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COMMENTARY - UNSOLICITED

Emergency department–based COVID-19 vaccination: Where do we stand?

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Cautious optimism suggests that the COVID-19 pandemic in the United States has reached a turning point. Cases have declined precipitously from their heights in the early winter months and vaccine distribution and administration has moved ahead at an accelerated pace. As of late March, more than 140 million doses of COVID-19 vaccine had been administered in the United States, with more than 27% of the population receiving at least one dose.[1] Nevertheless, challenges with COVID-19 remain. Rates are increasing in select parts of the country, as nonpharmaceutical interventions such as mask mandates and capacity limits are relaxed, more transmissible variants now represent a greater proportion of new cases, and vaccine hesitancy persists in many sectors of the population. With this shifting landscape, it is imperative that the United States continue to rapidly vaccinate as many individuals as possible.

Although the primary role of the emergency department (ED) is one of acute illness and injury treatment, engaging in public health interventions is not new to ED settings. Interventions ranging from HIV testing[2] and opioid use disorder screening[3] to hepatitis A and influenza vaccination[4] have been successfully implemented in many EDs across the country. Given the ongoing need for rapid COVID-19 vaccine scale-up, the strong interest in reaching communities with less access to traditional health care services, and the unique population EDs regularly care for, U.S. EDs could offer an invaluable service to the health of the public by offering COVID-19 vaccinations to unvaccinated ED patients, with a particular focus on those from underserved and vulnerable communities.

There are currently three COVID-19 vaccines (Pfizer-BioNTech, Moderna, and Janssen–Johnson & Johnson) in the United States that have received a Food and Drug Administration (FDA) emergency use authorization (EUA) during this pandemic. While the typical vaccine process requires years for development and FDA approval, the EUA allows for the COVID-19 vaccines to reach the American public in a rapid timeline, prior to long term follow-up data in study participants. Vaccines administered through an EUA require consent before vaccination, although there are no specific requirements regarding written versus verbal consent, and patients must be given the vaccine's EUA fact sheet rather than the standard vaccine information sheet (VIS) required with other FDA-approved vaccines.[5]

The first two vaccines to be emergency use authorized in the United States (Pfizer-BioNTech, Moderna) are based on a similar technology utilizing a lipid vector to deliver an mRNA to code for expression of the viral spike protein. Both are designed to be administered as part of a two-dose regimen, with doses separated by 21 or 28 days, respectively. Large, randomized controlled trials have shown excellent vaccine efficacy after two doses for both vaccines (Pfizer-BioNTech 94.6%, 95% CI = 89.9 to 97.3%; Moderna 94.1%, 95% CI = 89.3 to 96.8%).[6,7] While these studies also revealed a significant decrease in COVID-19 infection after

one dose of the mRNA vaccines,[8] the current lack of studies designed to specifically determine efficacy in one-dose regimens limits any broad recommendations for use of mRNA vaccines in this manner.

The third vaccine authorized by the FDA through EUA comes from Janssen–Johnson & Johnson Pharmaceuticals and utilizes adenoviral vectors as the basis for vaccine technology. Adenoviral-based vectors have been in use in basic science research for many years, with recent adoption for vaccine development. The benefits of this vector are the more stable expression of the vaccine target protein and a more robust temperature stability for transport. This vaccine, assessed primarily on interim phase three trial data designed with a single-dose regimen, demonstrated efficacy of 66.9% (95% CI = 59.0% to 73.4%) against moderate to severe COVID-19, with the vaccine arm recording no COVID-19–related deaths and few adverse reactions.[9] The ability to deliver an efficacious vaccine as a single dose vastly increases the utility and appropriateness of this type vaccine for use in many settings in which follow-up may be difficult to ensure. This is particularly pertinent for the ED, in which many patients have high-risk criteria for not following up, including transient housing, job insecurity, limited access to reliable transportation and phone capabilities, mental health issues, and substance use disorder.

In addition to the three COVID-19 vaccines already in use in the United States, other vaccines are in use around the world (while not having applied to the U.S. FDA for authorization) and vaccine development and testing continues at a breakback pace. The AstraZeneca vaccine, a two-dose regimen (chimpanzee) adenoviral-based vaccine currently being used in Europe, is under review at the FDA for EUA at the time of this writing. Further recommendations on the use of vaccines authorized in the United States will be guided by state and national authorities.

As the COVID-19 pandemic progresses, genetic variants are emerging raising concern for increased infectivity and the potential of eluding vaccine-induced immunogenicity. The B.1.351 and B.1.1.7 variants have caused particular concern, as they appear to be more contagious than wild-type SARS-CoV-2. The extent to which each vaccine is efficacious against each variant is still being studied. While some studies suggest that the vaccines may produce reduced neutralizing antibodies against certain variants (e.g., B.1.351), other data suggest that current COVID-19 vaccines maintain good clinical efficacy against the variants despite the reduction in neutralizing antibodies.[10] Because these variants currently are not thought to represent the bulk of new infections in the United States and given that these vaccines very likely provide robust protection against the known circulating variants, distribution and administration of currently approved vaccines remains a top priority. The available vaccine technologies also allow for rapidly created booster vaccine doses targeted to SARS-CoV-2 strains circulating within the community (similar to annual Influenza vaccinations). As public health entities across the United States continually screen for the emergence and proportion of variants, we might anticipate the ED as a venue for both surveillance of virus variants (with some EDs already obtaining samples for this purpose) and direct participation in annual COVID-19 vaccinations for difficult-to-reach populations.

COVID-19 vaccine supply remains dynamic. As of the writing of this paper, vaccines continue to be a constrained resource, with queuing for vaccines common throughout most of the United States. However, with vaccine production scale-up and the potential of new vaccines, we can anticipate an inflection point, perhaps before the end of the spring, where vaccine supply meets demand. While it is difficult to predict exactly what fraction of Americans will still require a vaccination once this inflection point is reached, many public health experts anticipate that there will not yet be a sufficient number of Americans vaccinated to reach herd immunity in all U.S. locations, particularly given the relatively high rates of vaccine hesitancy in certain populations.

Engaging vaccine-hesitant and difficult-to-reach populations may represent one of the major public health challenges in U.S. history. EDs are well poised to play an essential role in meeting this next phase of the pandemic response. As state and local public health agencies have rapidly implemented COVID-19 vaccinations across many settings, the ED will not likely play a large role as a primary vaccine location for those actively seeking vaccination. Instead, as we transition from vaccine scarcity to sufficient supply, the ED has a unique opportunity and window to engage vaccine-hesitant and difficult-to-reach individuals. These populations include individuals who have less access to primary care services, a higher degree of social needs, and those who are more vulnerable to becoming infected with or having complications from COVID-19. Unvaccinated populations may also include a cohort that is skeptical of medical care but willing to trust ED providers.

There will be challenges with ED-based COVID-19 vaccination. EDs must find ways to identify appropriate patients; streamline the vaccination process; engage vaccine-hesitant and difficult-to-reach populations; communicate vaccinations with state or regional vaccine databases, as appropriate; and arrange for follow-up vaccination, when needed. With ingenuity and lessons learned from successful implementation of prior ED-based preventive interventions (e.g., HIV screening) these barriers can be overcome.

EDs across the country have stepped up in unprecedented ways throughout the COVID-19 pandemic. Physicians, advanced practice practitioners, nurses, and staff have demonstrated incredible resilience accompanied by a sense of duty and purpose to stem the tide of the pandemic. Our response could be amplified by offering COVID-19 vaccinations to ED patients, thereby supporting a push to end the pandemic. Given our prior experience and expertise addressing public health issues, our unique patient population, and our volume of patient encounters, EDs now have an opportunity and obligation to participate in the U.S. COVID-19 vaccination campaign.

CONFLICT OF INTEREST

The authors have no potential conflicts to disclose.

AUTHOR CONTRIBUTIONS

All authors contributed to the ideas and drafting of the manuscript.

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