

SARS CoV-2 Surveillance and Exposure in the Perioperative Setting with Universal testing and Personal Protective Equipment (PPE) Policies

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Key Points: Pre-procedure SARS CoV-2 PCR positivity rate on surveillance testing declined with limited community spread. Most individuals who tested positive were asymptomatic and with a low viral RNA. Low attack rates were observed in HCW exposed to unrecognized cases.

Abstract

Background: New York City (NYC) experienced a surge of COVID-19 cases in March and April 2020. Since then, universal PCR based surveillance testing and PPE measures are in wide use in procedural settings. There is limited published experience on the utility and sustainability of PCR based surveillance testing in areas with receding and consistently low community COVID-19 rates.

Methods: The study was conducted at a tertiary care cancer center in NYC from March 22, 2020, until August 22, 2020. Asymptomatic patients underwent SARS CoV-2 testing before surgeries, interventional radiology procedures, and endoscopy. Contact tracing in procedural areas was done if a patient with an initial negative screen re-tested positive within 48 hours of the procedure.

Results: From March 22 until August 22, 2020, 11,540 unique patients underwent 14,233 tests before surgeries or procedures at MSKCC. Overall, 65 patients were positive, with a peak rate of 4.3% that fell below 0.3 % after April 2020. For the 65 positive cases, three were pre-symptomatic, and 38 were asymptomatic. Among asymptomatic test-positive patients, 76 % had PCR cycle threshold (Ct) > 30 at first detection. Five patients tested newly positive in the immediate post-operative period, exposing 82 employees with one case of probable transmission (1.2%).

Conclusion: The prevalence of SARS-CoV-2 infection identified on pre-procedural surveillance was low in our study, which was conducted in an area with limited community spread at the later stage of the study Universal PPE is protective in procedural settings. Optimal and flexible diagnostic strategies are needed to accomplish and sustain the goals of comprehensive pre-procedure surveillance testing.

Key Words: SARS CoV-2, COVID-19, surveillance, surgery

Introduction

Procedural areas are high-risk settings for exposure to unrecognized cases of Severe Acute Respiratory Syndrome Coronavirus -2 (SARS CoV-2) infections (1). In regions with rising community spread, there is a higher likelihood of pre-symptomatic individuals or those with mild coronavirus disease 2019 (COVID-19) presenting for surgery and other interventions (2, 3). Several professional societies endorse testing for SARS CoV-2 before surgery and other invasive procedures to reduce the risk of transmission to healthcare workers and avoid post-surgical complications from COVID-19 in patients (4). Because false-negatives may occur with testing, CDC recommends universal Personal Protective Equipment (PPE) measures, including use of N95 masks for aerosol-generating procedures (AGPs) in places with medium to high community transmission (4-8). The guidelines are less clear about surveillance testing strategies when the regional prevalence of SARS-CoV-2 subsides.

On March 1, 2020, New York City (NYC) confirmed the first case of coronavirus disease 2019 (COVID-19). The regional epidemic peaked in mid-April, and, since then, the city has witnessed a sustained daily low case count through the phased reopening (9). By March 10, 2020, Memorial Sloan Kettering Cancer Center (MSKCC), a cancer center located in New York City, had developed polymerase chain reaction (PCR) testing for COVID-19. On March 22, pre-procedure testing was implemented for patients before all procedures: major surgery, interventional radiology procedures, and endoscopy.

This report summarizes a single center experience with pre-procedure testing as the COVID-19 epidemic evolved in NYC. We also describe a series of exposure events to healthcare workers (HCWs) originating from patients who underwent a procedure after testing negative by SARS CoV-2 PCR and who were later found to have laboratory-confirmed SARS-CoV-2 infection within two days after the procedure.

Methods

MSKCC is a tertiary care cancer center with 42 operating rooms (OR) and 14 interventional radiology (IR) procedure rooms across the metropolitan area, including NYC, New Jersey, and Westchester County, NY.

SARS CoV-2 PCR testing was done within 48 to 72 hours of the scheduled surgery, interventional radiology procedures, or endoscopy (collectively referred to as procedures). Those without viral detection underwent further symptom screening on the day of procedure assessing for COVID-19 like symptoms and recent contact with laboratory-confirmed cases. For patients who tested positive, postponement of non-urgent procedures was as per clinician's discretion regardless of COVID-19 symptoms. Urgent procedures proceeded with the CDC recommended precautions. All non-hospitalized patients who tested positive were followed daily by a dedicated COVID Cohort Management Team (CCMT) as described elsewhere (10). CCMT monitoring continued until 14 days had elapsed since the last positive test, and the patient remained symptom-free or until clinical resolution of symptoms for at least three days. Data on symptoms over the follow-up period was extracted from CCMT or hospital medical records. Patients were classified as follows: 1) "pre-symptomatic" were clinically well at the positive test time but subsequently developed signs and symptoms of COVID-19; 2) "symptomatic" had symptoms at the time of the positive test; 3) "asymptomatic" patients had no compatible symptoms or illness at the time of the positive result or in subsequent 14-day follow-up period."

Contact investigation proceeded as follows: Index patients identified by PCR testing were investigated for their location at the time of test collection, symptoms and onset date, roommates, and HCW who provided direct care. All exposed individuals received an e-mail notification to complete a post-exposure survey that determined their level of risk based on use of PPE, duration, and intensity of exposure, as defined by the Centers for Disease Control and Prevention (CDC) (8). The recommendation for surveillance testing for

significant exposures was after 5-7 days and 14 days following the index event. Independent of contact tracing efforts, this survey was also completed by any employee for self-reported exposures in the community or to co-workers. All symptomatic employees underwent testing immediately regardless of the intensity of or time post exposure.

Universal PPE at the center included masks for all clinical care activities starting March 20, 2020, with the addition of face shields on April 22, 2020. N95 respirators were used for all AGPs (7). Beginning on April 13, all hospitalized patients also underwent surveillance testing every three days.

Laboratory methods

Nasopharyngeal (NP) swab samples were collected using flocked swabs (Copan Diagnostics) and placed in viral transport media. SARS-CoV-2 RNA was detected using either a laboratory-developed test (LDT) based on the CDC protocol targeting two regions of the nucleocapsid gene (N1 and N2) (11), the Xpert Xpress SARS-CoV-2 test (Cepheid, Sunnyvale, CA) targeting the N and E gene or the cobas SARS-CoV-2 test (Roche Molecular Diagnostics, Indianapolis, IN) targeting the ORF1 a/b and E gene. Samples were reported as positive if both the N1 and N2 targets were detected for the LDT and as per the manufacturers' instruction for the Cepheid and Roche tests. The cycle threshold (Ct) value was retrieved from the instrument records. The Ct value is the PCR cycle number in the early exponential phase of the PCR reaction at which the target amplification signal crosses the baseline threshold above the background fluorescence. The Ct value is inversely proportional to the amount of target viral RNA in the PCR reaction. As the difference between the Ct values for the two targets in each assay and between all three tests were small (within $\pm 1-2$ Ct; data not shown), Ct value analysis were focused on one target (Target 1: N1, N or ORF).

SARS-CoV-2 IgG were measured using the Abbott Architect SARS-CoV-2 IgG (Abbott Laboratories, Abbott Park, IL) an EUA cleared, automated, qualitative, chemiluminescent,

microparticle immunoassay on the Architect platform (12). The assay targets the nucleocapsid protein of SARS-CoV-2 to detect IgG in serum and plasma samples.

Statistical analysis

Cycle threshold values by groups were reported as means with standard deviation. The Mann-Whitney-Wilcoxon test was used to estimate the median difference between the symptomatic and asymptomatic test positive patients.

The MSKCC Institutional Review Board granted a Health Insurance Portability and Accountability Act waiver of authorization to conduct this study.

Results

Pre-procedure surveillance test results, symptoms, and cycle threshold

From March 22 until August 22, 2020, 11,540 unique patients underwent 14,233 tests before procedures at MSKCC. Overall, 65 patients were positive, with a positivity rate of 0.6% (range 0.2-4.3%). This rate declined substantially after the peak phase of the epidemic as COVID-19 cases in the NYC community decreased (Figure 1A). As a comparison, the positive test rate for NYC and overall rates at the study institution are shown in graphs 1B and C, respectively.

For the 65 positive cases, 24 were symptomatic at the test time, three were pre-symptomatic, and 38 were asymptomatic and remained symptom-free for 14 days after the test. Procedures were postponed for 57/65 patients. Figure 2A shows the number of test-positive patients and rate over time. The mean Ct value of the target 1 for symptomatic and asymptomatic patients were 27.18 ± 5.8 (SD) and 32.91 ± 5.3 (SD), respectively, $p < 0.001$ (Figure 2 B). For patients testing positive in the post-peak phase (May-August), only 6/25 (24%) had a cycle threshold < 30 at the time of the positive test (Figure 3). Through the entire study period, 9/38 asymptomatic test positive patients had a Ct < 30 at detection. Anti-SARS CoV-2 antibody test was available for 17 patients; one had concomitant antibody

testing on the same day as the pre-procedure PCR test and was positive for both. For the remaining 16 patients, tested at a median of 51 days after the PCR test, 10/16 (63%) were seropositive.

Contact investigation for cases detected within 48 hours of procedures

Amongst 11,475 patients with an initial negative pre-procedure test, five (.04%) subsequently tested positive in the immediate post-operative period (day 0 to day 2). All were in the pre-symptomatic (n=1) or symptomatic (n=4) phase of the illness. One expired within four days of diagnosis and the other four recovered uneventfully. Table 1 details the procedural description of the five index cases and the contact investigation results. Overall, 84 HCWs were in close contact with these five individuals in procedural suites (Table 1); 2/84 with prior laboratory-confirmed COVID-19 illness were excluded. The remaining 82 HCWs received the self-evaluation survey, 55 completed the questionnaire, 48 reported symptoms and/or significant exposure. These 48 employees received 52 tests in the monitoring period. The median time from exposure to the first SARS CoV-2 PCR test was five days (range 1-14). Out of the employees without prior COVID-19 (n=82, total; 48, tested), four were positive in the follow-up period: 1/36 asymptomatic, and 3/12 of symptomatic employees tested positive.

Among the four HCWs who were positive, one was symptomatic before the exposure occurred. Two newly positive employees had completed the survey due to other significant unprotected HCW to HCW exposures. A detailed risk assessment showed that both, a nurse in the recovery area room and a radiology technician, had followed universal PPE guidance during the patient encounter, but had extended unprotected contact during a HCW to HCW interaction; the latter was considered the probable transmission event. One patient care technician with limited contact to an unmasked index patient during the pre-operative assessment, and with no other known high-risk activities occupational or community-based

exposures, developed symptoms and tested positive for SARS-CoV-2 five days after this exposure.

No incident cases of SARS COV-2 were diagnosed in any of the other exposed employees regardless of the monitoring period. Overall, we suspect that 1 out of 82 exposed HCWs developed COVID-19 due to patient exposure (1.2%).

Discussion

As the COVID-19 epidemic evolved in NYC between March and August, the overall risk gradient of pre-procedural SARS CoV-2 positivity was 4.3% at the height of the pandemic (March- April) and fell below 0.3 % after April, corresponding with a steady decline in test positivity rate in NYC (Figure 1 A-C). Only 3/65 test positive patients (4.6%) were pre-symptomatic. The post-peak phase had a higher proportion of asymptomatic individuals with positive tests. Most remained symptom-free in the follow-up period and had low amounts of viral RNA (cycle threshold > 30) at diagnosis, likely representing residual nucleic acid detection in the convalescent phase or possibly false positives PCR, although this cannot be conclusively determined in our study. We also demonstrate low transmission risk to HCWs from unrecognized cases in the perioperative setting (1.2%).

Our findings on the low transmission risk to HCW are similar to observations from other US medical centers where transmission from patients to HCW is only reported after extended contact and inadequate PPE (13, 14). Among the 82 employees exposed to the five patients, testing hinged upon completion of a risk assessment survey, 67% of exposed healthcare exposed workers in our study completed the evaluation, 59% received testing. The only healthcare worker with a probable transmission was in close contact with the index case when obtaining vital signs, during which the patient was not wearing a mask. Despite exposure to aerosolizing procedures, none subsequently developed an infection.

Pre-procedural testing for SARS-CoV-2 is universally applied in areas with substantial community transmission with short term postponement of surgery for those that test positive.

Besides that, universal PPE practices are standard across many centers. The prevention of HCWs becoming exposed to SARS-CoV-2 and minimizing postoperative COVID-19 complications in surgical patients is paramount. There is a broad consensus that widespread testing for SARS CoV-2 is essential to combat the COVID-19 pandemic by facilitating contact tracing efforts. However, it is vital to recognize the limitations of nucleic acid detection in asymptomatic individuals with declining COVID-19 community rates. A typical scenario where a positive PCR test lingers for weeks and months without clinical and epidemiologic consequence is woefully frequent in areas where the virus established a foothold several months before (15-17). A crucial question many centers are grappling with in the post-surge phase is whether the routine application of PCR -based surveillance is the appropriate test strategy when the probability of encountering long term RNA shedders supersedes the detection of new cases. At the same time, the looming risk of explosive resurgence requires continued vigilance. The application of a rapid and optimally sensitive antigen test in asymptomatic individuals could achieve the purpose of identifying those who are most likely to be in the early and contagious phase of the illness. PCR testing can be reserved for confirmation and symptom-based testing to circumvent the lower sensitivity of other assays and higher chances of false-positive results in low disease prevalence areas(18-20).

It is also essential to remain aware that the large-scale PCR based testing of asymptomatic patients in regions with a low level of community spread might strain and divert necessary testing supplies away from areas experiencing a surge of COVID-19 cases. And, there are other potential negative consequences on routine laboratory operations. Most importantly, positive PCR test results from lingering RNA without a clinically apparent antecedent illness are complex to interpret, especially without readily available quantitative estimates or reliable serological assessment. Overly sensitive tests in recovered individuals can trigger unnecessary contact tracing efforts, quarantine, and lead to care delays. In our experience,

most asymptomatic individuals with positive tests remained symptom-free and demonstrated low amount of viral RNA at detection, especially in the post-peak phase.

There are several limitations to our study. For pre-procedural testing, the combined interpretation of PCR results with cycle threshold value, presence of symptoms, past illness, and antibody status may be more informative in these scenarios to infer infectivity and acute vs. convalescent phases of infection. Viral culture is the current gold standard to infer infectiousness but not readily accessible or safe for routine use. We based many of our study findings on cycle threshold values, which are not standardized across assays and have substantial inter-assay variability. Cycle threshold is a useful estimate of viral RNA in clinical practice (21), with low Ct a good proxy for infectivity when interpreted in conjunction with other relevant clinical and laboratory data (22-25). Our study is derived from a single specialized center in New York City, and the findings may not be generalizable. Disparities in infection rates within the same geographic area are essential considerations when devising local test strategies.

For contact investigation, only 59% of exposed employees accepted testing for contact investigation, but we followed all exposed for symptomatic illness. We may have possibly missed transmission events that resulted in mild or asymptomatic infections where HCW were either tested too early or not tested. The risk assessment that guided testing was based on self-reported symptoms, and PPE adherence was not measured. The desire for immediate testing may have influenced employee responses to the survey.

This report adds to the literature that PPE substantially mitigates the risk of COVID-19 transmission from unrecognized contagious cases in procedural settings. Healthcare centers should reexamine the utility of widespread pre-surgical SARS Cov-2 testing with PCR assays when background infection rates are low. It is vital to devise and invest in nimble and alternative surveillance test strategies that can quickly adapt to the scale of local community spread and are easy to interpret in all settings.

Conflicts of interest and financial disclosures

DK reports that her spouse serves on the Scientific Advisory Boards of Vedanta Biosciences and Opentrons and does consulting work for Takeda.

None for all other authors.

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Table and Figure legends

Table 1. Case characteristics of five index patients who tested positive for SARS CoV-2 in the immediate post-operative period (48h) after an initial negative pre- procedure test. The number of exposed and tested healthcare workers is shown with one case of probable transmission *

Figure 1. Pre-procedure test positivity rate at the study institution [MSK] (A), NYC regional test positivity rate during the same time (B), and among all tested patients at the study institution (C)

Figure 2. Pre-procedure test positive cases by month and symptoms (A), PCR cycle threshold at detection (B)

Figure 3. Cycle threshold value distribution for Target 1 by symptoms and time (month)

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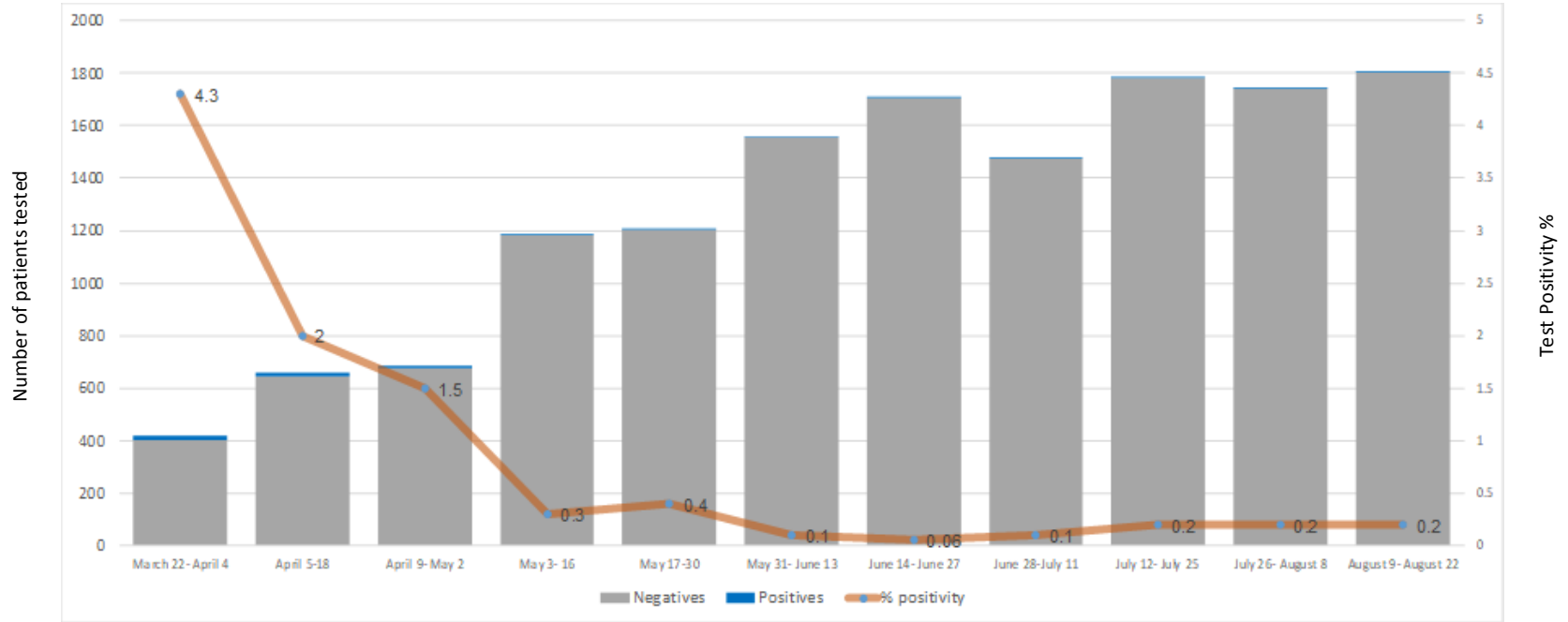
Table 1. Case characteristics of five index patients who tested positive for SARS CoV-2 in the immediate post-operative period (48h) after an initial negative pre- procedure test. The number of exposed and tested healthcare workers is shown with one case of probable transmission *

Setting/ Month	Procedure and duration AGP (Y/N)	Index Case diagnosis (post-operative day) and symptoms	Index case PCR cycle threshold at diagnosis for Target 1	Number of exposed HCW, tested [%]	Number of exposed HCW with a positive SARS CoV-2 PCR Test Within 14 Days (Attributed transmission)
OR /March	Laparoscopic hysterectomy 2 h 39 m Y	Day 0, Symptomatic	18.42	20, 12 [60%]	1 (0)
OR / March	Glossectomy, cervical lymphadenectomy 5 h 22 m Y	Day 1, Asymptomatic	23.24	20, 12 [60%]	2(1*)
OR/ April	Nephrectomy 3 h 53 m Y	Day 2, Symptomatic	13.65	14, 8 [57%]	0
IR / April	Liver needle biopsy 0 h 51 m N	Day 1, Symptomatic	16.86	17,10 [59%]	1(0)
OR / May	Cystectomy 5 h 18 m Y	Day 1, Symptomatic	33.43	11, 6 [55%]	0

OR, operating room; IR, interventional radiology; AGP, aerosol generating procedure; Y, yes; N, no; N/A, not applicable

Figure 1, Pre-procedure test positivity rate at the study institution [MSK] (A), NYC regional test positivity rate during the same time (B), and among all tested patients at the study institution (C)

A



B

New York City



C

MSK

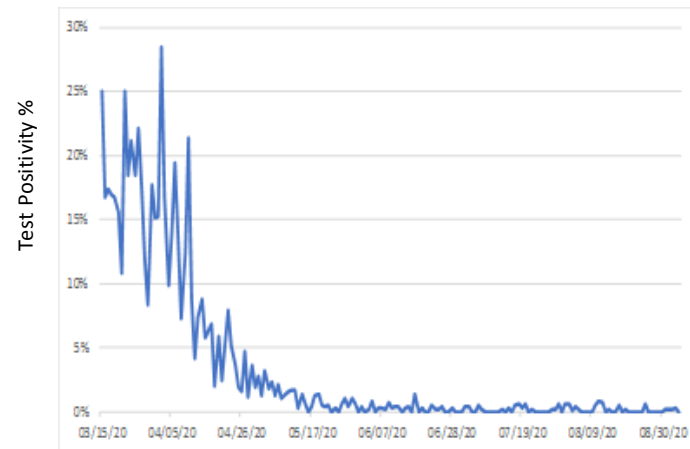
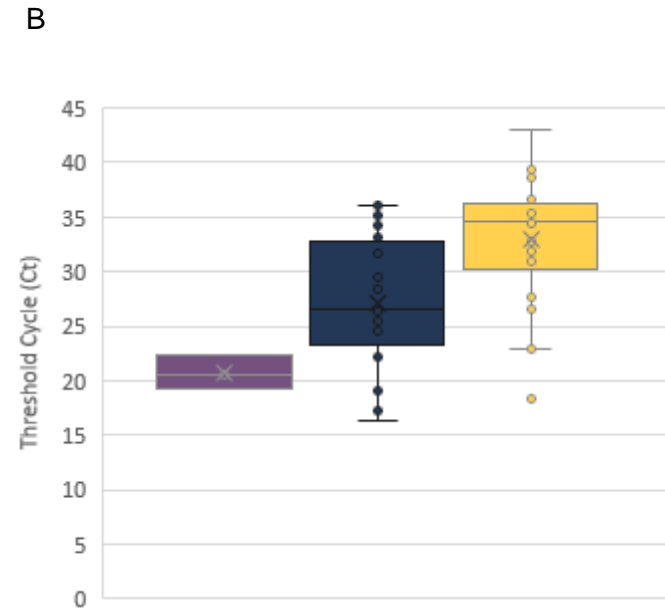
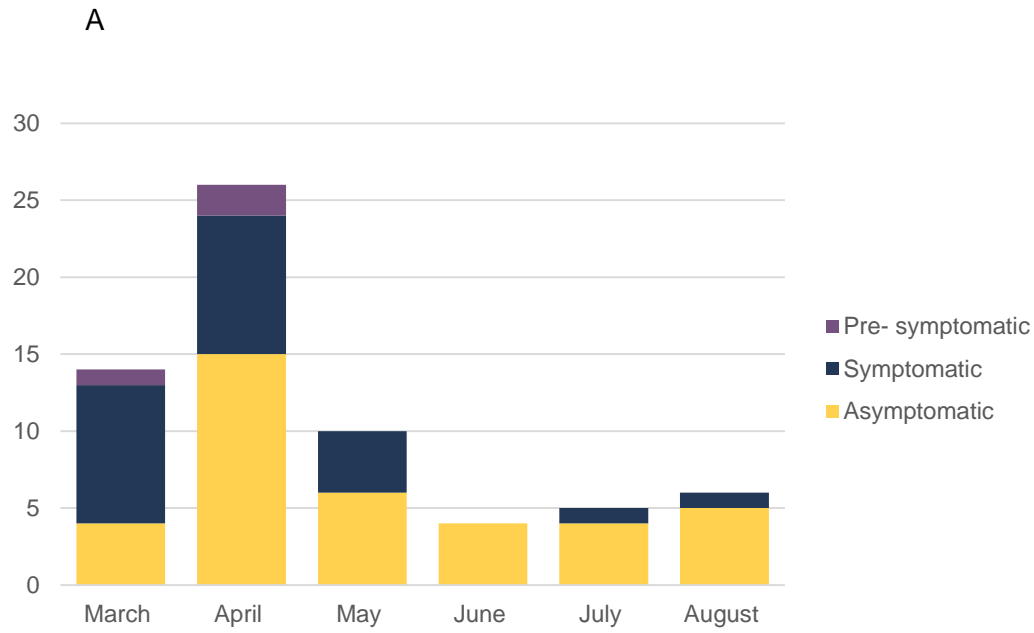


Figure 2. Pre-procedure test positive cases by month and symptoms (A), PCR cycle threshold at detection (B)



Symptomatic vs asymptomatic, $P < 0.001$

Figure 3. Cycle threshold value distribution for Target 1 by symptoms and time (month)

