COMMENTARY

Covid SAFE: Rapid Implementation of a Saliva-Based SARS-CoV-2 Surveillance Testing Program with Automated Scheduling and Reporting

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To manage the Covid-19 pandemic, a multi-stakeholder group at Penn Medicine recognized a need to implement a surveillance testing program for its faculty, staff, and students. Such a program would help to identify asymptomatic, presymptomatic, or mildly symptomatic cases that would otherwise go undetected, and could monitor for spread of possible vaccine-resistant viral variants. Covid SAFE (Screening Assessment for Exposure) was designed to leverage separate but existing tools and resources at the health system to accomplish this goal. The data provided by Covid SAFE have allowed health system leadership to make informed decisions about resumption of research and reopening of campus while providing the community with reassurances about their safety. Their experience, having enrolled more than 4,000 participants and conducted more than 25,000 tests, can be used as a framework for other institutions to develop and launch their own programs.

KEY TAKEAWAYS

» The rapid implementation of a novel program for Covid-19 surveillance testing required diverse stakeholder engagement.
Leveraging existing resources to avoid duplication of efforts and create synergy was vital to developing a scalable and sustainable program. This included the use of novel technologies for texting, scheduling, test kit identification, and result delivery.

Designing a program that was fast, flexible, and convenient for participants proved to be a cornerstone of program success.

The program provides leadership with the population-level data needed to make informed decisions about return-to-work policies, while regular testing and fast result reporting provides individual participants peace of mind in navigating work and home.

The Challenge

The coronavirus disease 2019 (Covid-19) pandemic has resulted in significant morbidity and mortality worldwide. Initial efforts to address the Covid-19 pandemic were aimed at testing symptomatic individuals, implementing stay-in-place orders, and increasing hospital capacity to meet surge demands. Even with the arrival of effective vaccines, their impact will depend on the speed of manufacturing and distribution, and a willingness by the public to get vaccinated. For the foreseeable future, widespread testing will be necessary to safely reopen schools and businesses across the country. Because an estimated 40% of Covid-19 cases are asymptomatic and 50% of transmissions occur from asymptomatic persons, surveillance testing will be needed to help identify asymptomatic, presymptomatic, or mildly symptomatic cases that would otherwise go undetected, and to monitor for spread of possible vaccine-resistant viral variants. The design and implementation of such programs requires diverse resources and the cooperation of multiple stakeholders. Through an iterative approach, we developed a surveillance testing program that remotely enrolls participants, uses automated bidirectional text message communications, incorporates symptom monitoring, and automatically reports test results. Insights from our experience can be used as a framework for institutions to develop and launch their own programs.

The Goal

We sought to rapidly design and implement a Covid-19 surveillance testing program for Penn Medicine faculty, staff, and students. From the outset, we aimed to leverage separate but existing tools and resources at the health system to:

- Provide a fast, convenient, and flexible testing option
- Recruit and enroll participants remotely
- Communicate with participants via automated text messaging
- Monitor daily symptoms
- Manage and deliver laboratory results
Inherent to these goals was a desire to design a behaviorally informed and user-friendly program that would encourage program uptake.

**The Execution**

We developed a biweekly (every other week) asymptomatic screening program, called Covid SAFE (Screening Assessment for Exposure), for faculty, staff, and students affiliated with Penn Medicine (Figure 1).

**FIGURE 1**

**Covid SAFE Workflow**

Depending on program stage, participants completed a biweekly (every other week) or weekly saliva-based Covid-19 surveillance test. Way to Health (W2H), a web-based platform, was used to administer and manage the program. Multiple additional data integrations were made to incorporate daily symptom tracking and securely distribute test results. If a participant screened positive for Covid-19, they were referred to centralized university call center to schedule a confirmatory test and to receive guidance on quarantine and return-to-work.

Participants enroll and complete consent remotely. Throughout the program, participants receive text message reminders and prompts via Way to Health.

Participants complete daily symptom monitoring via existing university-wide program, PennOpen Pass. Participants must be asymptomatic to submit a sample.

Depending on program stage, biweekly (every other week) or weekly testing on participant’s preferred day. Testing completed at centralized location.

Automatic result notification sent to participant. Result typically delivered in 1 day.

If negative, participants return to symptom monitoring and are scheduled for their next test.

If positive, participants are connected to centralized call center to schedule confirmatory testing and manage next steps.

Source: The authors

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Surveillance testing requires access to certain resources, including Covid-19 tests. To reliably increase and scale testing, it is important to consider the supply chain. Early in the pandemic, shortages of swabs and chemical reagents severely limited access to the standard, nasopharyngeal test. Mounting evidence suggests that saliva-based tests are a safe, convenient, and inexpensive alternative. In addition, this approach avoids the need for direct interaction between health care workers and patients and does not require specialized, consumable materials that may be in short supply. Aware of these advantages, in April 2020, scientists at Penn Medicine started working on a saliva-based assay to identify SARS-CoV-2 viral infection, using internally developed and manufactured reagents. Once the method, named LAMP-BEAC, was validated in July 2020, we had the testing capacity needed to implement a surveillance program. The limit of detection for this test was 100 copies per microliter, test sensitivity was 100%, and test specificity was 99%. However, because this test was not yet approved by the U.S. Food and Drug Administration, Covid SAFE was designed as a clinical trial.

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Providing access to an experimental surveillance test required multiple moving components. From a research perspective, the clinical trial required institutional review board approval and informed consent. From an operational perspective, we needed a way to remotely enroll participants, regularly communicate with participants, schedule testing appointments, safely label and collect saliva samples, and securely deliver test results. To limit testing to asymptomatic individuals, we also needed daily data on self-reported Covid-19 symptoms and exposures.

Taking advantage of previous investments in technology required for rapid health system innovation, we used Way to Health (W2H) to design and manage the Covid SAFE program. Way to Health is an automated platform created in 2010 with National Institutes of Health funding for clinical trials of patient engagement; the platform combines messaging capabilities and other automated features, such as electronic patient consent and secure data collection. Since its creation, W2H has been the foundation of more than 170 clinical trials.

Automating the program required integrating the W2H platform with multiple other data sources. For example, developers helped to create a data feed between W2H and LabVantage, which provides the laboratory information management system (LIMS). This connection allowed us to notify the lab of scheduled visits, print barcoded labels, track whether a participant completed their scheduled test, and securely transfer results. Similarly, we connected W2H with data on daily symptoms and exposures via PennOpen Pass, an existing university-wide initiative. Via this data feed, if a Covid SAFE participant reported Covid-19 symptoms, W2H automatically messaged the participant and paused further saliva-based screening until the participant was cleared by the symptom monitoring platform. Finally, W2H was integrated with the Epic electronic health record to track confirmatory test results. Together, these data connections and partnerships created
important synergies and avoided duplication of work — they were integral to the quick and precise implementation of this program.

Participants were invited to enroll via email. If interested, participants followed a link to learn more about the program and to create a W2H account. Participants then provided informed consent and completed a handful of surveys, which included a question about their preferred test day. Further participant communications took place via automated text messages: a study welcome message, a reminder on the Friday before a test, and a reminder on the morning of a test.

On a test day, participants were instructed to go to the centralized collection site and provide a saliva sample. Participants were also notified if they missed a scheduled test. For speed of communication, participants were notified via text when their result was available. If someone registered with their secure, Penn Medicine email, results were sent there, otherwise, results were posted to their W2H participant dashboard. If positive, participants were instructed to contact a centralized university call center to arrange for a confirmatory clinical test and to receive guidance on quarantining and returning to work.

Successful innovation requires rigorous experimentation. Developing Covid SAFE as a research study allowed us to experiment in ways that may not have been possible had it been launched as a clinical program. As an example, we built a randomized controlled trial into program implementation to test the impact of using opt-in-versus opt-out-framed recruitment emails on program enrollment (NCT04506268). We also preregistered Covid SAFE as an observational research study so that we could formally test important components of the program, like long-term test adherence (NCT04508777). Because of this approach, we were able to design and implement a program that met important operational and public health needs, while simultaneously testing different ways to improve program effectiveness and scalability.

Our team first discussed the need for an asymptomatic screening program on May 21, 2020, and the work of several groups quickly came together. Covid SAFE was launched via three iterative pilot stages, which ran for 6 weeks, from July 31 to September 11, 2020. The pilot provided the chance for the laboratory to finalize its own internal processes and to stand up the physical collection site.

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The first post-pilot main trial invitation was sent to approximately 1,800 people in early September; these individuals were randomized to receive an opt-in- or opt-out-framed recruitment email. Shortly thereafter, an invitation was sent to the entire listserv of the author (JAE) who serves as Penn Medicine Executive Vice Dean and Chief Scientific Officer (EVD/CSO); the listserv includes approximately 12,000 faculty, staff, and students. Since then, periodic invitations and reminders
have been sent to targeted groups, e.g., house staff, frontline health care workers, and nonfaculty staff.

**The Team**

The Covid SAFE team comprised members from the Penn Medicine Nudge Unit, Penn Medicine Genetic Diagnostic Laboratory, Penn Medicine Department of Microbiology, Penn Medicine LIMS Team, and the Way to Health development team. During the peak of program development and implementation, across all teams approximately 25 individuals were working closely on the program. Via a weekly meeting, program execution was overseen by the Rapid Assay Task Force (RATF) Logistics Team, a novel group led by the Penn Medicine EVD/CSO, focused on developing improved methods for assay of SARS-CoV-2 and implementation of these methods to help slow the Covid-19 epidemic. Important group decisions were made during these meetings.

**Metrics**

As of January 2021, more than 4,000 people have enrolled in the Covid SAFE program and the lab has completed more than 25,000 tests (Figure 2). More than 85% of individuals successfully complete their first screening test within 2 weeks of enrollment. The program has identified more than 35 positive individuals and the 7-day test positivity rate has ranged from 0.0% to 0.3%.
To share program data with our community, in January 2021 we launched a public-facing dashboard that tracks weekly and cumulative program enrollment, weekly and cumulative test counts, and the 7-day positivity rate.

Other metrics demonstrate overall satisfaction with the program. For example, more than 90% of participants reported that the saliva test is easy, not painful, and feels safe to complete. Among participants who reported previously completing a nasopharyngeal swab test, the majority prefer the saliva test (Figure 3). In addition, more than 90% of participants reported that the saliva test takes less than 10 minutes to complete. Participant retention has also remained high, with fewer than 50 people unenrolling from the program.
Fast result reporting is also critical to program effectiveness; same-day results can prevent 80% of new transmissions, whereas a 7-day delay stops only 5%. On average, time between Covid SAFE test completion and result delivery was less than 24 hours.

Hurdles

There have been several lessons learned as we addressed hurdles in implementing this program.

In rolling out Covid SAFE, it became apparent that individuals are maintaining highly variable on-campus work schedules. As a result, our biweekly (every other week) testing schedule proved to be too rigid for many. Initially, helping participants with rescheduling accounted for a significant
In response to this, we built a new bidirectional text messaging feature in which participants could text the word *reschedule* to change or skip their current test (Figure 4).

**FIGURE 4**

**Example SMS Communications**

This figure shows an example of the automated SMS text message communications between Way to Health and Covid SAFE participants. At any time, participants could text the word “reschedule” to change their test day. In addition, SMS text messages were used to remind participants about upcoming tests and to link participants to their test kit ID.

In addition, we shifted to a weekly testing schedule at the end of November 2020. This change provided further scheduling flexibility as well as a more effective surveillance strategy. At the beginning of the program, we required participants to pick a 30-minute time slot to prevent overcrowding at the collection site. Developing a scheduling tool to accomplish this was challenging and required us to link participants to an external website. With the help of a more
efficient test kit identification system (discussed below), we removed this constraint, telling participants that they could go to the collection site at any time on their designated day. In analyzing collection site visit data, we learned that participants naturally distributed themselves throughout the day (Figure 5). In addition, we added information on popular test days and times to the Covid SAFE dashboard to further encourage efficient use of the collection sites.

**FIGURE 5**

**Open Scheduling and Test Distribution**

To improve participant experience, in November 2020 we introduced a more flexible scheduling method in which participants were able to visit the lab at any time during operating hours without having to choose a specific time slot. We found this to be a sustainable improvement — participants naturally distributed themselves throughout the day.

In partnership with Penn Medicine leadership and the Penn Medicine Environmental Health and Radiation Safety office, it was determined that participants needed to complete the saliva test in a designated laboratory space. This approach guarantees chain of custody, allows participants to ask questions to laboratory staff, and ensures that participants provide their sample under safe conditions, e.g., a properly ventilated room.
Fast result reporting is also critical to program effectiveness; same-day results can prevent 80% of new transmissions, whereas a 7-day delays stops only 5%. On average, time between Covid SAFE test completion and result delivery was less than 24 hours.

While advantageous in many ways, physical space comes with certain constraints. At program launch, there was one collection site with hours from 9:30 a.m. – 3:00 p.m. However, many participants, especially clinical staff, expressed that the combination of lab hours and location were a significant barrier. We thus began opening the collection site at 8:00 a.m. Based on data about participant work location, we opened a second collection site in December 2020. In addition to being better located for a significant proportion of participants, this second site doubled the number of tests that could be conducted in a given day.

A key component to any testing program is determining an effective and efficient way to link participants to their sample. At the launch of the program, we opted for a traditional method: each day, W2H would automatically push a list of expected participants to the LIMS, allowing lab staff to print participant-specific labels and affix them to test kits. While this system was reliable, it was a time-consuming and rigid method that proved to be a bottleneck. Timed with our move to weekly testing, we switched to a self-service model in which any participant could take any test kit.

To accomplish this, we switched to participant-agnostic labels that had a unique 6-digit Kit ID number. To link the test kit to their account, participants were instructed to text the word “Ready” to W2H and prompted to reply with their unique Kit ID number (Figure 4). Based on participant phone number, W2H and the LIMS worked together to pair the Kit ID and Participant ID number. This method sped up collection site processes and allowed the laboratory staff to prep unlimited numbers of test kits in advance. It also made use of multiple collection sites operationally feasible — we did not need to know which participants to expect when or where.

The development and implementation of this program has required a large set of staff with diverse expertise and skills: lab attendants to manage the collection site, lab staff to run the novel SARS-CoV-2 assay, clinical and research operations staff to manage participant scheduling and field participants questions, as well as engineers and software developers to design the required data platforms. Many staff have reallocated their time from other research projects in order to contribute to Covid SAFE. That said, in certain instances, workforce limitations have directly impacted program implementation (e.g., collection site hours).

Where to Start

For Covid SAFE to be successful, it had to be simple, fast, and convenient. Throughout the design and implementation of this program, participant experience was made a priority. We recommend that health systems and universities begin by assessing the existing infrastructure and workflows that could be leveraged and modified for surveillance testing purposes. Like the development of any new program, it will require thoughtful planning and the dedication of new or reallocated
resources. Involved parties will need to make make-or-buy decisions to compare the costs and advantages of producing certain program components in-house versus buying them elsewhere. Given the inherit complexity and sensitive nature of this kind of program, well-trusted clinical and administrative leadership will be essential.

Next Steps

The data provided by Covid SAFE have allowed health system leadership to make informed decisions about resumption of research and the ongoing reopening of campus. In addition, regular testing has provided individuals working on campus with assurances about their safety. The Covid SAFE dashboard has proven particularly valuable in disseminating real-time information to our stakeholders. The use of automated text messaging, easy scheduling and rescheduling, and the simplicity of the saliva test have made for an overwhelmingly positive participant experience. With the program having achieved somewhat of a steady state, we will continue to elicit stakeholder feedback and make iterative improvements where possible. We expect that surveillance testing will prove to be useful tool for the foreseeable future, even after widespread vaccination.

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