CHICAGO

COVID-19 Vaccine Planning Healthcare Call #5

2020.12.11

Presenters

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Recent COVID-19 Vaccine Announcements

- Pfizer and Moderna have requested emergency use authorization for COVID-19 vaccines to FDA

- FDA advisory committee December 10th Pfizer vaccine
  - Committee voted to recommend approval of EUA
  - "Following yesterday's positive advisory committee meeting outcome regarding the Pfizer-BioNTech COVID-19 vaccine, the U.S. Food and Drug Administration has informed the sponsor that it will rapidly work toward finalization and issuance of an emergency use authorization."

- FDA to meet December 17th and to discuss Moderna vaccine

https://www.fda.gov/news-events/press-announcements/fda-statement-vaccines-and-related-biological-products-advisory-committee-meeting

December 2020

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	2	3	4	5
6	7	8	9	10 FDA met: Pfizer EUA	11 ACIP meets	12
13 ACIP meets	14	15 First doses of Pfizer vaccine potentially arrive in Chicago	16	17 FDA meet: Moderna EUA	18 CDC/ACIP meet?	19
20 CDC/ACIP recommend?	21	22 First doses of Moderna vaccine potentially	23	24	25 arrive in Chicago	26
27	28	29	30	31		

Pfizer Vaccine Storage and Handling

- Must be stored at ultra cold temperatures, at -80° to -60°C (-112° to -76°F).
- If the vaccine is thawed and stored in a refrigerator, it must be used within 5 days; once it is reconstituted with the diluent, it must be used within 5 hours. Temperatures must be monitored continuously where vaccine is stored using a data logger.
- Because of the storage requirements, Pfizer will be distributing this vaccine, shipping it directly from their facilities.
- Requires 2 doses at least 21 days apart. The minimum order amount is 975 doses.
- Reconstitution with diluent is required after thawing.
- ~20-30 million doses expected to be available in the US by end of December.

Moderna Vaccine Storage and Handling

- Must be stored frozen at -25° to -15°C (-13° to 5°F). Standard freezers can usually reach these temperatures.
- If the vaccine is thawed and stored in a refrigerator, it must be used within 30 days. Temperatures must be monitored continuously where vaccine is stored using a data logger.
- Vaccine will be shipped by a central distributor under a Federal Government contract, the same one used to distribute vaccines under the Federal Vaccines for Children Program.
- Does not require reconstitution. Two doses are required, at least 28 days apart. The minimum order amount for this vaccine is 100 doses.
- ~15 million + doses expected to be available in the US by end of December

FDA Briefing Document—Pfizer COVID-19 Vaccine Efficacy*

- Efficacy in preventing confirmed COVID-19 was 95.0%
  - 8 COVID-19 cases in the vaccine group and 162 COVID-19 cases in the placebo group.

- Subgroup analyses showed similar across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

*Released in advance of Dec 10 Advisory Committee Meeting: https://www.fda.gov/media/144245/download

Efficacy Unknowns

- Duration of protection
- Efficacy in certain high-risk populations (e.g. immunocompromised individuals)
- Efficacy in pediatric populations
- Efficacy in previously infected individuals
- Efficacy against mortality
- Efficacy against asymptomatic infection
- Future vaccine efficacy as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections
- Efficacy against transmission

FDA Briefing Document—Pfizer COVID-19 Vaccine Safety*

- Available safety data from 43, 252 participants enrolled in the Pfizer vaccine trial through the November 14, 2020 with median follow-up of 2 months did not raise specific safety concerns.

- The known and potential benefits of the Pfizer COVID-19 Vaccine outweigh its known and potential risks for use in individuals 16 years of age and older.

Released in advance of Dec 10 Advisory Committee Meeting:
https://www.fda.gov/media/144245/download

Side Effects from Pfizer Covid-19 Vaccine

- For some people COVID-19 vaccine side effects are more noticeable than side effects from other adult vaccines (like pneumonia or flu vaccines).
- Side effects usually last a day or two, and are more common after the 2nd dose.
- Side effects indicate that the body is developing an immune response.

Local Reactions after 2nd Dose of Pfizer Vaccine

- Pain at Injection Site:
  - Age 18-55: 78%
  - Over age 55: 66%

- Redness and swelling: 4-7%

Systemic Side Effects After 2nd Dose of Pfizer Vaccine Age 18-55

59% fatigue (23% for placebo)

52% headache (24% for placebo)

37% muscle pain (8.0% for placebo)

35% chills (4.0% for placebo)

Less common: fever, diarrhea, vomiting, joint pain

These side effects are less common in people over age 55.

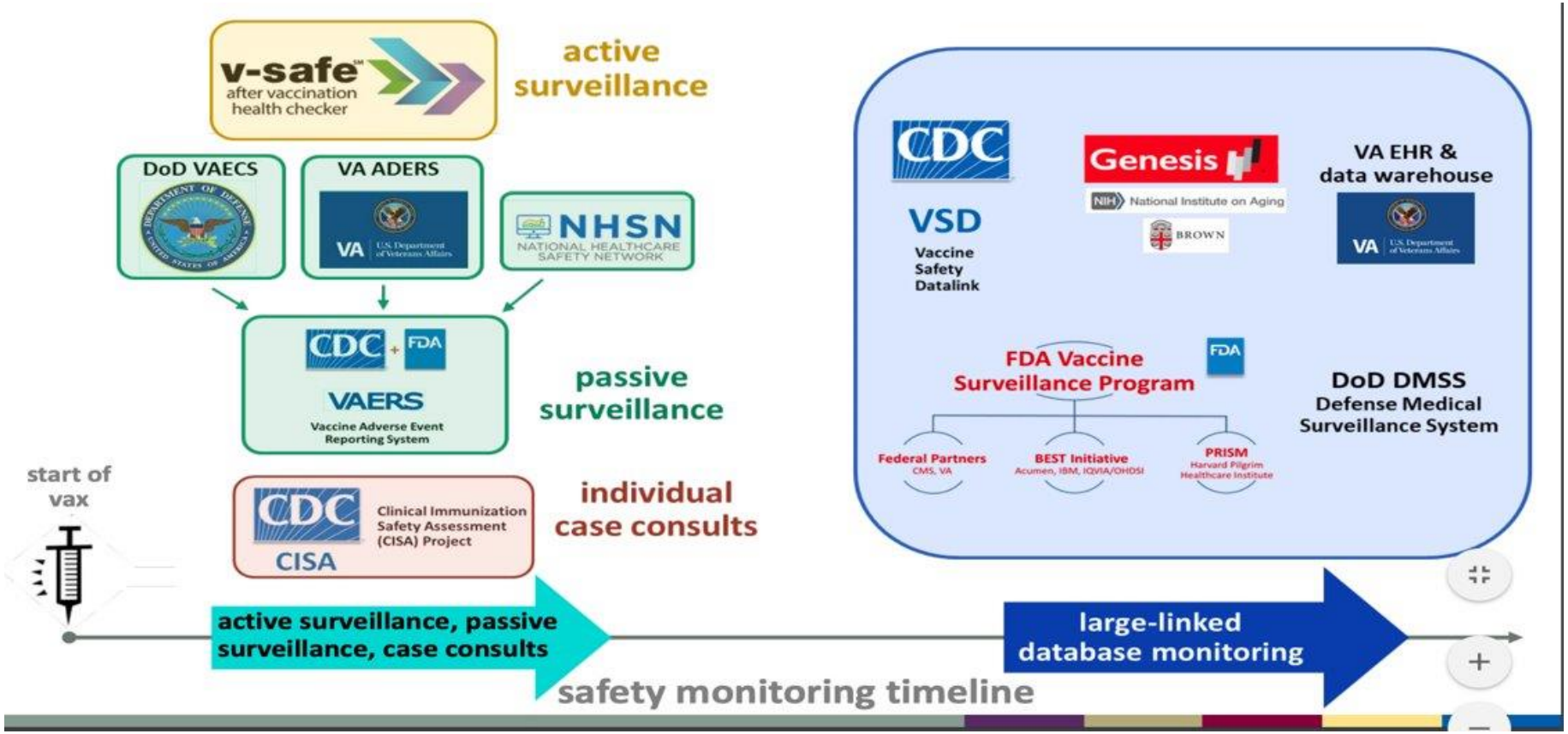
Adverse Event Analysis: Deaths during Pfizer Trial

- A total of six (2 Pfizer vaccine, 4 placebo) of 43,448 trial participants (0.01%) died during the reporting period from April 29, 2020 to November 14, 2020/
- Both vaccine recipients were >55 years of age; one experienced a cardiac arrest, and the other died from arteriosclerosis
- The placebo recipients died from myocardial infarction, hemorrhagic stroke (n=1) or unknown causes (three of the four deaths occurred in the older group (>55 years of age).
- **All deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate.**

Safety Unknowns

- Safety in certain subpopulations (e.g. children)
- Adverse reactions that are very uncommon or that require longer follow-up to be detected
- Further signal detection efforts for these adverse events will take place with more widespread use of the vaccine.

Ongoing Vaccine Safety Monitoring

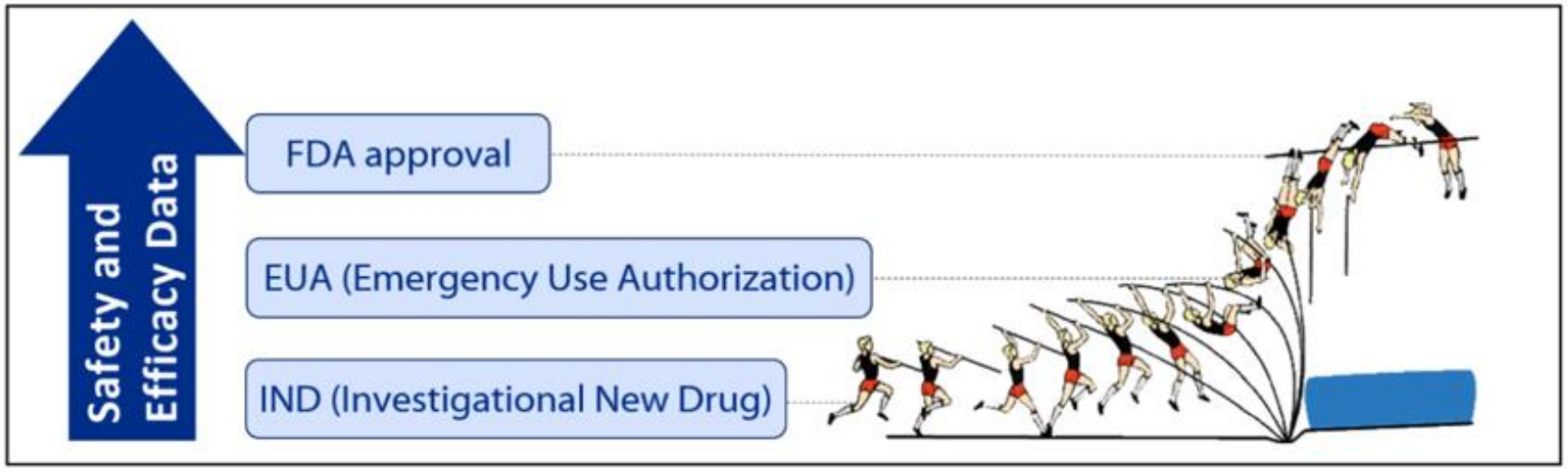


Emergency Use Authorization (EUA)

- Authority of FDA Commissioner to permit emergency use of certain medical products under Project Bioshield Act 2004
  - For emergencies involving chemical, biological, radiological or nuclear agents
  - FDA can authorize an EUA for:
    - unapproved medicine products or
    - unapproved use of an approved product
  - Statutory criteria must be met:
    - Serious of life-threatening disease/conditions
    - Reasonable belief product may be effective
    - Known/potential benefits outweigh known/potential risks
    - No adequate, approved, available alternative

Emergency Use Authorization (EUA)

- Allows for rapid and widespread deployment for millions of individuals during a public health emergency



EUA Requests by COVID-19 Vaccine Manufacturers

- Pfizer/BioNTech and Moderna submitted EUA requests
  - Submitted to FDA on Nov 10 and Nov 30, respectively
- Vaccines and Related Biological Products Advisory Committee
  - Public Meetings scheduled for Dec 10 and Dec 17
- Advisory Committee on Immunization Practices
  - Public meetings regarding COVID-19 since June 2020

FDA-issuance of EUA

- When FDA issues an EUA for a product, the following will become available:
  - EUA Letter of Authorization
  - EUA Fact Sheets
    - Fact sheet for Vaccination Providers
    - Fact sheet for Recipients and Caregivers
    - Can be provided in print/hardcopy or through mass media (internet/weblinks or other electronic means)
  - Issued EUA documents and any subsequent amendments will be posted on FDA's website:
    - https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
  - Additional CDC educational materials and communication materials consistent with EUA

EUA Letter of Authorization

- Describes the scope and criteria for EUA issuance for each vaccine product
- Conditions of use = safeguards
  - Information on emergency use (Fact Sheets)
  - Data collection and record keeping
  - Monitoring and reporting of adverse events
  - Roles (e.g., vaccine manufacturer, vaccination providers/healthcare providers, emergency response stakeholders)
  - Limitations on advertising and promotion

References for more information

- https://www.chicagohan.org/covidvax
- www.chicago.gov/covidvax

Fact Sheet for Vaccination Providers

- Anticipated to include EUA Full Prescribing Information and will provide specific information for each COVID-19 vaccine, including:
  - COVID-19 disease description
  - Dosage and administration information
  - Storage and Handling instructions
  - Dose preparation and administration information
  - Requirements for use of vaccine under EUA
  - Risks and benefits, including common adverse events
  - Any approved available alternatives for preventing COVID-19
  - Reporting requirements, including reporting adverse events to VAERS
  - Additional resources

Fact Sheet for Vaccine Recipients and Caregivers

- Similar to Vaccine Information Statement (VIS) for license vaccines
- Will provide specific information about each COVID-19 vaccine, including:
  - Basic information on COVID-19, symptoms, and what to discuss with a healthcare professional before vaccination
  - Who should and should not receive the vaccine
  - That recipients have the choice to receive the vaccine
  - Vaccine series information
  - Risks and benefits of the vaccine, including common side effects
  - Information on reporting side effects to VAERS
  - An explanation of what an EUA is and why it is issued
  - Any approved available alternatives for preventing COVID-19
  - Additional resources
- Written informed consent is not required under EUA
- Translation anticipated to be available

Adverse Event (AE) Reporting

- EUA anticipated to require the following AEs to be reported to VAERs:
  - Vaccine administration errors (whether associated with an AE or not)
  - Serious AEs (irrespective of attribution to vaccination)
  - Multisystem inflammatory syndrome (MIS)
  - Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine
- Any clinically significant AEs that occur after vaccine administration should also be reported to VAERs
- Provide a CDC information sheet to recipients on v-safe, a smartphone-based tool to help monitor for AEs

v-safe
after vaccination
health checker

Liability Protection Under Public Readiness and Emergency Preparedness (PREP) Act

- Declaration by the HHS Secretary to provide immunity from liability (except for willful misconduct):
  - For claims casually related to development, distribution, administration and use of "covered countermeasures" in a declared public health emergency
  - Countermeasures Injury Compensation Program (CICP) fund administered by Health Resources and Services Administration (HRSA)
    - Serious physical injuries or death directly caused by use of covered countermeasures
  - Product used under appropriate regulatory mechanism (e.g., FDA-approved status, IND, EUA)

Additional EUA Resources

- What is an EUA
  - https://www.youtube.com/watch?v=jGkwaESsGBQ
- EUA for Vaccines Explained: Q&As
  - https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained
- FDA Guidance: EUA for COVID-19 Vaccines
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19
- FDA Guidance: Development & Licensure of COVID-19 Vaccines
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19
- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
  - https://www2.cdc.gov/vaccines/ed/covid19/

Clinical considerations: Healthcare Personnel Sub-prioritization

- HCP with direct patient contact and thus who are unable to telework, including those who work in inpatient, outpatient, or community settings, who provide services to patients or patients' family members, or who handle infectious materials

- HCP working in residential care or long-term care facilities

- HCP with documented acute SARS-CoV-2 infection in the preceding 90 days may choose to delay vaccination until near the end of the 90 day period in order to facilitate vaccination of those HCP who remain susceptible to infection
  - Current evidence suggests reinfection is uncommon during this period after initial infection.
  - Of note, previous SARS-CoV-2 infection, whether symptomatic or asymptomatic, is not considered a contraindication to vaccination and serologic testing for SARS-CoV-2 antibodies is not recommended prior to vaccination.

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html

Clinical considerations:
Vaccination of pregnant and breastfeeding HCP

- Evidence suggests that pregnant women are potentially at increased risk for severe COVID-19-associated illness and death compared to non-pregnant women, underscoring the importance of disease prevention in this population.
- Given the predominance of women of child-bearing potential among the healthcare workforce, a substantial number of HCP are estimated to be pregnant or breastfeeding at any given time.
- Currently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations. **Further considerations around use of COVID-19 vaccines in pregnant or breastfeeding HCP will be provided once data from phase III clinical trials and conditions of FDA Emergency Use Authorization are reviewed.**

Clinical Considerations: Post-vaccination symptoms in HCP

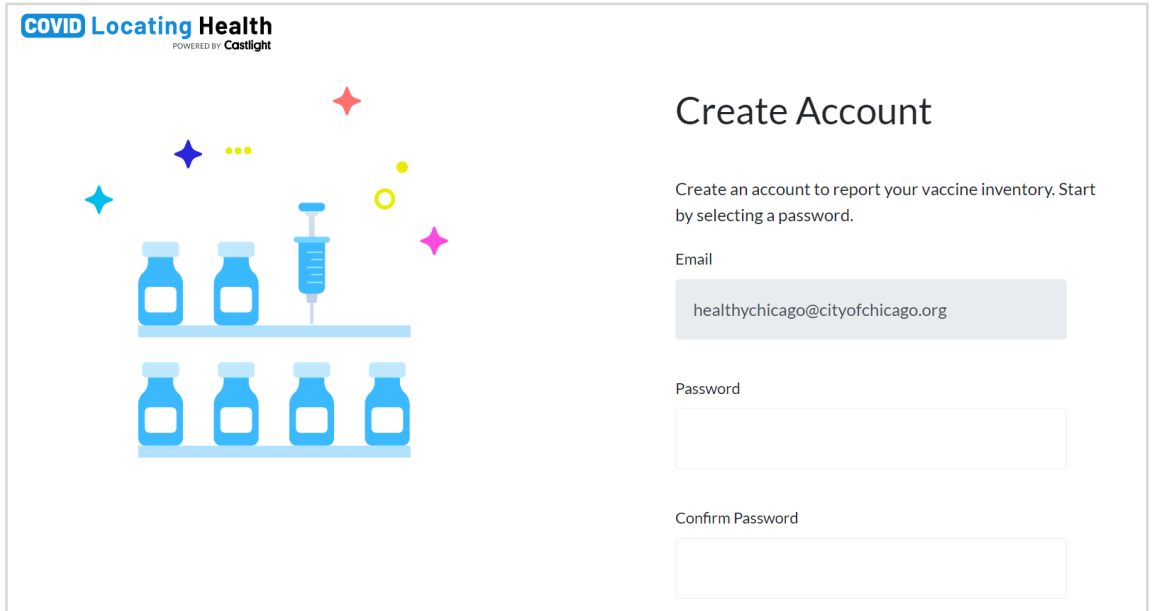
- Based on available data, COVID-19 vaccination is expected to elicit systemic post-vaccination symptoms, such as fever, headache, and myalgias. While the incidence and timing of post-vaccination symptoms will be further informed by phase III clinical trial data, strategies are needed to mitigate possible HCP absenteeism and resulting personnel shortages due to the occurrence of these symptoms. Considerations might include:
  - Staggering delivery of vaccine to HCP in the facility so that personnel from a single department or unit are not all vaccinated at the same time. Based on greater reactogenicity observed following the second vaccine dose in phase I/II clinical trials, staggering considerations may be more important following the second dose.
  - Planning for personnel to have time away from work if they develop systemic symptoms following COVID-19 vaccination.
- **Further considerations on the management of post-COVID-19 vaccination symptoms among healthcare personnel is under development.**

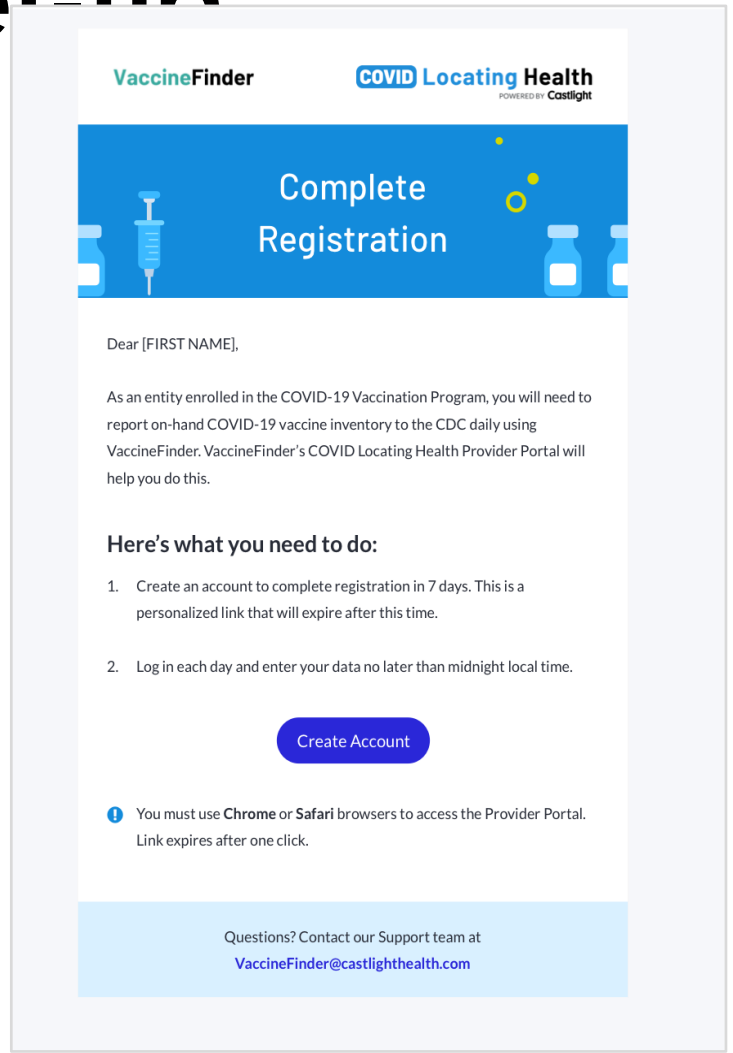
VaccineFinder (Reminder and Clarifications)

- All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into VaccineFinder as out lined in the Provider Agreement
- Report daily doses on hand for each vaccine product
- **New:** Expired and wasted vaccine are not collected in VaccineFinder

VaccineFinder Account Set-up

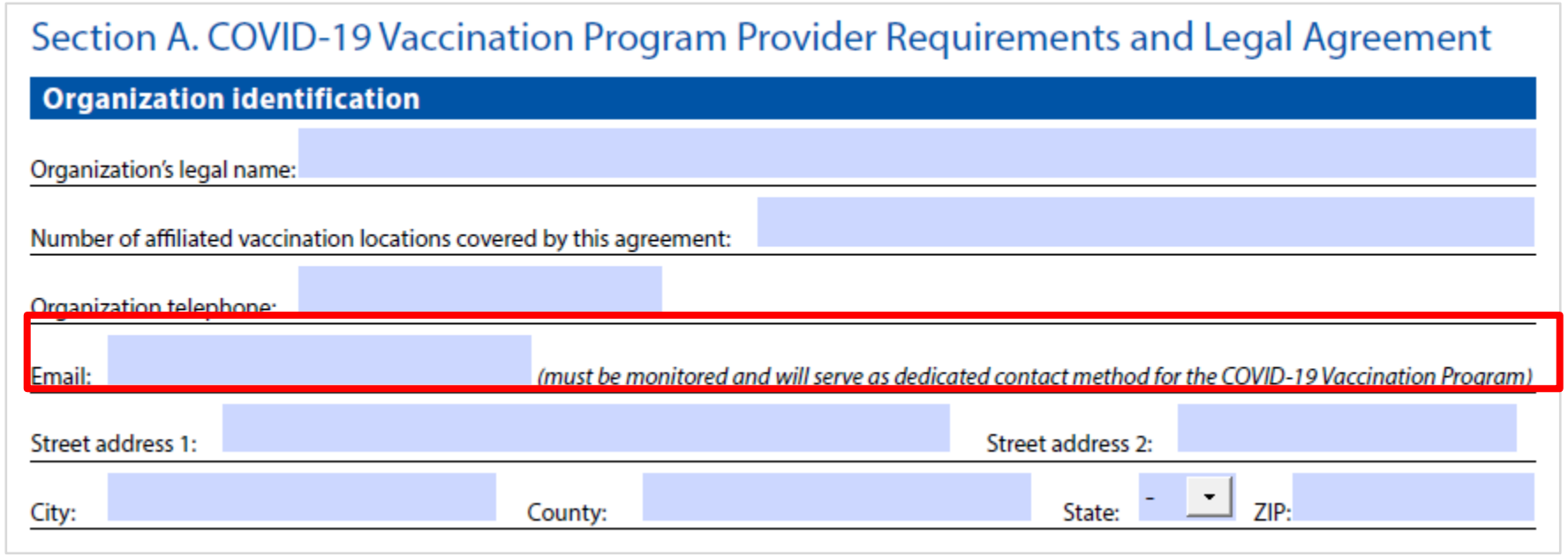
- Email from vaccinefinder@auth.castlighthealth.com
- Click the "Create Account" link to complete VaccineFinder onboarding
- Expect links next week
- Check spam!





VaccineFinder Account Set-up

- Account set-up email is sent to the **organization email address** provided in Section A of the Provider Agreement
- If you need to change the organization email address, please email us at COVID19vaccine@cityofchicago.org



Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

Organization identification

Organization's legal name:

Number of affiliated vaccination locations covered by this agreement:

Organization telephone:

Email: *(must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)*

Street address 1: Street address 2:

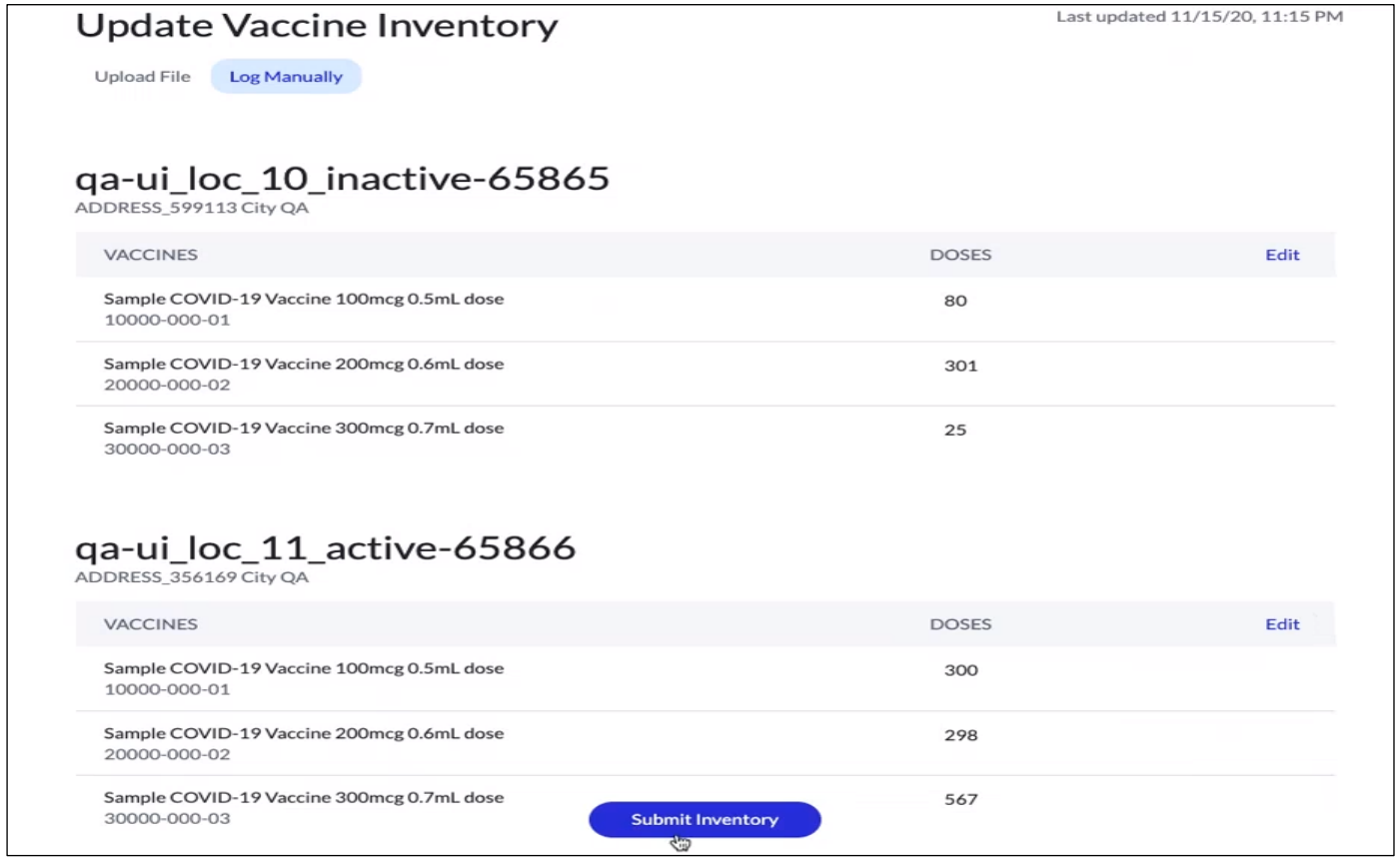
City: County: State: - ZIP:

VaccineFinder Account Set-up

- Organizations will determine whether they will:
  - report daily on-hand inventory on behalf of all their provider locations (e.g., a clinic headquarters office reporting on behalf of satellite clinics), or
  - individual provider locations will be responsible for reporting this information
- Once a determination is made, it must be maintained for the duration of the COVID-19 Vaccination Program.

Reporting Inventory

- When vaccines are available, log into the provider portal to submit daily COVID-19 vaccine inventory reports via online form or batch upload.



Resources

- **CDC COVID-19 Vaccination Provider Support, Data and Reporting:** https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html
- **VaccineFinder COVID-19 Vaccine Provider Information website (includes video trainings):** https://vaccinefinder.org/covid-provider-resources

Do you have a Q about Vaccines in Chicago?

COVID19VACCINE@cityofchicago.org

Contact information for IDPH (Non-Chicago Organizations)

- General vaccination questions: DPH.immunizations@illinois.gov
- ICARE specific: dph.icare@illinois.gov

CDPH
Chicago Department of Public Health

Online Questions?


Chicago.gov/Health


HealthyChicago@cityofchicago.org


@ChicagoPublicHealth


@ChiPublicHealth