CDC's COVID-19 Activities in the Dialysis Setting

Dialysis Safety Team, Prevention and Response Branch

Division of Healthcare Quality Promotion

Centers for Disease Control and Prevention

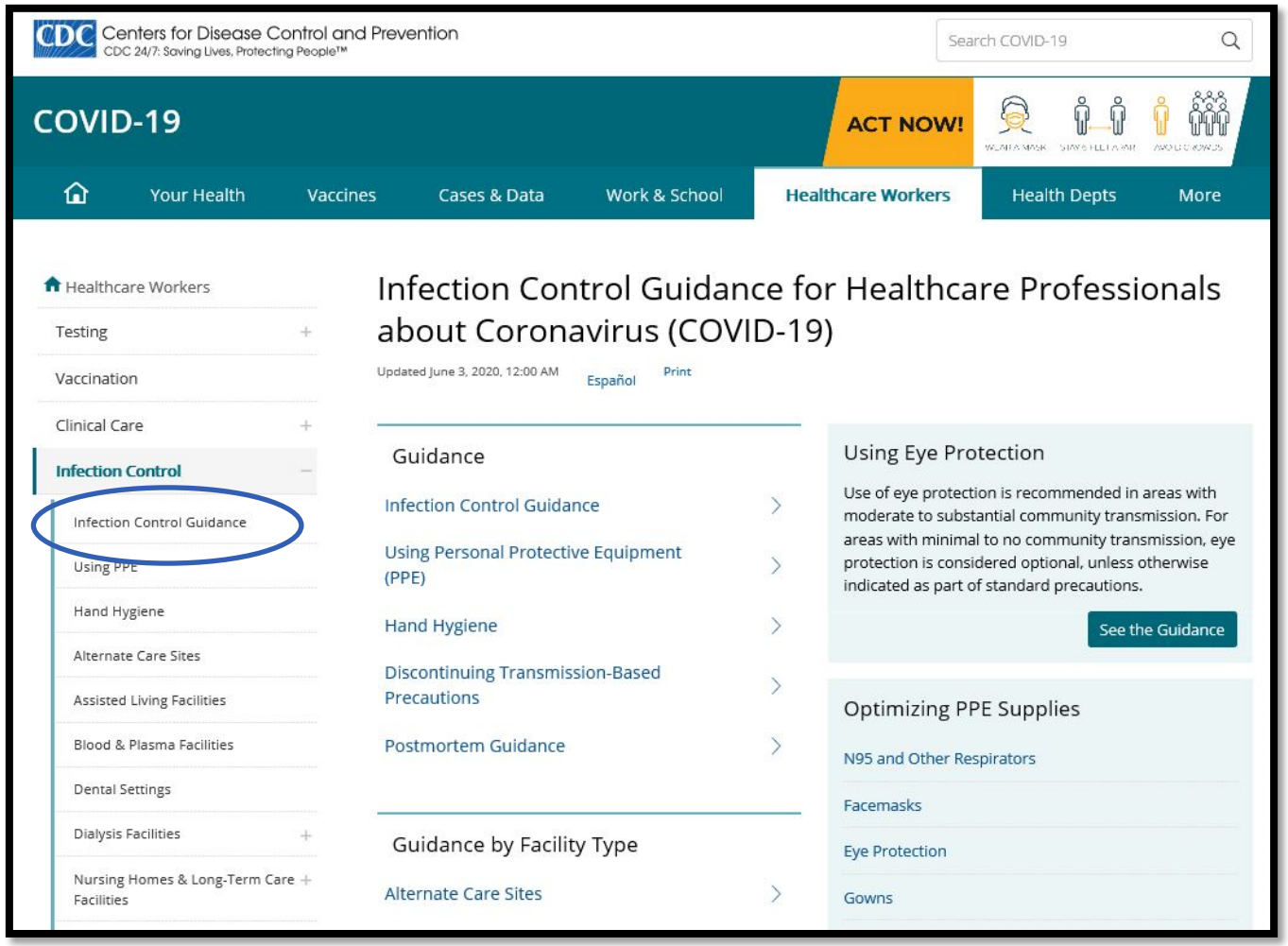
Kidney Community Emergency Response (KCER) Summit

March 10, 2021

cdc.gov/coronavirus

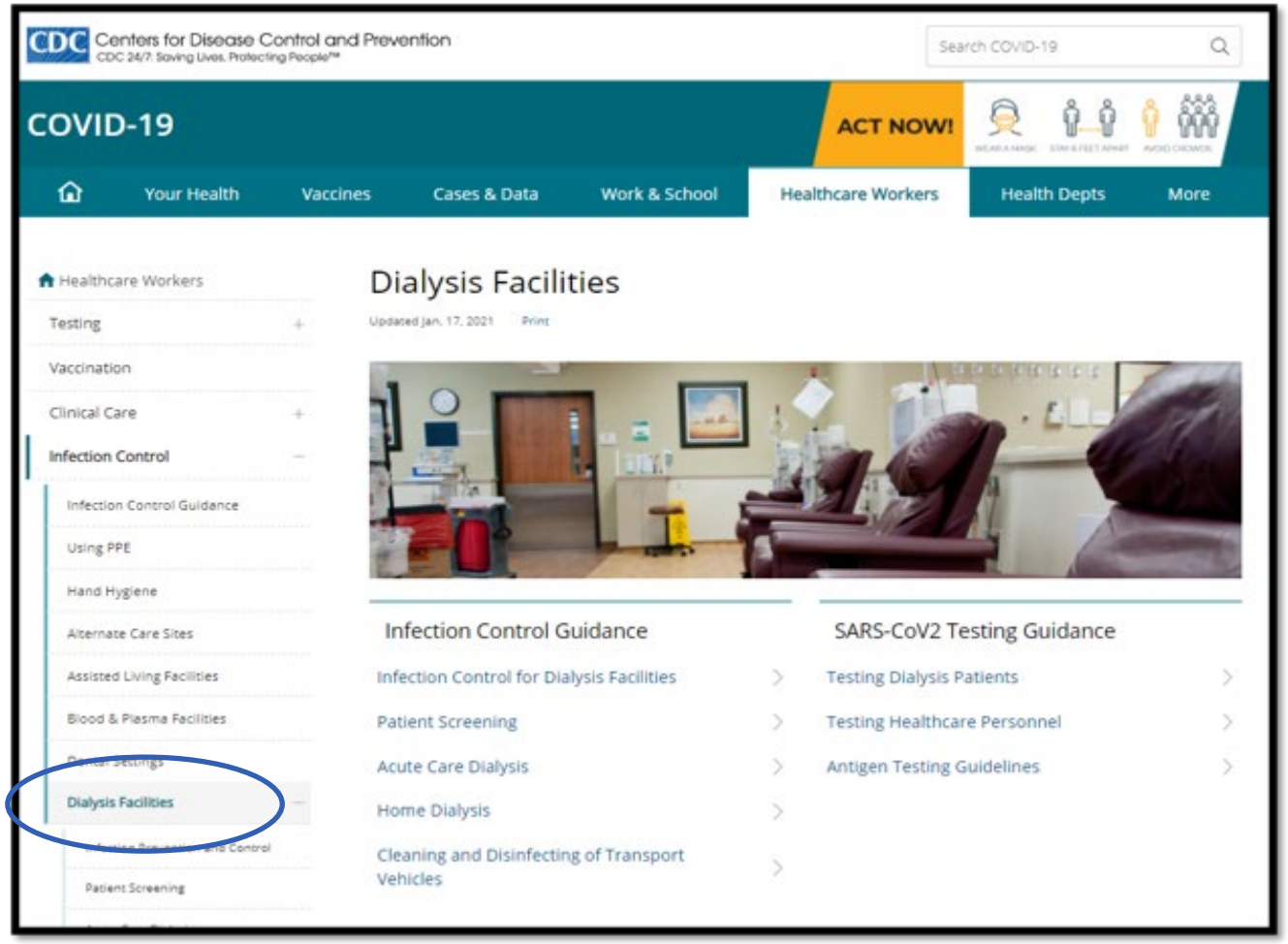
CDC = Centers for Disease Control and Prevention

CDC Guidance on Infection Control for COVID-19



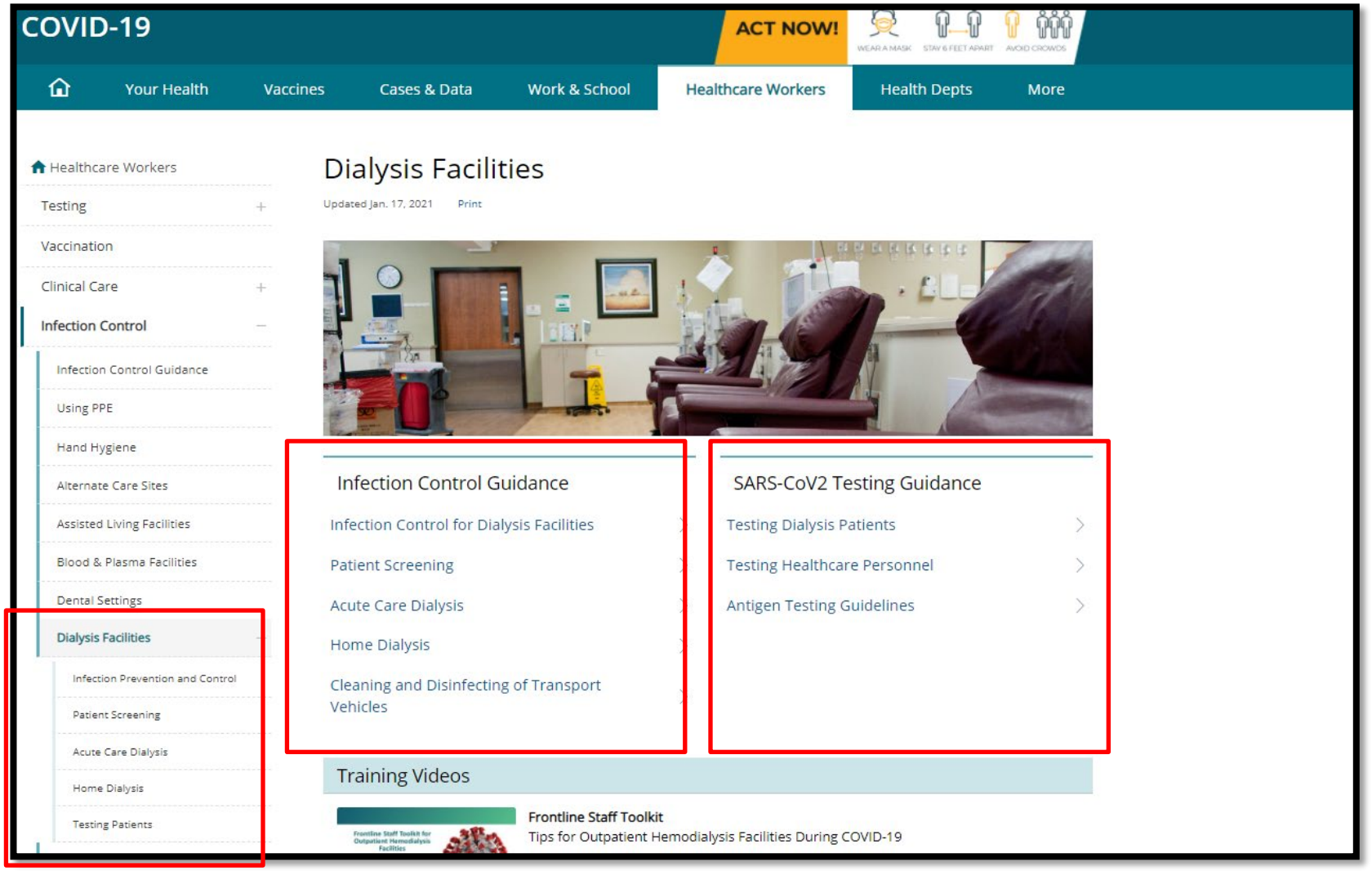
https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

CDC Guidance on Infection Control for COVID-19 (cont.)



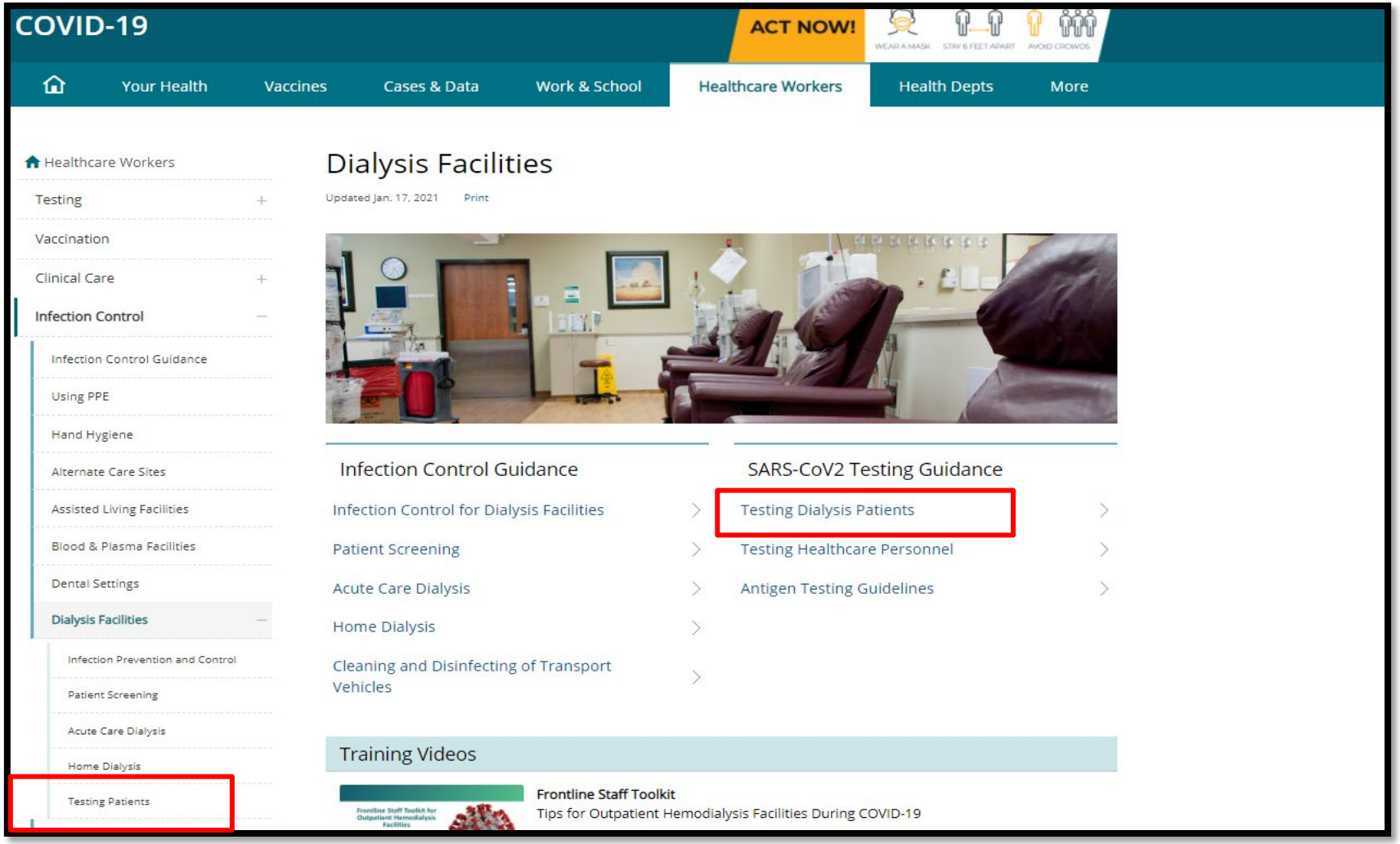
https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/infection-prevention-control.html

COVID-19 Dialysis Guidance



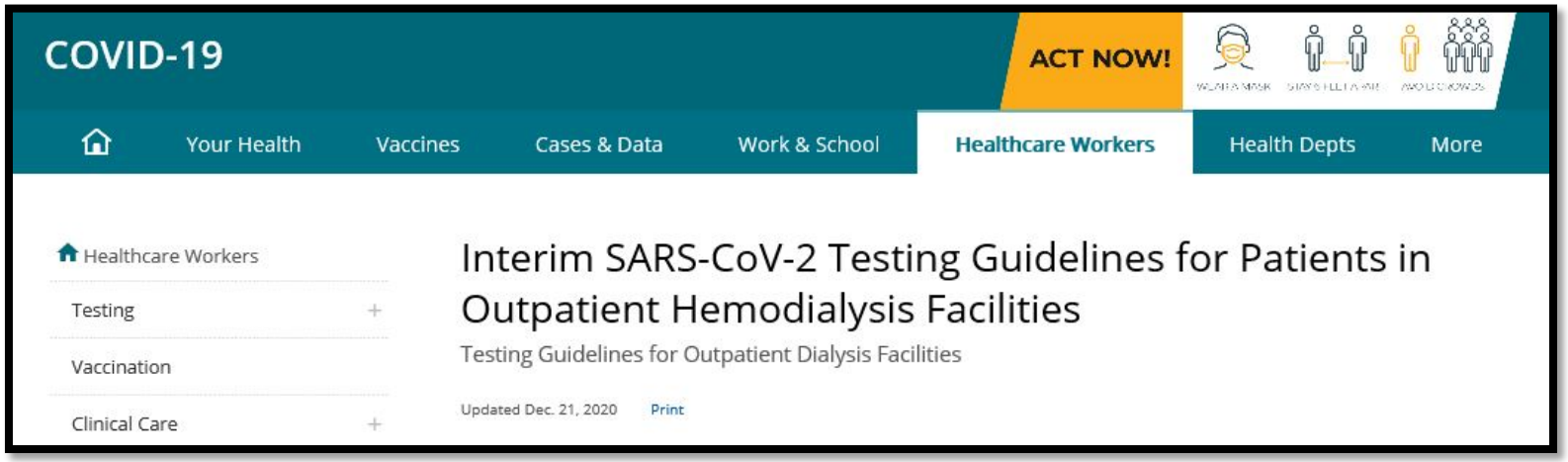
https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/dialysis.html

COVID-19 Dialysis Guidance (cont.)



https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/dialysis.html

Testing Guidelines



- Testing patients with signs and symptoms of COVID-19.
- Testing asymptomatic patients with known or suspected exposure to an individual infected with SARS-CoV-2, including close and expanded contacts (e.g., there is an outbreak in the facility) to control transmission.
- Testing to determine resolution of infection.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/testing-patients.html

Testing Asymptomatic Patients with Known or Suspected Exposure to an Individual Infected with SARS-CoV-2, Including Close and Expanded Contacts (e.g., There Is an Outbreak in the Facility) to Control Transmission

- Consider testing all patients and healthcare personnel (HCP) in the facility or at least all patients and HCP of the same shift.
- Identifying transmission within a dialysis facility can be challenging.
  - SARS-CoV-2 infections among HCP or patients with epidemiological links and no other exposures suggest transmission may have occurred within the facility.
  - Transmission within the facility should be considered an outbreak.
- Testing all patients as soon as transmission is suspected will allow:
  - Quick identification of infected patients.
  - Clinical management of patients.
  - Rapid implementation of infection prevention control (IPC) interventions.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/testing-patients.html

Testing Asymptomatic Patients with Known or Suspected Exposure to an Individual Infected with SARS-CoV-2, including Close and Expanded Contacts (e.g., There Is an Outbreak in the Facility) to Control Transmission (cont.)

- Facility leadership should be prepared to continue to provide dialysis and isolate patients as needed.
- HCP should also be tested.
- The following website has considerations on performing broad-based testing for SARS-CoV-2 infections in congregate settings: https://www.cdc.gov/coronavirus/2019-ncov/hcp/broad-based-testing.html
- Notify local public health authorities of suspected or confirmed outbreaks in the dialysis facility.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/testing-patients.html

Coronavirus Disease 2019 (COVID-19) Outpatient Dialysis Facility Preparedness Assessment Tool

All U.S. outpatient dialysis facilities should be prepared for the possible arrival of patients with Coronavirus Disease 2019 (COVID-19). All outpatient dialysis facilities should ensure their staff are trained, equipped, and capable of practices needed to:

- Prevent the spread of respiratory infections, including COVID-19, within the dialysis facility.
- Promptly identify and isolate patients with possible COVID-19 and inform the correct dialysis facility staff and public health authorities.
- Provide dialysis for a limited number of patients with confirmed or suspected COVID-19 as part of routine operations.
- Potentially provide dialysis for a larger number of COVID-19 patients in the context of an escalating outbreak.
- Monitor and manage any healthcare personnel that might be exposed to COVID-19.
- Communicate effectively within the dialysis facility and plan for appropriate external communication related to COVID-19.

The following checklist is not a list of mandatory requirements; rather, it highlights important areas CDC recommends outpatient dialysis facilities review in preparation for potential arrivals of COVID-19 patients.

Elements to be assessed

1. Infection prevention and control policies and training for healthcare personnel (HCP):	Completed	In Progress	Not Started
Facility leadership including, but not limited to, the Chief Medical Officer, quality officers, medical directors, facility administrator, nurse manager, infection prevention personnel, chief operating officer, nephrologists, nurse practitioners has reviewed the Centers for Disease Control and Prevention's COVID-19 guidance for dialysis facilities. www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/dialysis.html	☐	☐	☐
Facility provides education and job-specific training to HCP regarding COVID-19 including:			
Signs and symptoms of infection.	☐	☐	☐
Importance of hand hygiene, respiratory hygiene, cough etiquette and wearing a facemask or cloth face covering for source control.	☐	☐	☐
Use of personal protective equipment (PPE) including competency evaluation.	☐	☐	☐
Triage procedures and patient placement.	☐	☐	☐
HCP sick leave policies.	☐	☐	☐
Self-monitoring for fever or respiratory symptoms including not reporting to work when ill.	☐	☐	☐
How and to whom suspected and confirmed COVID-19 cases should be reported.	☐	☐	☐

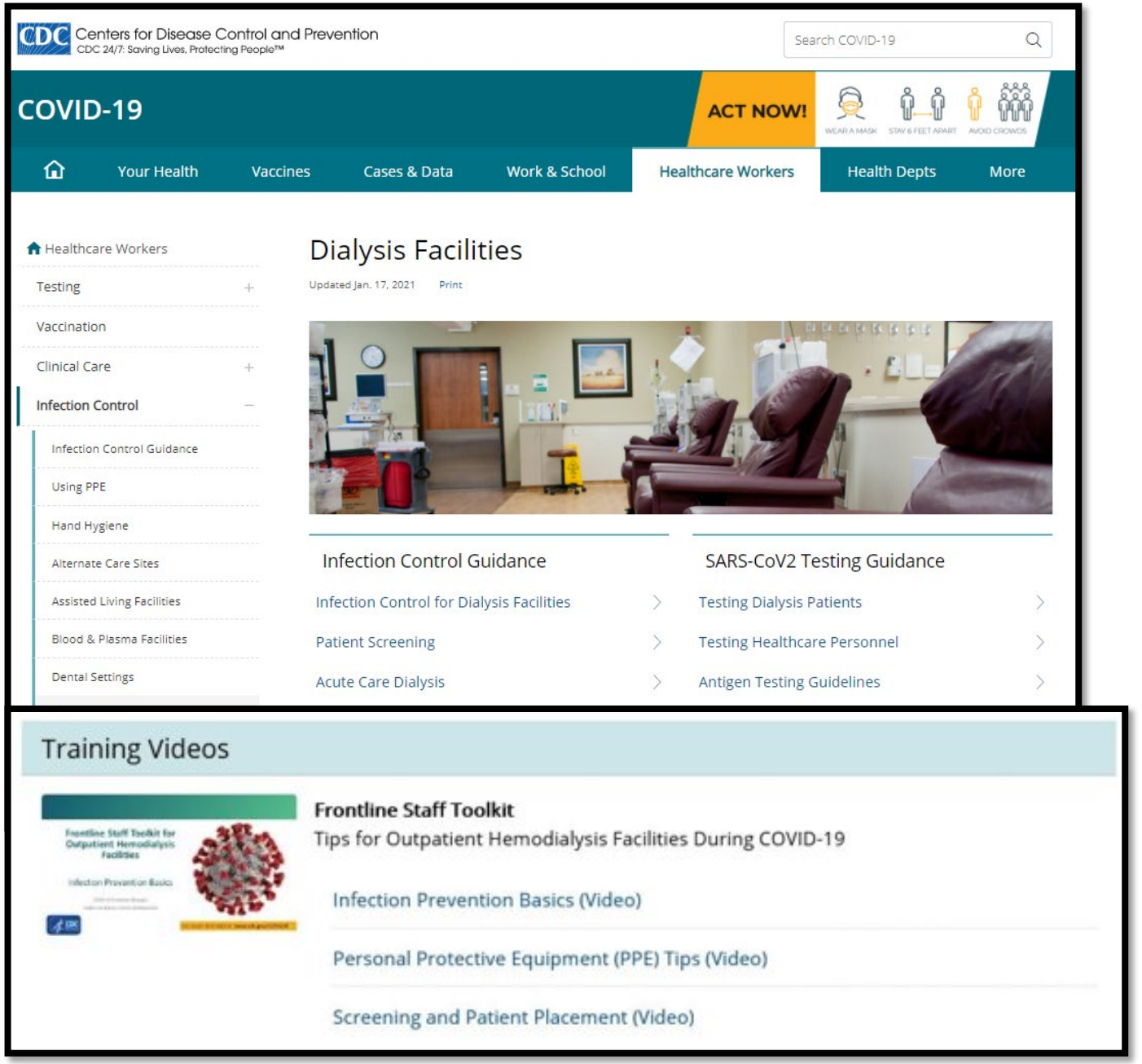
www.cdc.gov/coronavirus

2. Process for rapidly identifying and isolating patients with confirmed or suspected COVID-19:	Completed	In Progress	Not Started
Facility has notified patients to call ahead and report fever or symptoms of respiratory infection.	☐	☐	☐

4. Transmission-Based Precautions:	Completed	In Progress	Not Started
Facility has a procedure for assessing supply (inventory) of personal protective equipment (PPE) and other infection prevention and control supplies (e.g., hand hygiene supplies).	☐	☐	☐

8. Monitoring and managing HCP:	Completed	In Progress	Not Started
Facility has sick leave policies that are non-punitive, flexible and allow ill healthcare personnel (HCP) to stay home.	☐	☐	☐

https://www.cdc.gov/coronavirus/2019-ncov/downloads/COVID-19-outpatient-dialysis.pdf


CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™
Search COVID-19
COVID-19
ACT NOW!
WEAR A MASK
STAY 6 FEET APART
AVOID CROWDS
Your Health
Vaccines
Cases & Data
Work & School
Healthcare Workers
Health Depts
More
Healthcare Workers
Testing
Vaccination
Clinical Care
Infection Control
Infection Control Guidance
Using PPE
Hand Hygiene
Alternate Care Sites
Assisted Living Facilities
Blood & Plasma Facilities
Dental Settings
Dialysis Facilities
Updated Jan. 17, 2021
Print
Infection Control Guidance
Infection Control for Dialysis Facilities
Patient Screening
Acute Care Dialysis
SARS-CoV2 Testing Guidance
Testing Dialysis Patients
Testing Healthcare Personnel
Antigen Testing Guidelines
Training Videos
Frontline Staff Toolkit
Tips for Outpatient Hemodialysis Facilities During COVID-19
Infection Prevention Basics (Video)
Personal Protective Equipment (PPE) Tips (Video)
Screening and Patient Placement (Video)

COVID-19 Dialysis Resources

How our facility is keeping patients safe from COVID-19

Our outpatient dialysis facility is prepared for the possible arrival of patients with coronavirus disease 2019 (COVID-19). We are committed to keeping patients safe and are taking the following steps to reduce the risk of COVID-19 in our patients and staff:

- **We are providing extra training for staff and education for patients about the importance of hand hygiene, facemasks, respiratory hygiene,and cough etiquette.**

  Tissues, alcohol-based hand sanitizer, and trash cans will be provided in the waiting area and treatment area. Soap and water will continue to be available at all handwashing sinks and in the restrooms.

- **We are monitoring all staff for symptoms of COVID-19.**

  We are instructing staff who have symptoms of COVID-19 (e.g., fever, cough, shortness of breath, sore throat, muscle aches, tiredness) to stay home and not come to work.

- **We are monitoring patients on dialysis and visitors for symptoms of COVID-19.**

  Call ahead if you have fever, new cough, sore throat, tiredness, muscle aches or shortness of breath. This allows us to plan for your arrival and take infection prevention steps to keep you safe.

  Call us at:

- **We are prepared to quickly identify and separate patients with symptoms of COVID-19.**

  All patients will be screened upon entry to the facility and instructed to continue wearing their cloth face covering (or offered a facemask, if available). Patients with symptoms of COVID-19 will be treated in a separate area or at a corner or end-of-row station, away from the main flow of traffic.

  This may affect your chair location, treatment time or day, or you may need to be transferred to another facility based on symptoms or diagnosis of COVID-19.

- **We are training staff about proper use of personal protective equipment for COVID-19.**

  You may see a change in the personal protective equipment (i.e. gowns, masks, gloves) that staff are asked to wear.

- **We are continuing our routine cleaning and disinfection procedures as these procedures are recommended for protecting patients from COVID-19 in dialysis settings.**

  Any surface, supplies, or equipment located within the patient station will continue to be disinfected or discarded. We will ensure any surface, supplies or equipment located within 6 feet of an ill patient is disinfected or discarded.

- **We are limiting staff and visitors coming into the dialysis facility.**

  We are limiting non-essential staff entry into the dialysis facility by exploring ways to provide care to patients remotely (e.g., using telehealth options).

  We are restricting visitor access to only those who are essential for the patient's care. Visitors will be screened for fever and symptoms of COVID-19 prior to entry. Visitors will be asked to wear their cloth face covering and limit their movement in the facility.

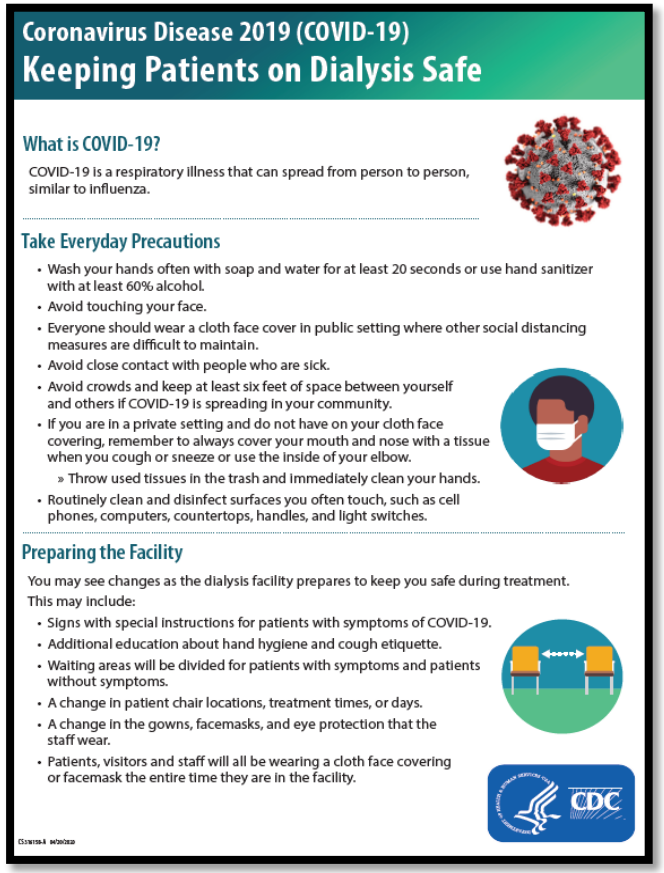
- **We are encouraging patients and staff to share all questions and concerns related to COVID-19.**

  Don't be afraid to use your voice. It is okay to askstaff questions about treatment changes and waysto protect yourself and your family.

- **We are staying up-to-date with the latest information from CDC's COVID-19 web page: www.cdc.gov/coronavirus.**

  Thank you for everything you are doing to keep yourself and your loved ones safe. We will keep you informed about any new precautionswe think are necessary. Please feel free to contact us with additional questions.

cdc.gov/coronavirus



Coronavirus Disease 2019 (COVID-19)
Keeping Patients on Dialysis Safe

What is COVID-19?

COVID-19 is a respiratory illness that can spread from person to person, similar to influenza.

Take Everyday Precautions

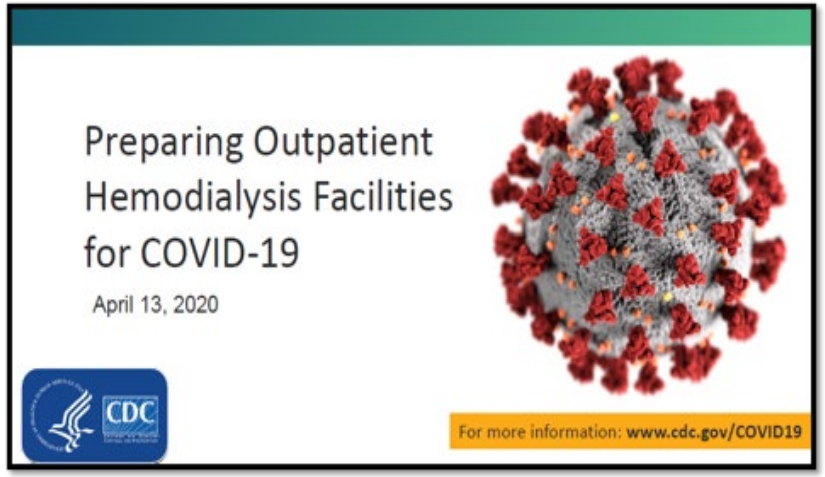
- Wash your hands often with soap and water for at least 20 seconds or use hand sanitizer with at least 60% alcohol.
- Avoid touching your face.
- Everyone should wear a cloth face cover in public setting where other social distancing measures are difficult to maintain.
- Avoid close contact with people who are sick.
- Avoid crowds and keep at least six feet of space between yourself and others if COVID-19 is spreading in your community.
- If you are in a private setting and do not have on your cloth face covering, remember to always cover your mouth and nose with a tissue when you cough or sneeze or use the inside of your elbow.
  - » Throw used tissues in the trash and immediately clean your hands.
- Routinely clean and disinfect surfaces you often touch, such as cell phones, computers, countertops, handles, and light switches.

Preparing the Facility

You may see changes as the dialysis facility prepares to keep you safe during treatment.

This may include:

- Signs with special instructions for patients with symptoms of COVID-19.
- Additional education about hand hygiene and cough etiquette.
- Waiting areas will be divided for patients with symptoms and patients without symptoms.
- A change in patient chair locations, treatment times, or days.
- A change in the gowns, facemasks, and eye protection that the staff wear.
- Patients, visitors and staff will all be wearing a cloth face covering or facemask the entire time they are in the facility.

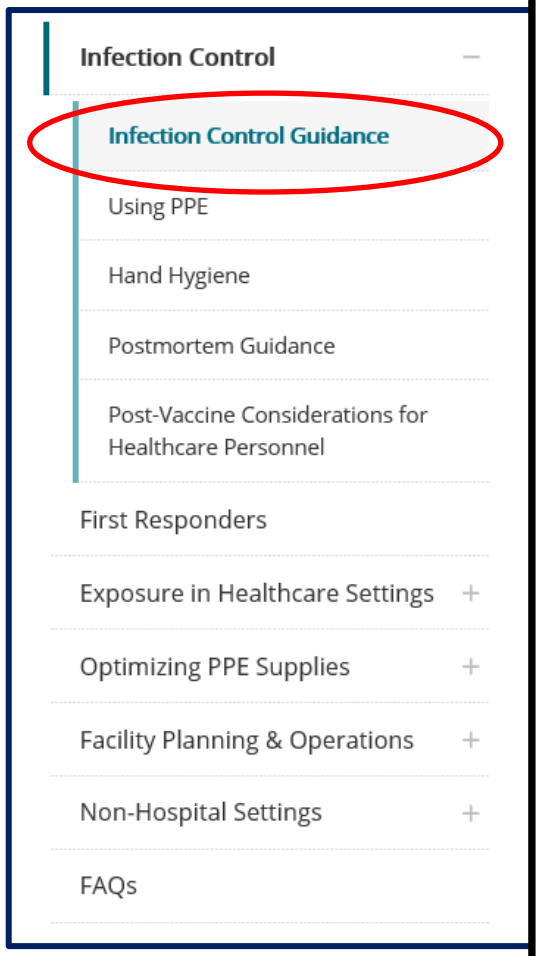


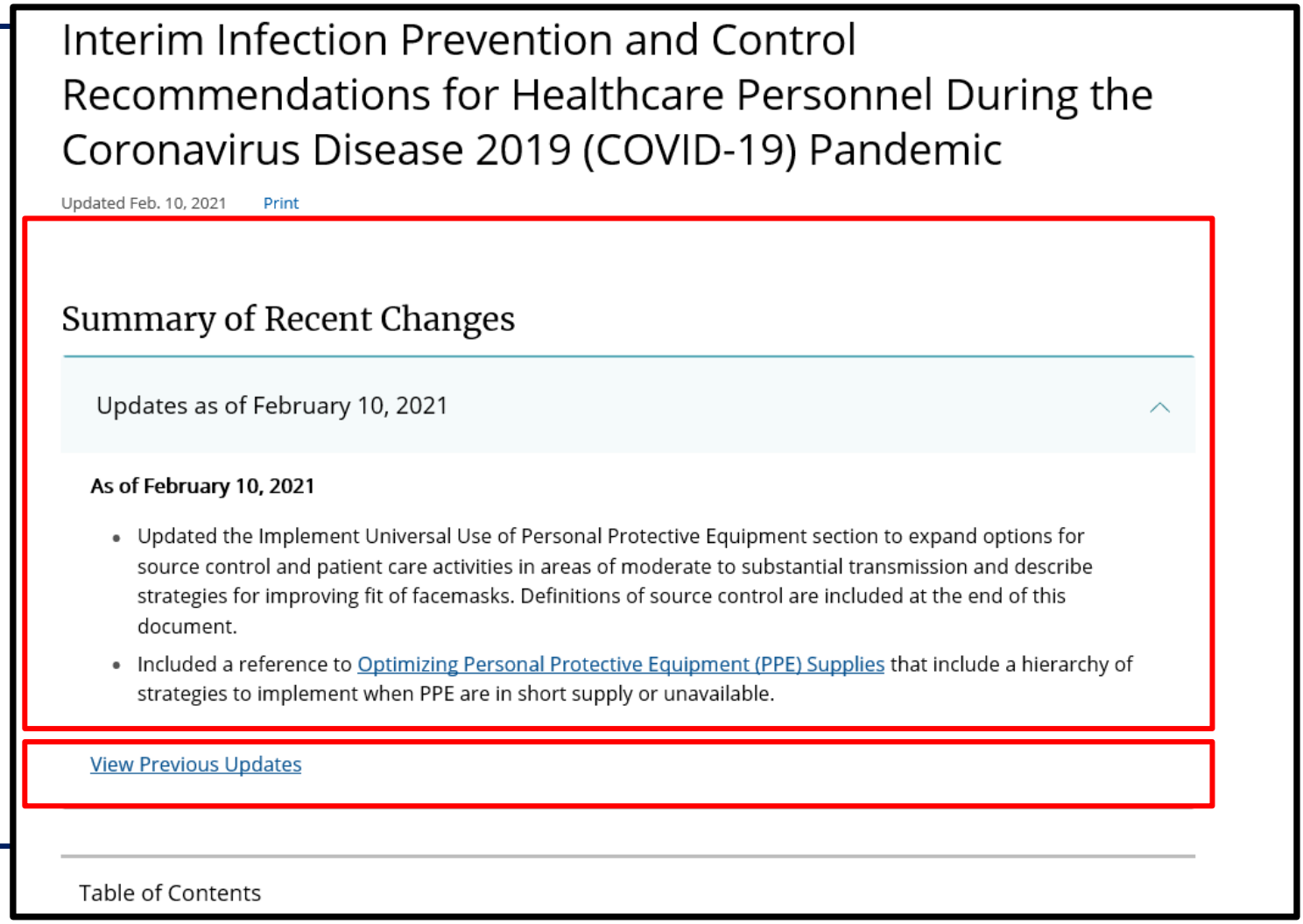
https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/home-dialysis.html

https://www.cdc.gov/coronavirus/2019-ncov/downloads/healthcare-facilities/316158-A_FS_ProtectSelfAndFam.pdf

https://www.cdc.gov/coronavirus/2019-ncov/downloads/healthcare-facilities/316157-A_FS_KeepingPatientsSafe.pdf

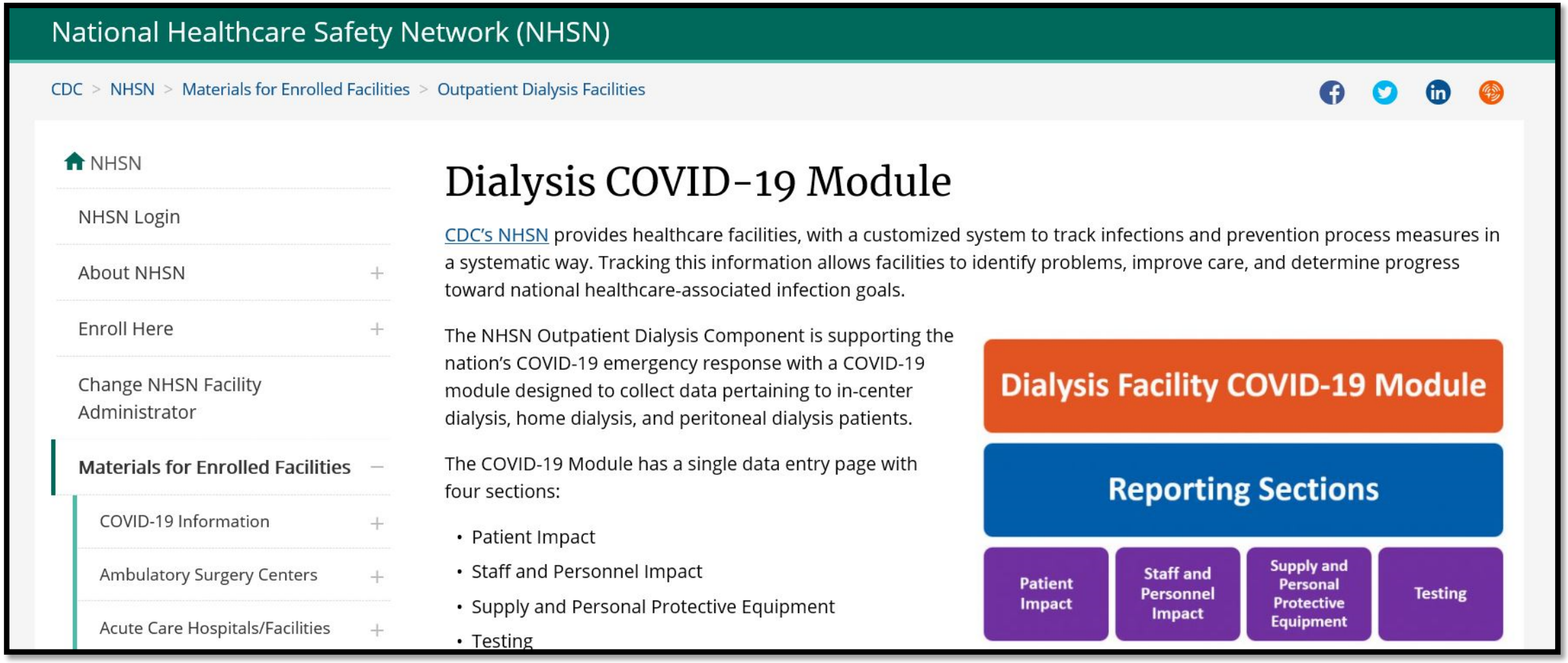
General IPC Guidance





https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html

Dialysis COVID-9 Module



https://www.cdc.gov/nhsn/dialysis/covid19/index.html

NHSN: Reporting HCP COVID-19 Vaccination

- Facilities participating in NHSN can report weekly COVID-19 vaccination data through the Healthcare Personnel Safety (HPS) Component
- Weekly reporting is currently optional
- Facilities can use the data to obtain a better picture of COVID-19 vaccination at their facility
  - Monitor vaccination rates over time
  - Identify HCP groups with lower vaccination rates
  - Improve vaccination tracking
  - Data from the HCP vaccination module can inform decision-making

https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html

NHSN = National Healthcare Safety Network

A Point Prevalence Survey Was Implemented at 4 Dialysis Facilities in the Metro Atlanta Area

~640 dialysis patients in-center

Decreasing, but high community spread.
No suspected outbreak or transmission in the facilities.

Results are preliminary.

634

patients enrolled at all 4 facilities.

548

available for consent

86

unavailable for consent

Results are preliminary.

634

patients enrolled at all 4 facilities.

548

available for consent

86

unavailable for consent

Results are preliminary.

Of the 86 Unavailable Patients, 51 (59%) Patients Did Not Have a Reason for Missing Dialysis

Reasons for Unavailability	A	B	C	D	All Facilities
Sick or hospitalized	2	4	2	3	11
Hospice	0	1	0	0	1
Cognitive impairment	4	4	1	4	13
Dialysis schedule change	2	0	0	1	3
Too late to sample (night shift)	0	0	0	4	4
Deceased	0	0	2	1	3
No show	25	9	8	9	51
Total	33	18	13	22	86

Results are preliminary.

634

patients enrolled at all 4 facilities.

548

available for consent

86

unavailable for consent

361 (66%)

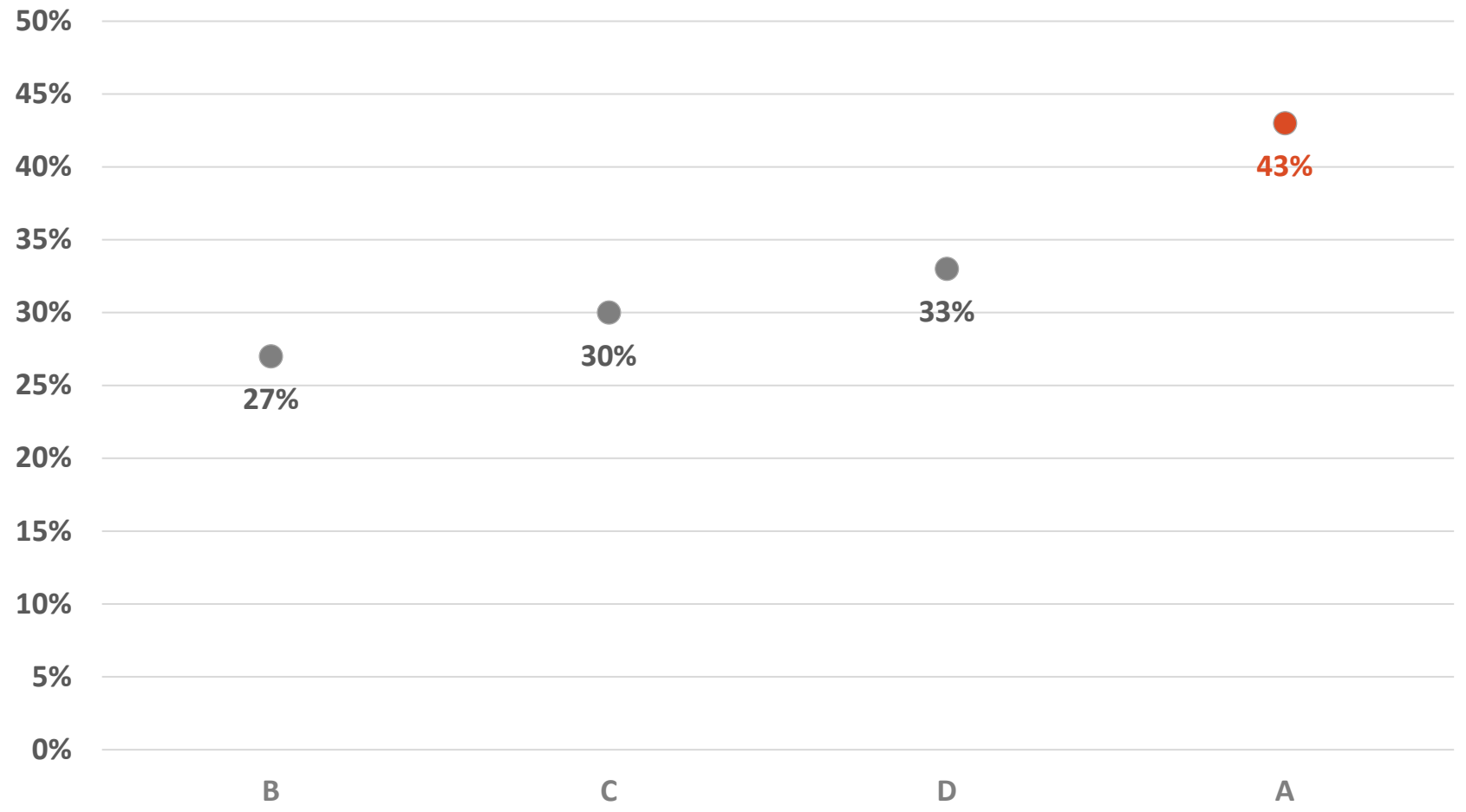
consented

187 (34%)

refused

Results are preliminary.

Refusal Rates Ranged From 27–43% Depending on the Dialysis Facility



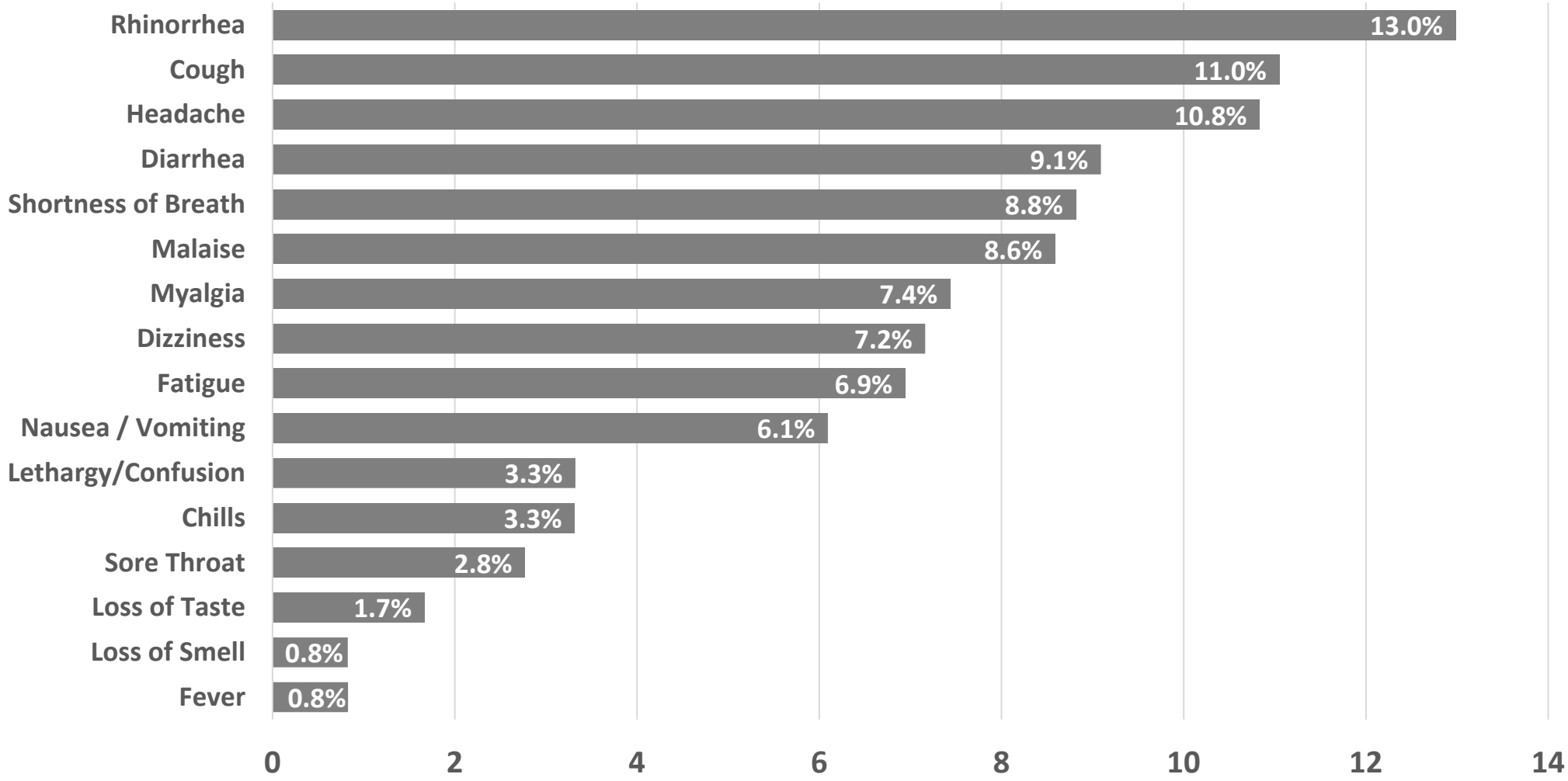
Results are preliminary.

Of the 187 Patients Who Refused, Nearly 1 in 4 Were Likely to Refuse Because of Testing in Recent Weeks

Reasons for Refusal	A	B	C	D	All Facilities
Previously Tested	9	3	12	19	**43 (23%)**
Did not want to alter dialysis schedule	0	1	0	1	2
Getting tested soon	1	2	0	5	8
Distrust (CDC, testing, etc.)	1	1	1	7	10
Fear of result or of procedure	0	3	1	8	12
Asymptomatic	1	1	0	6	8
Other	2	0	2	0	4
Total *(+ those with no reason listed)	64	34	26	63	**187**

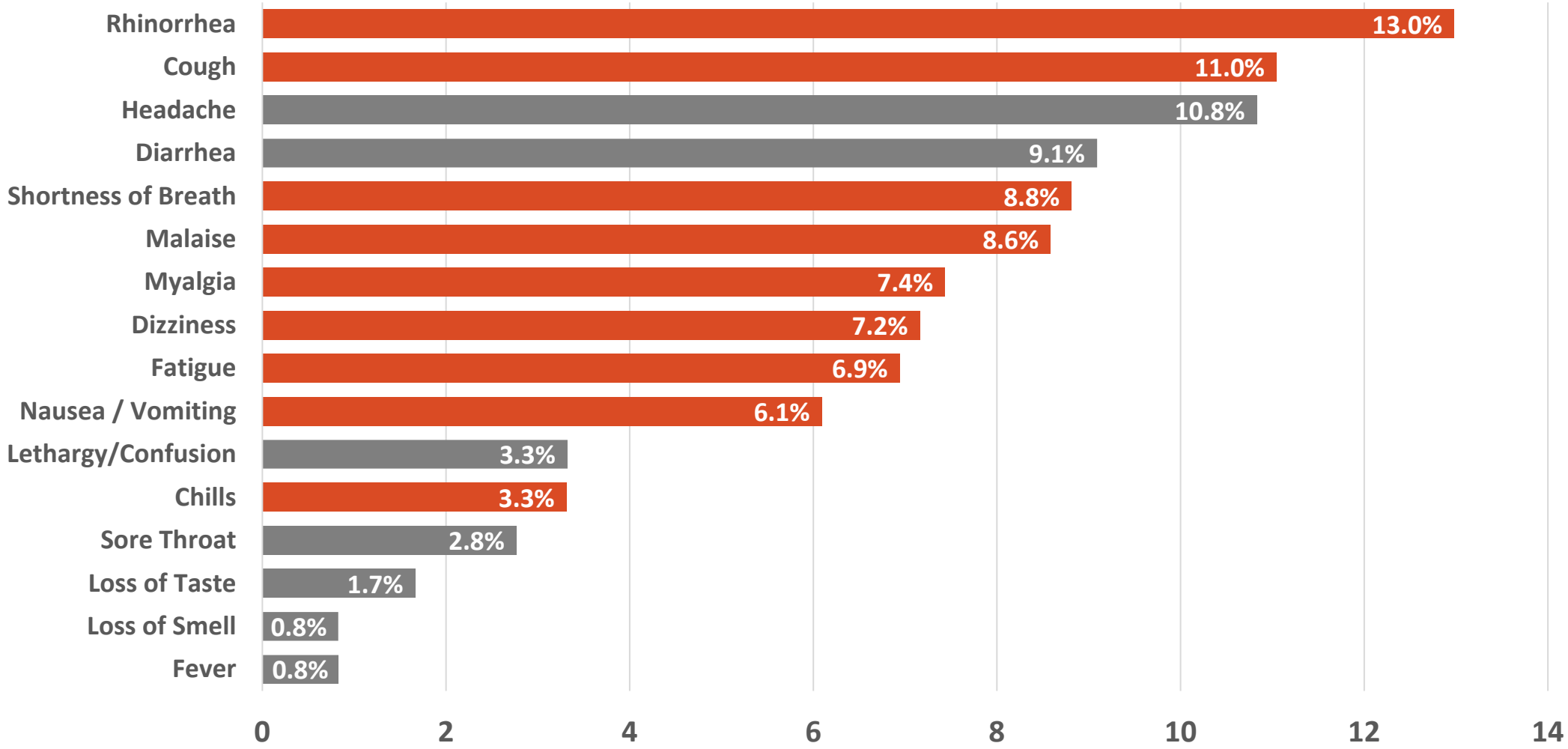
Results are preliminary.

Among the 361 Participants, 165 (46%) Reported Symptoms in the Last 14 Days



Results are preliminary.

Some of the Most Reported Symptoms May Be Frequently Encountered in ESRD Patients



Results are preliminary.

Among the 361 Patients Who Participated, Few Reported High-risk Exposures

2% had close contact to a person with COVID-19 at home or in the community

1% lived in a nursing home

Results are preliminary.

Among the 361 Patients Who Participated, Few Reported High-risk Exposures

1% worked in a healthcare setting

6% attended gatherings >10 people in the past 2 weeks

Results are preliminary.

Among the 361 Patients Who Participated,

Zero were positive for SARS-CoV-2.

Results are preliminary.

Heightened Infection Control Practices Were Already in Place

Universal masking

Enhanced social distancing

COVID-19 dialysis cohort

Results are preliminary.

Facility-wide Testing May Be More Useful When Specific Indicators Are Present

Increasing community spread*

Suspected transmission within a dialysis facility

***=increasing cumulative incidence or % test positivity in the past 7 days**

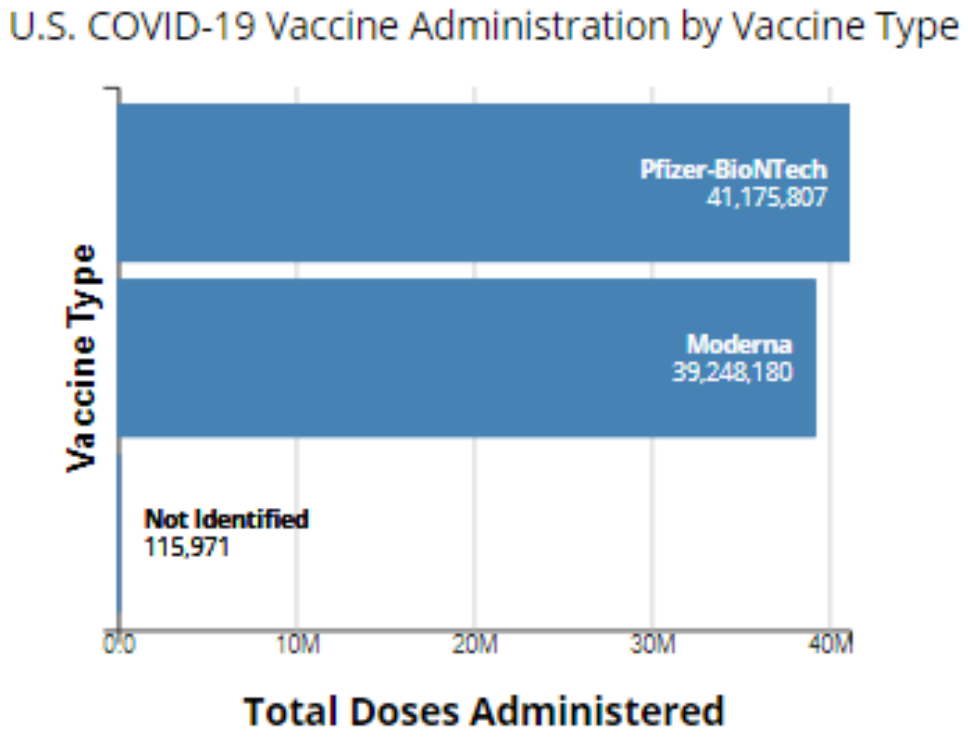
Results are preliminary.

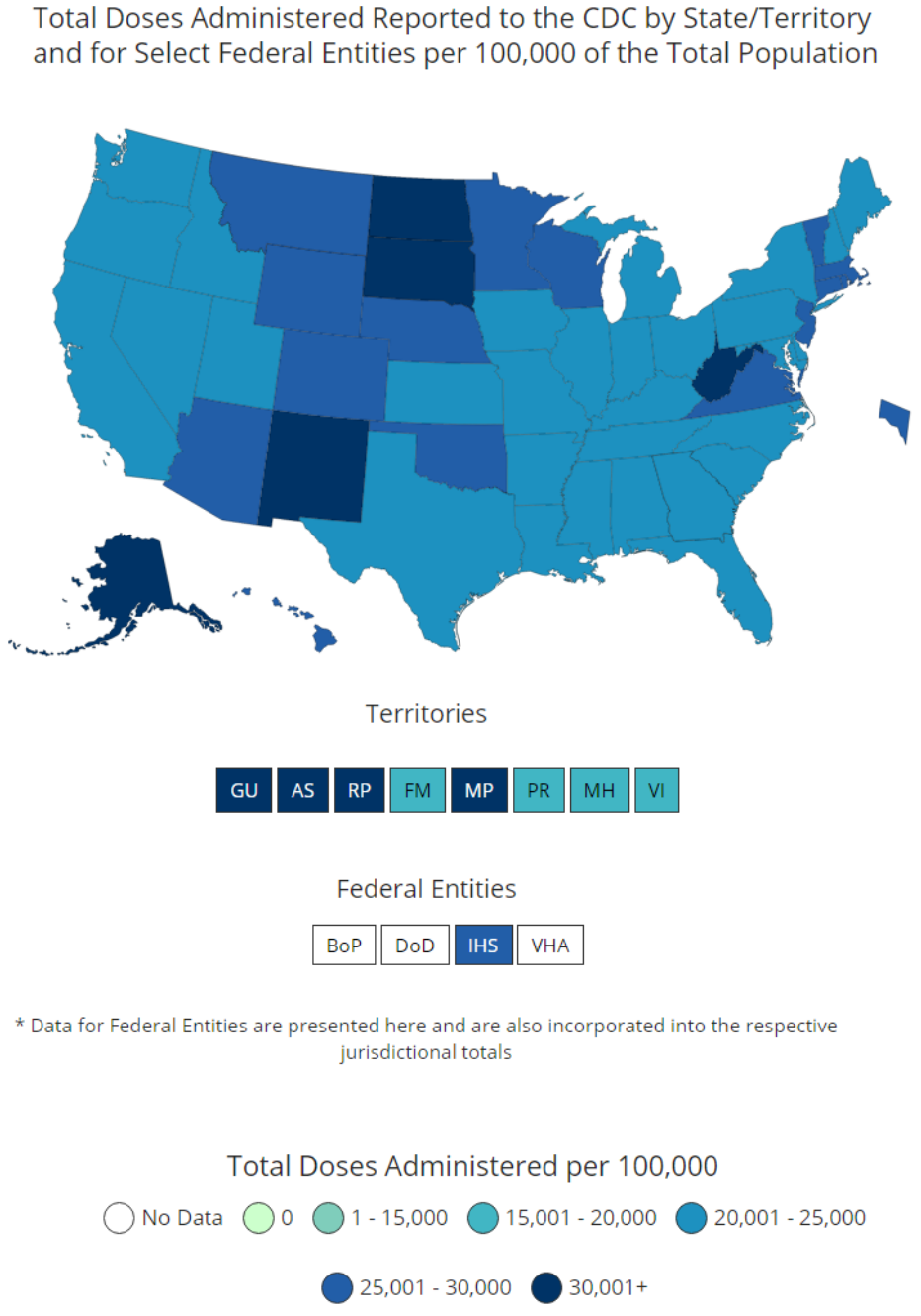
COVID-19 Vaccine Implementation

COVID-19 Vaccines Administered

As of March 3, 2021

Total Vaccine Doses Administered: 80,540,474





Available: https://covid.cdc.gov/covid-data-tracker

COVID-19 Vaccines Under FDA Emergency Use Authorizations (EUAs)

- Three vaccines have received Emergency Use Authorizations (EUAs) from the FDA:
  - **Pfizer/BioNTech:** 2 doses given at least 21 days apart
  - **Moderna:** 2 doses given at least 28 days apart
  - **Johnson & Johnson/Janssen**: 1 dose
- All three vaccines were tested in tens of thousands of adults from diverse backgrounds, including older adults and communities of color.
- All of the available vaccines have been proven effective at preventing serious illness, hospitalization, and death from COVID-19 disease.
- It is unknown how long protection from vaccines might last.

Sources: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine
https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy

ACIP's Origins and Role

- ACIP established in **1964** by the Surgeon General of the U.S. Public Health Service.
- Designated as a Federal Advisory Committee in 1972.
- **Role**: To provide advice and guidance to the CDC Director and the HHS Secretary on most effective means to prevent vaccine-preventable diseases in the U.S. civilian population.
  - Advises on population groups and/or circumstances in which a vaccine is recommended.
- ACIP deliberations include consideration of disease **epidemiology** and **burden of disease, vaccine efficacy** and **effectiveness, vaccine safety,** the **quality** of evidence reviewed**, economic analyses,** and **implementation issues**.

- CDC is the secretariat for ACIP, but ACIP is independent of the CDC; Voting ACIP members are not CDC employees.

ACIP = Advisory Committee on Immunization Practices
HHS = Health and Human Services Administration

ACIP Recommendations as HHS Policy

- ACIP recommendations become policy following approval by the CDC Director and MMWR publication.

- The Affordable Care Act (ACA) was enacted in 2010 and requires insurance coverage for immunizations included in ACIP's approved immunization schedules.

- Health plans have 1 plan year from MMWR publication to implement recommendations according to CDC immunization schedules.

MMWR = Morbidity and Mortality Weekly Report

ACIP

ACIP voting members

≥2

Chair

CDC

Lead

+ Subject Matter Experts
+ Immunization Safety Office
+ Immunization Services Division

***Ex-officio* members**

Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), Indian Health Service, U.S. Department of Defense, National Vaccine Program Office (NVPO), Biomedical Advanced Research and Development Authority (BARDA), National Institutes of Health,U.S. Department of Veterans Affairs, Health Resources & Services Administration (HRSA)

Liaison representatives

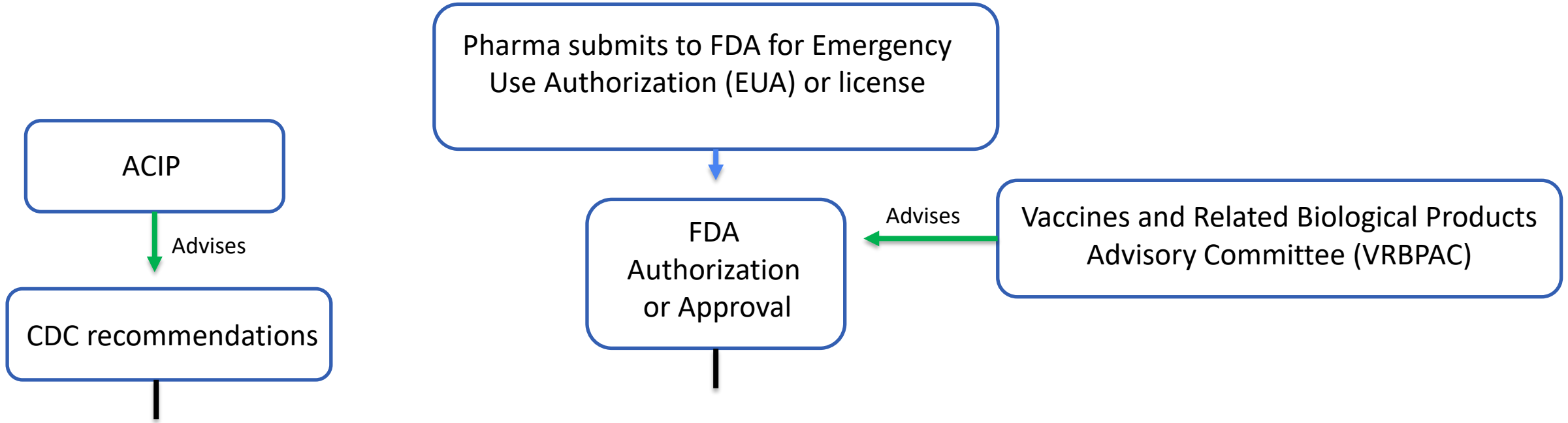
American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American Academy of Physician Assistants (AAPA), American College Health Association (ACHA), American College of Nurse-Midwives, American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), American Geriatrics Society (AGS), America's Health Insurance Plans (AHIP), American Immunization Registry Association (AIRA), Association of Immunization Managers (AIM), American Medical Association (AMA), American Nurses Association (ANA), American Osteopathic Association (AOA), American Pharmacists Association (APhA), Association for Prevention Teaching and Research (APTR), Association of State and Territorial Health Officials (ASTHO), Biotechnology Innovation Organization (BIO), Council of State and Territorial Epidemiologists (CSTE), Infectious Disease Society of America (IDSA), national Association of County & City Health Officials (NACCHO), National Association of Pediatric Nurse Practitioners (NAPNAP), Canadian National Advisory Committee on Immunization (NACI), National Foundation for Infectious Diseases (NFID), Mexican National Immunization Council and Child Health Program, National Medical Association (NMA), National Vaccine Advisory Committee (NVAC), Pediatric Infectious Diseases Society, Pharmaceutical Research and Manufacturers of America (PhRMA), Society for Adolescent Health and Medicine (SAHM), The Society for Healthcare Epidemiology of America (SHEA)

Consultants

See *ACIP Policies and Procedures* guidance for abbreviations

- **15** voting members
  - Includes 1 consumer representative and 14 members with expertise in specific disciplines
  - 4-year, overlapping terms
- **8** *ex-officio* members representing other government agencies involved in immunization
- **31** liaison representatives with broad involvement in immunization

Vaccine Licensure and Recommendations

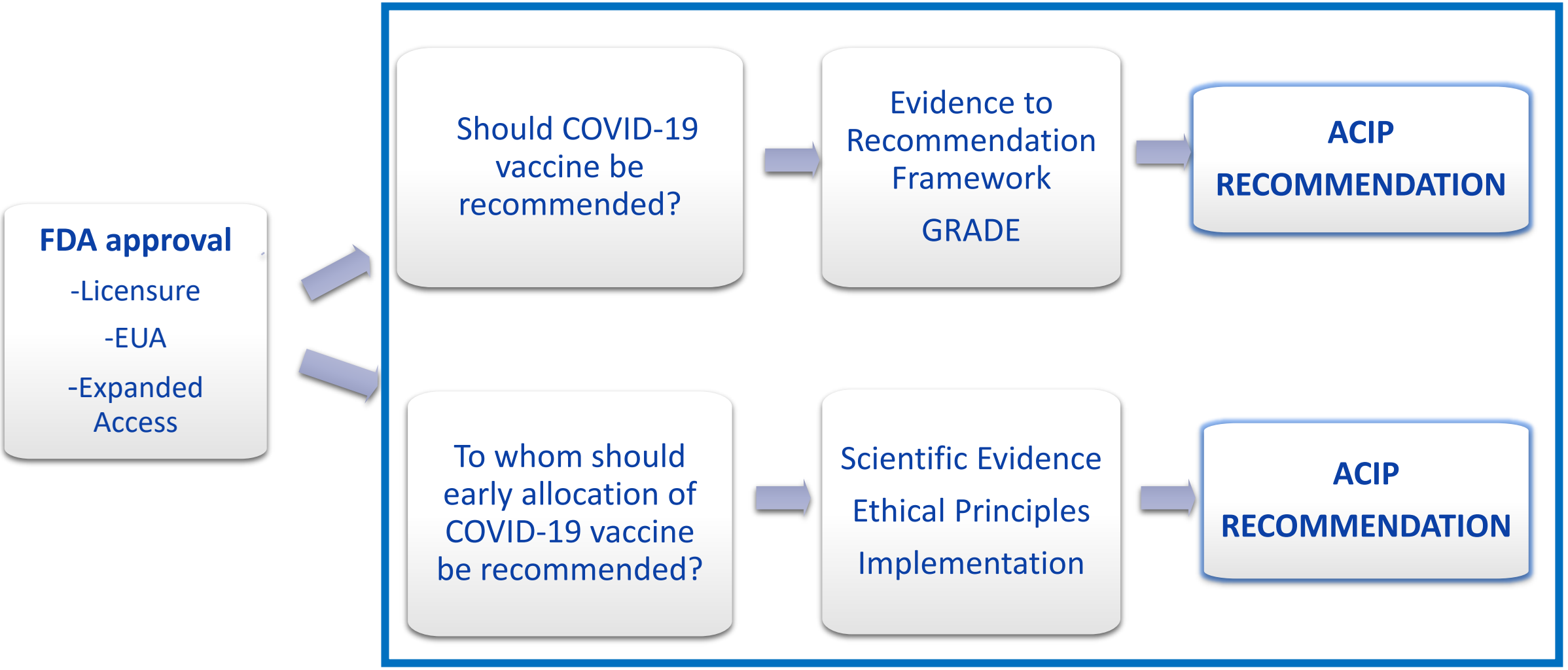


- Recommendation for use of EUA or licensed vaccines guided by FDA, labeling, and other considerations

- FD&C Act (section 564) and PHS Act (section 351(a))
- National Regulatory Agency, has enforcement authority
- Allows for availability and use of vaccines
- Labeling content restricted to stated intended use in studied population and supported by data from adequate and well-controlled studies provided by manufacturer

EUA = Emergency Use Authorization
FDA = Food and Drug Administration
FD&C Act = Food, Drug, and Cosmetic Act

ACIP Pathway to Recommendation



Do Not Distribute

Overview of Groups Prioritized by ACIP

Phase 1a

- ✓ Healthcare personnel
- ✓ Long-term care facility residents

Phase 1b

- ✓ Frontline essential workers
- ✓ Persons ages 75 years and older

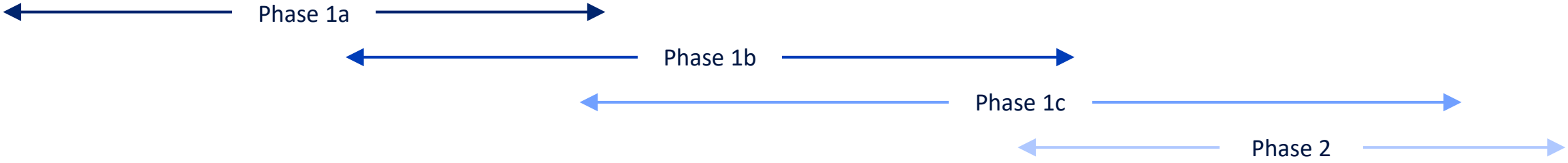
Phase 1c

- ✓ Persons ages 65–74 years
- ✓ Persons ages 16–64 years with high-risk conditions
- ✓ Essential workers not recommended in Phase 1b

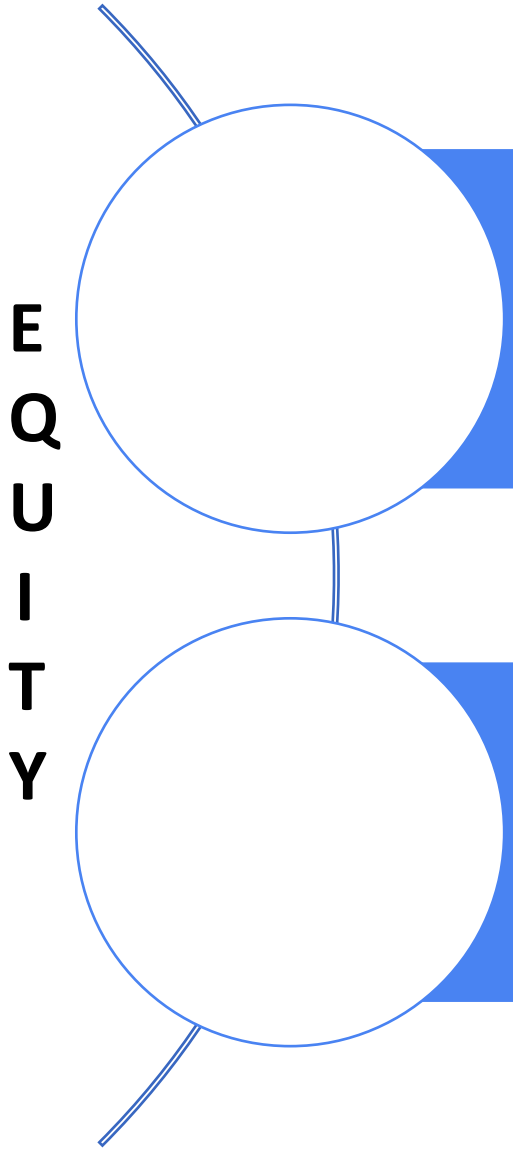
Phase 2

- ✓ All people ages 16 years and older not in Phase 1 who are recommended for vaccination

Initiation of phases will be overlapping



ACIP: COVID-19 Vaccine Guiding Principles



Efficient Distribution. During a pandemic, efficient, expeditious, and equitable distribution and administration of authorized vaccine is critical.

Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand.

Fast-tracking COVID-19 Vaccines While Ensuring Safety

- mRNA COVID-19 vaccines were developed based on years of research.
- Researchers used existing networks to conduct COVID-19 vaccine trials.
- Manufacturing began while clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials.
- mRNA vaccines are faster to produce than traditional vaccines.
- FDA and CDC are prioritizing review and authorization of COVID-19 vaccines.

*For more information, visit the COVID-19 Prevention Network: www.coronaviruspreventionnetwork.org/about-covpn

Safety of COVID-19 Vaccines Is a Top Priority

COVID-19 vaccines are being held to the same safety standards as all vaccines.

Before Authorization

- **FDA** carefully reviews all safety data from clinical trials.
- **ACIP** reviews all safety data before recommending use.

After Authorization

- **FDA** and **CDC** closely monitor vaccine safety and side effects. There are systems in place that allow CDC and FDA to watch for safety issues.

VAERS Vaccine Adverse Event Reporting System www.vaers.hhs.gov

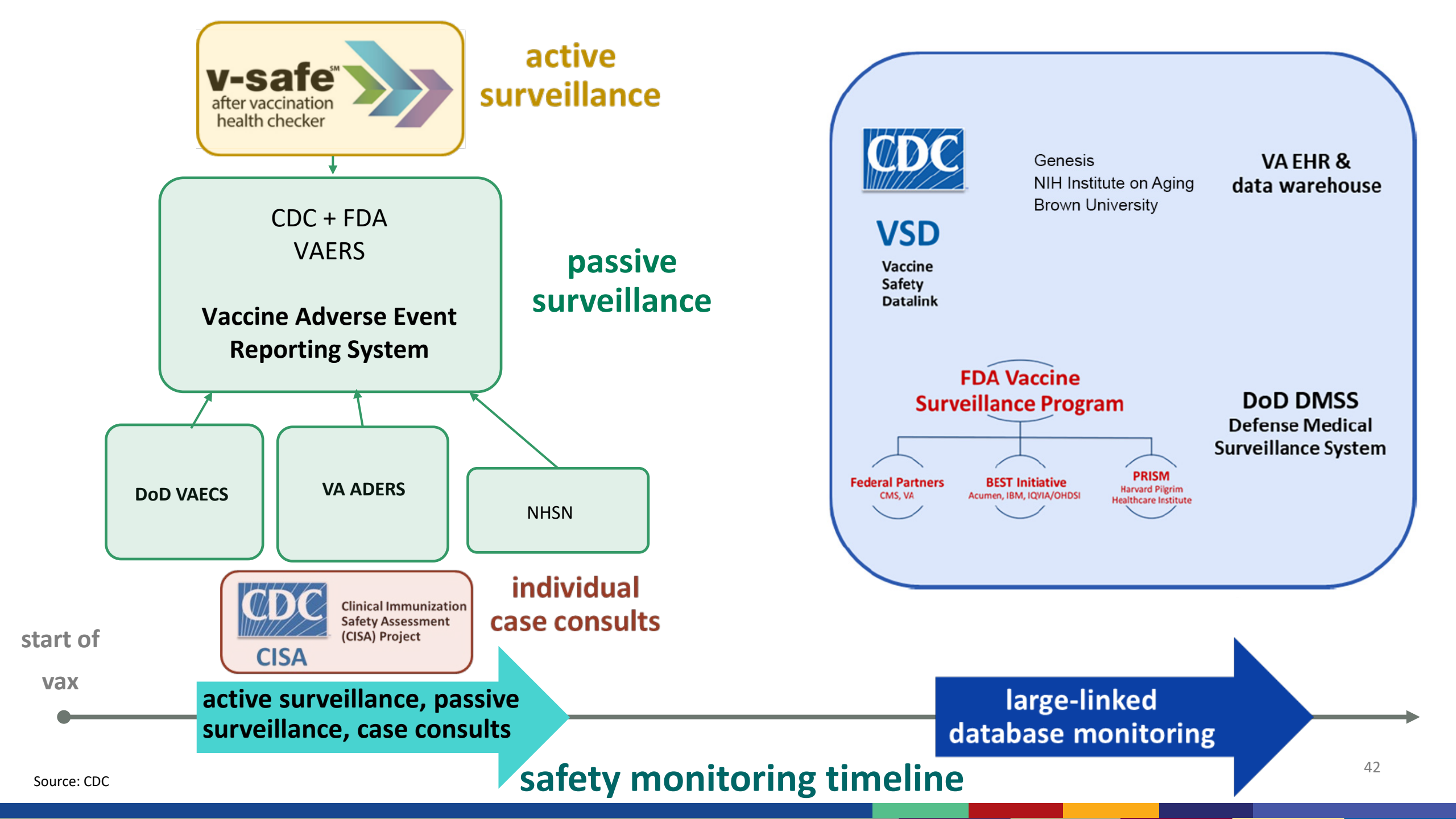
v-safe after vaccination health checker

V-safe: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

COVID-19 Vaccine Safety Strategy

1. **Use established systems** to implement heightened safety monitoring for COVID-19 vaccines.
2. **Develop new platforms** and leverage other federal data sources to complement existing systems.
3. **Communicate clearly** on the vaccine safety process and systems now; provide COVID-19 vaccine safety data and monitoring results once available.

CDC working with the FDA, DoD, Indian Health Service, and the U.S. Department of Veterans Affairs


v-safe
after vaccination health checker
active surveillance
CDC + FDA
VAERS
Vaccine Adverse Event Reporting System
passive surveillance
DoD VAECS
VA ADERS
NHSN
CDC
Clinical Immunization Safety Assessment (CISA) Project
CISA
individual case consults
CDC
Genesis
NIH Institute on Aging
Brown University
VA EHR & data warehouse
VSD
Vaccine Safety Datalink
FDA Vaccine Surveillance Program
Federal Partners
CMS, VA
BEST Initiative
Acumen, IBM, IQVIA/OHDSI
PRISM
Harvard Pilgrim Healthcare Institute
DoD DMSS
Defense Medical Surveillance System
start of vax
active surveillance, passive surveillance, case consults
large-linked database monitoring
safety monitoring timeline

Source: CDC

VAERS Is the Nation's Early Warning System for Vaccine Safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

Co-managed by the CDC and FDA.

http://vaers.hhs.gov

Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

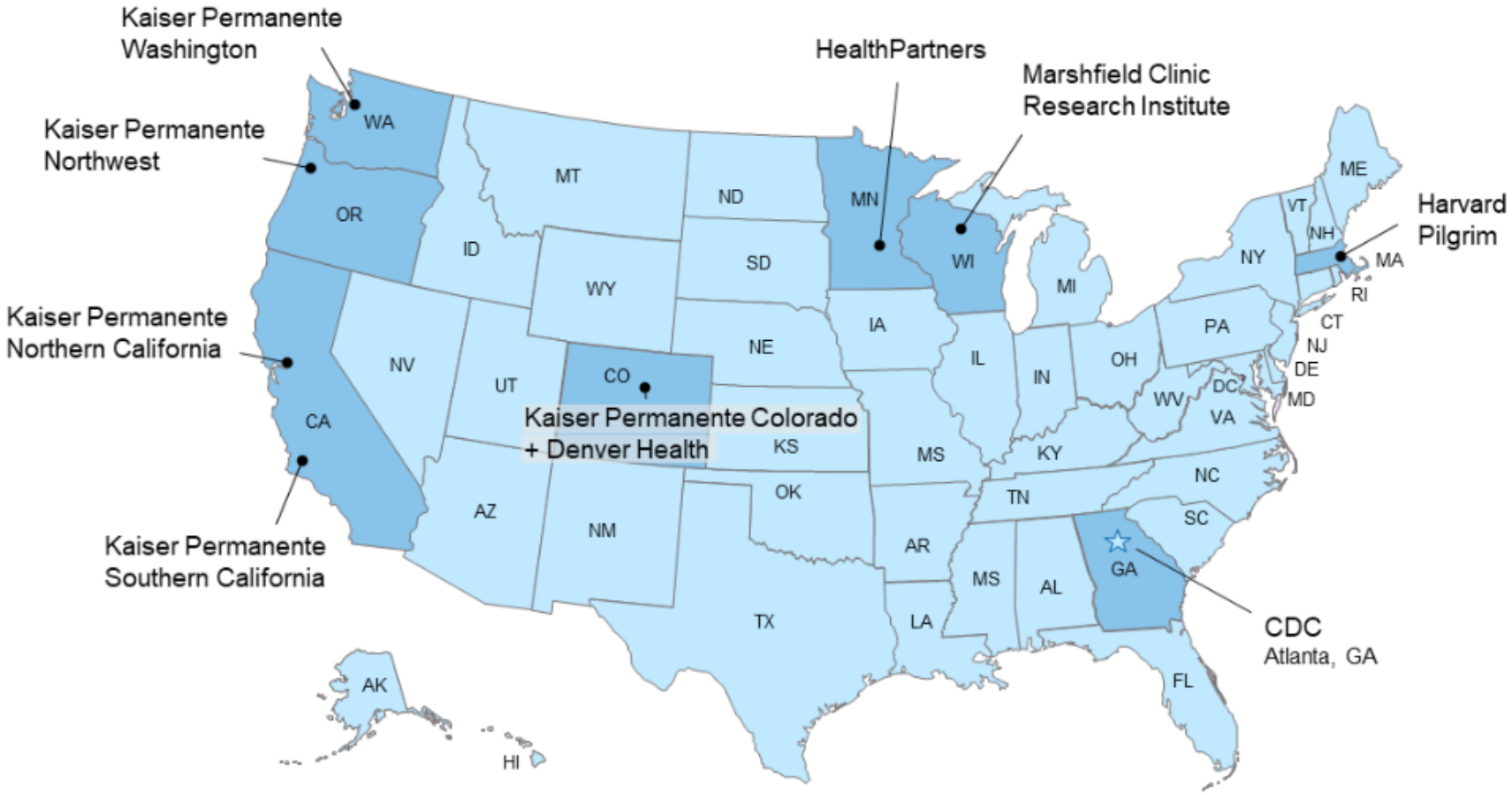
Limitations

- Reporting bias
- Inconsistent data quality and completeness of information
- Lack of unvaccinated comparison group
- Not designed to assess causality

- VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event
- As a hypothesis-generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

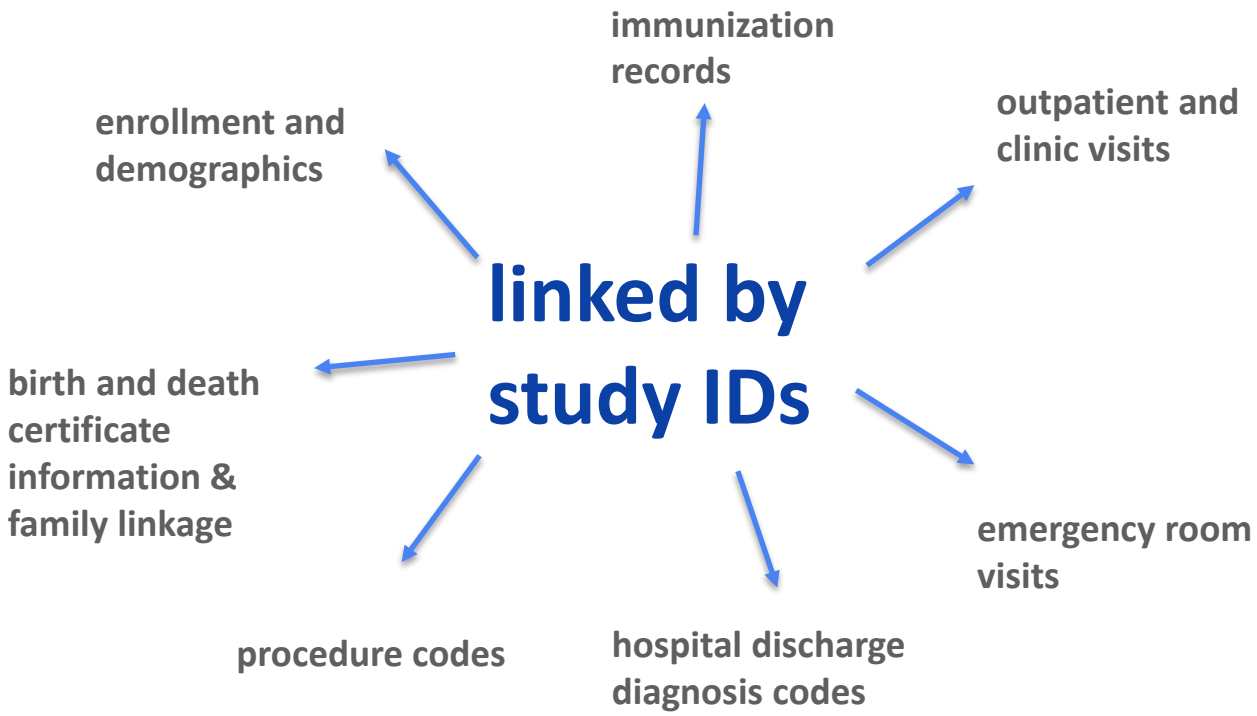
VSD

Vaccine Safety Datalink



- **9** participating integrated healthcare organizations
- data on over **12 million** persons per year

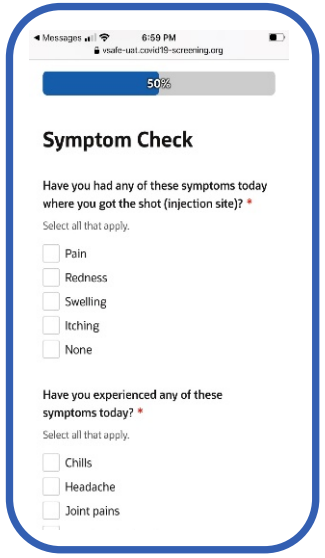
Types of Information in VSD



+ charts and electronic health records

Active Safety Monitoring for COVID-19 Vaccines

- V-safe is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety:
  - Uses text messaging and web surveys to check in with vaccine recipients after vaccination.
  - Participants can report any side effects or health problems after COVID-19 vaccination.
  - Includes active telephone follow-up by CDC for reports of significant health impact.



1. Text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

   vaccine recipient completes web survey*

Vaccine recipients

v-safe℠ after vaccination health checker

2. Clinically important health impact reported

✓ **received medical care**

Call center

3. **V-safe** call center conducts active telephone follow-up on a clinically important event and takes a VAERS report if appropriate

4. Pregnancy registry team conducts outreach to assess eligibility for registry and obtain consent for enrollment and follow-up

Call center

* Selected web surveys capture information on pregnancy status.

Source: CDC; v-safe

The Problem: Need to Instill Vaccine Confidence

- Overall acceptability of a COVID-19 vaccine is **moderate.**[1]
  - Proportion intending to receive vaccine ranged across surveys: 42–86% (as of Nov.–Dec. 2020 polls).

Factors weighing on acceptance:

Concern about side effects

Efficacy

Risk perception

Associated costs

Tyson A, Johnson C, & Funk C. (2020, September 17). *U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine.* Pew Research Center. https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/

COVID-19 vaccine more acceptable if:

Healthcare provider said it was safe

There are no costs to the individual

It would help get back to school and work

They could get it easily

Jackson C, & Newall M. (2020, September 29). *Despite COVID-19 spike, few individual behaviors are changing*. Ipsos. https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index

1. APNORC; Harris; Fisher Ann Intern Med.; ICF; Kreps JAMA Netw Open.; Lazarus Nature Med.; Malik EClinicalMedicine.; Pogue Vaccines.; Reiter Vaccine.; Thunstrom SSRN. Axios-IPSOS. Pew. KFF. ABC News-IPSOS.

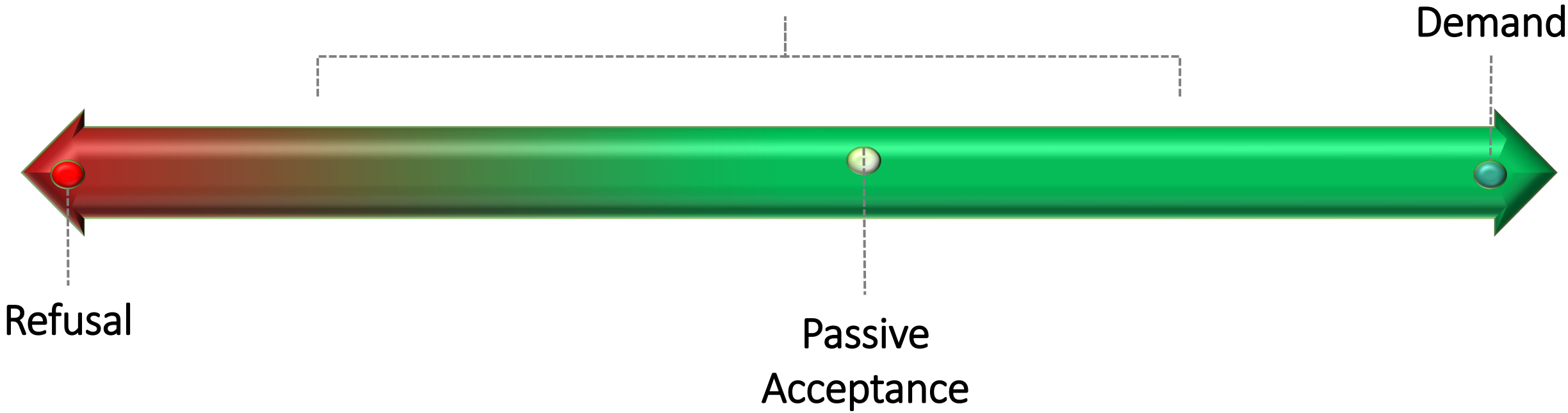
Defining Vaccine Confidence

- Vaccine confidence is the trust that patients, parents, or providers have in:
  - recommended vaccines;
  - providers who administer vaccines; and
  - processes and policies that lead to vaccine development, licensure, manufacturing, and recommendations for use.

The Vaccine Demand Continuum

INCREASING CONFIDENCE IN VACCINE, VACCINATOR, AND HEALTH SYSTEM

May have questions, take "wait and see" approach, or want more information.



Source: CDC

A New Pandemic, a New Vaccine, and a New Adult-Focused Platform Means Shifting Tactics

- Individuals across the spectrum will have concerns. These concerns are understandable and need to be addressed with empathy and transparency.
- Concerns among healthcare providers is a risk for overall vaccine confidence. Healthcare providers are the most trusted source for health information.
- Communities will have unique experiences informing COVID-19 vaccine perceptions. Engagement with community organizations and leaders will expand access to clear and accurate information on COVID-19 vaccines.

Vaccinate with **Confidence**

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

Reinforce Trust	**Objective: Regularly share clear and accurate COVID-19 vaccine information and take visible actions to build trust in the vaccine, the vaccinator, and the system.**
Empower Healthcare Providers	**Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.**
Engage Communities & Individuals	**Objective: Engage communities in a sustainable, equitable, and inclusive way—using two-way communication to listen, increase collaboration, and build trust in COVID-19 vaccine.**

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines (cont.)

Reinforce Trust

Objective: Regularly share clear and accurate COVID-19 vaccine information and take visible actions to build trust in the vaccine, the vaccinator, and the system.

Tactics

- ✓ **Communicate transparently** about the process for approving, making recommendations for, monitoring the safety of, and distributing COVID-19 vaccines.
- ✓ **Provide regular updates** on benefits, safety, and effectiveness, including updates from an independent vaccine safety monitoring group.
- ✓ **Proactively address and mitigate the spread and harm of misinformation** via social media platforms, partners, and trusted messengers.

Sample Products and Tools

- Web content: "Vaccine Information for You & Your Family"
- Interactive vaccine rollout timeline webpage
- Field guide to address and build resilience against COVID-19 vaccine misinformation

Vaccinate with **Confidence**

A National Strategy to Reinforce Confidence in COVID-19 Vaccines (cont.)

Empower Healthcare Providers

Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

Tactics

- ✓ Engage systems and healthcare personnel often and early to ensure clear understanding of the vaccine development and approval process, and the benefits of vaccination.
- ✓ Ensure healthcare systems and medical practices create a culture that is supportive of COVID-19 vaccine administration.
- ✓ Support empathetic vaccine conversations in healthcare encounters to confidently address vaccine-related questions and provide tailored vaccine information to patients.

Sample Products and Tools

- "Talking to patients about COVID-19 vaccine" slide deck for healthcare personnel (HCPs)
- Quick answers to common COVID-19 vaccine questions (fact sheet for HCPs)
- Guide for how to build COVID-19 vaccine confidence within health systems and clinics

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines (cont.)

Engage Communities & Individuals

Objective: Engage communities in a sustainable, equitable, and inclusive way—using two-way communication to listen, increase collaboration, and build trust in COVID-19 vaccine.

Tactics

- ✓ Work with jurisdictions to engage new community partners for vaccine distribution.
- ✓ Work with jurisdictions and national partners to collaborate with communities around vaccine uptake and service delivery strategies.
- ✓ Collaborate with trusted messengers in communities of color to tailor and share culturally relevant messages and materials.

Sample Products and Tools

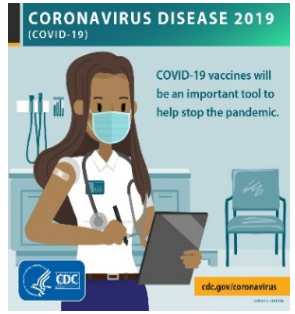
- Vaccinate with Confidence—Rapid Community Assessment Guide
- Vaccinate with Confidence with COVID-19 Vaccines slide deck in multiple formats/languages
- Briefing materials for ethnic media roundtable events

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines (cont.)

- Is NOT
  - An advertising, marketing, or communications “campaign.”
- Is
  - A cohesive framework to support health departments, healthcare providers, immunization partners, community partners, and leaders’ promotion of COVID-19 vaccines.
  - Evidence-based content to amplify messages that enable an individual to make the decision to vaccinate.
  - Critical to ensuring safe and effective COVID-19 vaccines can help control and reduce the impact of this pandemic.

Prepare for COVID-19 Vaccine Conversations



Choose to get vaccinated yourself.

- "I believe in this vaccine and plan to get it as soon as it is available."

Engage in effective conversations.

- Start from a place of empathy and understanding.
- Address misinformation by sharing key facts.

Be prepared for questions.

- Share CDC resources/toolkits.

Source: CDC

Key Facts About COVID-19 Vaccination

Getting vaccinated can help prevent you from getting sick with COVID-19.

People who have already gotten sick with COVID-19 may still benefit from getting vaccinated.

COVID-19 vaccines cannot give you COVID-19.

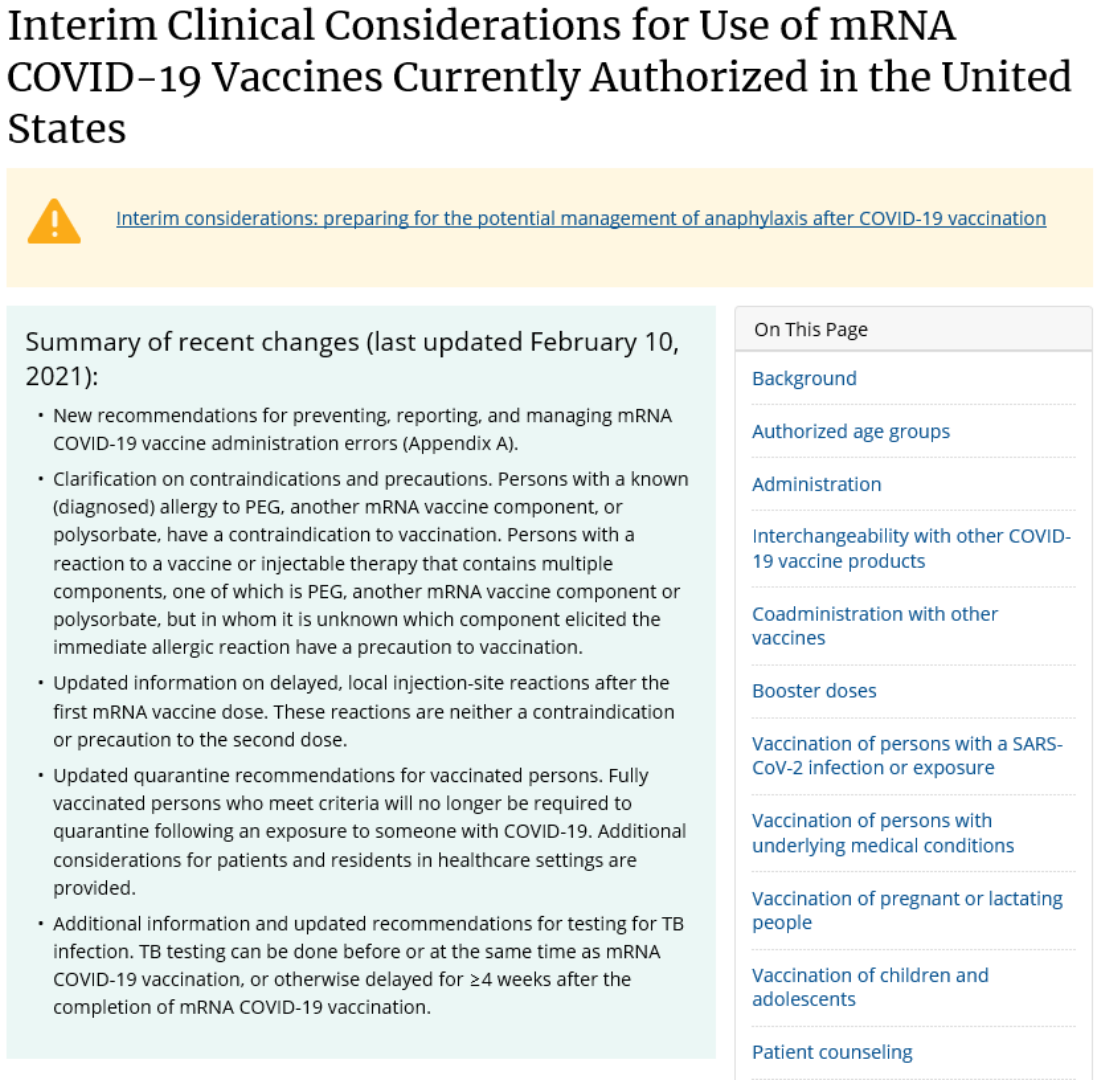
COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests.*

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines/vaccine-myths.html

*https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

Clinical Considerations for Use of mRNA COVID-19 Vaccines

- CDC clinical considerations for mRNA COVID-19 vaccines published previously:
  - https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- Clinical considerations are being updated to include Janssen COVID-19 vaccine.
  - Viral vector COVID-19 vaccine



Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Summary of recent changes (last updated February 10, 2021):

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

On This Page

Background
Authorized age groups
Administration
Interchangeability with other COVID-19 vaccine products
Coadministration with other vaccines
Booster doses
Vaccination of persons with a SARS-CoV-2 infection or exposure
Vaccination of persons with underlying medical conditions
Vaccination of pregnant or lactating people
Vaccination of children and adolescents
Patient counseling

Sign up to receive email updates when clinical considerations are updated: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

Your Role

COVID-19 vaccine safety gets stronger with your participation.

Public health partners

- Promote participation in **v-safe.**
- Promote reporting to **VAERS.**
- Communicate with your partners on vaccine safety.

Healthcare providers

- Encourage patient participation in **v-safe.**
- Report adverse events to **VAERS.**
- Communicate with patients on vaccine safety.

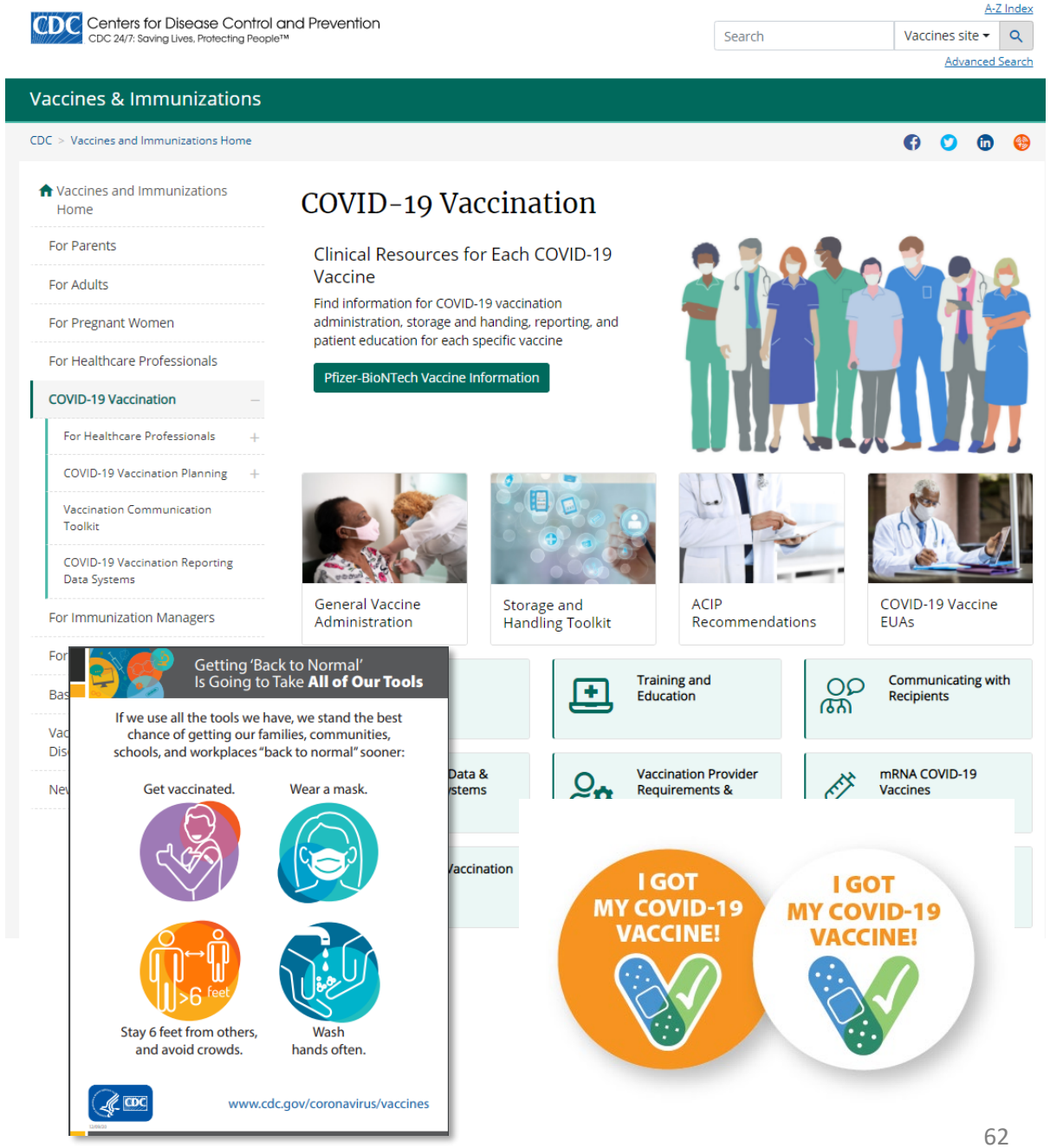
CDC Resources

Learn more with **CDC's COVID-19 vaccine tools and resources.** Find information for COVID-19 vaccine administration, storage, reporting, patient education, and more.

- COVID-19 vaccination: https://www.cdc.gov/vaccines/covid-19/index.html
- For healthcare professionals: https://www.cdc.gov/vaccines/covid-19/hcp/index.html

COVID-19 Vaccine Communication Toolkits

- Medical centers, clinics, and clinicians
- Long-term care facilities
- Community-based organizations
- Essential workers



Thank you.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov