

RESEARCH ARTICLE

Performance and feasibility of universal PCR admission screening for SARS-CoV-2 in a German tertiary care hospital

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Abstract

Anamnestic screening of symptoms and contact history is applied to identify coronavirus disease 2019 (COVID-19) patients on admission. However, asymptomatic and presymptomatic patients remain undetected although the viral load may be high. In this retrospective cohort study, all hospitalized patients who received polymerase chain reaction (PCR) admission testing from March 26th until May 24th, 2020 were included. Data on COVID-19-specific symptoms and contact history to COVID-19 cases were retrospectively extracted from patient files and from contact tracing notes. The compliance to the universal testing protocol was high with 90%. Out of 6940 tested patients, 27 new severe acute respiratory syndrome coronavirus-2 infections (0.4%) were detected. Seven of those COVID-19 cases (26% of all new cases) were asymptomatic and had no positive contact history, but were identified through a positive PCR test. The number needed to identify an asymptomatic patient was 425 in the first wave of the epidemic, 1218 in the low incidence phase. The specificity of the method was above 99.9%. Universal PCR testing was highly accepted by staff as demonstrated by high compliance. The costs to detect one asymptomatic case in future studies need to be traded off against the costs and damage caused by potential outbreaks of COVID-19.

KEYWORDS

admission screening, COVID-19, infection control, SARS-CoV-2, testing strategy

1 | INTRODUCTION

Since the end of February 2020, coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) belonging to the family *Coronaviridae*, genus *Betacoronavirus*, species *Severe acute respiratory syndrome-related coronavirus* has spread extensively worldwide. As no vaccination against SARS-CoV-2 is yet available, stringent infection control measures are needed to prevent nosocomial COVID-19 outbreaks, which have been described on several occasions.¹⁻³

Although the use of personal protective equipment is essential to protect staff, efficient separation of COVID-19 patients from non-infectious patients protects both patients and staff. Identification of COVID-19 patients can partly be achieved by the anamnestic screening of typical symptoms and close contact with previously diagnosed COVID-19 patients. However, patients with undetected infections who display mild or no symptoms remain undetected by clinical triage and pose a particular challenge in preventing SARS-CoV-2 spread in hospitals.^{4,5} This is of high importance as the viral load was described the highest in presymptomatic and newly symptomatic COVID-19 patients.⁶

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Universal testing for SARS-CoV-2 using nucleic-acid-amplification tests has been described for distinct patient groups such as pregnant women, stroke patients, or before interventions⁷⁻¹² as well as for a smaller sample size¹³ but to our knowledge not yet for the entire patient population of a large hospital with several thousand patients.

2 | MATERIALS AND METHODS

2.1 | Aim of the study

The aim of this study is to evaluate the potential and feasibility of universal testing to detect SARS-CoV-2 infections among asymptomatic patients.

2.2 | Universal admission testing program

A 1438-bed tertiary care hospital in Germany, located in the state of Bavaria, implemented a universal admission polymerase chain reaction (PCR) testing program for SARS-CoV-2 starting on March 26th, 2020. The program was launched in addition to the assessment of all inpatients and outpatients for COVID-19-typical symptoms as well as previous contacts to COVID-19 patients during the 14 days before admission which was recommended by the National Public Health Institute, the Robert Koch-Institute.

2.3 | SARS-CoV-2 testing

Detection of SARS-CoV-2-RNA by real-time reverse transcriptase PCR was conducted routinely at the Institute for Virology and Immunobiology using primers and probes located in the SARS-CoV-2 E-gene as described by Corman et al.¹⁴ and alternatively using the test kit FTD SARS-CoV-2 (Siemens Healthineers) according to the manufacturers' instructions. C_t -values below 35 cycles were assessed positive, C_t -values between 35 and 40 cycles weakly positive. The PCR was terminated after 40 cycles.

2.4 | Study design and data collection

In this retrospective, observational study hospital admissions between March 26th and May 24th were included. Data on all SARS-CoV-2 tests performed in the virological laboratory were merged with patient admission data using unique case numbers representing one admission of a patient. Oropharyngeal swabs taken within two days before or after a patient's admission were considered to be admission testings as swabs were taken one or two days before elective admissions in some departments, on the day of admission and missed testing swabs were caught up on during the

days after admission. Multiple swab results of individual cases were consolidated. In the case of conflicting test results, the positive result was counted. Testing was conducted irrespective of a previous COVID-19 diagnosis.

Data on COVID-19-specific symptoms and contact history to COVID-19 cases were extracted from patient files.

The number of daily SARS-CoV-2 infections were obtained from the public records of the Robert Koch Institute (the German public health institute), using the Robert Koch-Institute Covid-19 dashboard.¹⁵ Case numbers in the federal state of Bavaria and in the hospital's main catchment area, the government district of Lower Franconia, where 73% of all hospital patients came from in 2018, were selected for comparison. Data on incidence by age in the Bavarian population was obtained from the Bavarian Health and Food Authority.¹⁶ Data on population demographics was obtained from the Bavarian Statistical Office.¹⁷

Calculation of costs for PCR assays was conducted using the German doctors' fee schedule EBM.¹⁸

2.5 | Statistical analysis

During the study period, the German government started implementing extensive social distancing measures for the population on March 21st. Considering a maximum incubation period of 14 days for SARS-CoV-2 infection, the measures were estimated to take full effect on the infection rate by April 4th.¹⁹⁻²² Thus, the interval from the beginning of the policy until April 4th was assigned to the first wave of the COVID-19 pandemic in Germany while the interval after April 4th represented a low incidence setting. The positivity rate in tested patients during the first wave and in the low incidence setting was compared by Fisher's exact test.

2.6 | Ethics approval and consent to participate

The Ethics committee of the University of Würzburg after viewing the design of the study waived the need to formally apply for ethical clearance because routine data of the clinical information system were to be retrospectively evaluated (University of Würzburg, Ethics committee, #20200507 06).

3 | RESULTS

3.1 | Study population

As expected, the age distribution in the hospital admission cohort differed substantially from the general Bavarian population. As observed elsewhere, the COVID-19 incidence was highest in the Bavarian age strata 80-89 and above 90 years (see Figure 1).

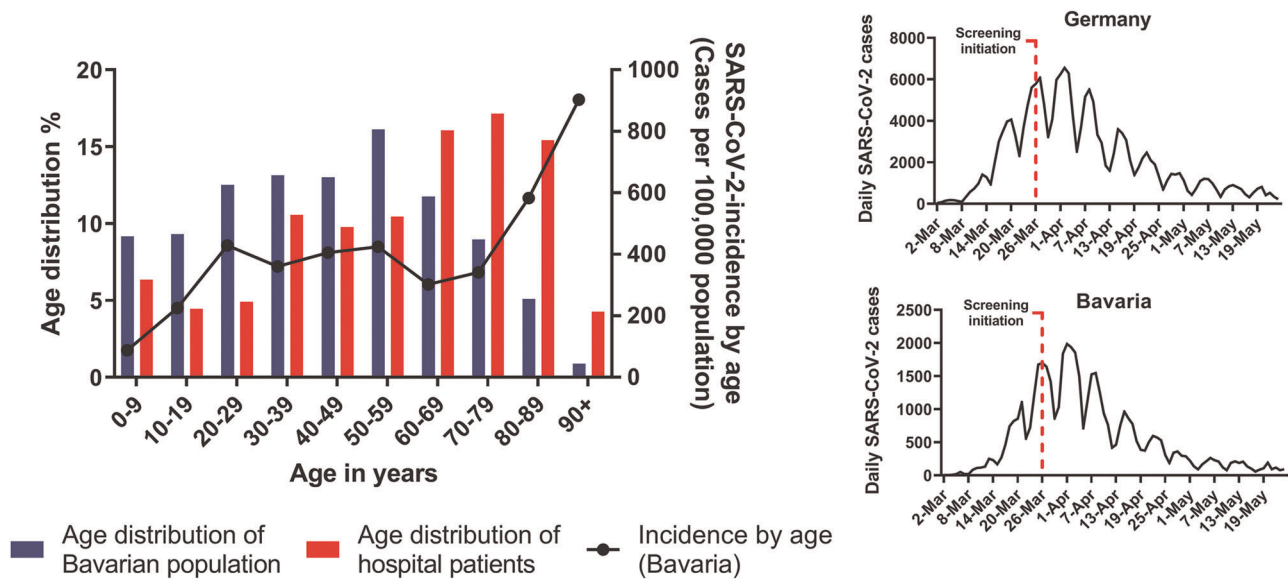


FIGURE 1 Hospital demographics, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) incidence by age and national and local epidemiology. A, Red bars show age distribution of hospitalized patients during the study period. Blue bars show age distribution of the Bavarian population as of December 31st, 2018. Black line shows the SARS-CoV-2-incidence by age in the Bavarian population until May 25th, 2020. B, Daily detected SARS-CoV-2 infections in Germany. Red line shows the date of general testing implementation. C, Daily detected SARS-CoV-2 infections in the federal state of Bavaria. Redline shows the date of general testing implementation. Public data was obtained from the Robert-Koch Institute, the Bavarian Ministry of Health, the Bavarian Statistical Office^{15–17}

3.2 | Testing results

From March 26th to May 24th, 2020, 6940 hospitalized patients were tested at admission using an oropharyngeal swab. For patients who tested positive, the patient files were retrospectively assessed for symptoms and contact history. Sixty patients tested positive for SARS-CoV-2. Thirty-three of these positive cases had been diagnosed with SARS-CoV-2 infection in this hospital or other healthcare facilities before the implementation of universal testing and were not considered for further analysis. The PCR testing detected 27 previously unknown SARS-CoV-2 infections representing 0.4% of all tested patients. 16 out of 27 detected cases presented with symptoms of a respiratory tract infection at the time of hospital admission, eleven appeared asymptomatic regarding COVID-19-related symptoms. Out of the symptomatic patients, six reported close contact with a confirmed COVID-19 patient in the 14 days before symptom onset while the other ten did not report any exposure to the virus. Out of the eleven asymptomatic newly detected COVID-19 patients, two patients recalled exposure to a SARS-CoV-2 infected person in the 14 days before admission, while nine patients did not report any contact. One completely asymptomatic patient with a weakly SARS-CoV-2 PCR test result probably did not have an acute, newly acquired infection, but rather a persistence of SARS-CoV-2 RNA in oropharyngeal specimens following a recent, unrecognized infection as IgG antibodies directed against SARS-CoV-2 were detected in five different serological tests. Prolonged PCR positivity has been described many weeks after symptom onset despite complete symptom resolution and absence of viable virus, which has only been isolated

until approximately one week after the first symptoms.^{6,23,24} Like in every diagnostic test, there may also be false-positive SARS-CoV-2 PCR tests as one asymptomatic patient was SARS-CoV-2-PCR-negative in seven consecutive swabs as well as seronegative for antibodies directed against SARS-CoV-2 (see Figure 2).

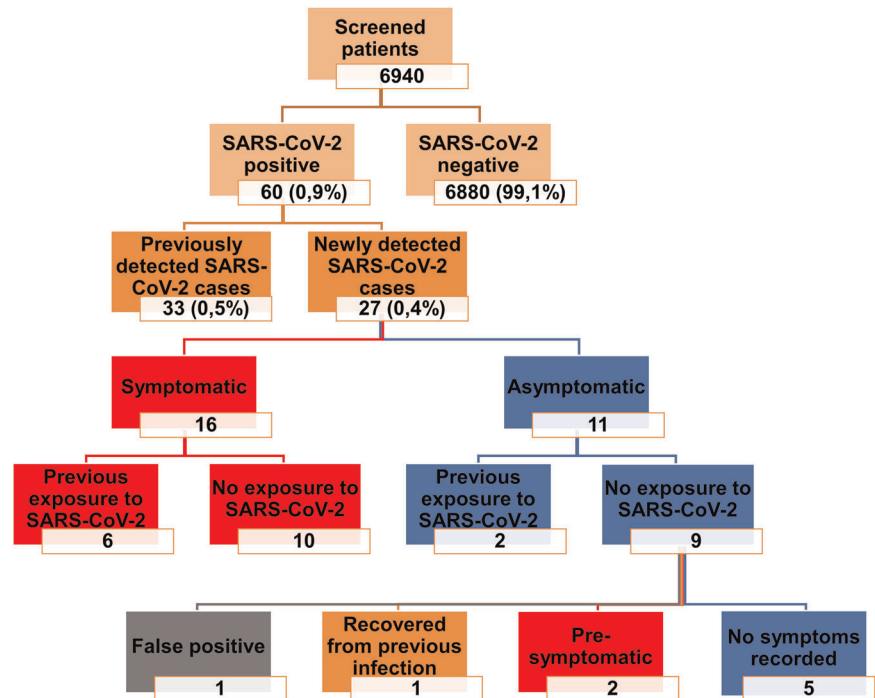
Only one false positive in 6940 tested patients indicates a specificity of the test of 99.9% or above.

The seven clinically undetectable acute SARS-CoV-2 PCR positive patients were hospitalized in five different departments: one in the departments of general surgery, one in the department of otorhinolaryngology, three in the department of gynaecology, and two in two different departments of internal medicine. Six of the seven were female, the average age of the clinically undetectable patients was 52.1 years compared to 52.0 years in all tested patients.

Characteristics of the 11 asymptomatic SARS-CoV-2-positive patients are shown in Table 1.

The proportion of hospitalized patients covered by universal testing measures increased from 83% in the first week to 98% in the last week of the study period. Overall, 90% of all patients were covered by the testing, indicating the high compliance of staff. Further analysis of SARS-CoV-2 positive cases shows a shift regarding clinical characteristics of positively tested patients over the course of time. Most new cases early in the study period reported clinical features indicative of a higher probability of infection such as previous contact with a COVID-19 patient or typical COVID-19 symptoms. Later in the study period, most new SARS-CoV-2 cases reported no such features, appeared asymptomatic at presentation, and were exclusively identified through a positive PCR test.

FIGURE 2 Polymerase chain reaction (PCR) testing results from March 26th till May 24th, 2020. The 6940 patients were tested for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) using quantitative reverse transcriptase PCR. Displayed percentages refer to the total number of 6940 patients



Accordingly, the weekly positivity rate of universal testing results declined from 2.1% in the first week 13 of the program to 0% in week 21 (see Figure 3).

3.3 | Accordance with the epidemiology in the general population

Statistical comparison of the frequency of positive results before and after this intervention shows a significantly higher SARS-CoV-2 positivity rate from March 26th till April 3rd compared to the testing period after April 4th (1.41% vs. 0.25% positive test results). The number needed to identify an asymptomatic patient was 425 in the first wave of the pandemic, and 1218 in the low incidence phase (see Figure 4).

In the hospital's catchment area Lower Franconia, the incidence rate declined from more than 60 weekly cases per 100,000 population to less than 5 weekly cases per 100,000 population.

3.4 | Costs of the universal PCR testing on admission

In this setting, the average testing costs were approximately 58,469 € per newly detected asymptomatic SARS-CoV-2 patient (59 € per SARS-CoV-2 PCR test) differing significantly between the first wave (25,075 € per newly detected asymptomatic SARS-CoV-2 patient) and the low incidence setting (71,862 € per newly detected asymptomatic SARS-CoV-2 patient). The total costs of universal testing including 393 redundant oropharyngeal swabs amounted to 432,647 € for the entire observation period.

4 | DISCUSSION

The implementation of universal SARS-CoV-2 testing proved effective in identifying otherwise undetectable infections in patients at the admission level. The measure, therefore, reduced the risk of unknown exposure of patients and health care workers to SARS-CoV-2. However, the costs of the program were high especially in the low-incidence phase, and the number needed to screen to identify one case increased to 1218.

The most important measure to detect COVID-19 infections on admission was the interview of all patients regarding symptoms and contact with COVID-19 cases. 67% of cases were theoretically detectable through clinical triage and targeted testing. During the first three weeks, 90% of new COVID-19 patients could actually be identified by asking for symptoms and previous contact with a confirmed COVID-19 patient. This highlights the importance of clinical triage that other studies have demonstrated to be effective in concentrating and separating suspected and definitive SARS-CoV-2 infections in a designated hospital area.²⁵⁻²⁸ Studies investigating clinical triage to prevent transmission of MERS-CoV and SARS-CoV-1 in hospitals support the concept of screening for clinical criteria and contact history as well.^{28,29}

Still, one in three detected cases was asymptomatic and identified only through universal PCR testing. In particular, in the second half of the study period, asymptomatic COVID-19 patients represented the majority of newly detected cases. The reason for this is unclear and may be related to different age groups affected, seasonal effects or the more widespread use of face coverings. Nevertheless, there is substantial evidence that viral shedding and disease transmission occur during the asymptomatic or presymptomatic period of

TABLE 1 Characteristics of the 11 asymptomatic SARS-CoV-2 positive patients

No.	Date of detection	Age strata (years)	Sex	Admission diagnosis	Contact history (14 days before admission)	Development of symptoms	C _t -value on initial PCR	Additional findings	Assessment
1	2020-03-27	80-89	Male	Acute coronary syndrome	Yes	8 days later	37.03	7 PCR-positive swabs	Presymptomatic COVID-19
2	2020-04-23	60-69	Female	Syncope	Yes	Admission day	27.92		Presymptomatic COVID-19
3	2020-03-28	60-69	Female	Ovarian cancer	No	1 day later	31.31	1 PCR-positive swab	Presymptomatic COVID-19
4	2020-05-13	40-49	Female	Chronic sinusitis	No	Admission day	36.08		Presymptomatic COVID-19
5	2020-03-27	60-69	Female	Syncope	No	No	26.50	3 PCR-positive swabs	Asymptomatic COVID-19
6	2020-04-16	30-39	Male	Splenic artery aneurysm	No	No	30.11		Asymptomatic COVID-19
7	2020-04-26	50-59	Female	Atrial fibrillation	No	No	32.33		Asymptomatic COVID-19
8	2020-04-27	60-69	Female	Endometrial cancer	No	No	31.41	COVID-19 contact 17 days before admission	Asymptomatic COVID-19
9	2020-05-12	30-39	Female	Miscarriage	No	No	33.26		Asymptomatic COVID-19
10	2020-05-13	50-59	Male	Hyperaldosteronism	No	No	35.66	3 PCR-negative swabs, serology positive	Recent COVID-19 infection
11	2020-04-16	70-79	Male	Multiple myeloma	No	No	33.35	7 PCR-negative swabs, serology negative	Probably false positive

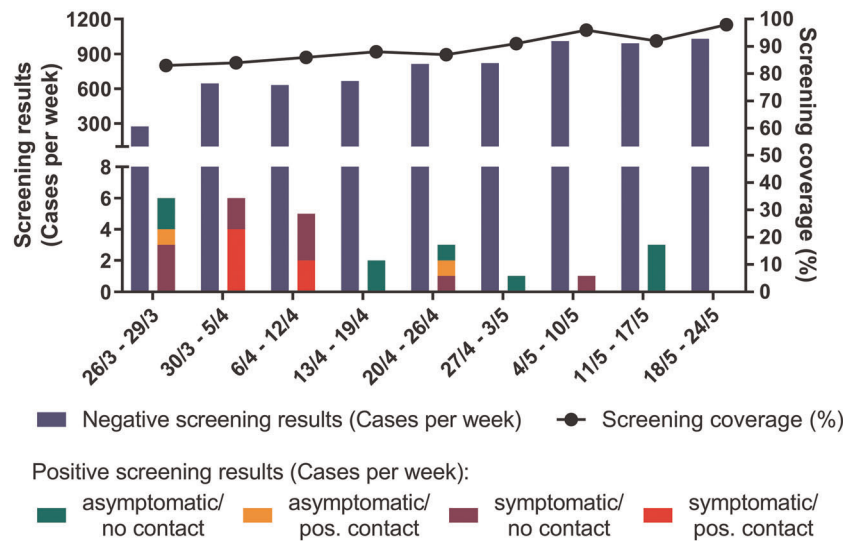


FIGURE 3 Polymerase chain reaction (PCR) testing results per week. The x-axis shows calendar weeks starting with incomplete calendar week 13. Bars are plotted on the left y-axis which is interrupted to better accommodate the range of values. Blue bars show all weekly negative PCR testing results. Multicoloured bars show positive PCR testing results divided into indicated groups characterized by the presence/absence of symptoms and positive/negative contact history. The black line plotted on the right y-axis shows weekly coverage rates of universal testing defined as the proportion of hospitalized patients who received severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing

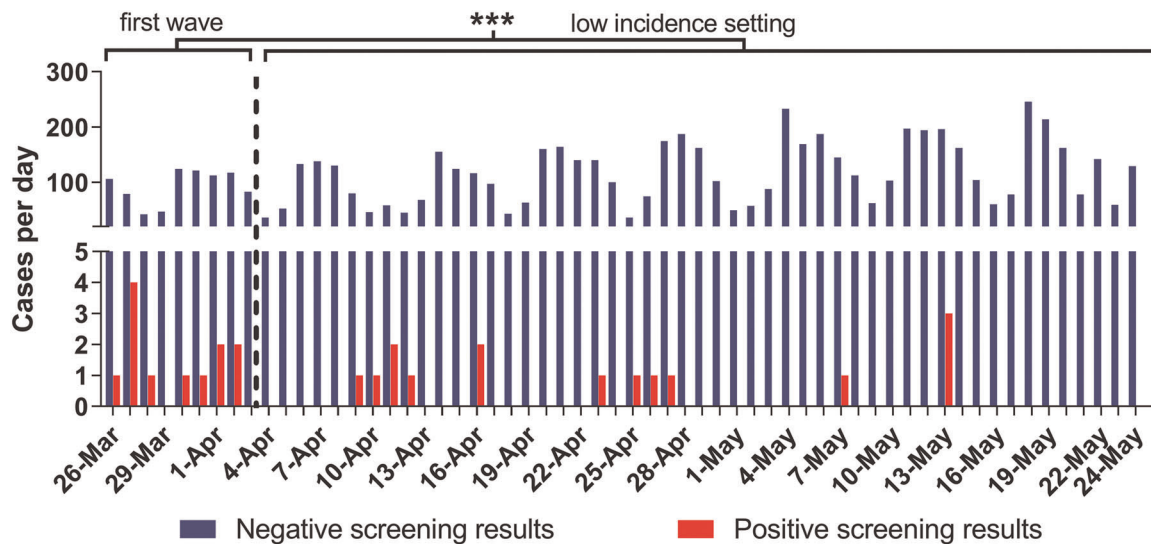


FIGURE 4 Polymerase chain reaction (PCR) testing results and local epidemiology following social distancing interventions. Blue bars show the absolute number of daily negative PCR testing results. Red bars show the absolute number of daily positive PCR testing results. Y-axis is interrupted to better display the range of values. Vertical dotted line indicates the border between the first wave of the pandemic and the low incidence setting when social distancing measures were taking full effect on the epidemic on April 4th, two weeks after their implementation (March 21st). *** $p < .001$ in a two-tailed Fisher's exact test comparing positive testing results before and after April 4th

the disease.^{6,30,31} In fact, various studies have demonstrated that many SARS-CoV-2 infections are transmitted during the pre-symptomatic phase and that transmission can precede the development of symptoms by several days indicating high contagiousness of these individuals.^{4,32,33} Thus, detecting these patients early in the presymptomatic period appears to be particularly important to effectively control disease transmission, especially when the prevalence is unknown, and infections are rising.

The high proportion of symptomatic patients at the beginning of the study period can be explained by ongoing outbreaks in the hospital's catchment area, especially in nursing facilities. In the context of these outbreaks, patients can be expected to report more vigilantly about possible exposure and typical COVID-19 symptoms which improves the probability of positive clinical screening. Later, when the outbreaks were contained, and infections spread more inconspicuously clinical triage probably was less effective in the

absence of obvious red flags such as current outbreaks and more patients were classified as asymptomatic and without recent exposure to SARS-CoV-2. The number-needed-to-screen to detect one additional truly asymptomatic case was 991 in this study and the associated costs amounted to an estimate of 58,469 €. In contrast, nosocomial transmissions of SARS-CoV-2 by an undetected SARS-CoV-2-positive patient may lead to costs to treat the infected patients, but also indirect costs by ward closures and reputation losses. These can rapidly amount to several hundred thousand euro. In addition, morbidity and mortality in the affected patients must be considered. As the University Hospital of Würzburg treats 70,000 inpatients per year, about 70 asymptomatic cases could be detected considering the current prevalence of SARS-CoV-2 infections. Reliable detection of these patients of whom at least a part showed at least moderate Ct-values in the PCR assay provides reassurance for health care workers and benefits all hospital patients' and their safety. However, future studies should assess the cost-benefit ratio, by quantifying the gain achieved by avoiding potential transmissions.

Health care workers' compliance with carrying out the testing procedure was remarkably high resulting in more than 90% coverage of patients throughout the study period. Previous research on factors influencing health care workers' adherence to infection control measures shows that organizational and environmental factors are particularly important in this context. Health care workers are more likely to implement preventive measures if they are easy to understand, implement, and perceived as beneficial for their own safety.³⁴⁻³⁶ It appears that the simple and concise design of universal testing compared to more complex risk-stratified screening strategies contributed to its success in a workplace environment that emphasizes health care worker safety and is able to provide the necessary resources. Moreover, studies on the SARS-1 pandemic have shown that implementing appropriate organizational strategies to prevent infections is protective of adverse mental health outcomes in health care workers.^{37,38}

Furthermore, this study observed a significant decline of newly detected cases among hospital patients in parallel with the trend in the local population following the implementation of extensive social distancing measures in Germany.¹⁵ Although further studies on the efficacy of social distancing measures for the prevention of SARS-CoV-2 transmission need to be conducted, our findings are in accordance with previous studies showing a reduction of new COVID-19 cases following the introduction of various non-pharmaceutical interventions.³⁹⁻⁴²

Considering the observed correlation between the epidemiology of SARS-CoV-2 infections among hospital patients and the general population, a cautious deduction about the epidemiology in the general population can be inferred from the hospital data. Although the SARS-CoV-2 incidences among hospital patients were higher than in the general population, SARS-CoV-2 infections might be rather overrepresented among them compared to the general population for two reasons. First, older people are strongly overrepresented among hospital patients and the incidence rate of COVID-19 in Germany increases progressively with age.^{15,16}

Secondly, people with COVID-19 related symptoms are more likely to seek health care services than healthy individuals leading to a clustering of COVID-19 patients in hospitals. Taking this into consideration, it is probable that the cumulative incidence of 0.4% positive cases in this universal testing indicates a low prevalence of both documented and undocumented infections in the local population and may contradict the assumption of massive underreporting in the German population. This observation is in contrast to results from admission SARS-CoV-2 testing data among distinct groups in high incidence settings,^{7,10,11} which resulted in a 11% to 15% positivity rate, implying a positive correlation between SARS-CoV-2 positivity rate in hospital admissions and local infection prevalence as well. Our data suggest that universal PCR testing on hospital admission may function as an early warning system for changes in the COVID-19 epidemiology in the population.

One must be aware of the pretest probability and the chance of false-positive results, especially of nontargeted testing. Repeating tests, preferably on various platforms, reduces the chance to report false-positive results. Rapid testing for IgG antibodies in asymptomatic patients with a positive test result is recommended to rule out the possibility of earlier silent infection, especially if cycle threshold values are very high. Although in this retrospective study not all test results could be confirmed by repeat testing, the number of false-positive cases was very low among 6,940 screened patients, indicating a specificity of the methods of above 99.9%. Test specificities have not been reported before.

The admission testing may also miss potentially infective SARS-CoV-2 patients: False-negative results may occur due to incorrect sampling or the limited sensitivity of every diagnostic test. As universal testing is only performed once per patient, patients in the incubation period at the time of the testing may become infective during their stay. Transmissions by undetected SARS-CoV-2-positive staff and visitors may also cause nosocomial infections. Additional tests of patients who become symptomatic despite testing SARS-CoV-2 negative on admission may detect a proportion of these. In a high incidence setting, even regularly (e.g. weekly) universal testing of all patients may be useful, but the benefit must be traded off for the additional costs.

Limitations of our data arise from the identification of testing data: As admission swabs were not marked as such, all oropharyngeal swabs taken within two days before and two days after admission were identified as belonging to the universal testing. Data on symptoms, and previous COVID-19 contacts were only evaluated for SARS-CoV-2 positive patients as the systematic electronic recording of this information had just started in the middle of the study period and this data had to be extracted manually from medical notes. As this study was conducted in a low incidence country with a high number of SARS-CoV-2 tests in the general population, these results are only partially transferable to settings with a high prevalence of COVID-19 or limited availability of COVID-19 tests. The retrospective design of the study did not allow further analysis of the clinical impact of SARS-CoV-2 detection in asymptomatic patients.

The universal PCR testing for SARS-CoV-2 has been continued through manuscript submission for several reasons. These include

the high acceptance in staff and patients and the positive impact on health workers' and patients' feeling of safety. In addition, reports of large COVID-19 outbreaks in other hospitals cemented the decision to continue the universal testing.

5 | CONCLUSIONS

PCR-based testing on admission is an effective component of the detection of SARS-CoV-2 infections. Applying it to all patients facilitates the testing procedure, as evidenced by the high coverage achieved at our hospital. The cost-benefit ratio needs to be further studied considering the dynamic epidemiological situations. A marked decline of COVID-19 incidences in the population argue against the continuation of such programs for economic reasons and because of the higher likelihood of false-positive results. On the other hand, re-opening of hospital services after lock-down bears specific risks of COVID-19 transmission due to the increasing number of individuals assembling in healthcare facilities. This risk might be addressed by the continuation of admission testing.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Ulrich Vogel and Manuel Krone designed and coordinated the study. Sören Krüger, Patricia Schuller, Ulrich Vogel, and Manuel Krone collected epidemiological, organizational, and clinical data. Christiane Prifert and Benedikt Weißbrich performed laboratory investigations. Sören Krüger, Miriam Leskien, Ulrich Vogel, and Manuel Krone analyzed and interpreted the data. Sören Krüger and Manuel Krone drafted the manuscript. Miriam Leskien, Patricia Schuller, Christiane Prifert, Benedikt Weißbrich, Ulrich Vogel contributed to the writing of the paper.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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