Briefing for November 12-20, 2020

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.

Vaccine development is moving fast now. Initial data show about 95% efficacy for 2 mRNA vaccines—Moderna’s mRNA-1273 and Pfizer and BioNTech’s BNT162b2. Emergency Use Authorization (EUA) may be granted by the US Food and Drug Administration (FDA) before this Scan is published, but concerns remain over early use of any vaccine. ECRI continues to call on the FDA to insist on 6 months of follow-up data and the Vaccine Working Group on Ethics and Policy is proposing the use of expanded access for those at greatest risk rather than a blanket EUA. Plans for equitable allocation and safety monitoring are now paramount (See Topics to Watch).

For our early coverage of mRNA vaccines, see PCORI COVID-19 Scan, May 28-June 10, 2020 for mRNA-1273 and see PCORI COVID-19 Scan, July 9-July 22, 2020 for BNT162.

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.

COVID-19 Vaccine Allocation Planner

Categories: Systems and management

Areas of potential impact: Population health, clinician and/or caregiver safety, health care delivery and process

Description: As safe and effective COVID-19 vaccines become available, early supplies will likely be insufficient to allow everyone who wants a vaccination to receive one. To help with orderly and equitable early distribution of COVID-19 vaccines, researchers at Ariadne Labs and the Surgo Foundation developed the COVID-19 Vaccine Allocation Planner. It is intended to help state and county decision makers distribute early vaccines to the 13 priority populations identified in the Framework for Equitable Allocation of COVID-19 Vaccine guidelines, which were created by the National Academies of Sciences, Engineering, and Medicine. The planning tool purportedly lets users estimate the size of high-priority populations in their respective geographic regions. It considers other factors, such as community vulnerability, to assign relative weights to groups when considering which groups should have highest priority. The allocation planner also helps users...
estimate the number of vaccine doses available and the percentage of vaccine coverage achievable under different scenarios.

**Commentary:** Use of the COVID-19 Vaccine Allocation Planner might standardize vaccine distribution to help local officials effectively dispense COVID-19 vaccines to the highest-priority populations. A more systematic approach might improve transparency of the vaccine distribution process, potentially increasing public acceptance of vaccine distribution plans. The planning tool could also provide a framework for fair distribution of COVID-19 vaccines among the wider population after the highest-priority groups are vaccinated.

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**COVID-19 Vaccine Safety Assessment for Essential Workers (V-SAFE)**

**Categories:** Systems and management

**Areas of potential impact:** Patient outcomes, population health, clinician and/or caregiver safety

**Description:** Vaccine Safety Assessment for Essential Workers (V-SAFE) is a smartphone-based active surveillance program to measure COVID-19 vaccine safety. The CDC developed V-SAFE to measure vaccine safety among health care staff, essential workers, and others expected to be among the first vaccine recipients.

V-SAFE will use text-to-web and email-to-web surveys to conduct health checks in up to 20 million (or more) early COVID-19 vaccine recipients during the first months of a vaccination program. After vaccination, the CDC will monitor subjects’ health via text or email daily for the first week and weekly for the next 6 weeks. The CDC will actively telephone all subjects who report a clinically important adverse event during a V-SAFE health check and file a Vaccine Adverse Event Reporting System report, if appropriate.

The CDC states it has validated text messaging as an effective method of vaccine safety monitoring. V-SAFE will purportedly let the CDC estimate rates of local and systemic immune reactions and vaccine-related adverse events; then compare coronavirus vaccine adverse event rates with other vaccinations’ rates (eg, influenza) and background population rates.

**Commentary:** Use of V-SAFE might allow the CDC to identify vaccine-related adverse events sooner and more accurately than standard safety reporting methods. Also, earlier detection of vaccine-related adverse events might let clinicians intervene sooner to mitigate adverse-event risks. Implementing V-SAFE might increase public

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Early feedback from ECRI internal stakeholders suggested equitable distribution is a highly desirable goal that would depend on data that are timely, verifiable, and reliable, as well as consistent adherence among states. Stakeholders noted a coordinated federal effort is critical to ensure consistent messaging and support to states and to county health departments overseeing local vaccination programs. Further, stakeholders stated that effective tools to organize distribution logistics are needed to prevent doses from sitting unused, especially because some vaccines have complex transport and storage requirements (eg, ultra-cold storage).
acceptance of a COVID-19 vaccine if it helps assure the public that appropriate safe measures are in place. If effective, V-SAFE could offer a new surveillance model for future pandemics and corresponding vaccination and treatment efforts.

Early feedback from ECRI internal stakeholders found active CDC surveillance using real-world data might be critical to provide assurance regarding safety as well as efficacy questions and promote public confidence in the vaccines during the aggressive rollout timelines. Stakeholders further suggested that if essential workers accept vaccination and use the app, V-SAFE might offer crucial insight on the vaccine’s impact on minority population members, who are disproportionately affected by coronavirus and also represent a large share of essential workers.

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.

Commentary in this COVID-19 Scan reflects preliminary views of ECRI Horizon Scanning and internal ECRI stakeholders. The information contained in this document has not been vetted by other stakeholders.
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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None of the individuals compiling this information has any affiliations or financial involvement that conflict with the material presented in this report.

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