

## ARTICLE

# Pre-Procedural Covid-19 Screening of Asymptomatic Patients: A Model for Protecting Patients, Community and Staff During Expansion of Surgical Care

Basil A. Ferenczi, MD, Chris Baliga, MD, Pascale Akl, MD, Alison Bradywood, RN, Craig Blackmore, MD, Michael Glenn, MD, Donna Smith, MD, Gary Kaplan, MD, John M. Corman, MD

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In response to the Covid-19 pandemic, Virginia Mason Medical Center committed to screen all asymptomatic patients prior to any surgical or procedural care, to facilitate care for patients who might otherwise be harmed by treatment delay, to help provide a safe care environment for procedural staff, and to allow significant conservation of N95 masks. While Covid-19 infections were almost nonexistent in this group during the study period, we will continue our screening policy as we resume offering discretionary procedures, to maintain a safe care environment.

## Introduction

The advent of Covid-19 in Washington State has led to unprecedented challenges as hospitals work to provide care for their communities in a manner that is safe for patients and staff, while simultaneously working to maintain limited inventories of personal protective equipment (PPE).

In order to conserve PPE and to ensure hospital capacity for Covid-19 infected patients, Washington State Governor Jay Inslee directed that all elective surgical procedures be suspended on March 19, 2020.<sup>1</sup> However, other urgent and emergent care needs still had to be met.

Early data indicated that the presence of typical Covid-19 presenting symptoms alone was insufficient to effectively screen patients, as a significant number of cases are asymptomatic at the time of presentation.<sup>2,3</sup> Some asymptomatic carriers never develop symptoms, yet still have the

potential to be a source of disease transmission.<sup>4</sup> It has also been established that endotracheal intubation and extubation can generate aerosols,<sup>5</sup> and per CDC guidelines, fit-tested N95 or higher respirators are required when caring for patients with suspected or proven infections transmitted by respiratory aerosols.<sup>6</sup> Providing fit-tested N95 masks to all procedural care staff is not a viable option given the acute international shortage of personal protective equipment.<sup>7</sup> To provide all procedural staff with N95 masks for scheduled interventional care, we estimate that our hospital supplies would be depleted within 5 days.

Another challenge is that the prevalence of Covid-19 in our community is not well understood. In highly populated areas such as New York, there are more than 1,700 confirmed infections per 100,000 people, compared with 235 confirmed infections per 100,000 people in Washington State.<sup>8</sup> Working to account for asymptomatic infections, a hospital-based screening study from New York demonstrated an active infection rate of 13.7% in screened patients.<sup>9</sup> Two seroprevalence studies from Santa Clara County and Los Angeles showed cumulative infection rates of 1.5% and 4.1% respectively.<sup>10,11</sup> Taken together, these studies demonstrate significant geographic variability in Covid-19 burden within the United States.

On April 1st, 2020, Virginia Mason Medical Center committed to screen all asymptomatic patients prior to any surgical or procedural care in order to facilitate care for patients who might otherwise be harmed by treatment delay. It was hoped that negative test results would help us provide a safe care environment for procedural staff. This intervention also allowed significant conservation of N95 masks. Finally, data on the rate of positive screening would provide insight into the prevalence of Covid-19 in King County, WA, in response to a request in the gubernatorial directive.

## Planning the testing program

Effective April 1, 2020 all asymptomatic pre-procedural patients, for both inpatient and outpatient procedures, were tested for Covid-19. Testing occurred within 48 hours prior to the scheduled intervention, or at the time of hospital admission. A nasopharyngeal swab specimen was collected and tested using the Abbott RealTime SARS-CoV-2 assay. Mid-turbinate testing was substituted for nasopharyngeal swabs on May 3, 2020 in accordance with expanded CDC sampling guidelines.<sup>12</sup> Patients who screened positive for Covid-19 were rescheduled to a later date.

In emergent situations, patients were screened with a rapid ePLEX SARS-CoV-2 test, which could provide results in 75 minutes. If a procedure was so emergent that it could not accommodate this delay, it was performed in a specially engineered negative air pressure “Covid pod,” utilizing Powered AirPurifying Respirators (PAPRs) or fitted N95 facemasks and eye protection.

PPE for patients who tested negative for Covid-19 included standard surgical masks and protective eye shields.

The Abbott RealTime SARS-CoV-2 assay is a real-time reverse transcriptase polymerase chain reaction (PCR) test that targets the RdRp and N genes and has a lower limit of detection of 100 copies/mL.<sup>13</sup> The ePlex SARS-CoV-2 assay is a nucleic acid amplification test that targets two regions on the N gene and has a limit of detection 10000 copies/mL.<sup>14</sup>

All cases were triaged into one of five tiers: Emergent, Urgent, Planned Procedure level 1, Planned Procedure level 2, and Discretionary Procedure. Emergent and urgent cases, as designated by the surgeon, were allowed to proceed. Purely discretionary procedures were not performed during the March 19 to May 18, 2020 prohibition period. The two tiers of planned procedures were reviewed by an independent multidisciplinary committee to determine whether any were discretionary. All procedures permitted to proceed were deemed necessary in that “a delay in performing the intervention could result in harm to the patient.” A total of 1,354 procedures were cancelled or delayed.

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Infection testing data were collected in a prospective fashion. Only asymptomatic patients were included in the analysis, defined initially as absence of fever, cough, or shortness of breath. On April 28<sup>th</sup> the criteria were made more rigorous by adding the absence of any combination of chills, rigors, myalgias, headache, sore throat, or new onset anosmia or loss of sense of taste. Patients undergoing all surgeries, transesophageal echocardiography, bronchoscopy, pulmonary function testing, and any intervention that required systemic anesthesia (with its inherent risk of mask ventilation and intubation) were screened.

Employee testing data was included for the same time period. Symptomatic staff with even vague or mild symptoms (including presence of fever or myalgia, and one of the following: cough, shortness of breath, chills, sore throat, respiratory congestion, diarrhea, GI symptoms) were tested for Covid-19 in order to prevent nosocomial transmission. Procedural staff tested included all those working in perioperative environments.

## Results

A total of 840 consecutive asymptomatic patients were screened between April 1, 2020 and May 6, 2020. Of these, 745 (89%) were tested in the outpatient setting, and 95 (11%) as inpatients or in the emergency department. 506 tests were completed using the RealTime SARS CoV-2 assay, and 334 using the rapid EPLEX test.

Of the 840 patients tested, three were Covid-19 positive (Table 1). All of these occurred in the fourth week of the test period. No patients tested positive for the first three weeks. There was no statistically significant difference for rate of positivity between weeks. Of the three Covid-positive patients, all had their surgeries rescheduled.

Prior to the April 1, 2020 initiation of pre-procedural Covid-19 screening, 17 procedural staff became symptomatic and were tested for Covid-19, and one tested positive. Since instituting widespread preoperative screening, nine staff have developed symptoms potentially indicating Covid-19 infection and have been tested. None of the tests were positive.

Table 1.

		Number of Patients Tested	Number Positive for COVID-19	% positive for COVID-19
Week 1	4/1-4/7	124	0	0
Week 2	4/8-4/14	139	0	0
Week 3	4/15-4/21	130	0	0
Week 4	4/22-4/28	202	3	1.4
Week 5	4/29-5/6	225	0	0
Total	4/1-5/6	820	3	0.4

Analysis of pre-procedural COVID-19 screening tests in asymptomatic patients: 0.4% of patients screened prior to procedural care between 4/1/20-5/6/20 were positive. Source: Virginia Mason Medical Center

“ Over the course of 5 weeks we performed 837 procedures on asymptomatic patients at Virginia Mason without a single documented case of Covid-19 amongst procedural staff.”

This study demonstrates the utility of pre-operative screening as a means to safely accommodate procedural and surgical care during the Covid-19 pandemic. Over the course of 5 weeks we performed 837 procedures on asymptomatic patients at Virginia Mason without a single documented case of Covid-19 amongst procedural staff. Staff were only tested if symptomatic, per institutional protocols. Of the 840 patients tested, 3 (0.4%) were positive for Covid-19 and all were safely rescheduled.

Recent studies have investigated the prevalence of Covid-19 and concerns regarding asymptomatic transmission. Bendavid et al. (2020) demonstrated the raw seroprevalence of Covid-19 antibodies in Santa Clara County to be 1.5% in early April, 2020.<sup>10</sup> Using screening data in obstetric patients admitted for delivery in New York, Sutton et al. (2020) showed a positive testing rate in 13.7%, with 87.9% of patients lacking any associated symptoms.<sup>9</sup> Although the Seattle area was the first region in America to identify a Covid-19 positive patient<sup>15</sup> and to have the first Covid-19 associated death,<sup>16</sup> infection and mortality rate have remained comparatively low.<sup>17</sup> Our data reaffirm this finding, with an overall positivity rate of 0.4% in asymptomatic patients. In areas with higher Covid-19 burden, other factors may lead to a decrease in ability to perform procedural care. These include a loss of available healthcare providers secondary to infection or diversion to Covid-19 wards, and greater need to conserve PPE. In this case the least urgent non-discretionary cases would be delayed while continuing to treat more acute disease processes in an attempt to limit harm to patients.

## Challenges

Several challenges emerged in the implementation of institution wide testing for Covid-19.

First, we recognized the need to separate operational flows of symptomatic versus asymptomatic patient testing to avoid nosocomial infections. Ensuring that patients who ultimately had a very low likelihood of being Covid-19 positive were sequestered from patients who were more likely to have the disease ensured that pre-procedural patients maintained their health without risk of undue exposure. The associated challenge was establishing parallel systems, which requires duplication of resources, redundant staff training, and having testing staff at multiple locations,

Second, integrating routine testing into existing processes turned out to be complex. We were able to leverage our institutional lean Virginia Mason Production System management model to identify resources and support tools such as flow mapping to minimize the impact to patients and staff. Through this approach we were able to integrate Covid testing into our pre-existing pre-operative anesthesia assessment clinic (PAAC) as the routine testing site for asymptomatic pre-procedural patients. Symptomatic patients were tested in designated respiratory clinic sites or in the emergency department. We considered community-based testing, but the reliability and critical timeliness of obtaining results led to the decision to perform testing in the hospital.

Importantly, we acknowledge that the impact of testing on individual patients is significant. Not only is an additional visit required for testing, but the test itself is uncomfortable and provokes anxiety. To address this, we have utilized testing as a shared decision-making opportunity to help patients to better understand the complexity of their care during a pandemic and to make informed decisions regarding interventional care. For example, a patient with a known low-grade malignancy must balance the risk of disease progression if left untreated with the theoretical risk of Covid-19 exposure by leaving the relative safety of one's home.

Third, we faced limits on our testing capabilities: reagents, swabs and media. To date, we have been able to support both the Abbott RealTime SARS-CoV-2 assay (8-hour turnaround time) and the EPLEX (2-hour turnaround) which has more limited capacity due to limited reagent availability. Triage of exceptions and hardship cases that required the shorter turnaround test remains a challenge in resource stewardship. As testing supplies and options become more readily available, faster turnaround will allow for more convenient care with lower risk of exposure because patients can undergo preoperative testing and procedural care during the same visit.

Finally, there is the issue of cost. Our institution has incurred a substantial financial impact with this screening program, though the precise impact is difficult to measure because of price fluctuations. We view this cost through the lens of expanded elective surgery and facilitation of staff confidence during patient care. As of April 5th, 12,252 healthcare workers in Italy tested positive for Covid-19, accounting for 10% of total cases.<sup>18</sup> The cost of employee absenteeism is profound, both to the individual and to the health care system. Workplace safety, work force availability, and prevention of nosocomial transmission to vulnerable hospitalized patients are key priorities.

## **Strengths and weaknesses**

This study has several important strengths. First, it demonstrates the viability of a safe screening approach to procedural care during the Covid-19 pandemic. After five weeks of testing, despite performing most procedures using basic PPE, we have seen no documented Covid-19 infections in procedural or surgical staff. This extent of time makes it unlikely that the lack of symptomatic, positive cases is due to a prolonged incubation period. Secondly, this prospectively collected data provides insight into the current burden of Covid-19 in the greater Seattle area. The infection rate, significantly less than 1%, suggests that exposure today in King County is low and implies the effectiveness of social distancing. Finally, although cases in King County have declined, other areas of the country are experiencing Covid-19 spikes with the end of stay-at-home orders. Arizona has seen a significant increase in cases, and is currently at approximately 80% hospital capacity.<sup>19</sup> As

health systems in different areas confront a significant increase in Covid-19 cases, pre-procedural screening in conjunction with patient triage is a safe model for treatment of patients requiring urgent procedural care.

There are several weaknesses in this study:

First, it was performed in a single institution during a time of suspension of discretionary surgical care. King County continues to have a relatively low prevalence of Covid-19 during the Safe Start reopening plan.<sup>20</sup> It is unclear whether our approach to procedural care could be replicated in locations with greater exposure.

Second, all screening was done on patients requiring non-discretionary procedures. This subset of the population is likely less healthy than the general population, more likely to have comorbidities, and therefore potentially more likely to manifest symptoms in the event of a Covid-19 infection. As such, they may be more likely to fall into a symptomatic, rather than asymptomatic cohort. If this is the case, we may see a higher rate of asymptomatic Covid-19 infections in the patient cohort undergoing discretionary procedural care.

Third, we do not know if the positive healthcare workers prior to the implementation of universal pre-procedural testing were infected from work or from the community. Documented incidence rates in the general community were highest at the inception of the screening program with a peak in confirmed cases in Washington State on 4/1/2020.<sup>20</sup> Finally, currently we are not testing asymptomatic procedural staff. Therefore, we cannot state the true prevalence of Covid-19 amongst our team.

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Despite significant challenges to patients and staff in implementation, we believe that preprocedural Covid-19 testing is a scalable intervention that will provide a means to safely care for our community. The primary limitation to implementation remains testing capacity - a universal obstacle. To date, we have been able to meet our testing needs, but as testing demands increase across our organization (in part fueled by increasing demands from medical and surgical specialty societies, often based more on speculation than evidence), we may well be challenged to meet broader testing volume requests. Were surgical volume to exceed testing capacity we would be required to reinstitute a triage process to ensure our ability to protect patients and staff. This process would begin with reduction in discretionary care. In order to avoid withholding procedural care in the future it is essential that testing capacity remains vigorous.

## Conclusion

As PPE levels have become more stable, the directive to suspend elective surgery in Washington State expired on May 18<sup>th</sup>, leading to a projected increase in surgical and procedural volumes.<sup>21</sup> This increase has occurred despite the absence of herd immunity or a functional vaccine. It is estimated that viral herd immunity only occurs when the immunity rate is above 70%.<sup>22</sup> Our observed levels of Covid-19 infection suggest that our community is well short of that prevalence. Furthermore, current estimates for development of a Covid-19 vaccine suggest that it will be many months before it is developed and widely available.<sup>23</sup> As elective procedural care is resumed, screening for Covid-19 infection prior to all surgical and procedural care seems to be a viable model to provide care in a manner that is safe for both patients and staff.

### **Basil A. Ferenczi, MD**

Urology Resident Physician, Virginia Mason Medical Center

### **Chris Baliga, MD**

Medical Director of Infection Prevention, Virginia Mason Medical Center

### **Pascale Akl, MD**

Medical Director Clinical and Anatomical Laboratories, Virginia Mason Medical Center

### **Alison Bradywood, RN**

Senior Director, Clinical Quality, Virginia Mason Medical Center

### **Craig Blackmore, MD**

Center for Health Care Improvement Science, Virginia Mason Medical Center

### **Michael Glenn, MD**

Chief Medical Officer, Virginia Mason Medical Center

### **Donna Smith, MD**

Executive Medical Director, Virginia Mason Medical Center

### **Gary Kaplan, MD**

Chairman/CEO, Virginia Mason Medical Center

### **John M. Corman, MD**

Senior Medical Director, Virginia Mason Medical Center

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