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CLINICAL COMMENTARY

A Road Map for Inpatient COVID-19 Vaccinations: Lessons Learned

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COVID-19 Vaccines at the West Los Angeles Veterans Affairs Medical Center

In the ensuing weeks after the BNT162b2 mRNA (Pfizer-BioNTech) vaccine was granted Emergency Use Authorization by the U.S. Food and Drug Administration,⁴ the two-dose Pfizer-BioNTech mRNA COVID-19 vaccine became available to patients and frontline healthcare workers at the West Los Angeles Veterans Affairs (WLA VA) Medical Center, a hospital with 264 acute care beds. The WLA VA serves a diverse, at-risk Veteran patient population with high rates of housing insecurity, unemployment, functional disability, substance use disorders, and mental health disorders.⁵

At our campus, COVID-19 vaccinations were distributed widely to patients and VA employees based on Centers for Disease Control and Prevention (CDC) interim recommendations for vaccine allocation.⁶ Due to storage constraints requiring a cold chain to preserve viability, vaccinations for eligible patients were distributed from one central location. In January 2021, we devised a process to begin delivery of the Pfizer-BioNTech COVID-19 vaccine to hospitalized patients.

A Road Map for Inpatient COVID-19 Vaccination

There are many potential barriers to providing mRNA vaccines to hospitalized patients. Due to the time limitation of vaccine viability and cold chain storage requirements, administering mRNA COVID-19 vaccinations to hospitalized patients requires coordination of multiple stakeholders. First among these is coordinating time of administration, as hospitalized patients may often be out of their designated room due to procedures or radiologic studies. At our institution, influenza vaccinations are routinely offered through a pre-discharge checklist via a nurse-driven protocol. We considered mirroring this process for mRNA COVID-19 vaccinations, but due to time and cold chain limitations, this ad hoc process could not easily translate to mRNA COVID-19 vaccinations without the potential for generating wasted doses. Lastly, ensuring a sufficient number of appropriately trained vaccinators is often the most prevalent challenge to large-scale mass vaccination operations, an issue still relevant in acute care hospitals.⁷

There are also clinical considerations with COVID-19 vaccine administration in hospitalized patients. Although post-vaccine observation for adverse effects is feasible in the hospital, high rates of systemic reactogenicity such as fever, with an incidence of 11-16% after the second dose of Pfizer-BioNTech COVID-19 vaccine,⁸ may confound clinical care for acutely ill patients. Beyond the confounding of clinical care is also the concern for an attenuated immunologic response in acute illness.^{9,10}

To address these concerns, we developed a screening and ordering process for inpatient COVID-19 vaccination. We established eligibility criteria that mirrored CDC guidance at the time,⁶ tailored specifically for hospitalized patients, and implemented a process map (Figure 1) to streamline the daily workflow.

Lessons Learned

At the time of this submission, more than 366 Pfizer-BioNTech COVID-19 vaccine doses have been administered to patients admitted under acute medical, surgical, rehabilitation, and psychiatric care through our process. There include 111 second doses. No immediate post-vaccine serious adverse events were noted.⁸ We hope this process can be applied in other acute care hospitals to optimize vaccination efforts, and share lessons learned in this process.

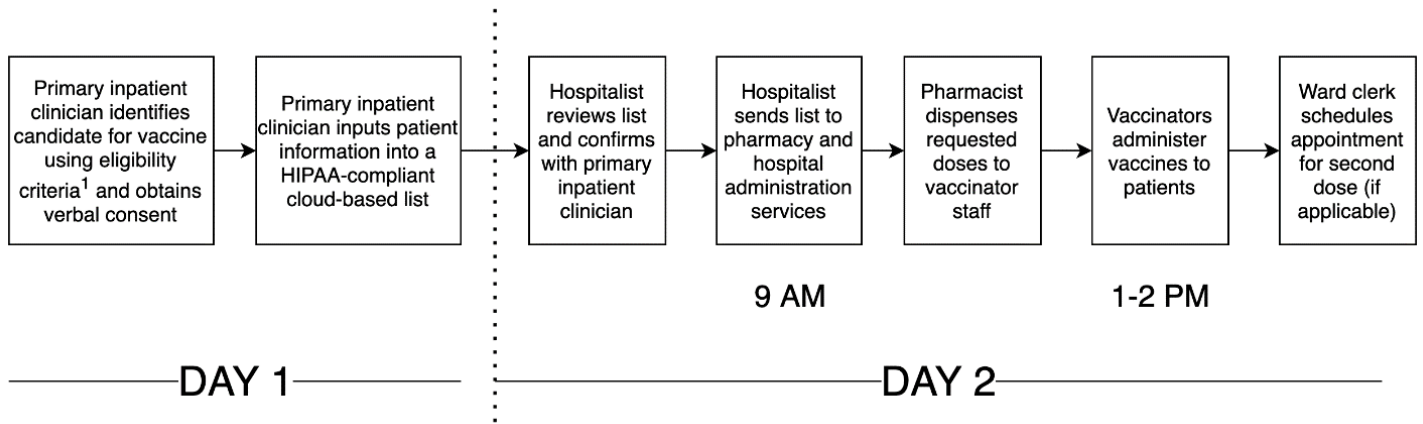
First, more stringent vaccine eligibility criteria may be needed in the inpatient setting to avoid confounding potential post-vaccine systemic reactogenicity with a worsening clinical course. Treating providers must be aware of potential post-vaccination adverse effects, such as fever, to avoid unnecessary diagnostic testing. For this reason, we excluded patients in our progressive and intensive care units from our initial vaccination rollout.

Second, it is crucial to involve key stakeholders early in the development of an inpatient vaccination process to determine time constraints in daily workflow. For example, clinicians

must screen patients with enough advanced notice to those downstream in the process. Pharmacists require time to reconstitute vaccine vials and dispense doses while ensuring availability of epinephrine auto-injectors and other medications needed for anaphylaxis. Vaccinators must be trained and available to coordinate timing of vaccine administration with inpatient hospital flow. Nurse managers must be aware of post-vaccine observation needs for patients receiving vaccination on their units. Bedside nurses must be aware of the limited timeframe for vaccine administration to ensure patients are physically in their hospital room to receive the vaccine. Finally, hospital administration services must be involved in coordinating follow-up doses after discharge, a large area of vulnerability, given the multiple potential discharge locations.

Lastly, this should be done without delaying hospital discharge, especially if the available vaccine administration window is later in the day. This highlights the importance of identifying potential candidates early in their hospitalization so patients are more likely to receive the vaccine.

For pragmatic reasons, an age cutoff of 65 years or older was initially set as an inclusion criterion in our process to mirror phase 1c CDC recommendations for COVID-19 vaccination allocation at the time.⁶ On March 15, 2021, our institution expanded COVID-19 vaccinations for inpatients of all ages, provided that they do not fulfill any exclusion criteria (which remained unchanged). On August 12, 2021, we made third dose booster vaccinations (Pfizer-BioNTech only) available to inpatients who met eligibility criteria for moderate or severe immune compromise set forth by the CDC. On September 27, 2021, the criteria for third dose booster vaccinations were further widened to include patients over age 65 or those at increased risk due to occupational or institutional risk based on CDC recommendations. Thus far, at the time of submission, 6 inpatients have received third dose booster vaccinations through our process. We look forward to continue providing opportunities for COVID-19 vaccination to our inpatients through the coming year.



¹Inclusion criteria (must satisfy both):

- Age ≥ 65 years
- Patient or surrogate (if applicable) agrees to vaccination.

Exclusion criteria (one or more present):

- Patient opts out
- Acute infection on intravenous antibiotics and worsening
- Hemodynamic instability (defined by clinician judgment)
- Temperature > 38°C within prior 24 hours
- Patients with laboratory-confirmed COVID-19 infection and date of first positive SARS-CoV-2 PCR test < 21 days prior
- Receipt of COVID-19 directed monoclonal antibody treatment within past 90 days*
- Receipt of convalescent plasma within past 90 days
- Receipt of at least one dose of the mRNA-1273 (Moderna) vaccination**

*Bamlanivimab or casirivimab/imdevimab available at our institution

**The mRNA-1273 (Moderna) vaccine is not available at our institution

Conclusions

The COVID-19 pandemic has driven rapid innovation in hospital systems to innovate how we deliver care. While early measures focused on the delivery of care to patients with COVID-19 disease, with the advent of multiple effective COVID-19 vaccines, a shift is needed to address preventive

measures for our most vulnerable patient populations. Hospitalized patients are a highly vulnerable population that should be offered COVID-19 vaccination to improve vaccination rates.

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