IHS COVID-19 Response Webinar Series

IHS COVID-19 VACCINE TASK FORCE

Objective

- Determine the needs for COVID-19 planning and preparation at the facility level, including resources for identifying high risk groups, training materials for vaccinators, and planning resources on the IHS COVID-19 vaccine website.
- Explain the different documentation strategies required for COVID-19 vaccine administration data.
- Describe the first COVID-19 vaccines anticipated to be available and the complexities associated with the storage and handling of the earliest available vaccines.

****Information changes frequently, as often as daily****

Information current as of 11/18/20

COVID-19 and Indian Country

- The COVID-19 pandemic has disproportionately affected the American Indian/Alaska Native (AI/AN) populations across the country.
- AI/AN are 3.5 times more likely to be infected with the Sars-CoV2 virus.[1]
- In addition to many preventative measures, such as social distancing, mandatory curfews, mask wearing, and hand hygiene, COVID vaccination remains the most promising countermeasure to further reduce disease, morbidity and mortality in the AI/AN people.
- CDC is working with IHS along with other federal members of Operation Warp Speed (OWS) to plan and implement a COVID-19 vaccination program as soon as vaccine(s) is available.

1. Reference: COVID-19 Among American Indian and Alaska Native Persons — 23 States, January 31–July 3, 2020 Weekly / August 28, 2020 / 69(34);1166–1169 https://www.cdc.gov/mmwr/volumes/69/wr/mm6934e1.htm

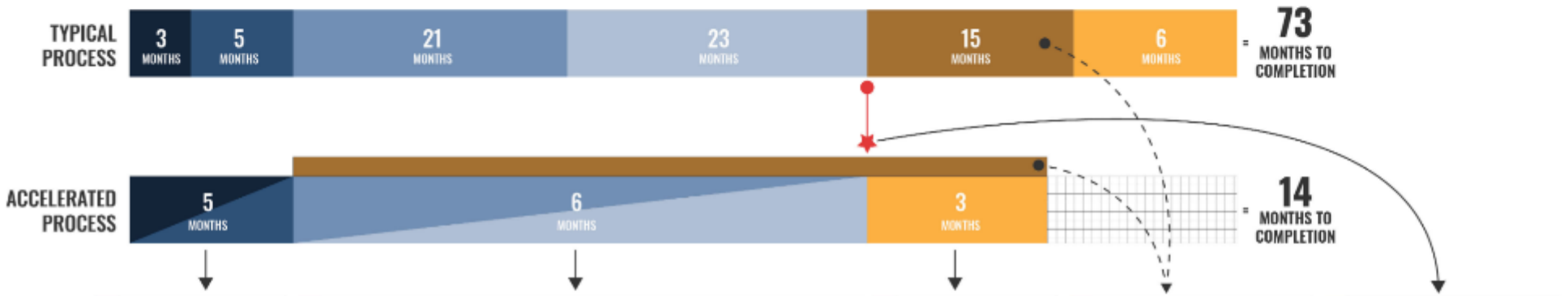
Operation Warp Speed (OWS)

- Goal
  - To produce and deliver 300 million doses of safe and effective vaccines
- Collaboration between Health & Human Services (HHS) & Dept of Defense (DoD)
- Strategy
  - Released Strategy for Distributing a COVID-19 Vaccine
  - Released CDC COVID-19 Vaccination Program Interim Playbook.
  - Vaccine will be reviewed under FDA's standards per June 2020 guidance.
  - CDC Advisory's Committee on Immunization Practices (ACIP) will independently review and make vaccine recommendations.

https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf
https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

OPERATION WARP SPEED
ACCELERATED VACCINE PROCESS

MISSION: Deliver 300 million doses of safe and effective vaccine by 1 January 2021.



1

A typical 8-month process is accelerated by:

- Creating vaccine candidates immediately after viral genome sequence is available.
- Using vaccine platforms developed for other diseases.

2

A typical 42-month process is accelerated by:

- Large scale Phase III clinical trials of 30,000 volunteers allowing for rapid collection and earlier analysis of safety and efficacy data of demographically diverse populations by the FDA, reducing the typical 12-month approval process to three months.
- Two promising candidates began Phase III clinical trials in July, with others to follow quickly in coming months. Before beginning Phase III, candidates must show safety data from animal and human studies.
- The U.S. Government funding at-risk, large-scale manufacturing of the most promising vaccine candidates during Phase III clinical trials to ensure any vaccine proven to be safe and effective is available immediately upon FDA Emergency Use Authorization (EUA) approval or licensure.

4

A typical 6-month process is accelerated by:

- A tiered approach based on CDC recommended allocation methodology used as part of pandemic flu planning and the COVID-19 response will be used to determine vaccine distribution.

3

A typical 15-month process is accelerated by:

- Planning for infrastructure and distribution before the vaccines are approved or authorized.
- CDC leading distribution planning with DoD augmentation.

5

A typical 12-month FDA review for EUA approval or licensure is accelerated by:

- Providing continuous safety and efficacy data collected in large Phase III clinical trials.

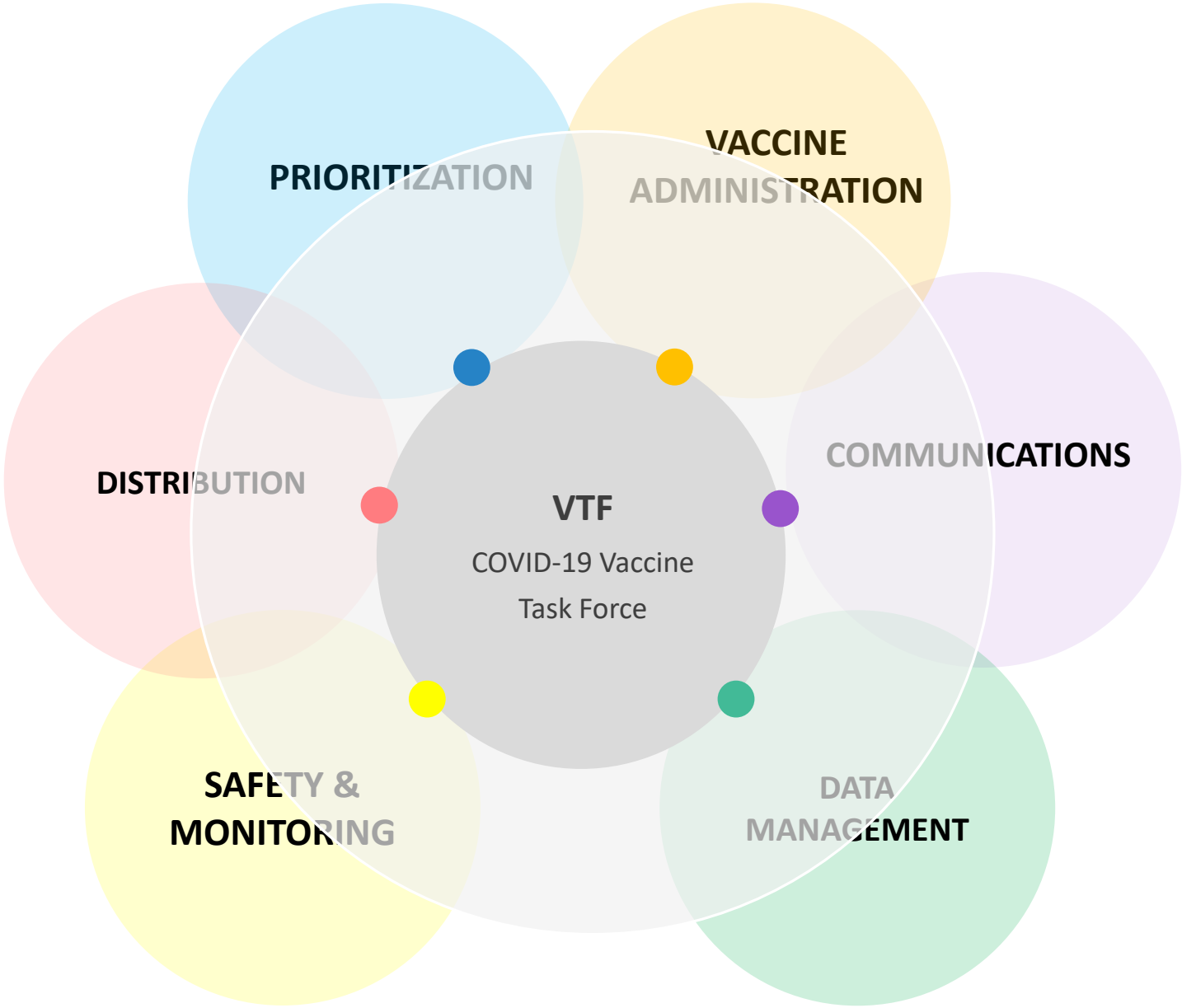
R&D + Preclinical Trials Vaccine Candidate/s Identified
Phase I Clinical Trials
Phase II Clinical Trials
Phase III Clinical Trials
Manufacturing
Distribution

https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

Indian Health Service (IHS)

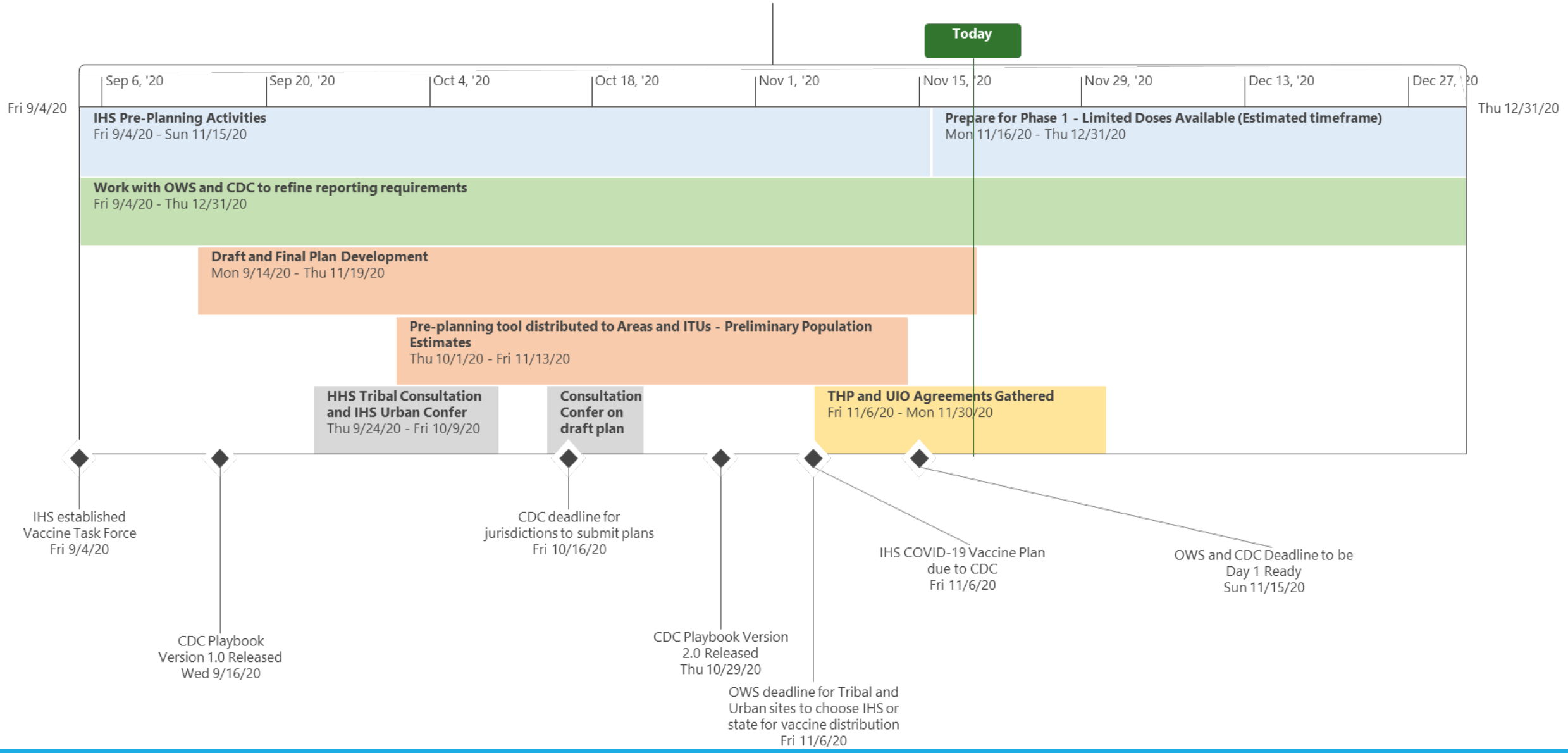
- CDC has recommended all jurisdictions be prepared to immediately vaccinate identified critical populations when the earliest COVID-19 vaccine doses are available and approved.
- IHS is recognized as a “jurisdiction”, similar to a state, for vaccine distribution.
- IHS established the COVID-19 Vaccine Task Force (VTF) to develop COVID-19 vaccination distribution and implementation plans for the safe and equitable delivery of vaccine to AI/AN patients.
- IHS is collaborating with tribal and federal partners to ensure shared information for planning and distribution.

IHS COVID-19 Vaccine Task Force (VTF)



IHS Vaccine Task Force

Activities September – December 31. 2020



IHS COVID-19 Pandemic Vaccine Plan

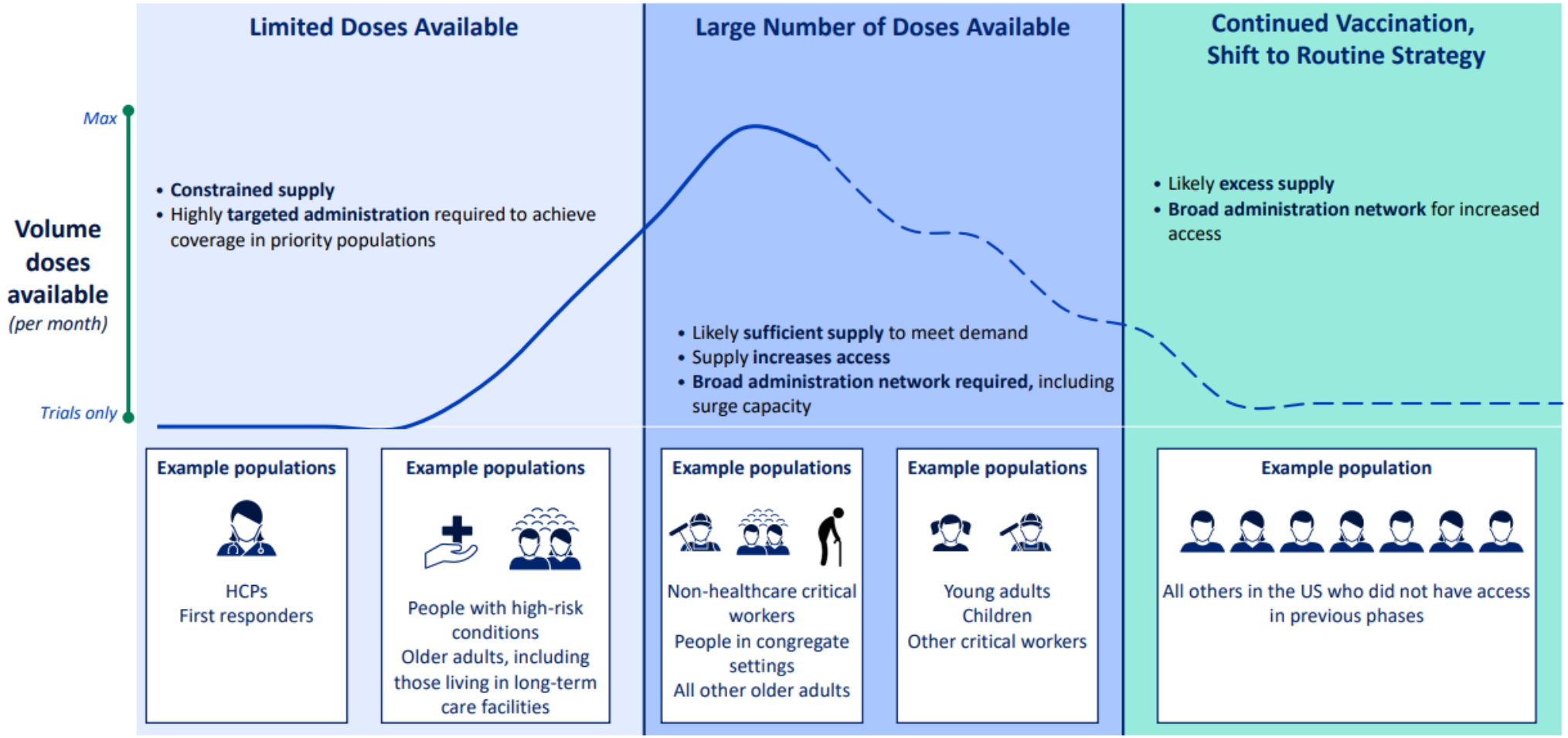
- IHS COVID-19 Pandemic Vaccine Plan, November 2020 can be found at https://www.ihs.gov/coronavirus/vaccine/.
- Details how the IHS health care system will prepare for and operationalize COVID-19 vaccine when it becomes available.
- Plan provides information for IHS Direct facilities, Tribal Programs and Urban Indian Organizations as they prepare for receiving and administering COVID-19 vaccine.
- Plan has reviewed feedback from CDC as well as Tribal Consultation and Urban Confer.

Vaccine Pre-Planning

- Program Agreements
  - CDC COVID-19 Vaccination Program Tribal Health Program Agreement
  - CDC COVID-19 Vaccination Program Urban Indian Organization Agreement
  - Memorandum of Agreement (MOA) between IHS Direct Facilities and CDC for COVID-19 Vaccination Program
- Identify critical patient and total population estimates
  - Including beneficiaries and non-beneficiaries
- Phase 1 planning for ultracold or frozen vaccine
- Ordering and documentation platforms
- Training, resources and tools

Illustrative scenario for planning purposes; will be adapted based on clinical / manufacturing information on all OWS candidates & vaccine prioritization

Distribution will adjust as volume of vaccine doses increases



Illustrative example populations; final prioritization to be decided by ACIP

Reference: COVID-19 Vaccine Implementation Planning Update, Janell Routh, ACIP Presentation 10.30.20

Prioritization

- Awaiting priority group guidance from Advisory Committee on Immunization Practices (ACIP).
- Health Care Personnel (HCP) have been identified as the first likely priority population.
- Additional priority groups may include:
  - Residents in congregate living facilities, such as long-term care facilities and jails (especially elders).
  - Those aged ≥65 years or older.
  - High risk individuals who have underlying medical conditions.
  - Some combination of high-risk individuals (e.g., essential workers 65 years and older or who have one or more high-risk medical conditions).
  - Essential workers.
- Local sites can determine their own priority populations.

Prioritization

- Estimated Population – Based on Pre-planning Tool Estimates
  - HCP – 43,783
  - Residents in Tribal Long-Term Care – 76,311
  - Elders – 374,411
  - High-risk for COVID-19 Illness (underlying medical conditions) – 894,260
  - Essential Workers – 120,671
  - Total Estimated people anticipated to receive COVID-19 Vaccine – 2,056,347
- HCP Survey about views regarding COVID-19 vaccine to inform planning
  - Results will be collated and reported for overall National data, Results by Area, and Results by facility.
  - Survey open through Friday, November 20, 2020.
    https://www.surveymonkey.com/r/IHS_Covid19_Vaccine_HCP_Survey

Vaccine Distribution

- Priority Populations
  - IHS priority populations guided by CDC's ACIP.
  - Based on priority population estimates provided by I/T/U.
  - I/T/U's may prioritize populations based on local priorities (see program agreements).
- Distribution
  - Fully distribute enough vaccine for each priority population.
  - Example: IHS receives 10,000 vaccine doses during the initial vaccine allocation from CDC, this is enough for ~25% of our healthcare personnel (HCP), site would receive ~25% of their HCP population estimate during first allocation.
  - Phase 1 distribution for ultracold vaccine will be coordinated with Areas.
  - Phase 1 distribution for frozen vaccine will be ordered at the local levels.

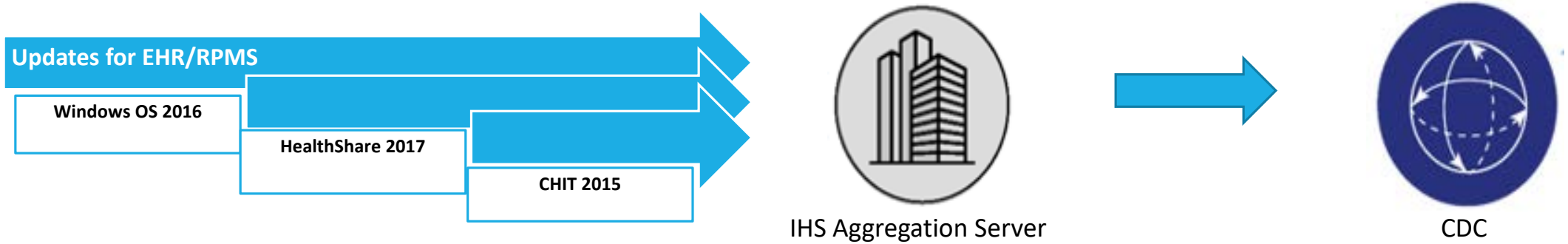
Data Reporting Requirements

Once completed CDC COVID-19 Vaccination Program Agreements are returned to IHS, the site will be entered into the CDC platforms for reporting and ordering.

- Data reporting
  - Administration of Vaccine - All vaccine administration must be documented and uploaded to CDC within 24 hours.
  - Accountability – Inventory, wastage, returns, and temperature excursions.
- Vaccine ordering
  - Products can be determined by the site's preference.
- Assessment of technology platforms and OIT needs
  - Office of Information Technology (OIT) is actively reviewing the IHS distribution list and reaching out to offer assistance (See Resources slide for contact information).

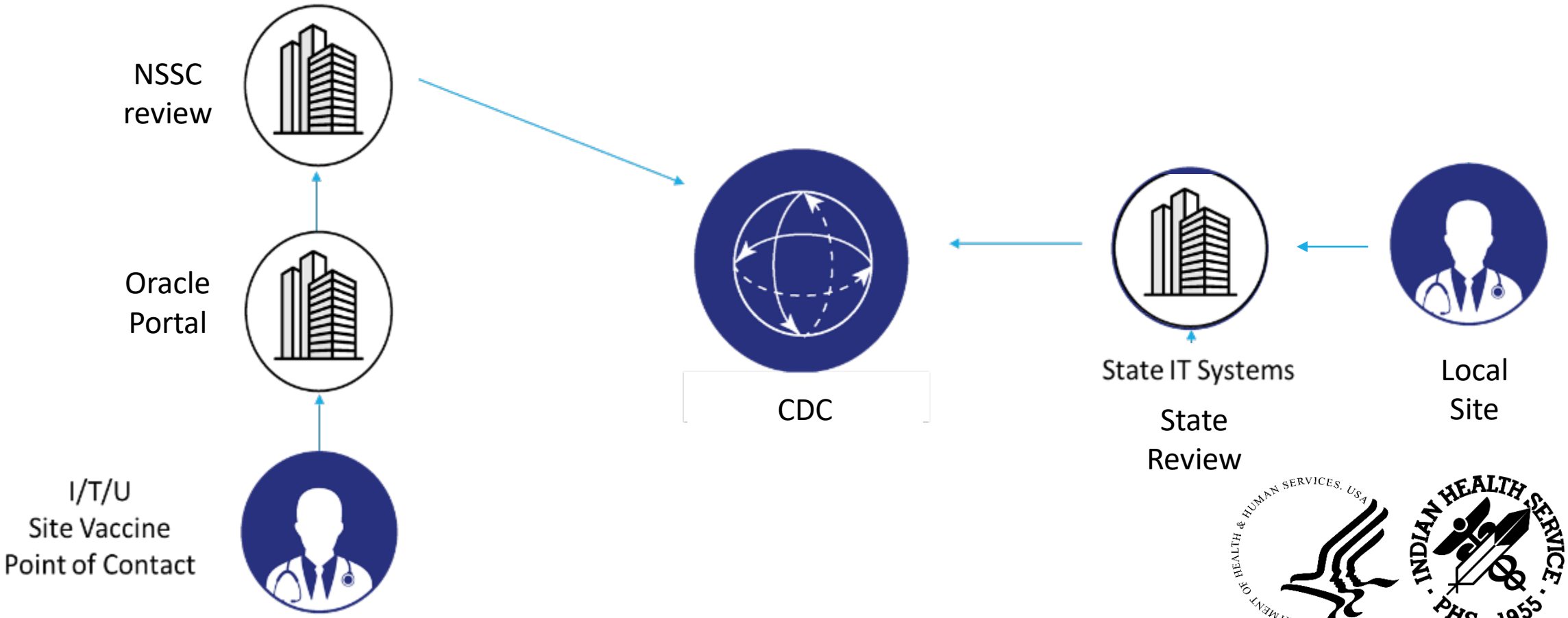
Vaccine Documentation

- Two potential Data Flows
  - RPMS/EHR sites or other EHR - All Current Patches Installed - Data flow directly to IHS, then to CDC.



- EHR Patches NOT Current (RPMS/EHR or other EHR) – Use VAMS
  - RPMS/EHR upgrades and support identified for each site electing IHS for distribution
  - Sites will use Vaccine Administration Management System (VAMS).
    - CDC developed application for documentation.

Vaccine Ordering and Inventory



Training, Resources and Tools

- Training
  - Vaccine storage and handling.
  - Vaccine administration.
  - Communicating with patients about vaccines.
  - COVID-19 vaccine training and clinical materials.
- Frequently Asked Questions (FAQs)
  - IHS COVID-19 vaccine FAQs.
  - CDC COVID-19 vaccine FAQs.
- Resources and Tools in Development
  - Documentation Templates.
  - Consent Forms.
  - Standing Order – in development.

Emergency Use Authorization (EUA)

- Allows FDA to help strengthen the nation's public health protections against threats by facilitating the availability and use of medical counter measures needed during public health emergencies.
- May allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threatening agents when there are no adequate, approved, and available alternatives.
- Products must still meet minimum threshold requirements to demonstrate that a vaccine is safe and effective.
- Additional elements may be required, such as safety monitoring, documentation, or consents.
- The vaccine can move on to licensing later.
  - Example drug therapy remdesivir, moved from EUA to licensed.

Safety and Monitoring

- IHS systematic approach to Vaccine Adverse Event reporting
  - Passive Reporting
    - VAERS – CDC and FDA program to monitor the safety of all vaccines in the U.S.
  - Active Monitoring
    - Sentinel surveillance sites across IHS – Hub and Spoke Model.
      - Will provide opportunities for internal review and potential early safety signals.
      - Similar to Remdesivir and dexamethasone reports recently released.
- Additional voluntary active vaccine surveillance
  - v-safe – a new reporting system.

-- Indian Health Service, National Pharmacy & Therapeutics Committee --

Reporting a Suspected Vaccine Adverse Event

The safety of modern vaccines is based on scientific evidence obtained through clinical research and pharmacovigilance. Although rare, adverse events related to vaccine administration may occur. When you suspect an adverse event, it should be documented in the patient's medical record and a report submitted through the Vaccine Adverse Events Reporting System (VAERS). VAERS is an on-line tool that can be used to easily submit suspected ADEs related to vaccine administration.

Healthcare providers are ***required by law*** to report to VAERS if:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination occurs within the specified time period after vaccinations.
- An adverse event is listed as a contraindication to further doses of the vaccine.

Healthcare providers are strongly ***encouraged*** to report to VAERS if:

- Any potential adverse event occurs after the administration of a vaccine.
- Any vaccine administration errors occur.

1. **Open a web browser and go to: https://vaers.hhs.gov/reportevent.html**
2. **Scroll to the bottom of the page and select "Option 1 - Report Online to VAERS."**
3. **Begin filling out the form with as much information that you can provide.**
4. **Click the "Next" button at the bottom of the page to go on to the next page.**
5. **When you reach item #26 (called Immunization project report number), it is very important that you enter the letters "*IHS*." This enables the IHS Pharmacovigilance program to evaluate vaccine safety among our patient population.**

6. **Once you have completed the form, please select the "Submit" button.**

For more information about documenting or reporting adverse vaccine or drug events, please visit the IHS Pharmacovigilance website or contact Chris.Lamer@ihs.gov

VAERS Educational Document and Slide-set:

Available on www.ihs.gov/nptc

Active Vaccine Surveillance - v-safe

- New smart-phone based active surveillance program for COVID-19 vaccine
  - Uses text messaging to initiate web-based survey monitoring.
  - Conducts electronic health checks on vaccine recipients.
  - Daily for first week post-vaccination; weekly thereafter until 6 weeks post-vaccination, then at 3, 6, 12 months.
- Includes active telephone follow-up for any clinically relevant events reported
  - The VAERS program will contact the individual and create a VAERS report, is appropriate.
- Healthcare professionals (HCPs) will play an important role in v-safe enrollment
  - Counsel on the importance of enrolling in v-safe post-vaccination.
- CDC will create a one-page printable information sheet
  - Electronic version sheet for printing will be available.

COVID-19 Vaccines in Development

- mRNA Vaccines
  - Provide instructions to our cells to make a viral protein that can be recognized by the immune system.
    - BNT-162b2 (Vaccine A - Ultracold)
    - mRNA-1273 (Vaccine B - Frozen)
- Many additional vaccines in development
  - 5 of the 6 early vaccines are a 2-dose series.
  - Variable storage requirements.
    - 1 of the 6 early vaccines is stored at refrigerated temperatures.
    - 1 stored at ultracold temperatures.
    - 4 stored at regular freezer temperatures.

General Details

- The majority of the leading vaccine candidates are 2 dose series at 21-28 days.
  - Must plan for timely 2nd dose of same brand of vaccine.
    - Brands are not interchangeable.
- In early phases, OWS will reserve supply for 2nd dose of vaccine.
- Co-administration with other vaccines was not studied, therefore unlikely to be recommended.
- Duration of protection is unknown at this time.

Ancillary Kits

- Ancillary Supplies will be packaged in kits and will be automatically ordered and sent to the facility in amounts to match vaccine orders in VTrckS.
  - Needles, Syringes, Alcohol prep pads
  - PPE: 4 surgical masks and 2 face shields per kit
  - COVID-19 vaccination record cards for vaccine recipients, 100 per kit; and,
  - Vaccine needle guide detailing injection information based on route, age, gender, and weight
  - If a COVID-19 vaccine requires mixing with diluent is ordered and shipped from CDC's centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order.
- Additional supplies anticipated (will need to be provided by site).
  - PPE gloves
  - Bandages
  - Sharps containers

BNT-162b2 (Vaccine A – Ultracold)

- Vaccine Developer: Pfizer/BioNTech
- Type of vaccine: mRNA
- Clinical Trial Status: Phase III
  - Enrollment: ~44,000
    - Study Populations: Age 16-85 years, Non-pregnant
    - Expanded to Age 12 years and older, October 2020
    - Diversity of participants
      - 30% diverse population
      - 300 AI/AN participants enrolled
- Distribution
  - Manufacturer plans to seek FDA EUA no earlier than 3rd week in Nov.

References: www.hhs.gov, clinicaltrials.gov; Mulligan, M et al, **Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults,** Nature | Vol586 | 22October2020 .

Vaccine A - Ultracold

- Tolerability (Phase I and II):
  - Well tolerated
  - Mild to moderate side effects (Soreness at the injection site, fever, chills, headache, and muscle or joint pain).
- Immunogenicity
  - Neutralizing titers 1.9 to 4.6 times higher than serum plasma from patients diagnosed with COVID-19 disease.
- Efficacy – announced 11/9/20
  - Independent Data Monitoring Committee from the Phase 3 clinical study found vaccine to be over 90% effective in the first interim analysis.

References: www.hhs.gov, clinicaltrials.gov - Mulligan, M et al, **Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults,** Nature | Vol586 | 22October2020 .
Press Release Pfizer 11.9.20 available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against

Vaccine A - Ultracold

- Cold Chain: Ultracold (-60 to -80 ℃)
  - Shipped to the site directly from the manufacturer in ultracold shipper.
    - Recharged shipper with pelleted dry ice within 24 hours of receipt (first recharge of dry ice sent to the site at no cost by the US Government).
      - Replenish with dry ice every 5 days thereafter to maintain required temperature.
      - Total amount of pelletized dry ice needed per thermal shipper “recharge” is ~23 kg.
    - On day 15, transfer the vaccine to refrigerated temperatures (2°C to 8°C). Use within 5 days (120 hours).
    - Shippers may only be opened two times a day, ideally less than 3 minute.
    - Shippers will come with data logger and will need to be returned to manufacture within 20 days.

Vaccine A - Ultracold

- Stability
  - Transport shipper – up to 15 days (with dry ice recharges)
  - Ultracold freezer – up to 6 months
  - Refrigerator – up to 5 days
  - Room Temperature – 2 hours
  - After dilution – 6 hours
- Available in increments of 975 doses (1 tray → up to 5 trays per shipper)
  - 5 doses per vial
  - Requires dilution
- Dosing Schedule: 2 dose series at 0 and 21 days

mRNA-1273 (Vaccine B – Frozen)

- Vaccine Developer: Moderna
- Type of vaccine: mRNA
- Clinical Trial Status: Phase III
  - Enrollment: 30,000 (completed enrollment)
    - Study Populations: Age≥ 18y, Non-pregnant, High-risk
    - Diversity of participants
      - 37% minority patients
      - 42% medically high risk
      - Manufacturer estimates 150-200 AI/AN participants enrolled
- Manufacturer announced it aims to seek FDA EUA by Nov 25.

References: www.hhs.gov, clinicaltrials.gov
Jackson, L et al, An mRNA Vaccine against SARS-CoV-2 — Preliminary Report, NEJM, https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022483?articleTools=true

Vaccine B – Frozen

- Tolerability/Adverse Events
  - Generally well tolerated
    - Pain at the injection site, followed by fatigue, muscle pain, headache and chills.
  - Side effects were more common after the second dose of the vaccine.
- Immunogenicity
  - Neutralizing titers higher than serum plasma from patients diagnosed with COVID-19 disease.
- Efficacy – announced 11/16/20
  - NIH-appointed Data Safety Monitoring Board (DSMB) for the Phase 3 study informed the manufacturer that the trial had met the statistical criteria pre-specified in the study protocol for efficacy, with a vaccine efficacy of 94.5%.

Rferences: www.hhs.gov, clinicaltrials.gov
Jackson, L et al, An mRNA Vaccine against SARS-CoV-2 — Preliminary Report, NEJM, https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022483?articleTools=true

Vaccine B – Frozen

- Cold Chain: Frozen (-20°C)
  - Shipped to the site from McKesson (similar to varicella vaccine).
  - Stable for 30 days once taken to refrigerated temperatures (2°C to 8°C).
  - Stable at room temperature for 12 hours.
- Available in increments of 100 doses
  - 10 MDV with 10 doses per vial.
  - Does not require dilution/mixing.
- Dosing Schedule: 2 dose series at 0 and 28 days

References: www.hhs.gov, clinicaltrials.gov
Jackson, L et al, An mRNA Vaccine against SARS-CoV-2 — Preliminary Report, NEJM, https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022483?articleTools=true

AI/AN Study Populations

- AI/AN patient volunteers who meet enrollment criteria are eligible to participate in clinical vaccine trials.
- The Navajo Nation, in partnership with the Johns Hopkins Center for American Indian Health, announced participation in Pfizer COVID vaccine trial.
- It is unlikely that sufficient numbers of AI/AN participants in phase III trials will be adequate to draw statistically significant conclusions about the unique efficacy/safety profile in this subgroup.
- Post-marketing surveillance will be especially important.

Considerations and Next Steps

- Connect to Area Vaccine Point of Contact (AVPOC) and Site Vaccine Points of Contact (SVPOC) to begin assessments and planning.
- Review IHS COVID-19 Facility Planning Checklist in the IHS COVID-19 Pandemic Vaccine Plan, November 2020 at: www.ihs.gov/coronavirus/vaccine.
- Determine local priority populations and identification for outreach methods.
- Consider potential use of ultra cold vaccine and pre-planning for this product.
- Complete training documentation processes and vaccine administration (once available).

Multifaceted Approach Needed

- Stopping a pandemic requires using all the tools available.
- Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed.
- Other steps, like covering your mouth and nose with a mask and staying at least 6 feet away from others, help reduce your chance of being exposed to the virus or spreading it to others.
- Together, COVID-19 vaccination and following CDC's recommendations to protect yourself and others will offer the best protection from COVID-19.
- Ensure you and your family are vaccinated for influenza this month.

Resources

- Division of Information Technology Points of Contact for technical assistance
  - Upgrade to Windows 2016 Operating System software
    - Kathryn Lewis & Paul Kundtz
  - Upgrade AIX version 7.2 Operating System or Database Operating System from Ensemble to HealthShare 2017
    - Raymond Richardson & Glenn Janzen
- Area Vaccine POCs (AVPOCs)
- IHS COVID-19 Vaccine Task Force
  - www.ihs.gov/coronavirus/vaccine

Questions?

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