



COVID-19 VACCINE ENROLLMENT

October 5, 6, and 7, 2020

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COVID-19 VACCINES

- Multiple (over 200) COVID-19 vaccines in clinical trials.
 - Six are being manufactured at the same time as trials.
- Two (Moderna and Pfizer) furthest along in trials are mRNA* vaccines:
 - Vaccine contains messenger RNA, called mRNA.
 - mRNA is processed in cells to make proteins.
 - Once the proteins are produced, the immune system will make a response against them to create immunity.
 - In this case, the protein produced is the COVID-19 spike protein.
- No currently licensed vaccines use this approach.

*Children's Hospital of Philadelphia
Vaccine Education Center

COVID-19 vaccines in human clinical trials – United States*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
mRNA-1273	Moderna TX, Inc.	mRNA	III	<ul style="list-style-type: none"> • 2 doses (0, 28d) • IM administration • 18-55, 56+ years 	NCT04470427	✓
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	<ul style="list-style-type: none"> • Single or 2 doses • IM administration • 18-85 years 	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	<ul style="list-style-type: none"> • 2 doses (0, 28d) • IM administration • ≥18 years 	NCT04516746	On Hold
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	I/II	<ul style="list-style-type: none"> • 2 doses (0,56d) • IM administration • 18-55, 65+ 	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	<ul style="list-style-type: none"> • Single or 2 doses • 18-49, 50+ 	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II		NCT04368988	✓
AV-COVID-19	Aivita	AuDendritic cell	I/II		NCT04386252	
INO-4800	Inovio Pharmaceuticals, Inc.	DNA plasmid	I	<ul style="list-style-type: none"> • 2 doses (0, 4w) • SC administration/ electroporation • ≥18 years 	NCT04336410	

As of September 14, 2020. Presented at ACIP meeting on September 22, 2020.

COVID-19 VACCINE TIMELINE

- Some of the approaches that are being employed to shorten the timeline ***without sacrificing quality and safety*** include:
 - Utilizing existing technology – many of the methods for producing a COVID-19 vaccine were previously being developed and explored for other vaccines.
 - Developing vaccines immediately after viral genome sequence is available.
 - Manufacturing – While completing the large phase III clinical trials, manufacturers can begin producing the vaccine, so that if it is shown to be safe and effective, they will have large numbers of doses ready. This is not typical because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.

COVID-19 VACCINE TIMELINE

- Support efforts – While waiting for a vaccine to be ready, many other aspects of vaccine delivery can be prepared, including:
 - Federal financing
 - Developing plans for how to distribute the first, limited quantities that will be available
 - Ensuring adequate supplies for distributing and administering vaccine, like vaccine vials, syringes and other equipment needed to vaccinate
 - Establishing mechanisms for distribution to large subsets of the population

COVID-19 VACCINE APPROVAL

- The FDA is planning on setting a higher standard for Emergency Use Authorization (EUA) approval of a vaccine.
- Safety and efficacy corners have not been cut.
 - More than 30,000 people enrolled in phase III clinical trials for all vaccines.
 - Will most likely have two months post vaccination data (90% of adverse events occur within 42 days per September National Vaccine Advisory Committee meeting)
- COVID-19 vaccine will be reviewed by an independent FDA committee (VRBPAC) and ACIP.

PARTICIPANTS IN CLINICAL TRIALS

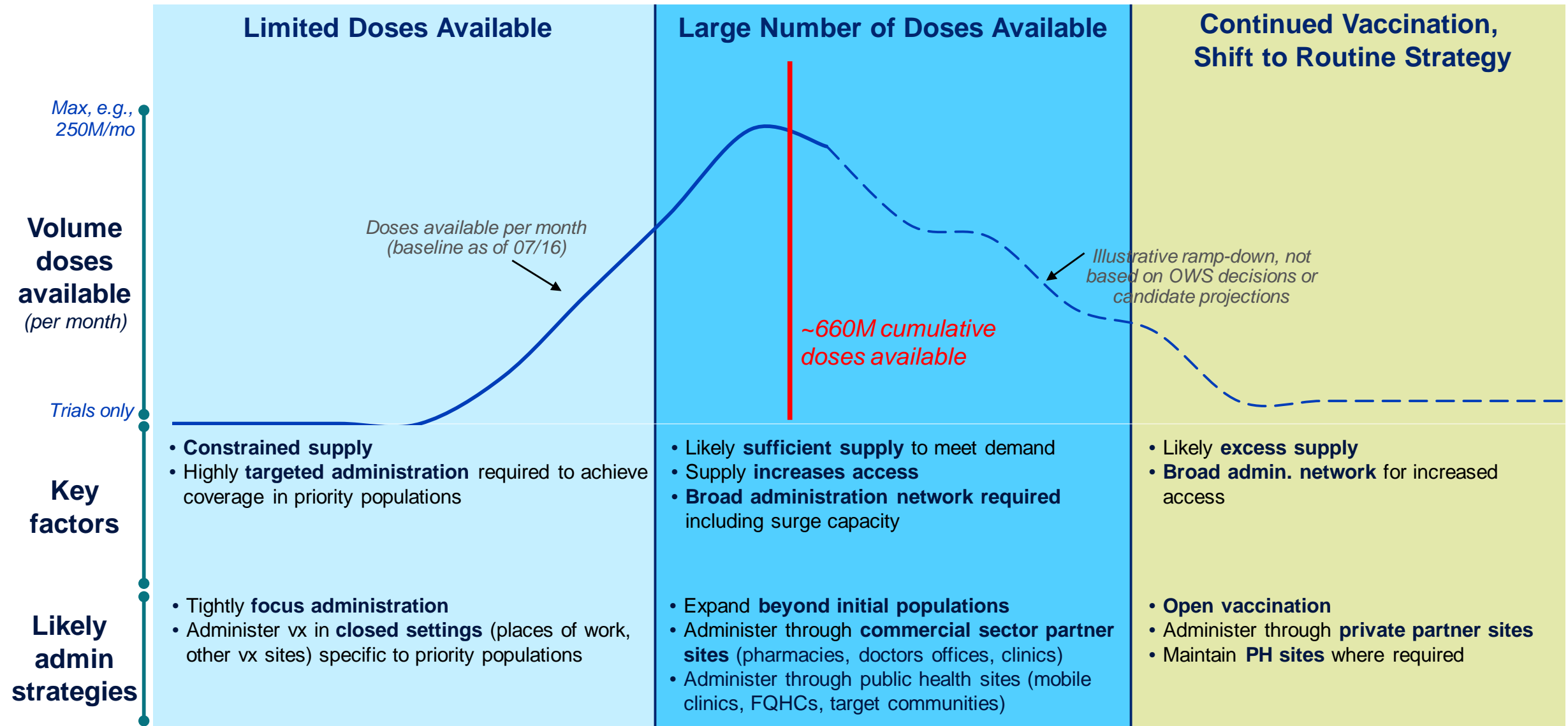
- mRNA-1273 vaccine (Moderna)
 - **25,296** participants enrolled as of 9/16/2020
 - 28% of participants enrolled are from “diverse communities”
- BNT162b2 vaccine (Pfizer/BioNtech)
 - **31,928** participants enrolled as of 9/21/2020
 - 26% of participants enrolled have “diverse backgrounds”
 - Proposed expansion to 44,000 participants

Prophylactic vaccines licensed in US from 2000–2011, rank-ordered by year of licensure, with inflation-adjusted initial prices of immunization series and number of subjects enrolled in clinical trials per phase (Human Vaccines & Immunotherapeutics 8:8, 1066-1070; August 2012)									
Vaccine name	Approval year	Doses	2010 Inflation adjusted CDC contract Price	CDC price of immunization series	2010 Inflation adjusted private sector price	Private price of immunization series	phase II n	phase III n	Late phase (II+III) n
IPOL	2000	4	\$9.81	\$39.24	\$19.53	\$78.12	361	2,358	2,719
Prevnar	2000	4	\$56.03	\$224.12	\$73.45	\$293.80	1,062	41,661	42,723
Daptacel	2002	5	\$15.45	\$77.25	\$23.82	\$119.10	7,471	10,575	18,046
Boostrix	2005	1	\$32.10	\$32.10	\$39.36	\$39.36	647	5,545	6,192
Adacel	2005	1	\$34.33	\$34.33	\$39.92	\$39.92	*2854	8,904	11,758
Menactra	2005	1	\$75.92	\$75.92	\$91.55	\$91.55	3,106	7,836	10,942
RotaTeq	2006	3	\$56.24	\$168.72	\$68.41	\$205.23	3,201	64,268	67,469
Gardasil	2006	3	\$103.84	\$311.52	\$129.52	\$388.56	4,047	22,938	26,985
Zostavax	2006	1	\$113.51	\$113.51	\$152.86	\$152.86	1,799	40,144	41,943
Rotarix	2008	2	\$83.30	\$166.60	\$103.81	\$207.62	6,374	80,427	86,801
Cervarix	2009	3	\$96.08	\$288.24	\$128.75	\$386.25	3,964	45,025	48,989
Menveo	2010	1	\$79.75	\$79.75	\$103.41	\$103.41	740	8,989	9,729
Prevnar 13	2010	4	\$91.75	\$367.00	\$108.75	\$435.00	1,478	49,296	50,774
						mean	2,854	29,844	32,698
						median	2,453	22,938	26,985

COVID-19 VACCINE ASSUMPTIONS

- Limited COVID-19 vaccine doses may be available by early November 2020 if a COVID-19 vaccine is authorized or licensed by FDA by that time, but COVID-19 vaccine supply may increase substantially in 2021.
 - Initial vaccine will likely be approved under EUA.
- Two doses of COVID-19 vaccine, separated by either 21 or 28 days, will be needed for most COVID-19 vaccine products, and second-dose reminders for patients will be necessary.
 - Both doses will need to match each other (i.e., be the same vaccine product).
- Some COVID-19 vaccine products will likely require reconstitution with diluent or mixing adjuvant at the point of administration.

RECALL: ADMINISTRATION OF COVID-19 VACCINE WILL REQUIRE A PHASED APPROACH



COVID-19 VACCINE ASSUMPTIONS

- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C) temperatures, and ongoing stability testing may impact these requirements.
 - *Note: These temperatures are based on information available as of September 15, 2020.*
- In addition to vaccine, ancillary supplies (needles, syringes, mixing vessels, alcohol pads, record cards) will be supplied by federal government.

Scenario 1: FDA has authorized vaccine A for Emergency Use Authorization (EUA) in 2020

Availability Assumptions

Vaccine availability under EUA by				
Candidate	End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	~2 million (M) doses	10M–20M doses	20M–30M doses	Ultra-cold (-70 °C) storage requirements, for large sites only

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
SHIPMENT <i>3 separately acquired components (mixed on site)</i> 1. Vaccine <ul style="list-style-type: none">Direct to site from manufacturer (on dry ice)Multidose vials (5 doses/vial) 2. Diluent <ul style="list-style-type: none">Direct to site from the US Government (USG) at room temperature) 3. Ancillary supply kits (for administration and mixing) <ul style="list-style-type: none">Direct to site from USG (at room temperature)	ON-SITE VACCINE STORAGE <i>Frozen (-70 °C ± 10 °C)</i> <ul style="list-style-type: none">Must be used/recharged within 10 daysStorage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later) <i>Thawed but NOT reconstituted (2–8 °C)</i> <ul style="list-style-type: none">Must use within 5 days (discard unused doses after 5 days) <i>Reconstituted (room temperature)</i> <ul style="list-style-type: none">Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)
ORDERS <i>Large quantities, to large administration sites only</i> <ul style="list-style-type: none">Minimum order: ~1,000 dosesMaximum order: ~5,000 doses	ADMINISTRATION <i>2-dose series (21 days between doses)</i> <ul style="list-style-type: none">On-site mixing required; reconstitute with diluent just prior to administrationAdminister by intramuscular (IM) injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES <i>Healthcare personnel</i> — public health, closed point of dispensing (POD), temporary/off-site vaccination clinics + potential for mobile clinics <i>Other essential workers</i> — public health, closed POD, temporary/off-site vaccination clinics + potential for mobile clinics <i>People at higher risk of severe COVID-19 illness</i> — potential for mobile clinics to long-term care facilities (LTCFs)	

SCENARIO 1: VACCINE A DEMONSTRATES SUFFICIENT EFFICACY/SAFETY FOR EUA IN 2020

Scenario 2: FDA has authorized vaccine B for EUA in 2020

Availability Assumptions

Vaccine availability under EUA by				
Candidate	End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine B	~1M doses	~10M doses	~15M doses	Central distributor capacity required (-20 °C)

Distribution, Storage, Handling, and Administration Assumptions

Vaccine B	
SHIPMENT <i>2 separately shipped components</i> 1. Vaccine <ul style="list-style-type: none">To central distributor (at -20 °C)Multidose vials (10 doses/vial) 2. Ancillary supply kits <ul style="list-style-type: none">Direct to site from USG (at room temperature)	ON-SITE VACCINE STORAGE <i>Frozen (-20 °C)</i> <ul style="list-style-type: none">Storage in shipping container OK <i>Refrigerated (2–8 °C)</i> <ul style="list-style-type: none">Must use within 14 days <i>Room temperature</i> <ul style="list-style-type: none">Must use within 6 hours (discard any unused vaccine after 6 hours)
ORDERS <i>Central distribution capacity required</i> <ul style="list-style-type: none">Required by Dec 2020Maintained at -20 °C	ADMINISTRATION <i>2-dose series (28 days between doses)</i> <ul style="list-style-type: none">No on-site mixing requiredAdminister by IM injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES <i>Healthcare personnel</i> — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics <i>Other essential workers (specifics TBA)</i> — occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics <i>People at higher risk of severe COVID-19 illness (e.g., LTCF residents)</i> — commercial pharmacy partners + mobile clinics	

SCENARIO 2: VACCINE B DEMONSTRATES SUFFICIENT EFFICACY/SAFETY FOR EUA IN 2020

SCENARIO 3: VACCINES A AND B DEMONSTRATE SUFFICIENT EFFICACY/SAFETY FOR EUA IN 2020

Availability Assumptions

Vaccine availability under EUA by				
Candidate	End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	~2M doses	10M–20M doses	20M–30M doses	Ultra-cold (-70 °C), for large sites only
Vaccine B	~1M doses	~10M doses	~15M doses	Central distribution capacity required (-20 °C)
Total	~3M doses	20M–30M doses	35M–45M doses	

COVID-19 VACCINE ASSUMPTIONS

- Final decisions are being made about use of initially available supplies of COVID-19 vaccines.
- These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include:
 - Healthcare personnel likely to be exposed to or treat people with COVID-19
 - People at increased risk for severe illness from COVID-19, including those with underlying conditions and people 65 years of age and older
 - Other essential workers
- National Academy of Medicine, Engineering and Sciences
- Advisory Committee on Immunization Practices

NATIONAL ACADEMY OF MEDICINE FRAMEWORK (10/02/2020)

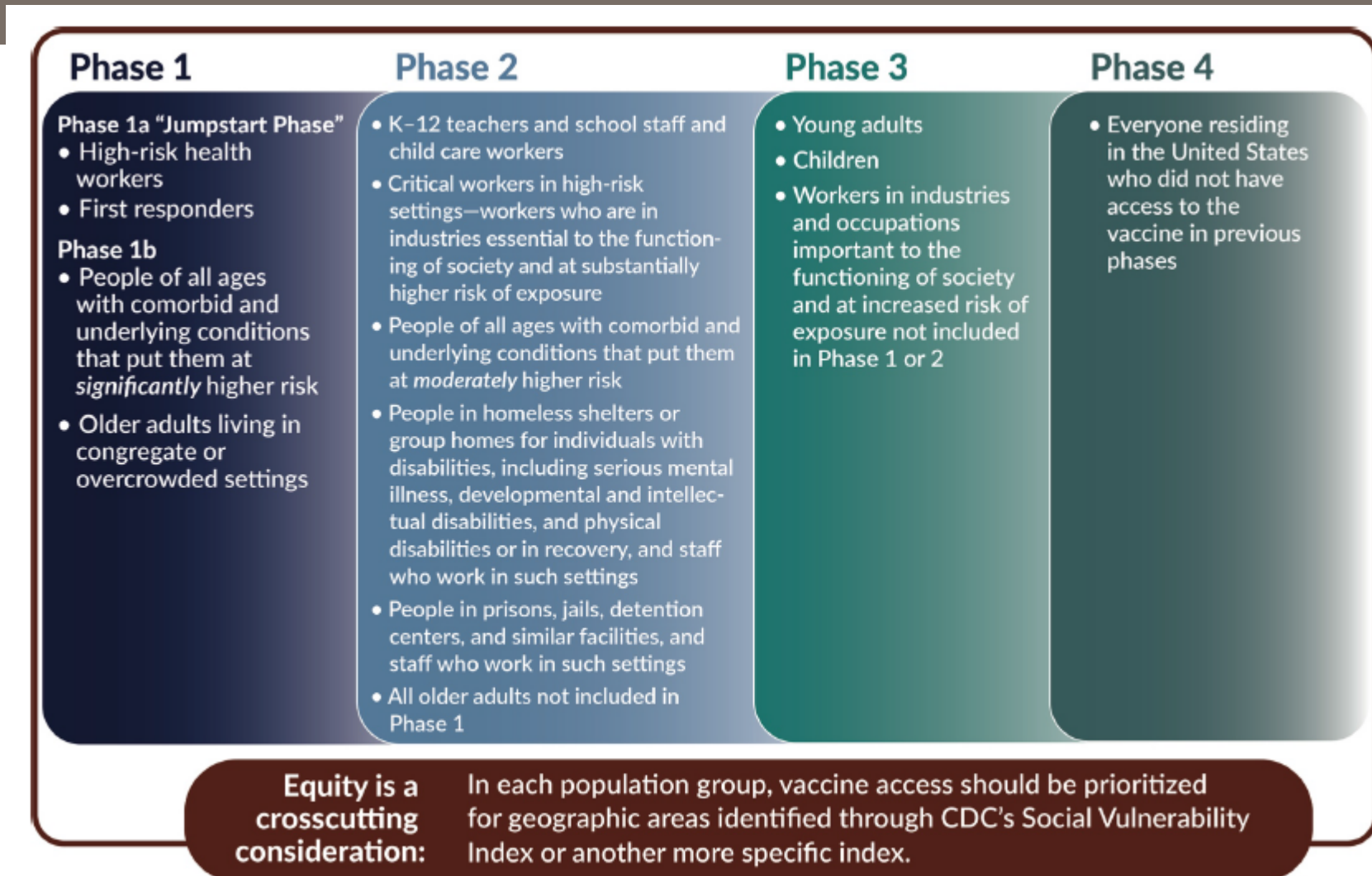


FIGURE S-2 A phased approach to vaccine allocation for COVID-19.

COVID-19 VACCINE ASSUMPTIONS

- COVID-19 vaccine will most likely not be available (at least at first) for children or pregnant women.
- Receipt of vaccine into the state will probably be in proportion to the state population (about 0.2% of the US population) but is unlikely to consider persons crossing over into North Dakota from other states.
- The Department of Defense and Veterans Administration will receive vaccine directly from federal Government.
- Indian Health Services/Tribal Health are being consulted and will be able to express a preference for whether to receive vaccine directly from federal government or through state.

COVID-19 VACCINE ASSUMPTIONS

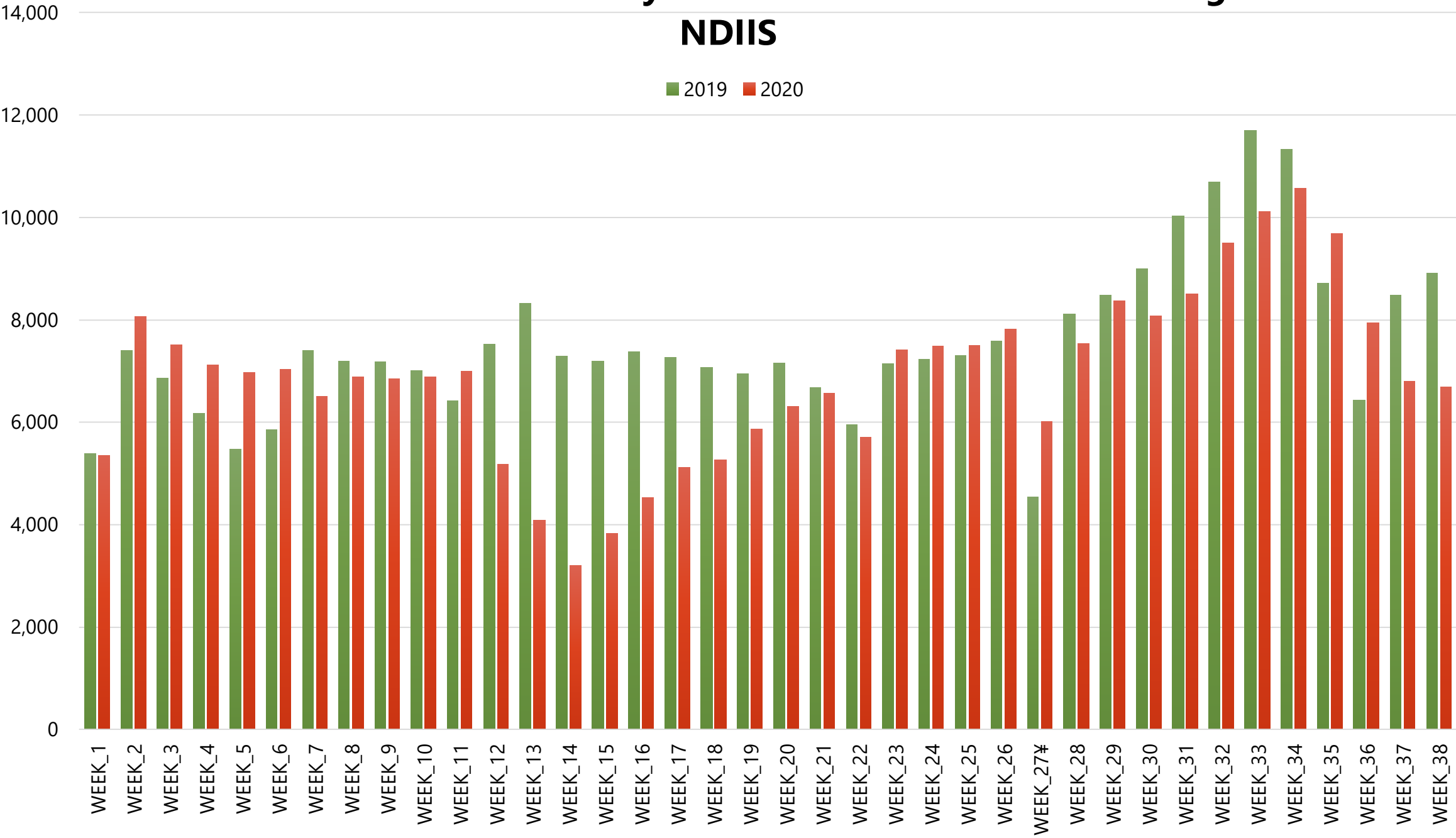
- Some chain pharmacies may contract directly with the federal government to receive vaccine.
 - These pharmacies will be paired with long term cares for vaccination.
 - Unknown which pharmacies in ND or how this will work.
- Long term cares will be notified that they can request vaccination by a pharmacy through NHSN or RedCap starting October 15th.
- States will be notified in November of which pharmacies and long term cares are paired.

COVID-19 VACCINE ASSUMPTIONS

- Routine immunization for other diseases will need to continue at the same time.
 - Gaps in vaccination have expanded among all populations which must be made up.
- Response to COVID-19 will have to continue at the same time. This includes testing, treating patients and contact tracing.

Total Doses Administered by Week in North Dakota According to NDIIS

2019 2020



UNKNOWN

- Interval between COVID-19 vaccine and other vaccines
- Interval between COVID-19 illness and COVID-19 vaccine
- Impact of COVID-19 vaccine and need for PPE, quarantine, social distancing, masking, etc.
- Others...

HEALTHCARE PROVIDER ENROLLMENT

- CDC provided most of the language for provider enrollment documents.
- Enrollment with the state will be required to receive COVID-19 vaccine.
 - Due **10/23/2020**
- Does not guarantee facility will receive COVID-19 vaccine.
- Qualtrics online survey (similar process to VFC enrollment).
 - Complete online with contact information, Medical Director information, patient estimates, storage and handling and business hours.
 - Medical and Executive Directors should sign and return electronically via email covidvaccine@nd.gov.

POTENTIAL PROVIDERS

- Hospitals
- Clinics
- Local public health departments
- Pharmacies
- Long term cares
- Correctional facilities
- Group Homes
- University health centers
- Occupational health
- Emergency Medical Services
- Mass vaccinators
- Dialysis Centers
- Indian Health Services (IHS) and/or tribal health*

HEALTHCARE PROVIDER ENROLLMENT

- Given the recent Health and Human Services (HHS) authorization, pharmacists no longer need a physician standing order to vaccinate against COVID-19 for ages three and older.
 - Therefore, pharmacies can enroll themselves and operate as their own Chief Medical Officer.
- Hospitals will need to include all prescribers associated with their facility that may write orders for COVID-19 vaccination.
 - Large health systems should think through which providers will fall into this role and do their best to include them in the COVID-19 vaccine enrollment.

HEALTHCARE PROVIDER ENROLLMENT

- A COVID-19 redistribution agreement was provided by the CDC with the provider enrollment documents but there is still more clarification from the CDC on what is needed for the COVID-19 vaccine redistribution agreements.
- Redistribution will be addressed once vaccine is more readily available and we have a better sense of what vaccines are available.

AGREEMENT REQUIREMENTS

- Administer COVID-19 vaccine in accordance with ACIP recommendations.
- Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), the dose must be recorded in the vaccine recipient's record and report required information to the NDIIS.
- Providers are unable to bill for the cost of the vaccine or supplies that are provided by the NDDoH.

AGREEMENT REQUIREMENTS (CONT.)

- Providers must administer vaccine regardless of the patient's ability to pay the administration fees.
- Provide an EUA fact sheet or VIS, as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.

AGREEMENT REQUIREMENTS (CONT.)

- Comply with CDC requirements for vaccine management, including storage and handling, temperature monitoring at all times, complying with jurisdiction's instructions for dealing with temperature excursions, and monitoring expiration dates.
- Providers must keep all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by law.

AGREEMENT REQUIREMENTS (CONT.)

- Providers must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired or wasted to the NDDoH.
- Providers must comply with all federal instructions and timelines for disposing of COVID-19 vaccine and adjuvant.
- Providers must report moderate and severe events following vaccination to VAERS.

AGREEMENT REQUIREMENTS (CONT.)

- Provide a completed COVID-19 vaccination record card to every vaccine recipient/parent/legal representative.
- Comply with the U.S. Food and Drug Administration's requirements, including EUA-related requirements, if applicable. Providers must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws.

AGREEMENT REQUIREMENTS (CONT.)

- Once vaccine is publicly available North Dakota will require facilities receiving COVID-19 vaccine to post vaccine availability to vaccinefinder.org or to a similar vaccine locator website (once publicly available).

IDENTIFY AND ESTIMATING CRITICAL POPULATIONS

- Populations that may include, but are not limited to:
 - Critical infrastructure workforce
 - Healthcare personnel
 - People at increased risk for severe COVID-19 illness
 - LTC residents
 - People with underlying medical conditions
 - People 65 years and older

IDENTIFY AND ESTIMATING CRITICAL POPULATIONS (CONT.)

- People at increased risk of acquiring or transmitting COVID-19
 - People from racial and ethnic minority groups
 - People from tribal communities
 - People who are incarcerated/detained in correctional facilities
 - People experiencing homelessness/living in shelters
 - People attending colleges/universities
 - People who work in educational settings (e.g. childcares and schools)
 - People living and working in other congregate settings

IDENTIFY AND ESTIMATING CRITICAL POPULATIONS (CONT.)

- People with limited access to routine vaccination services
 - People living in rural communities
 - People with disabilities
 - People who are un/underinsured

HIGH RISK

- Underlying medical conditions at high risk include:
 - Cancer
 - Chronic kidney disease
 - COPD
 - Immunocompromised state from solid organ transplant
 - Obesity
 - Serious heart conditions, such as heart failure, coronary artery disease or cardiomyopathies
 - Sickle cell disease
 - Type 2 diabetes

REQUIRED EDUCATION

- Provider enrollment education (current presentation)
- SIRVA prevention webinar, will be live on October 14th at noon, but will be recorded for those who cannot attend and posted to our website
[https://www.health.nd.gov/covid-19-vaccine-information.](https://www.health.nd.gov/covid-19-vaccine-information)
- Other training in the future after vaccine is approved.

VACCINATION DOCUMENTATION

- NDIIS: All providers must agree to submit the data to NDIIS if they wish to become vaccine providers.
 - Doses must be reported within 24 hours of administration.
- PrepMod will allow for members of the public to preregister for COVID-19 vaccine online.
 - This will include electronic registration, consent to vaccination, review the Vaccine Information Statement (VIS), report their high risk/ priority group and also to find the vaccination clinic nearest to them.
 - Reports to NDIIS and/or EMR
- NDIIS will report up to federal government.
- NDIIS training available on immunization website.

VACCINE ADMINISTRATION FEES

- Providers will be unable to charge for the cost of the COVID-19 vaccine, as it will be provided at no cost.
- It is expected that enrolled providers will be allowed to bill administration fees for COVID-19 vaccine.
 - The cap for administration fees is unknown at this time.
- According to the Health Resources and Services Administration (HRSA), providers may submit a claim for reimbursement to cover costs for patients who were unable to pay.

STORAGE AND HANDLING

- Three possibilities to consider for vaccine:
 - Refrigerated
 - 2° to 8 °C
 - Frozen
 - -15° to -25°C
 - Ultra cold
 - -60° to -80°C
 - Will also require the use of dry ice
 - Do not purchase units if your facility does not currently have

STORAGE AND HANDLING (CONT.)

- Temperatures should be monitored as all other vaccines and reported to the NDDoH monthly.
- Temperature excursion **MUST** be reported immediately to the NDDoH Division of Immunization.

INVENTORY MANAGEMENT

- It is anticipated that the COVID-19 vaccines will initially be authorized under an EUA. Vaccines authorized under an EUA will contain slight variations from approved FDA products:
 - Expiration dates
 - The vaccine will not contain a printed expiration date. CDC is developing BUD tracker labels to assist with tracking expiration dates at the point of vaccine administration.

INVENTORY MANAGEMENT (CONT.)

- Variations (Cont.)
 - Manufactured date
 - This date is to be used for stock rotations and not as an expiration date.
 - 2D Barcode
 - The barcode will include NDC, lot number and a placeholder for the expiration date of 12/31/9999.
 - QR Coding
 - Each vaccine manufacturer will include a QR code on the vaccine carton for accessing FDA- authorized, vaccine specific EUA fact sheets for the COVID-19 vaccine product.

VACCINATION MANDATES

- The state is not planning to enact any mandates requiring vaccination for COVID-19.
- However, specific institutions or businesses may choose to mandate the vaccination of employees as a condition of employment.
 - COVID-19 vaccines distributed under Emergency Use Authorization cannot be mandated.

ENROLLMENT CHECKLIST

- A checklist has been provided to outline the enrollment process as well as other steps facilities should be doing to prepare for COVID-19 vaccine.
 - Enrollment
 - NDIIS access
 - Storage and Handling
 - VAERS
 - Vaccine Administration
- “Office Hours” every Monday at noon
 - Starts October 12th

COVID VACCINE ORDERING

- Early Stages: NDDoH will allocate and enter vaccine orders. COVID vaccine contacts identified in enrollment will receive an email and have 24 hours to respond. If confirmed, the order will be placed.
- Once more vaccine is available, we will begin to do automatic allocations (similar to influenza vaccine allocation process).
- Eventually when vaccine is plentiful facilities will be able to order COVID-19 vaccine in the NDIIS.

LOCAL PLANNING AND COORDINATION


- All healthcare providers should have discussions locally with other providers in the community.
- Make sure all priority group populations and congregate settings have access to COVID-19 vaccine.
- Facilities include:
 - Group Homes
 - Homeless shelters
 - Long Term Care
 - County jails
 - Schools
 - Colleges/ Universities
 - Large employers
 - Homebound individuals

RESOURCES

- CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
- CDC Vaccinating During a Pandemic <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>
- ND COVID-19 Vaccine Website: <https://www.health.nd.gov/covid-19-vaccine-information>
- covidvaccine@nd.gov

NORTH DAKOTA DIVISION OF IMMUNIZATIONS

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TBD COVID-19 Vaccination Coordinator			



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