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The Trouble with Testing:

Navigating Uncertainty on the Road to Resuming Elective Surgeries

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As countries begin to re-open and the policies that once postponed elective surgeries slowly disappear, many are looking to establish a strong testing regime that will allow them to safely resume, business as usual. However, what happens when these tests are not available or the circumstances in which they are used effectively do not exist? Do we have a plan B? We examine the reliability and availability of different testing strategies, explore the procedures already being followed to resume elective surgeries, and provide insight for those still navigating this uncertainty.

Insights

- The ability to test for COVID-19 is an important factor in being able to resume elective surgical procedures.
- The availability of tests is greatly varied and can depend on access to chemical reagents and laboratory productivity.
- The reliability of most tests has yet to be validated.
- Molecular RT-PCR tests are considered the gold standard and are recommended over the use of less accurate, immunoassay tests.
- There is concern over how much hospitals should rely on test results given the availability and reliability concerns.
- Resuming elective surgeries should occur under specific circumstances and only when patient and staff safety will not be compromised.
- Operating room staff can minimize risks by considering each patient as potentially infected.In addition to widespread RT-PCR testing, safety guidelines should be followed and plans should be made to optimize the use of resources.

> "Testing is central to the effort to fight the spread of the virus. Countries that test widely can isolate infected people and prevent or slow new infections. Without early and widespread testing, health officials and policymakers will be flying blind. [1]"
>
> **Matt Apuzzo and Selam Gebrekidan**
> New York times, March 20, 2020

Testing is at the heart of reopening strategies worldwide and with good reason. Many experts agree that getting out in front of the virus is not possible unless you know who is infected.[1,7] For many health care workers, the idea of facilities returning to regular capacity is hard to imagine, and the steps required to get there are difficult to grasp. With restrictions only just starting to ease, one very important question remains. What exactly does back to 'business as usual' look like?

On May 4th, 2020, Stanford Health Care began resuming all surgeries, procedures and diagnostic tests that had previously been put on hold. In the first week, operations began at 50-60 percent capacity and were planned to be at full capacity within just three weeks.[2] This very confident resumption of procedures began with – you guessed it – testing. In the two weeks prior to their reopening, Stanford began testing all staff with the help of an in-house diagnostic test that was created back in March. More than 11,000 of 14,000 staff were tested (as of May 4th, 2020) with only 0.3 percent testing positive. There were also no reported cases of transmission from staff to patients.[2] This low infection rate, combined with strong safety measures and a steady supply of personal protective equipment (PPE), seems to have set a new standard for resuming elective procedures (**Exhibit 1**).

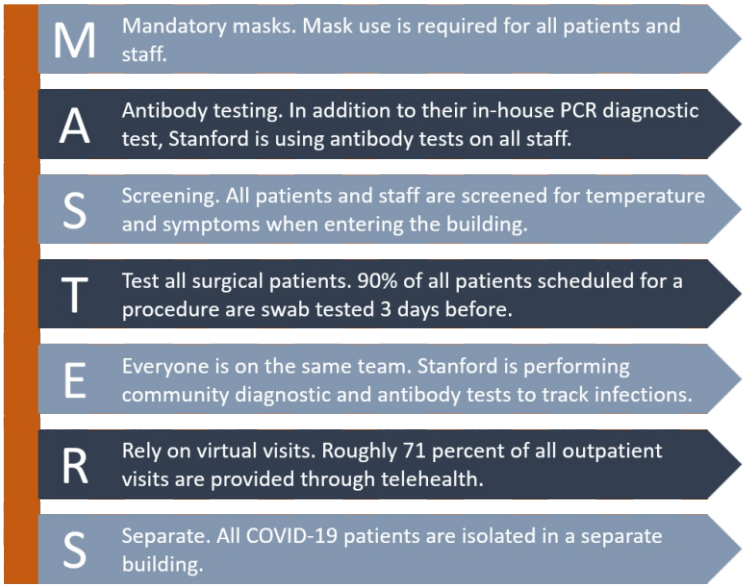

Exhibit 1: Stanford's Strategies to Becoming MASTERS In the fight against COVID-19

A large factor in this success, of course, is the knowledge that widespread testing provides. Simply knowing who is infected and who isn't is a very powerful way to inform decisions and plan ahead. However, like most golden standards, it is not so easily achieved.

The Trouble with Testing

Availability: The loosening of restrictions has helped speed along the production of testing kits worldwide, but countries still find themselves racing to procure chemical reagents, which are in increasingly short supply. As more and more countries look to increase testing capability, this demand will only continue to grow.

> "A core component of any reopening strategy is broad testing capacity to minimize resurgence of COVID-19, however, current restrictions on capacity and shortages of swabs and reagents force health systems to limit testing, prioritizing patients and front-line workers who are symptomatic. Even with these strict conservation protocols, capacity needs to at least triple before enough is available to support even a partial restoration of non-emergency services. This represents a major challenge to patient care, as an inability to offer elective procedures and diagnostics can mean a missed opportunity to detect preventable illnesses early or begin treatments that are necessary for health and wellness. [5]
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> **Michael J. Alkire**
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According to recent estimates, there is a global availability of roughly twenty million polymerase chain reaction (PCR) test kits per week.[3] To put this into perspective, a recent report suggested that the USA alone could require the same amount of tests per week in order to fully reopen the country.[4] These numbers suggest that perhaps many countries are currently operating at a less than optimal testing capacity.

In an effort to identify specific limitations experienced at the hospital level, a recent survey was conducted across 150 hospitals. The results showed that 80% of hospitals would like to increase their testing capability on-site, however, 41% reported that this was not possible due to reagent shortage and 40% due to viral swab shortage.[5] Until more supplies become available, 44% said they would

need to limit employee testing to those who are symptomatic and only 22% said they would be able to test support workers, such as cleaners or food services workers. Sixty percent of respondents said they required more guidance and best practices to determine how they should prioritize testing.[5] An OrthoEvidence poll (**Exhibit 2**) echoes this uncertainty, with 25% of members reporting that there were no protocols for testing in place at their institution. The main barriers to testing? Thirty one percent reiterated that a lack of testing protocols or changing protocols was to blame, 20% felt that it was a lack of tests and 23% suggested a lack of testing reliability.

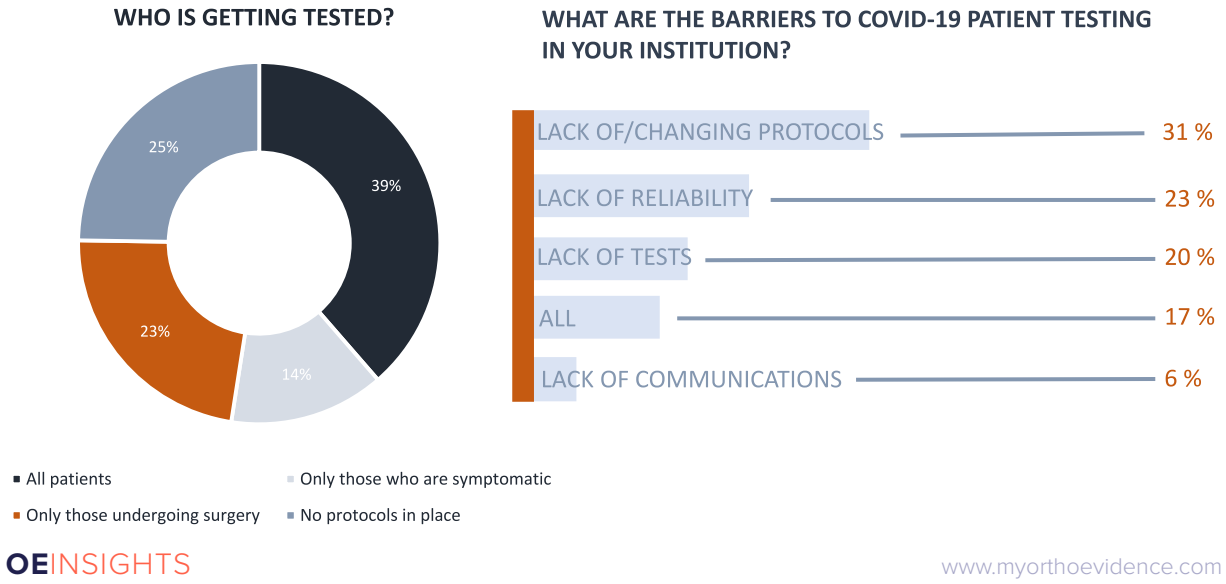

Exhibit 2: COVID-19 Pandemic Testing- Barriers to Testing.
OrthoEvidence Random Sampling N45

Reliability: The World Health Organization (WHO) has commended the worldwide effort to ramp up test development and innovation in the face of a worldwide shortage. Unfortunately, this has also meant a lot of unvalidated tests in circulation.[6]

> "At this point, we are focusing on patients who, without surgical intervention, would clinically deteriorate. Every patient is being tested for COVID-19 at least 48 hours before their surgical procedure. We have the ability to test the same day but prefer not to do that if possible, for logistic reasons. Since the tests have varying degrees of reliability, our lab is using both testing platforms. We are doing our best with a moving target…last week six COVID-19 patients came back negative on the rapid 2-minute test but then turned up positive when the other test was run. [7]
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In partnership with the WHO, the Foundation for Innovative Diagnostics (FIND) is currently working to evaluate the sensitivity and specificity of over 300 COVID-19 tests worldwide to compare their results to a gold standard. [6,8] There are currently three types of tests on the market, each with specific advantages and disadvantages.

- Molecular tests: This type of test is the gold standard. It is also known as a reverse transcription polymerase chain reaction (RT-PCR) test. These tests are designed to identify the viruses' genetic code and, therefore, require a genetic sample, which is often collected from the upper respiratory system with a swab.[9] These tests are considered the most accurate, especially in the early days of a COVID-19 infection. These tests are often expensive and require trained personnel, special lab equipment and 24 hours to process.[9] New PCR tests are reported to have an increased sensitivity compared to the original gold standard PCR test.[9] The WHO recommends that molecular tests be used in the identification of COVID-19.6

- Immunoassay tests:
  - Antigen tests: These tests are also referred to as rapid diagnostic tests (RDT). A sample is usually collected from the upper respiratory tract using a swab. If enough antigens are present in the sample, they will react with the antibodies present on the test strip and produce a visible signal.[6] The results are much quicker than RT-PCR tests (often available in a few minutes) and do not require a laboratory setting; however, the results are much less accurate, especially in the early days of infection.9 Since the quality of a sample can vary from patient to patient, the sensitivity of these tests has varied from 34% to 80%.6 This would mean an unacceptably high false negative rate; therefore, this type of test is not recommended by the WHO.[6]

  - Antibody tests: These tests require a blood sample in order to identify the presence of antibodies in people who have already been infected. It does not accurately diagnose someone who is currently infected, as the antibody response is usually detected in patients who have already recovered.[9] Due to its ability to cross react with other coronaviruses, this type of test can lead to false positive results. Also, the assumption that the presence of antibodies can prevent a second infection has yet to be substantiated.6 The WHO does not recommend the use of this test, but encourages the establishment of its usefulness in disease surveillance.[6]

When in Doubt, Think (COVID) Positive!

Although the reliability and availability of testing kits remains uncertain, the benefits might outweigh the risks. A recent retrospective study examined the outcomes of 34 surgical patients who were originally identified as COVID-19 negative, but, in reality, were in the incubation period of the infection. The results showed that all patients developed COVID-19-related pneumonia shortly after surgery, with 91% developing fever, 74% developing fatigue, and 53% developing a dry cough. In the end, 44% of patients needed to be admitted to the intensive care unit and 21% died after admission.[10] Surgical procedures on asymptomatic patients poses a great risk to patients' risk and impacts recovery. Moreover, they increase the risk of disease transmission between patient and operating room staff. Motivated to improve patient and worker safety, outcomes like this, combined with new evidence on COVID-19 transmission, have led to the creation of a new approach – assume every patient is positive.

> While there is a lot of interest in planning for a ramp up, there is a dearth of leadership guidance on how to proceed. Just because I want to do surgery and the hospital wants to restart doesn't make for a smooth runway. Consider the issue of preoperative COVID testing…when should it be done…24, 48, 72 hours beforehand? The tests are only about 70% sensitive anyway, so some 'negatives' will actually be positive. There needs to be in-depth discussion around what risks we are willing to accept. There is inconsistent guidance from various entities so for the time being, we may have to treat everyone as if they are positive for the virus. [7]

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One example of this approach is an algorithm created by Forrester et al. (2020) that outlines precautions for resuming operating room procedures when PPE and testing kits may be in short supply (**Exhibit 3**).[12] For all emergency procedures (or procedures where screening for symptoms or RT-PCR test is not possible) the patient is to be assumed COVID-19 positive. For urgent cases (or prioritized procedures where testing and screening is possible) patients should be divided into two categories: high- or low-risk procedures.[12] For high-risk procedures (any open aerodigestive tract procedure), a symptom screen should be done first (fever, cough, sore throat). If the patient screens positive, the surgery should be delayed, if possible. Otherwise, the patient should be tested with an RT-PCR test prior to the operation. If the patient screens negative, an RT-PCR test should also be done. For low-risk procedures, a symptom screen is also performed. Positive patients should follow the same procedures as in high-risk procedures. For negative patients, a standard risk protocol can be used with standard surgical attire.[12]

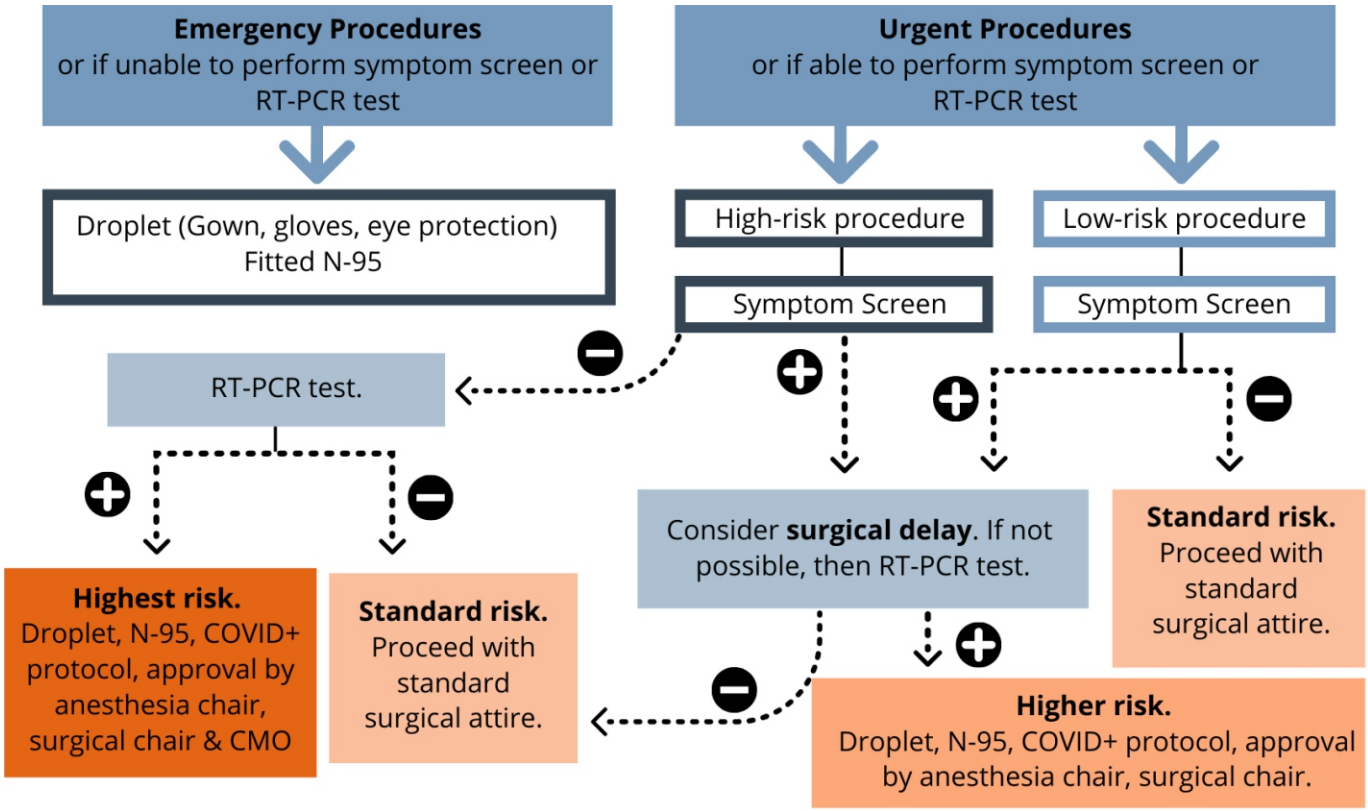

Exhibit 3: Algorithm for resuming operating room procedures.12

> At NYU Langone Health we are presently taking care of patients who require medically necessary surgery that can no longer be delayed. Getting back to orthopedics all of our faculty, house staff, nurses, staff and company representatives all require COVID testing. All patients are also tested before surgery. People entering the hospital are questioned about symptoms and temperatures are taken. Patients who are undergoing surgery require a negative test prior to surgery. If they are asymptomatic but COVID positive then surgery is delayed two weeks if medically appropriate, when it is anticipated that there will be no live viral shedding. [7]

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