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BIWEEKLY COVID-19 SCAN

PCORI HEALTH CARE HORIZON SCANNING SYSTEM

VOLUME 1, ISSUE 24

Briefing for April 1-14, 2021

This briefing provides an at-a-glance view of some important developments in the information universe surrounding COVID-19. The views presented here are solely those of ECRI Horizon Scanning and have not been vetted by other stakeholders.

The highly transmissible *B.1.1.7 variant is now the most prevalent coronavirus in the United States*. Although early studies suggested the variant was more deadly, *recent work has not linked the B.1.1.7 to more severe disease*. Calls are being made to better track variants, *perhaps through a national genomic sequencing initiative*, yet simpler assays might be more readily available (see Topics to Watch).

Vaccination rates are steadily rising, and access is opening up to all adults across the country. However, appointment scheduling remains difficult for many, and programs are aiming to both ease the process and prevent waste of valuable vaccine resources (see Topics to Watch). Programs like these may become even more vital if vaccine supply is bottlenecked by the *pause that began April 13 in use of the Johnson & Johnson vaccine because of deaths from a rare blood clotting risk* similar to that connected to *AstraZeneca's vaccine in Europe*.

Topics to Watch

ECRI Horizon Scanning has selected the topics below as those with potential for impact relative to COVID-19 in the United States within the next 12 months. All views presented are preliminary and based on readily available information at the time of writing. Because these topics are rapidly developing, we cannot guarantee the accuracy of this information after the date listed on this publication. In addition, all views expressed in the commentary section are solely those of ECRI Horizon Scanning and have not been vetted by other stakeholders. Topics are listed in alphabetical order.

Centralized Waiting Lists to Manage Distribution of Leftover COVID-19 Vaccine Doses

Categories: Systems and management

Areas of potential impact: Population health, health care delivery and process, health care disparities

Description: Vaccines are packaged in multiple-dose vials, with the Pfizer vial providing 6 doses and the Moderna, 10. *Based on the recommended storage and handling instructions, these vaccines can expire within hours after thawing and cannot be refrozen*. *Vaccine doses have gone unused because they have expired or been unclaimed* due to appointment no-shows or unexpected extra doses in vials. Individuals who have been unable to secure a vaccination appointment reportedly *wait in unofficial standby lines to receive leftover doses of vaccines*.

Health care workers at vaccination sites face challenges with maintaining waiting lists when individuals register on multiple waiting lists or when registrants do not meet the state guidelines for vaccine rollout. Centralized waiting lists have been created by *Dr. B*, *Vaccination Standby* (which subsequently merged with Dr. B), and others to better manage unused doses of vaccine by notifying preregistered

AT A GLANCE

- Vaccines are packaged in multiple-dose vials, with the Pfizer vial providing 6 doses and the Moderna, 10. These vaccines can expire within hours of thawing and cannot be refrozen, putting vaccine doses at risk of being wasted because of expiration, appointment no-shows, or unexpected extra doses in vials.
- People unable to secure a vaccination appointment reportedly wait in unofficial standby lines to receive leftover doses of the vaccines.
- Vaccination sites face challenges maintaining waiting lists when individuals register on multiple waiting lists or when registrants do not meet the state guidelines for vaccine rollout.
- Centralized waiting lists have been created by Dr. B, Vaccination Standby (which subsequently merged with Dr. B), and others to better manage unused doses of vaccine by notifying preregistered individuals of available leftover doses in their area. Upon being notified, individuals must confirm that they can get to the provider's location quickly.

individuals of available leftover vaccine doses in their area. Individuals registering on these waiting lists provide their name, phone number, zip code, and basic health information, which are used for vaccine prioritization. Upon being informed of leftover dose availability, individuals must *confirm that they can get to the provider's location within 15 to 30 minutes of notification* to receive the vaccine.

Commentary: Centralized waiting lists might improve the management and distribution of leftover vaccine to interested persons.

Early feedback from ECRI internal stakeholders suggested that this initiative could reduce vaccine waste and increase access to vaccinations in the presence of supply shortages in the United States. Conversely, multiple lists (eg, state, county, and Dr. B) might increase confusion for health systems regarding scheduling and tracking vaccinated individuals

Scheduling COVID-19 vaccine appointments is expected to remain a challenge for people who are not tech-savvy, live in rural areas, or are homeless, among other reasons. A centralized list that checks for eligibility and informs individuals when a vaccine is available for them could be an effective way to distribute COVID-19 vaccines equitably

Stakeholders thought that these lists would be useful only if people can reach the designated providers on short notice (within 15 minutes) when called and might increase disparities for the underserved populations who lack access to smartphones or transportation.

Variant-Specific Nucleic Acid–based Assays to Diagnose COVID-19 and Detect SARS-CoV-2 Variants

Categories: Screening and diagnostics

Areas of potential impact: Health care costs, health care disparities, patient outcomes, population health

Description: Multiple SARS-CoV-2 variants found in the United States are of concern because they exhibit higher transmissibility, cause increased disease severity, or might impact treatment or vaccine efficacy. *Circulating variants include B.1.1.7, first identified in the United Kingdom; B.1.351, first identified in South Africa; and variant P.1, first identified in Brazil*.

Surveillance for SARS-CoV-2 variants is largely performed using next-generation sequencing (NGS) genomic tests that have not received approval or Emergency Use Authorization from the FDA . Without such approval, *patient-specific results of variant tests cannot typically be provided to patients or clinicians*. Although some existing SARS-CoV-2 RT-PCR *tests can indicate the potential presence of these variants*, subsequent genomic sequencing is still required to confirm and identify a specific variant causing the infection.

Using its Allplex platform, Seegene, Inc (Seoul, South Korea) has developed an RT-PCR assay (the *Allplex SARS-CoV-2 Master Assay*) that provides full screening for SARS-CoV-2 infection and *five S-gene mutations present in one or more SARS-CoV-2 variants*. If authorized by the FDA, the assay could be used as a test to diagnose COVID-19, identify variants in the population, and provide patient-specific variant results. Seegene has not yet announced plans to apply for FDA authorization for this product. However, the company has obtained approval for *an RT-PCR–based COVID-19 test*.

AT A GLANCE

- Surveillance for SARS-CoV-2 variants is largely performed using SARS-CoV-2 reverse transcription-polymerase chain reaction (RT-PCR) testing followed by viral genomic sequencing tests, which have not received marketing clearance from the US Food and Drug Administration (FDA), limiting the availability of patient-specific variant test results.
- Using its Allplex platform, Seegene, Inc (Seoul, South Korea) has developed an RT-PCR assay (the Allplex SARS-CoV-2 Master Assay) that provides full screening for SARS-CoV-2 infection and five S-gene mutations present in one or more SARS-CoV-2 variants.
- If authorized by the FDA, the assay results could be used to diagnose COVID-19, identify variants in the population, and provide patient-specific variant results.
- Seegene has not yet announced plans to apply for FDA authorization for this product. However, the company has obtained approval for an RT-PCR–based COVID-19 test.

Commentary: The Centers for Disease Control and Prevention has identified variants of concern because of evidence of increased transmissibility and disease severity. Some variants harbor mutations that might reduce the efficacy of treatment with monoclonal antibodies or antibody responses from COVID-19 vaccines. Several laboratories have developed RT-PCR assays to help identify variant hotspots and assess the efficacy of tests, treatments, and vaccines.

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No variant-specific tests are authorized by the FDA for diagnostic use and no manufacturer has indicated plans to submit a test for authorization.

Initial comments from ECRI internal stakeholders suggested that variant-specific RT-PCR assays might help health care delivery by increasing our understanding of which variants are of clinical concern and which treatments or vaccines are effective against specific variants. The assays also might assist health officials in determining whether vaccines and treatments will require modifications to address emerging variants. When used for surveillance, the stakeholders also thought, the RT-PCR assays might detect and track the spread of variants more effectively and at a lower cost than NGS assays.

About Horizon Scanning

Horizon scanning is a systematic process that serves as an early warning system to inform decision makers about possible future opportunities and threats. Health care horizon scanning identifies technologies, innovations, and trends with potential to cause future shifts or disruptions—positive or negative—in areas such as access to care, care delivery processes, care setting, costs of care, current treatment models or paradigms, health disparities, health care infrastructure, public health, and patient health outcomes.

The PCORI Health Care Horizon Scanning System (HCHSS) conducts horizon scanning to better inform research investments at the Patient-Centered Outcomes Research Institute (PCORI). Initially, PCORI defined the HCHSS project scope to focus on interventions with high potential for disruption in the United States in 5 priority areas: Alzheimer's disease and other dementias, cancer, cardiovascular diseases, mental and behavioral health conditions, and rare diseases. In addition, the system captures high-level disruptive trends across all clinical areas, which may lead PCORI to expand the project scope to include other priority areas in the future.

In early 2020, the COVID-19 pandemic created a fast-moving, widespread public health crisis. In May 2020, PCORI expanded its HCHSS to elucidate the landscape of potentially impactful applications for COVID-19. The HCHSS COVID-19 supplement scans for, identifies, monitors, and reports on emerging and available COVID-19–related treatments, diagnostics, preventive measures, management strategies, and systems changes with potential for high impact to patient outcomes—for individuals and populations—in the United States in the next 12 months.

The HCHSS COVID-19 supplement produces 3 main outputs:

- Biweekly COVID-19 Scans (eg, this document) provide ECRI Horizon Scanning with a vehicle to inform PCORI and the public in a timely manner of important topics of interest identified during ongoing scanning and topic identification or through the ECRI stakeholder survey process.
- Status Reports (quarterly) briefly list and describe all COVID-19–related topics identified, monitored, and recently archived.
- High Impact Reports (every 4 months) highlight those topics that ECRI internal stakeholders (eg, physicians, nurses, allied health professionals, public health professionals, first responders, health systems experts, clinical engineers, researchers, business and finance professionals, and information technology professionals) have identified as having potential for high impact relative to COVID-19 in the United States.

We welcome comments on this document. Send comments by email to *horizonscan@pcori.org*.

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About This Report

The PCORI Health Care Horizon Scanning System is operated by ECRI under contract to PCORI, Washington, DC (Contract No. MSA-HORIZSCAN-ECRI-ENG-2018.7.12). The findings and conclusions in this document are those of the authors, who are responsible for its content. No statement in this report should be construed as an official position of PCORI.

A representative from PCORI served as a contracting officer's technical representative and provided input during the implementation of the horizon scanning system. PCORI does not directly participate in horizon scanning or assessing leads or topics and did not provide opinions regarding potential impact of interventions.

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Suggested citation: Lynch M, De Lurio J, Cuevas C, et al. PCORI Health Care Horizon Scanning System: Biweekly COVID-19 Scan. Washington, DC: Patient-Centered Outcomes Research Institute; April 16, 2021. Prepared by ECRI under Contract No. MSA-HORIZSCAN-ECRI-ENG-2018.7.12.

Financial Disclosure Statement

None of the individuals compiling this information has any affiliations or financial involvement that conflict with the material presented in this report.

All statements, findings, and conclusions in this publication are solely those of the authors and do not necessarily represent the views of PCORI or its Board of Governors. This publication was developed through a contract to support PCORI's work. Questions or comments may be sent to PCORI by email at *info@pcori.org* or by mail to Suite 900, 1828 L Street, NW, Washington, DC 20036. ©2021 Patient-Centered Outcomes Research Institute. For more information, see *www.pcori.org*.

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Contract No. MSA-HORIZSCAN-ECRI-ENG-2018.7.12

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