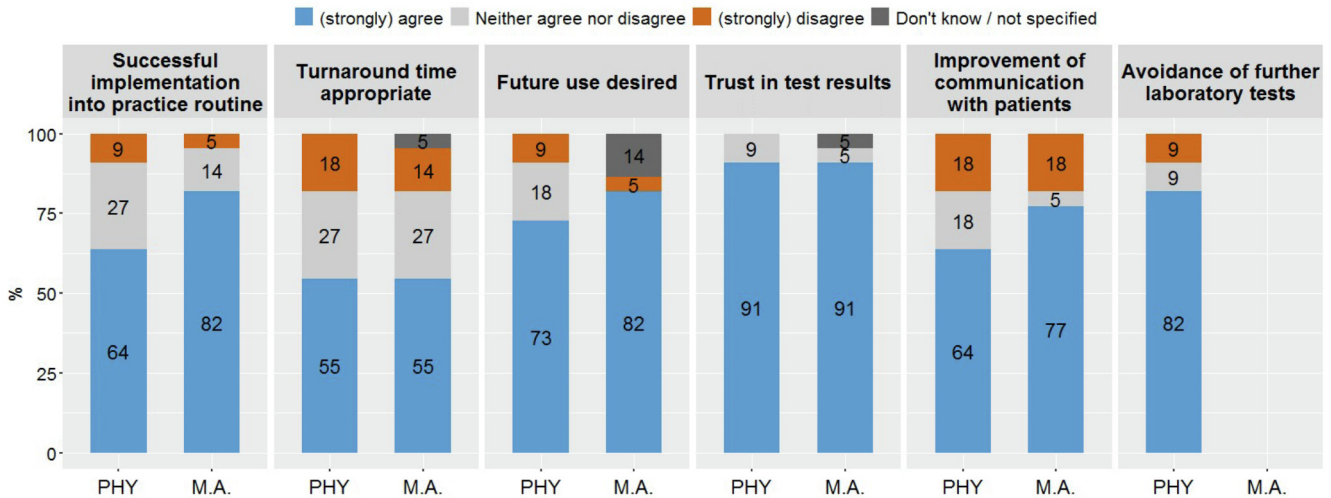


Figure 2. Degree of agreement on aspects concerning the implementation of the NAAT-based SARS-CoV-2 rapid test by physicians (PHY) and medical assistants (M.A.).

Perceived advantages and disadvantages of the use of a NAAT SARS-CoV-2 rapid test

Participating physicians stated prompt advice on home quarantine (90.0%), immediate information on appropriate symptom monitoring and follow-up (90.0%), and avoidance of additional patient contacts (80%) as main advantages of the use of NAAT-based SARS-CoV-2 rapid tests compared to a PCR laboratory tests. Moreover, physicians saw the possibility to initiate therapies immediately (50%) and time savings (60%) as further advantages. Two of the four physicians interviewed highlighted the importance of immediate availability and communication of test results, which led to organizational consequences such as workflow changes, avoidance of further laboratory tests or notification to local health authorities. The other two physicians interviewed emphasized the impact for their patients, especially if they were very anxious, had difficulties in self-quarantine or had important activities planned, such as a business trip or a holiday.

The majority of medical assistants cited the possibility to initiate therapies immediately (72.7%), prompt advice on home quarantine (68.2%), and avoidance of additional patient contacts (63.6%) as advantages of the use of SARS-CoV-2 rapid tests over PCR laboratory tests.

When asked for disadvantages of the use of NAAT-based SARS-CoV-2 rapid tests compared to a PCR laboratory tests, most physicians named the greater workload (70.0%) and the costs of the test cassettes and measuring device (70.0%). Four out of ten physicians (40.0%) rated the lower sample turnover as unfavourable. Other disadvantages, each mentioned by one physician, include the greater effort required during consultation and the amount of waste generated.

In contrast to the participating physicians, medical assistants less often perceived a higher workload and a lower sample turnover (27.3% each) as disadvantages of the use of NAAT-based SARS-CoV-2 rapid tests. The costs of the test cassettes and the measuring device were mentioned as a disadvantage by about half (54.5%) of the medical assistants. In addition, two medical assistants each reported the amount of waste generated and the long warm-up phase of the measuring device as further disadvantages.

Discussion

From March until April 2021, in the midst of a SARS-CoV-2 high incidence phase, the use of a NAAT-based SARS-CoV-2 rapid test in routine primary care was evaluated within general and paediatric

practices in Thuringia, Germany. Healthcare providers from ten of the 13 pilot practices participated in our survey. Our study shows that NAAT-based SARS-CoV-2 point-of-care testing could be implemented successfully into routine care. The rapid tests gained widespread acceptance among participating physicians and medical assistants and had a far-reaching impact by influencing workflows in primary care practices.

User-friendliness, result interpretation and technical reliability of the ID NOW™ COVID-19 rapid test were evaluated predominantly positive by the healthcare providers. Likewise, Hahn et al., showed that the staff from a large public health laboratory in the United States with varying degree of laboratory experience judged the ID NOW™ COVID-19 rapid test as *intuitive, associated with high user test success, and could be implemented by staff after minimal training* [16].

Although real-time PCR laboratory tests are viewed as the gold standard in SARS-CoV-2 diagnostics, their results are available with a profound delay of hours or days. POCTs, particular those based on nucleic acid amplification techniques, therefore represent serious alternatives to prevent delays in result availability [10,17]. Due to its diagnostic accuracy local healthcare authorities in Thuringia have officially approved results from the ID NOW™ COVID-19 rapid test as equivalent to PCR laboratory tests, highlighting its potential to substitute time-consuming laboratory tests. In line with this, participating physicians reported several advantages of NAAT-based SARS-CoV-2 rapid tests over PCR laboratory tests. In particular, the possibility of prompt advice on home quarantine (self-isolation), immediate information on appropriate symptom monitoring and follow-up, and the avoidance of additional patient contacts were mentioned. The physicians interviewed pointed out that the main benefit of the use of a SARS-Cov-2 rapid test was the fast transmission of results, which led to immediate consequences not only for practitioners and caregivers, but also for patients and their contacts. The German government has recognized the benefits of NAAT-based SARS-CoV-2 rapid testing and is funding the manufacturing of NAAT-based rapid test devices and test kits in Germany [18]. It remains to be seen to what extent this initiative will affect the availability and costs of NAAT-based rapid testing in the future.

However, our study also identified challenges concerning the implementation of NAAT-based SARS-Cov2 rapid tests in routine primary care. Some respondents considered the test duration of up to 13 minutes and the warm-up phase as critical. The test costs and the greater workload compared to a PCR laboratory test were

cited as additional inhibiting factors to the implementation of the rapid tests, although only about a quarter of the medical assistants rated the workload as a disadvantage. Though, the results of our study show that the comparatively low sample turnover (four tests per hour per device) could be problematic, especially in times of high numbers of suspected SARS-CoV-2 cases. Based on this limitation, healthcare providers must decide which patients benefit most from NAAT-based SARS-CoV-2 rapid testing. According to the German national testing strategy, NAAT-based rapid tests are particularly useful where a relatively reliable test result is needed at the point-of-care, for example in the context of emergency wards, ambulatory care centres and nursing facilities [2]. Primary care physicians play a central role as gatekeepers to these care settings. Another integral part of the German national testing strategy is the use of NAAT-based rapid tests for confirmation in individuals whose current rapid antigen test is already positive [2]. This diagnostic approach takes advantage of the high specificity of NAAT-based rapid tests [9,10]. However, citizen tests were not widely available at the time of the survey.

Overall, our study shows that the use of NAAT-based SARS-CoV-2 rapid tests can influence the workflow in primary care practices. For example, according to the physicians, the use of rapid tests reduced further laboratory tests. Primarily, this applies to the initiation of SARS-CoV-2 PCR laboratory tests, but savings in C-reactive protein and blood count tests were also mentioned by the physicians. In addition, particularly medical assistants felt that point-of-care SARS-CoV-2 testing improved communication with patients.

The participating physicians and medical assistants showed a high level of confidence in the rapid test results, which is a prerequisite for possible future routine use. Similarly high satisfaction rates for the ID NOW™ COVID-19 rapid testing in preoperative patients were obtained in a Canadian cross-sectional survey among operating room staff [19]. In our study, the high level of satisfaction with point-of-care NAAT-based SARS-CoV-2 testing is underlined by the fact that the majority of the responding physicians and medical assistants would continue to use the studied rapid test in the future. In addition to the high level of satisfaction among healthcare providers, responding physicians and medical assistants also reported that the ID NOW™ COVID-19 rapid test showed a high acceptance among patients.

Strengths and limitations

Our study is the first study that evaluated the use of a NAAT-based SARS-CoV-2 rapid test in primary care in Germany. One strength of our study is that point-of-care NAAT-based SARS-CoV-2 testing was evaluated in a real-world setting by different primary care practices during a SARS-CoV-2 high incidence phase, which increases the external validity of our study. A further strength is that we also investigated the experiences and perspectives of medical assistants. Medical assistants are involved in conducting point-of-care diagnostics in primary care practices and thus, the experiences and acceptance among this often overlooked group is pivotal for a successful implementation of POCTs. However, our study faces some limitations. The evaluation of the use of a NAAT-based SARS-CoV-2 rapid test only included 13 primary care practices. Healthcare providers from three of the 13 pilot practices did not return the questionnaires. Reminders to non-participants were not successful. Consequently, we were only able to survey a relatively small sample size (11 physicians and 22 medical assistants), which limits the transferability and generalizability of our study to some extent. However, the included practices represent a certain degree of heterogeneity observed in primary care in Germany since they were located in both rural

and urban regions and represent different types of practices. On the other hand, we cannot exclude a selection bias, since only particularly interested practices with potentially high research affinity participated in the piloting of the rapid tests within the Thuringian primary care setting.

No standardized and validated templates were available for our research objectives. We therefore designed custom questionnaires, but without external validation, systematic literature review, or item selection. However, the questionnaires were piloted by primary care physicians and researchers with expertise in cross-sectional surveys. In addition, recall bias needs to be considered, although the survey took place immediately after the eight-week pilot phase of the rapid test. The perceived feasibility and usability may be lower if evaluators had not received prior training in how to use the platform properly. As generally associated with interviews and written surveys about personal attitudes and experiences, we can exclude neither over- nor underestimation of the reported figures with regard to social desirability, acquiescence or estimation inaccuracy. Over the course of the pandemic, different virus variants emerged, testing strategies were adjusted, vaccination rates increased, and new treatment options were introduced. Since the ID NOW™ testing devices were available to the primary care practices only during the duration of the pilot study, we cannot assess the extent to which these and other contextual factors influence healthcare providers' attitudes towards NAAT-based SARS-CoV-2 rapid tests.

Conclusion

Our survey among primary care healthcare providers shows that the ID NOW™ COVID-19 rapid test is user-friendly, technically reliable and feasible. Point-of-care NAAT-based SARS-CoV-2 testing gained widespread acceptance among physicians and medical assistants, positively influences workflows, can improve patient communication and could therefore be implemented successfully into routine primary care. However, ID NOW™ COVID-19 rapid tests do not appear to be suitable for screening large numbers of asymptomatic subjects because of their limited sensitivity at low viral loads and the fact that only one test can be performed at a time. The low sample turnover and pre-test probability could be addressed by using NAAT-based rapid tests in specific situations, such as confirmation of SARS-CoV-2 infections in patients with positive rapid antigen tests. In sum, point-of-care NAAT-based SARS-CoV-2 testing represents an alternative to often time-consuming PCR-based laboratory testing in primary care. Since the results of our survey represent only a snapshot in an ongoing pandemic, future studies should examine the extent to which changing contextual factors (e.g., viral variants, testing regulations, vaccination rates, treatment options) affect the relevance and acceptance of NAAT-based SARS-CoV-2 rapid test in the primary care setting.

Conflict of Interest

All authors declare no financial or non-financial interests that are directly or indirectly related to the work submitted for publication. The cross-sectional survey was performed by members of the Institute of General Practice and Family Medicine, Jena University Hospital. The test kits including the analysing platform were provided by the manufacturer (Abbott Diagnostics Scarborough, Inc., USA). The manufacturer was not involved in survey design, data collection and analysis as well as decision to publish any obtained data.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.zefq.2022.09.006>.

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