ACEP Toolkit for SARS-CoV-2 Emergency Department (ED) Vaccination Programs

Introduction

While treatments and preventative measures show promise in curbing the morbidity associated with the SARS-CoV-2 pandemic, the development of safe and effective vaccines represents a clear and positive ray of hope amid the darkness. These vaccines have demonstrated increases in neutralizing antibodies and clinical efficacy of disease prevention with a high patient safety profile.[1][2][1] At least 3 vaccines (Pfizer, Moderna, and Astra-Zeneca) have now received FDA Emergency Use Authorization (EUA) and their administration began in mid-December to front line health care workers. As further distribution of vaccines ramps up, emergency department (ED)-based vaccination programs can play a critical public health role.

EDs have been a safety net and have played a key public health role for a number of public health initiatives.[3] Examples include the administration of screening and brief intervention for drug and alcohol use,[4] HIV screening programs,[5][6] and tetanus immunization.[7] More recently ED-based influenza vaccination programs have been described and recommended by a number of organizations.[8][9][10] The rising ED volumes continue to include a disproportionately increasing underserved, uninsured and minority population that is less likely to have had adequate preventive and primary care access and are more likely to be under-immunized. This population has also been disproportionately impacted by SARS-CoV-2 infections resulting in increased morbidity and mortality.[11] For these reasons, EDs represent a potentially important public health opportunity for COVID-19 vaccination programs. At the same time, given current vaccination strategies it is hard to predict when the supply chain and procurement processes will reach distribution to EDs; and, EDs will have to have a certain degree of flexibility and readiness in this process.

ED-based preventive interventions are varied and site specific. Each site will make these individual decisions when considering whether and whom to vaccinate. These decisions will take into consideration local resources, local demand and the ability to refer patients for their second vaccination.

This document presents a toolkit for the development of a COVID-19 ED Vaccination Program including the selection of appropriate vaccine candidates, ED requirements, best practices in ED vaccine administration and documentation. Four important caveats must be kept in mind when accessing this ED COVID-19 vaccination toolkit. First, the toolkit does not intend for any ED to become a primary vaccination site (i.e., patients come to the ED specifically for the vaccine). Second, the toolkit intends for ED patients to obtain a second vaccine (for vaccines requiring a second vaccination) at a site outside the ED. Third, since ED vaccination efforts will often overlap significantly with their larger hospital's vaccination program, consistency between the ED vaccination program and the larger hospital vaccination program is encouraged. And fourth, vaccinating for COVID-19 is a dynamic process, with new vaccines becoming available, evolving data, and new recommendations frequently promulgated. This vaccine toolkit gives the best available guidance and links to resources at the time of writing, most stemming from the Centers of Disease Control and Prevention (CDC) [COVID-19 Vaccination Toolkits]. Nevertheless, we recommend that each ED

[1] Voysey M, Clemens SAC, Madhi SA, Weckx LY, Folegatti PM, Aley PK, Angus B, Baillie VL, Barnabas SL, Bhorat QE, Bibi S, Briner C, Cicconi P, Collins AM, Colin-Jones R, Cutland CL, Darton TC, Dheda K, Duncan CJA, Emary KRW, Ewer KJ, Fairlie L, Faust SN, Feng S, Ferreira DM, Finn A, Goodman AL, Green CM, Green CA, Heath PT, Hill C, Hill H, Hirsch I, Hodgson SHC, Izu A, Jackson S, Jenkin D, Joe CCD, Kerridge S, Koen A, Kwatra G, Lazarus R, Lawrie AM, Lelliott A, Libri V, Lillie PJ, Mallory R, Mendes AVA, Milan EP, Minassian AM, McGregor A, Morrison H, Mujadidi YF, Nana A, O'Reilly PJ, Padayachee SD, Pittella A, Plested E, Pollock KM, Ramasamy MN, Rhead S, Schwarzbold AV, Singh N, Smith A, Song R, Snape MD, Sprinz E, Sutherland RK, Tarrant R, Thomson EC, Török ME, Toshner M, Turner DPJ, Vekemans J, Villafana TL, Watson MEE, Williams CJ, Douglas AD, Hill AVS, Lambe T, Gilbert SC, Pollard AJ; Oxford COVID Vaccine Trial Group. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet. 2021 Jan 9;397(10269):99-111. doi: 10.1016/S0140-6736(20)32661-1. Epub 2020 Dec 8. Erratum in: Lancet. 2021 Jan 9;397(10269):98. PMID: 33306989; PMCID: PMC7723445.

checks regularly with local, state, and national recommendations to see if there are important changes. [National Academy for state Health Policy States Plan for Vaccination against COVID-19]

Who should EDs target when developing COVID-19 vaccinations?

Any candidate ED must establish what are the goals of this program and how utilizing the ED can augment other local vaccination programs and the populations they serve. Patients most in need of vaccination in the ED setting are likely to have limited access to vaccination in traditional settings: immigrant and limited English-language proficiency communities, low-income populations, communities of color and other underserved populations, etc. The overall priority is to thus offer vaccination to all candidate patients with emphasis on vulnerable populations to whom the ED has unique access. Below are some early steps to plan for such a targeted program.

- Identify what other vaccination programs are available in the area and what populations they serve and their current level of efficiency/efficacy.
- Understand the overall current patient populations that the candidate ED serves.
- Recognize priority populations, with emphasis on vulnerable and underserved persons
- Align the gap on unique patients that the candidate ED serves that are not covered or served by other programs in the local area.

What is required when starting an ED COVID-19 vaccination program?

Instituting a program for COVID-19 vaccination in the ED requires engagement with key stakeholders at the Departmental, Institutional and Regional level.

Departmental engagement/partnership:

- ED Nursing. Unless there is an institutional plan for additional external staff to perform COVID-19 vaccination in the ED, vaccination will be performed by nursing and/or pharmacy staff. Nursing leadership needs to be engaged in issues regarding patient flow and vaccination process. Additionally, they will be needed to help facilitate nurse education regarding vaccination processes AND risks/benefits of vaccination for patients.
- ED Medical director and physician staff. Ensuring buy-in from physician leadership and those on shift is critical to facilitating successful ED vaccination programs.

Institutional engagement/partnership

- Pharmacy. Pharmacy consultation and partnership will be necessary for issues of vaccine storage, reconstitution, administration and reporting. Pharmacy staff can also be helpful with key aspects of nursing education. In institutions with ED pharmacists, consider how best to utilize this resource to support vaccination in the ED.
- Hospital leadership. Buy-in from hospital leadership is necessary to ensure the ED has a vaccine supply and receives the necessary external support. A focus on the population health mission of the ED, and special attention to vulnerable populations who may not seek care elsewhere may help facilitate these discussions. Furthermore, hospital leadership can facilitate discussion with primary care groups to support non-ED locations for the second dose in the two-shot series.

Regional engagement/partnership

- Department of Public Health (DPH). Work with local DPH to ensure clear messaging on the role of the ED in local vaccination efforts (i.e., the ED should not be the primary location for COVID-19 vaccination, but part of a regional effort).

- Regional EDs. Coordination of efforts between EDs, with alignment of mission and opportunities for cross learning of best practices will facilitate regional ED vaccination.
- ACEP state chapters. Leadership at the state level to align messaging and provide support to ED champions.
- Community-based organizations (CBOs). Partnership with CBOs is helpful to create opportunities for the second dose of the two shot vaccination series. CBOs are highly knowledgeable of the local community, including opportunities for primary and urgent care that focus on low-income and underserved communities.

Other important considerations when pursuing an ED-based vaccination programs

- Resources and Volume. Space and human resources need to be considered when pursuing an ED-based vaccination program. This is a dynamic process, which may need to adapt to the day-to-day volume and resources. Tightly linked to resources, ED volume is an important consideration when pursuing an ED-based vaccination program. In particular, low volume EDs may not be able to sustain an effective program. Conversely, the ED may be unable to provide vaccination during times of extremely high volume that strain available resources.
- ED flow. ED-based vaccination needs to fit within the normal ED flow. While modifications may be necessary, they should not lead to extended lengths of stay nor have negative impacts on other important ED metrics.

Continuous monitoring of ED-based vaccination

- Vaccination program monitoring. As with other ED interventions, a QI lens should be applied to a COVID-19 vaccination program. The dual focus of this program should be on ensuring high rates of vaccination and minimal impact on usual ED care and flow. The program should examine the following vaccination program metrics:
    - Patients screened for COVID-vaccination status
    - Patients eligible for ED-based vaccination program
    - Eligible patients vaccinated
    - When possible, the writers of this Toolkit recommend assessing for common reasons for vaccine refusal and important sociodemographic variables such as race, age, and comorbidities
    - The ED COVID-19 vaccination program
- Implementation of a QI process to integrate lessons learned is useful to ensure program success. Programs may consider utilizing a plan-do-study-act (PDSA) cycle, or another QI tool to implement program modifications.
- Furthermore, it is critical to examine local vaccination rates and epidemiologic trends to assess ongoing need or discontinuation for ED-based COVID-19 vaccination.

<u>COVID-19 specific topics</u>

Single dose vs. two doses

- As of the writing of this Toolkit there is no data on efficacy of a single dose of vaccine. The published studies thus far demonstrate some protection between doses one and two[1,2] and some countries have supported a strategy that delays the second vaccine dose in favor for more individuals receiving their first dose.[12] However, delayed second dose vaccination has not yet been expressly studied and delaying the second vaccine dose is not currently recommended by CDC or other U.S. recommendation bodies. As of the writing of this toolkit, there are no vaccines approved for single dose schedules, although this will need to be closely monitored as more data on differing vaccines develop. Moreover, the authors of this Toolkit welcome further discourse on the appropriateness of delivering a vaccine single dose to very hard-to-reach-and-vaccinate populations.

- For COVID-19 vaccines that do require two doses, the ED vaccine program should make specific arrangements to ensure the first-dose-vaccine recipients receive their second dose. Consider working with the hospital to fulfill this need (i.e., infusion centers, vaccine clinics, etc.). There may be unusual circumstances where ED patients with exceptionally high recidivism may receive their second dose in the ED.

How to physically vaccinate?

- For purposes of this discussion, it is assumed all manufacturer's recommendations for storage, transport and reconstitution are followed. Storage is generally a function of State or County entities. We recommend following local pharmacy and best nursing practice. Please find the following links for further information on the vaccination process.
    - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1118997/
    - https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html
    - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html

Who can order the COVID-19 vaccine?

- Standing orders are used for many ED functions. E.g., nurses in triage routinely order an EKG. This is a standing order, pre-signed by the department head, MD/DO. These are recognized as proper methods and are fully reimbursable. Having the offer to vaccinate done by nurses or pharmacists may increase uptake. This makes use of nurses as the most trusted profession.[13] It is helpful to have a nurse-champion for outreach to other nurses, using peer-conformity/conformity bias. This could be linked to a process-improvement (PDSA) project. (http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx)

Consent

- CDC does not specifically require consent for the COVID-19 vaccination. Instead, vaccine consent is guided by individual state laws and regulations, as well as institutional practices. The authors of this toolkit strongly recommend that COVID-19 vaccination is discussed with each potential vaccine recipient and the recipient (or appropriate caregiver) gives permission for the vaccine. Typically, there is at least some discussion with the vaccine recipient and documentation of this discussion in the medical record. This conversation may be the form of a typical signed informed consent or may be verbal or other forms. ED vaccine consent practices will likely be dictated by the institutional processes and forms, which should be consulted when developing an ED COVID-19 vaccine program.

Delivering COVID-19 Vaccine Specific Information to Recipients

- When any health care provider administers a vaccine, the recipient is provided with certain vaccine-specific information, typically in the form of a written piece of paper. For previously developed and authorized vaccines, this is in the form of a vaccine information statement (VIS). Vaccines authorized under an emergency authorization use (EUA) use an alternative document in the form of an FDA issued Fact Sheet, which in turn must be provided to recipients. This will typically be the same sheet given by the ED's hospital system. CDC maintains a clearinghouse for printable EUA fact sheets for each COVID-19 vaccine. https://www.cdc.gov/vaccines/covid-19/eua/index.html

Vaccine Recipients Receiving Documentation of Their Vaccine

- As of the writing of this toolkit, vaccines shipped to facilities are shipped with an ancillary kit, which includes the 'CDC COVID-19 Vaccine Record Card.' This card is filled out and given to the vaccine recipient as a personal

record of their COVID-19 vaccination. The recipient then produces this card for redocumentation for their second dose.

Communication with State and Federal Databases and Reporting

- There may be communication that occurs during vaccination between the vaccinating institution and local or state institutions. ED's will need to check with their own institution's policies and procedures regarding these communications.
- As of the writing of this toolkit, neither CDC nor any other federal organization has created a national database for all vaccine recipients.
- V-safe is administered through CDC as a way to track vaccine-related adverse events and to help remind recipients of their second dose. V-safe is described by CDC as 'a free, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. V-safe also reminds you to get your second dose if you need one.' www.cdc.gov/vsafe
- Individual states often have statewide databases tracking childhood vaccinations, some of which are currently being used for COVID-19 vaccines as well.
    - These statewide vaccine databases may have 'bidirectional' digital information flow from an institution's electronic health record (EHR) system to the statewide database. The New York State Immunization Information System (NYSIIS) is a good example. Many hospitals in New York State will have the vaccine status of each patient automatically entered in the hospital's EHR; and each vaccination event within the hospital automatically entered into NYSIIS.
    - Importantly, EDs may use either their own institutional EHR vaccine record keeping or the state vaccine record keeping system to identify ED patients eligible for vaccination.

Where in the ED should this be done?

- COVID-19 vaccination programs are likely to look quite different depending on the ED. While there is a common goal to promote vaccination as a key public health strategy to alleviate the COVID-19 pandemic, we believe that there is no uniform way to correctly pursue ED-based COVID-19 vaccination. Three examples of places where an ED might set up their COVID-19 screening and vaccination are (a) in triage, (b) during treatment, and (c) within discharge flow. Another model includes coordination and referral of appropriate ED patients to an onsite vaccination clinic or with offsite vaccine distribution site.

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