# Case Report

# Unveiling the silent threat among us: leveraging health information technology in the search for asymptomatic COVID 19 healthcare workers

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## ABSTRACT

Assuring the safety of both patients and healthcare workers (HCWs) in hospitals has been the primary focus of every healthcare organization during the COVID 19 pandemic. This article discusses the NIH Clinical Center's interdisciplinary approach to deploying an organizational Asymptomatic Staff Testing System.

**Key words:** COVID 19 asymptomatic testing, electronic health record, interdisciplinary team, healthcare workers, software development

## PROGRAM NEED AND INITIATION

The CDC provided guidance regarding infection prevention and control (IPC) related to SARS-CoV-2 built on four guiding principles of ensuring rapid identification of suspect cases, immediate isolation and referral for testing, safe clinical management and the adherence to standard IPC precautions.[1]

The implementation of patient testing is a key element of every hospital's infection control program in the United States. In a letter to The Lancet in April 2020, Black and colleagues,[2] make a case for the testing of healthcare workers (HCW), both symptomatic and asymptomatic to address workforce depletion; reduce spread in mild and asymptomatic cases; and to protect the healthcare workforce.[3]

The National Institutes of Health Clinical Center (NIH CC) is the 200-bed hospital that provides patient care and clinical research support to the Institutes and Centers (ICs) of the NIH Intramural Research Program (NIH-IRP). All research participants admitted to the NIHCC are enrolled in a research protocol and considered true partners in the research process. The NIHCC supports 1,600 active clinical research protocols—approximately 50% of these studies are Phase I or II clinical trials. This large portfolio of "proof of principle, first in human" research studies requires a keen focus on patient safety and risk reduction. Due to the type of research conducted in the NIH CC, over 60% of patients admitted to the NIHCC are highly immune-compromised—either from his/her underlying disease processes or because of receiving experimental therapies. This

"high risk/high reward" environment requires a heightened "pre-oc-cupation with failure," especially in the context of a global pandemic.

At the onset of the COVID-19 pandemic, like many hospitals in the United States, the NIH CC took measures to restrict clinical and research activity. Measures included restricting clinical and research activities by limiting non-urgent new admissions to protocols, cancelling elective surgeries, instituting telework broadly, restricting building access, and introducing additional infection control measures to the work environment to reduce the risk of COVID-19 transmission.

Guided by CDC recommendations, the NIH CC began easing these restrictions in early May 2020. Acutely aware of the risks associated with asymptomatic carriage of COVID 19 in the context of an increasing patient census and the concomitant return of more HCWs to the hospital, the NIH CC initiated an in-house Asymptomatic Staff Testing System (ASTS). The aims of the ASTS are:

1. Continuous surveillance to determine coronavirus activity in the NIH CC as related to HCW safety; and
2. Timely identification of asymptomatic COVID-19 positive HCW to facilitate risk mitigation strategies, including to reduce COVID-19 spread within the NIH Clinical Center.

The high reliability principles of "preoccupation with failure" and "sensitivity to operations" are particularly germane to providing a successful system. Preoccupation with failure refers to an organization's continuous surveillance of its environment to identify current, future, real, and potential clinical and operational risks. Sensitivity to operations occurs when an organization deploys intentional processes and methods to create widespread situational awareness about the status of hospital operations, including key threats. Successful implementation of this initiative required active and visible senior leadership support, an organizational culture focused on high reliability, staff understanding and acceptance of the rationale for the testing; access to accurate and timely laboratory, testing resources and supplies; and availability of experienced staff to conduct the testing. It was important that the information technology infrastructure provided an environment that allowed seamless scheduling, ordering, results, and communication of results.

## SYSTEM REQUIREMENTS

The NIH CC utilizes the commercially available electronic health record (EHR) from Allscripts, the Allscripts FollowMyHealth patient portal, and the Soft Computer Corporation (SCC) laboratory information system (LIS).

A crucial first step in the design of the ASTS was to determine the requirements for the initiative while assuring alignment with the NIH CC's existing EHR and health information technology infrastructure. By utilizing the existing EHR, LIS, website infrastructure and patient portal, the security and privacy controls of the existing systems remained intact throughout the implementation of the ASTS.

The Chief Executive Officer of the NIH CC charged an interdisciplinary workgroup to design and implement the ASTS. The workgroup identified the following key requirements when designing the ASTS.

- Be convenient for the Healthcare Workers to be Tested (HCWTBT) to use
- Protect HCW privacy[3]

- Require minimal training
- Support contact tracing procedures used by the NIH Occupational Medical Services (OMS)
- Leverage the NIH CC's existing EHR and patient portal[4]
- Accommodate the use of existing interfaces between systems
- Provide flexibility to adapt to ever-changing COVID 19 guidance.

Using process improvement methodology, the workgroup identified the following key steps in the NIH CC's ASTS process:

1. Identification of HCWs who are eligible for testing
2. Maintenance of a current list of eligible HCWTBT
3. HCWTBT notification of eligibility to be tested
4. HCWTBT registration into the ASTS
5. Self-scheduling of testing appointments via a web application
6. Testing appointment "check-in"
7. Specimen collection
8. Specimen transport to and analysis by the hospital clinical laboratory
9. Results verification in the LIS
10. Electronic transmission of results from the LIS to the EHR and the patient portal
11. Positive result reporting to HCWTBT by OMS staff

Automation drives many of the ASTS process steps. The overarching principles of the automation include protection of security and privacy while maximizing speed and ease of use of the system. Each step includes the requirements, decisions made, and the implementation decisions.

### Step 1 and 2. Identify eligible HCWs; create and maintain an approved HCWTBT list

The initial group of HCWTBT at the NIH CC were individuals with direct patient contact. We leveraged the NIH CC highly successful annual influenza vaccination program to identify the first HCWTBT list. Leadership of the myriad clinical research programs and NIH CC departments are responsible for providing an accurate list of eligible HCWs.

### Step 3. HCWTBT notification

All eligible HCWTBT receive an initial e-mail notifying them that they are eligible to participate in the ASTS providing them with information about the procedures for scheduling and testing. One of the goals of the ASTS is weekly testing of all eligible employees; therefore, weekly notifications are sent to HCWTBT to encourage the regular scheduling of COVID-19 testing.

### Step 4. HCWTBT registration

The registration process includes a validation step to determine if the HCW is eligible for the ASTS, an acknowledgment of a privacy notice, the collection of minimal demographics, and the automated creation of a record within the EHR via an interface component.

When the HCWTBT member logs on to the registration and scheduling website, it provides a prompt for a unique employee identification code. Entering this identification code initiates a check against the eligible HCWTBT list. When the identification code is not recognized, the ASTS presents the user an alert to contact his/her supervisor. The registration screen that the user is presented the first time the user logs in is in Figure 1.

The system writes the data to the database once the privacy notice is accepted and required demographic and contact information entered on the website. The fields entered by the HCWTBT member

**Figure 1.** Initial registration screen.

in conjunction with additional data from the NIH Enterprise Directory create an OMS record within the EHR. The HCWTBT member's personal e-mail address aids in the creation of a patient portal account. NIH HCWTBT members get a different medical record number range than those for NIH research participants within the EHR, which allows additional security measures to ensure that only OMS staff can access the record.

A Health Level Seven (HL7) interface process runs regularly to review any new registration recordsin the database related to HCWTBT. The system then determines the HL7 message to send to the EHR, either to update the existing record with new demographics or create a new record. Once completed, the HL7 interface process flags this record as processed. Upon OMS record creation, a laboratory order for COVID-19 testing is autogenerated within the EHR for the HCWTBT member.

## Step 5. "self-scheduling" of testing appointments

The web application accommodates 2 schedules: normal business hours and nonbusiness (evening and weekend) hours. The automation to create the OMS record, send confirmations to the HCWTBT, and create the order takes 10 minutes. This supported the need for 2 workstations on wheels (WOWs) to provide a walk-in option for testing.

The schedules use blocks of time with each block having a maximum number of HCWTBTs who can register for the block.

The calendar displays 2 weeks at a time for scheduling an appointment. The appointment schedule that is present to the user is shown in Figure 2.

Once the HCWTBT selects an appointment time, the HCWTBT confirms the appointment. The system sends an e-mail message to the HCWTBT to confirm the scheduled appointment along with the testing and patient portal instructions. The scheduled event can be downloaded as an iCalendar (RFC 7986) file to load into a personal scheduling system or cancelled by the HCWTBT. The system allows the HCWTBT to schedule additional appointments as long as they are more than 4 days apart from an existing appointment.

## Step 6. Testing appointment "check-in"

The check-in process during normal business hours involves 4 administrative staff, each with a WOW. The check-in staff scans the employee badge of the HCWTBT member via the LIS. The check-in staff confirms the identity of the HCWTBT member being tested using active positive identification asking his/her name and date of birth and verifying before selecting the order. The HCWTBT then receives the printed specimen label. For evening/weekend hours, a nurse manages both the check-in and collection process.

## Step 7. Specimen collection

The specimen label is the "ticket" to the testing area. The HCWTBT member proceeds to the testing queue, observing strict social dis-

**Figure 2.** Appointment time slot selection.

tancing— aided by floor indicators spaced 6 feet apart. A staff member sends the HCWTBT to a specific room. The collection staff member asks the HCWTBT his/her name and date of birth using active positive identification. The specimen is collected and the label affixed to the collection container. The HCWTBT member deposits the specimen in a transport container as he/she leaves, performs hand hygiene, and exits through a specified exit route.

## Step 8. Specimen transport to and analysis by the hospital clinical laboratory

Specimens are stored on ice or in a refrigerator until picked up for delivery to the Department of Laboratory Medicine (DLM), the hospital's clinical laboratory. During normal business hours, Messenger and Escort delivers the specimens every 30 minutes to DLM. During evening/weekend hours, the Nursing Department either delivers the specimens immediately or stores the specimens in the refrigerator for transport the following morning. Upon arrival in DLM, the specimens are accessed and analyzed.

For high volume SARS-CoV-2 RT-PCR testing, 'pooling specimens' workflow was adopted in order to reduce testing time and cost. Aliquots of 10 specimens are pooled into 1 tube. If the pool is negative, all specimens in the pool are resulted as negative. If the pool is positive, each of the specimens are retested individually to identify any positives. All specimens in a positive pool are resulted individually.

Changes in the laboratory accessioning and resulting for handling these specimens included:

• Creating a dummy test patient such as COVIDPOOL, COVIDPOOL (MRN NPPOOL001).

• Generating an order on COVIDPOOL dummy patient using the same surveillance test.
• Creating a task list to include pooled samples, and then scan the barcode of the pool sample.
• Transferring the racks of samples to technologists for manual pipetting to generate pools, followed by testing.

Once the test results are entered in LIS and sent back via an HL7 interface to the EHR, a new "Employee SARS-CoV-2 PCR, Mid-turbinate" order for the next test for the HCWTBT is generated. There is no link between the calendar and the test order, by design, to ensure that an order for testing is always available for the HCWTBT.

## Steps 9 and 10. Results verification in the LIS; electronic transmission of results from the LIS to the EHR and the patient portal

After the verified results from testing reach the EHR, a script runs to handle the result release process for the patient portal. Negative results are automatically immediately loaded from the EHR to the patient portal and the HCWTBT member receives an e-mail notification alerting them to login to the patient portal to review the result. A physician communicates positive results to HCWTBT members from OMS prior to release to the patient portal. Positive results are released to the portal automatically after 24 hours. Registration for the patient portal is strongly encouraged, but not mandated.

Whereas the OMS healthcare team can review the result information within the EHR, the high volume of asymptomatic testing for COVID-19 warranted another tool to support the review of results and to provide the OMS staff with critical demographic information about the affected HCWTBT members, such as the

**Table 1.** High/moderate risk failure modes

| Failure Mode Category | Failure Mode |
|---|---|
| **HCWTBT Communications** | • Initial e-mail information is critical (why, where, how, how often, results notifications)<br>• No process for sending confirmation notification re: dates and times of scheduled appointment/testing slot<br>• Information about post-testing process (eg, notification timing, access to portal, scheduling future testing)<br>• Process for notification of positive results<br>• Reminder e-mails about testing |
| **Managing HCWTBT** | • Availability of testing<br>• Contact information for staff and supervisors<br>• Positive results management |
| **Staff Check-in Process** | • Flow—"crowd" management<br>• Delays<br>• Managing "walk-ins"—"regular" and symptomatic |
| **Compliance with Testing** | • Assuring that HCWTBT get tested and then get retested |

HCWTBT member's building or room location. A series of dynamic dashboards and views enable the OMS staff to review results and to guide the notification of affected HCWTBT.

## PREOCCUPATION WITH FAILURE: ASSESSING POTENTIAL RISKS ASSOCIATED WITH THE ASYMPTOMATIC STAFF TESTING SYSTEM

In an effort to identify real and potential risks associated with the newly designed ASTS, the Office of Patient Safety and Clinical Quality facilitated a Failure Mode and Effects Analysis (FMEA) of the proposed process. The Veteran's Health Administration defines an FMEA as a model that provides "a method of evaluating a product or process to identify systems vulnerabilities, and the associated corrective actions, before an adverse event occurs."[5] Keay and Borycki (2010)[6] advocate for the use of FMEA as a tool to identify and manage the negative unintended consequences that are often associated with health information technology implementations.

The NIH CC follows the FMEA approach as part of the implementation of new processes and systems. Two trained FMEA staff facilitated the FMEA process with the ASTS workgroup of over 20 team members over three 1-hour meetings. Step 1 involved the identification of each proposed process step. Once the process steps were validated as a group, the failure modes (risk points) associated with each process step were identified and assigned a hazard risk score to each failure mode. The result was the prioritization of failure modes from high to low risk. Analysis of high and moderate risk failure modes resulted in the implementation of process changes, as appropriate.

Table 1 summarizes the high/moderate-risk failure modes identified by the workgroup.

The highest risk failure modes centered on staff communications. The full team met with NIH CC leadership to review the process and findings of the FMEA. The outcome of the meeting was the im-

plementation of the following enhancements to the automated process prior to deployment:

- Capacity for HCWTBT to cancel appointments via the web application
- Automatic confirmation notifications of testing appointments
- Automatic appointment reminder notifications to the HCWTBT

## MONITORING THE PERFORMANCE OF THE AST

Dashboards manage, evaluate, and monitor the ASTS and AST processes. The dashboards evaluate the AST process and stability of the system but not the enforcement of testing of individuals. The various views of the dashboard include tiles that identify the number of HCWTBT logins per day, the number of HCWTBT tested per day, and review of HCWTBT that have connected to the portal as well as block utilization.

The ASTS dashboards monitor staff resources for scheduling as well as to ensure a positive work environment. In addition, the ASTS dashboards provide data daily that allow the monitoring of all the supplies from personal protective equipment, collection swabs, and test reagents. An example of a dashboard used for the management of the program is shown in Figure 3.

## PROCESS

Reeves et al (2020)[4] identified the difficulty in following the organization's formal software development process under the time requirements and critical needs of an organization as part of COVID-19 information technology requests. To reduce the risk of introducing new software to the organization, we leveraged existing systems to implement the ASTS.

The components for the ASTS include a website, an HL7 interface between a database and the EHR, multiple medical logic modules in the EHR, multiple dashboards, an interface between the EHR and LIS for orders and results, and a feed from the EHR to the patient portal. Neither the EHR nor the LIS vendors were required for any development or configuration of the EHR, LIS or the patient portal. Utilizing the EHR and the LIS reduced the need for additional user training.

The new components developed to support this process include a new laboratory medicine orderable, the registration website, the interface between the registration system and the interface engine, and the dashboards. Building upon existing systems enabled the organization to follow existing configuration management and software development approaches, as well as to follow an agile development methodology for the website in order to rapidly introduce features and develop a prototype, receive feedback, and refine the system until the ASTS met the organization's requirements. NIH CC information technology staff developed the website, dashboards, and EHR medical logic modules.

The ASTS development timeframe from identification of the task by the NIH CC CEO to implementation and to early adoption was 4 weeks. We attribute the short timeframe to using existing systems and an agile approach. The request process, documentation, implementation in development, testing, migration into production, and validation in production, as well as all changes, followed existing organizational software development and configuration processes.

## Staff Testing Summary

**10**
Distinct Staff
Logged in Today

**1,377**
Distinct Staff
Logged in To Date

| Has Logged In | 39.7% | 1,376 |
|---|---|---|
| Has Not Logged In | 60.3% | 2,089 |
| Grand Total | | 3,465 |

| Has Accepted Agreement | 38.1% | 1,319 |
|---|---|---|
| Not Accepted Agreement | 1.6% | 57 |
| Has Not Logged In | 60.3% | 2,089 |
| Grand Total | | 3,465 |

## Testing Schedule by Day
Click for detailed list

Date Selected: Next 30 days ▾

| Day of Date Selected | | Evening or Weekend | Normal Business H.. | Grand Total |
|---|---|---|---|---|
| 06/06/2020 | Sat | 2 | | 2 |
| 06/07/2020 | Sun | 10 | | 10 |
| 06/08/2020 | Mon | 3 | 77 | 80 |
| 06/09/2020 | Tue | 1 | 51 | 52 |
| 06/10/2020 | Wed | 1 | 30 | 31 |
| 06/11/2020 | Thu | | 32 | 32 |
| 06/12/2020 | Fri | | 27 | 27 |
| 06/13/2020 | Sat | 6 | | 6 |
| 06/15/2020 | Mon | | 13 | 13 |
| 06/16/2020 | Tue | | 14 | 14 |
| 06/17/2020 | Wed | | 3 | 3 |
| 06/18/2020 | Thu | | 13 | 13 |
| 06/19/2020 | Fri | | 7 | 7 |
| 06/20/2020 | Sat | 1 | | 1 |
| Grand Total | | 24 | 251 | 275 |

## Portal Status (scheduled for testing)
Click for detailed list

| | |
|---|---|
| Joined | 835 |
| Invited | 324 |
| None - No Email On Record | 18 |
| None - Email On Record - No Portal I.. | 10 |
| Grand Total | 1,183 |

## Last Logins by Hour
Hover for details

| 1 | 7 | 8 | 10 | 14 | 15 | 17 | 18 |
|---|---|---|---|---|---|---|---|
| 1 | 1 | 2 | 1 | 1 | 2 | 1 | 1 |

| Go to Testing Roster | Go to Testing Schedule by Day and Time | Go to Testing Schedule with Portal Status |
|---|---|---|
| Go to Approved Staff List | Go to Specimens Collected List | Go to Staff List Not Connected to Portal |

**Figure 3.** Dashboard for managing the scheduling process.

## USAGE

Over the first 3 weeks of deployment, 1377 distinct healthcare workers (HCW) logged into the website, representing roughly 40% of the eligible HCWTBT list. Once logged in, HCWs must accept the Privacy Notice before proceeding with scheduling—approximately 2% of the HCWTBT did not accept the Privacy Notice and did not proceed with registration. The number of HCWTBT logging into the website steadily grew with the greatest increases aligning with e-mail reminders sent to HCWTBTs from the NIH CC CEO.

Most of the HCWs (58%) have scheduled only 1 test with 33% scheduling 2 or more tests. Through walking-rounds, the CEO identified that the discomfort of the nasopharyngeal swab sampling technique was the most frequently cited reason for HCWs avoiding asymptomatic testing. Based on this feedback, and after specificity testing confirmed an acceptable rate of identification of the COVID-19 virus, the asymptomatic sampling technique changed to a mid-turbinate swab—a subjectively less uncomfortable procedure. Ongoing reporting via the dashboards will assist the organization to measure the impact of system changes. Additionally, we continue to evaluate the efficacy of saliva testing.

We sent an MS Teams form to 30 of the 1377 HCWs that utilized the system within the first 3 weeks of use to collect feedback anonymously. The 30 HCWs were not part of the development of the system or of the ASTS interdisciplinary team but known individuals to the team. Nine of the 30 HCWs provided input on the complete process, the web registration, and scheduling component as well as the patient portal.

We found that the Asymptomatic Testing Process from registration to check-in to collection to result reporting was professional with 1 HCW stating: "All in all, I found the whole process to be easy to follow and all well-designed." A second HCW stated "Very quick to schedule. Very quick to perform the test. The tech kept me perfectly informed and comfortable."

The HCWs found the site to be user friendly and intuitive. Suggestions to improve the registration and scheduling process included changing requirements for the formatting of phone numbers and the HHS identification number as well as adding the ability to download an iCalendar (RFC 7986) for the user to add to his/her personal calendar. There was 1 comment that the use of a bar versus a button as well as the word "Proceed" on the bar was not intuitive which is under review to determine other options. The organization continues to gather input from users as the process expands to multiple sites and increases the population of those who are eligible for testing.

Those who provided comments reported no difficulty in creating the patient portal account or accessing results. In the first 3 weeks, approximately 21% of the HCWs did not create patient portal accounts. We sent reminder notifications to remind users to create accounts ver-

sus relying on a call from OMS if the result was positive. The Patient Portal Support Center received an increase in support calls, which identified that results were not releasing upon posting to the EHR. We entered a service ticket to the EHR vendor who resolved the issue.

## CONCLUSION

Healthcare organizations have faced unique operational challenges during the COVID 19 pandemic. Assuring the safety of patients and HCWs during this healthcare crisis is of paramount importance. Having situational awareness regarding the prevalence of asymptomatic healthcare providers in the hospital setting is a critical risk mitigation strategy in keeping our patients and HCWs safe.

The challenge of the ASTS implementation included the complexity of the system: the wide range of departments involved; the addition of this priority to staff who already had multiple high-priority items; and the short timeframe to develop the registration and scheduling sites. During the design, development, implementation and support processes, it is important to follow the approved organizational processes and not shortcut or change processes to accommodate a high-priority timeframe. When an organization changes processes, unintended consequences can be introduced which may lead to an unsuccessful implementation.

By following the NIH CC software development and system implementation processes that included design reviews, process walkthroughs, and an FMEA review, testing as well as defining the support process of the organization ensured the system meets organizational requirements and a successful implementation. The guidance to all organizations in implementing new processes and systems based on COVID-19 that require a quick turnaround time is to be true to the processes that you have in place and ensure all the right people are included, ensure that approved processes are followed, and verify that the organization is prepared for the new systems.

The design and implementation of an effective and efficient automated and interfaced Asymptomatic Staff Testing System (ASTS) required a "whole of organization" systems approach with a keen focus on prospective risk identification and mitigation. An interdisciplinary approach using the EHR and existing clinical information systems, people, and processes allowed the development of an ASTS that has made it possible for the NIH CC to manage asymptomatic testing.

## AUTHOR CONTRIBUTIONS

All authors wrote and reviewed the final manuscript.

## CONFLICT OF INTEREST STATEMENT

None declared.

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