NEW MEXICO DEPARTMENT OF HEALTH

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COVID-19 Vaccine Planning in NM

Presentation to Legislative Health and Human Services Committee

October 27, 2020

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COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

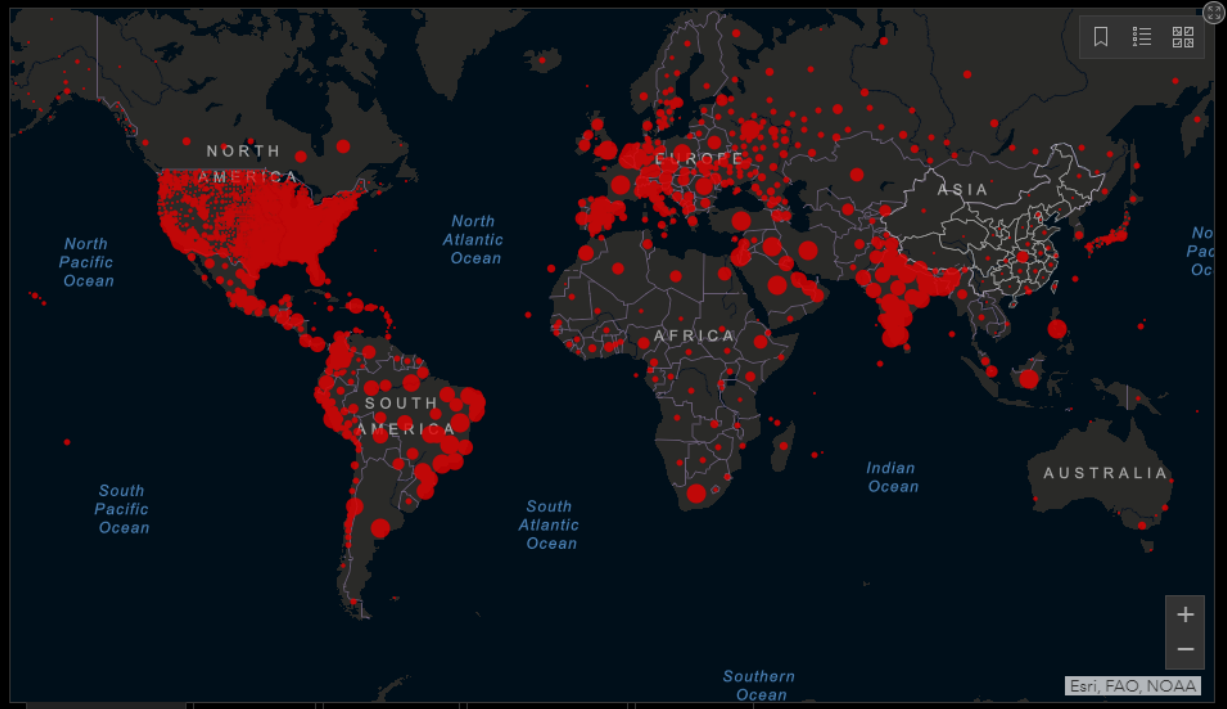
Global Cases
42,876,132

Cases by Country/Region/Sovereignty

8,619,935	US
7,864,811	India
5,380,635	Brazil
1,503,652	Russia
1,130,081	France
1,081,336	Argentina
1,046,132	Spain
1,007,711	Colombia
886,800	Mexico
886,214	Peru
876,840	United Kingdom
715,868	South Africa
568,896	Iran
525,782	Italy

Admin0 | Admin1 | Admin2

Last Updated at (M/D/YYYY)
10/25/2020, 2:24 PM



Cumulative Cases | Active Cases | Incidence Rate | Case-Fatality Ratio | Testing Rate

189
countries/regions

Lancet Inf Dis Article: Here. Mobile Version: Here. Data sources: Full list. Downloadable database: GitHub, Feature Layer. Lead by JHU CSSE. Technical Support: Esri Living Atlas team and JHU APL. Financial Support: JHU, NSF, Bloomberg Philanthropies and Stavros Niarchos Foundation. Resource support: Slack, Github and AWS. Click *here* to **donate** to the CSSE dashboard team, and other JHU COVID-19 Research Efforts. FAQ. Read more in

Global Deaths
1,152,215

225,111 deaths	US
156,903 deaths	Brazil
118,534 deaths	India
88,743 deaths	Mexico
44,986 deaths	United Kingdom
37,338 deaths	Italy

Global Deaths

https://coronavirus.jhu.edu/map.html

COVID-19 Response

Pandemic Response

- Mask and Social Distancing
- Testing
- Case Investigation, Isolation, Contact Tracing & quarantine to contain virus
- Vaccination

Vaccination

Herd Immunity ***through vaccination***; estimates are that we need to vaccinate ~ 70% of Population

- For NM: that is 2.9 million vaccine doses (using 2 doses per individual)
- Compared to annual flu vaccine administered in NM
  - Approximately 1.1 million

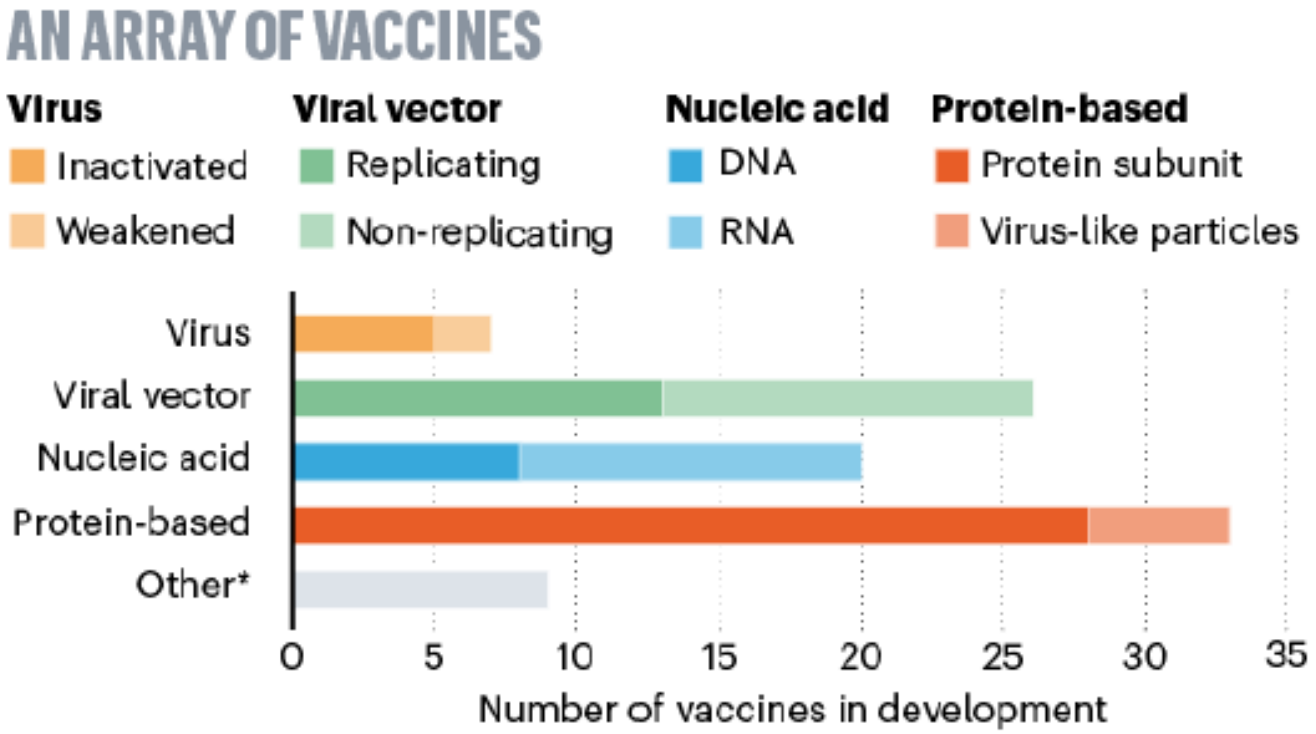
Coronavirus Vaccine Tracker

By Jonathan Corum, Sui-Lee Wee and Carl Zimmer Updated October 20, 2020

Phase 1	Phase 2	Phase 3
33	**15**	**11**
Vaccines testing safety and dosage	Vaccines in expanded safety trials	Vaccines in large-scale efficacy tests

In June, the F.D.A. advised vaccine makers that they would want to see evidence that vaccines can protect at least 50 percent of those who receive it. In addition, Phase 3 trials are large enough to reveal evidence of relatively rare side effects that might be missed in earlier studies.

Adapted from New York Times



Source: Nature

Vaccine Development: Unprecedented Speed

Vaccine Collaboration

Public-Private

- Industry, government and academia collaboration
- Large scale manufacturing in parallel with clinical development

Vaccine Platform Technology

Nucleic-Acid Vaccines

Advantage: quick development time, inexpensive to manufacture, stable vaccine

Disadvantage: ultra-low temperature storage

Vaccine Developers

Leading Vaccine Candidates

- Pfizer and BioNTech
- Moderna
- AstraZeneca
- Johnson & Johnson

Established Safeguards to Ensure Vaccine Safety & Efficacy

Before vaccines are approved for public use, vaccines undergo a robust system of review by career scientists and independent experts to ensure safety, efficacy, and continued monitoring

- Data Safety Monitoring Board (DSMB) independent review
- Application Review by career FDA scientific staff, as well as Vaccine Related Biological Products Advisory Committee (VRBPAC)
- Approvals will require plans for monitoring adverse events
- Advisory Committee on Immunization Practices (ACIP) reviews evidence and makes recommendations on use to CDC

Emergency Use Authorization (EUA)

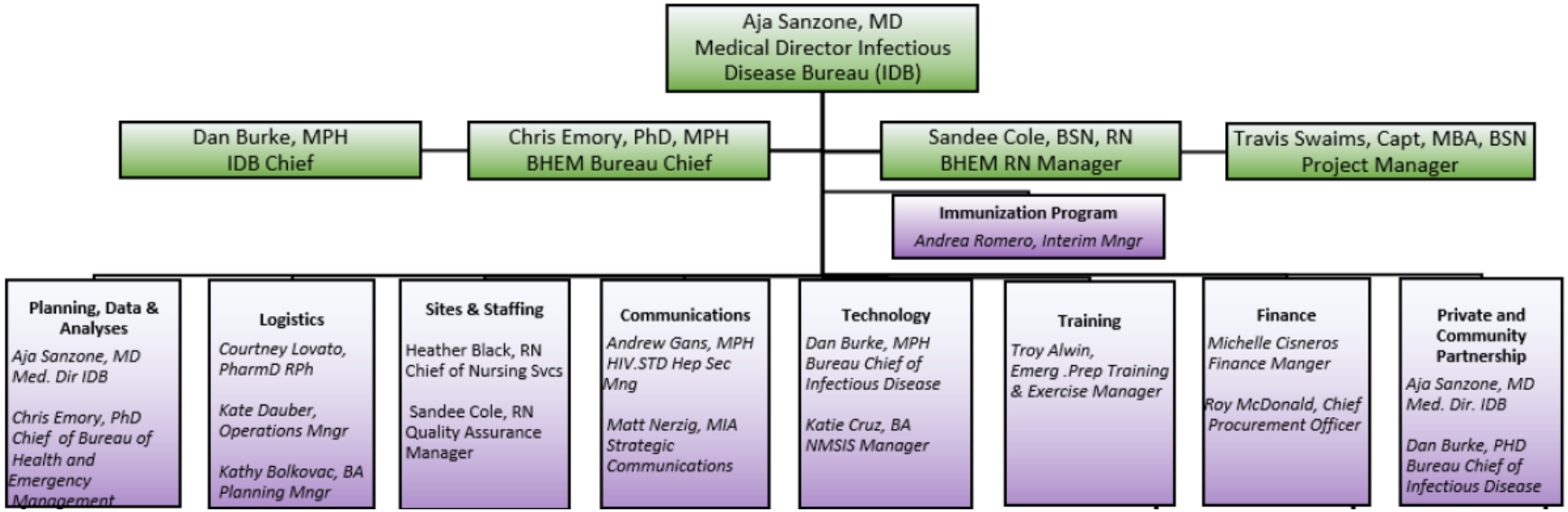
- Based on data from clinical trials, manufacturers will submit applications for Emergency Use Authorization (EUA) to FDA for vaccine candidate
- FDA will review EUA applications, approve or deny them, and oversee ongoing reporting (EUA might limit vaccine use to specific populations)
- Independent Advisory Committee to FDA (VRBPAC) met 10/22 to recommend standards for issuance of a COVID-19 vaccine EUA
- Independent advisory panel (Advisory Committee on Immunization Practices with input from Nat'l Academies of Science) informs CDC distribution & will advise regarding populations to receive each vaccine

Current Federal Government Vaccine Distribution Plans

- Much remains unknown – DOH is asking for more information as are NGA, Immunization experts, other states
- Federal government has not disclosed criteria for determining how it will allocate limited supply among states
  - Will it be based on prevalence of COVID-19? overall population?
  - How will they address unique needs (including efficient administration of vaccine) in rural & frontier communities?
- CDC and “Operation Warp Speed”:
  - Will oversee distribution of vaccine
  - Will track product that is delivered/administered

Statewide COVID-19 Vaccine Planning: Preparations for Safe & Effective Vaccines

- Creating Infrastructure
  - Vaccine distribution and administration
  - Mechanisms to address barriers to access
  - IT processes for vaccine tracking and safety
  - Community engagement
- DOH Vaccine Planning Team
- COVID-19 Vaccine Advisory Group


Aja Sanzone, MD
Medical Director Infectious Disease Bureau (IDB)
Dan Burke, MPH
IDB Chief
Chris Emory, PhD, MPH
BHEM Bureau Chief
Sandee Cole, BSN, RN
BHEM RN Manager
Travis Swaims, Capt, MBA, BSN
Project Manager
Immunization Program
Andrea Romero, Interim Mngr
Planning, Data & Analyses
Aja Sanzone, MD Med. Dir IDB
Chris Emory, PhD Chief of Bureau of Health and Emergency Management
Logistics
Courtney Lovato, PharmD RPh
Kate Dauber, Operations Mngr
Kathy Bolkovac, BA Planning Mngr
Sites & Staffing
Heather Black, RN Chief of Nursing Svcs
Sandee Cole, RN Quality Assurance Manager
Communications
Andrew Gans, MPH HIV.STD Hep Sec Mng
Matt Nerzig, MIA Strategic Communications
Technology
Dan Burke, MPH Bureau Chief of Infectious Disease
Katie Cruz, BA NMSIS Manager
Training
Troy Alwin, Emerg .Prep Training & Exercise Manager
Finance
Michelle Cisneros Finance Manger
Roy McDonald, Chief Procurement Officer
Private and Community Partnership
Aja Sanzone, MD Med. Dir. IDB
Dan Burke, PHD Bureau Chief of Infectious Disease

CDC Guidance & Instructions for Preparing Vaccination Plans

1. COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations
   Released 09/16/20

2. COVID-19 Vaccination Plan Template
   Released 09/21/20
   Deadline to submit: 10/16/20

3. CDC continues to provide updated information at least weekly, often more frequently

NM Preliminary Draft COVID-19 Vaccination Plan

- Submitted 10/16/20
- 15 sections, 60 pages
- Broad outline of state efforts to build infrastructure around allocation, identification of vaccine administration and distribution capacity, assimilation of new IT platforms and processes and the development of effective communication strategies for both providers and the public
- Includes several sets of questions where more information is needed therefore need flexible planning
- Living document as more information is revealed
- Based on available scenarios from CDC, draft plan assumes very limited supplies in early weeks of distribution & focuses on those early phases

Initial Goals Based on Very Limited Supplies

Goals for Early Distribution:

- Reduce transmission of COVID-19 virus to those most likely to come into contact with and care for COVID-19 patients
- Protect the most vulnerable and those at greatest risk of serious illness or death from the disease.

Pragmatic Goals: Maximize vaccine acceptance and minimize waste and inefficiency in initial phase

PHASE 1:

Very Limited Supply

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Phase 1: Very Limited Supply

Phase 1a ("kick-start" doses):

- Vaccinate health care personnel of key vaccinator entities with high exposure to COVID-19 (e.g., hospitals, large health systems)

Phase 1b (expanded but still very limited doses):

- First responders, EMS, other healthcare providers, staff and service providers who have direct contact with people with COVID-19
- Personnel who work in congregate care settings where the risk of spread to vulnerable populations is high
- Residents of Long-Term Care Facilities

Later Phase 1 will include:

- Residents of other congregate care facilities
- Other healthcare workers

Pharmacy Partnership for Long-Term Care Program

- U.S. Department of Health and Human Services and Department of Defense developed partnership with CVS and Walgreens to provide and administer COVID-19 vaccines to residents of long-term care facilities (LTCF)
- LTCF residents and staff will be able to safely and efficiently get vaccinated once vaccines are available and recommended for them
- CVS and Walgreens will schedule and coordinate on-site clinic date(s) directly with each facility.
- Free of charge to facilities

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Pharmacy Partnership for Long-Term Care Program (Cont.)

- Minimize burden on LTCF sites and local public health offices of vaccine handling, administration and fulfilling reporting requirements

PHASE 2:

Large Number of Vaccine Doses Available

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Phase 2 Large Number of Vaccine Doses Available

According to CDC, Supply=Demand

- Provide vaccine for a broader population
- Increase capacity to vaccinate the population
- Large group of vaccinators

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PHASE 3:

Sufficient Supply of Vaccine Doses for the Entire Population (surplus of doses)

Phase 3 Sufficient Supply of Vaccine Doses for the Entire Population (surplus of doses)

- Enough vaccine for all New Mexicans
- Sustain supply for use over time

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COVID-19 Vaccination Provider Recruitment and Enrollment

- Every COVID-19 vaccine Healthcare Provider is required to sign an agreement with CDC & states are required to facilitate enrollment
- Providers must commit to:
  - report data *within 24 hours*,
  - give vaccine regardless of ability to pay,
  - Being capable of storage and monitoring for ultra-cold temperature vaccine (although that may not be strictly required – some inconsistent information)
- NM is recruiting providers now
- Vaccine coordinator for each site
- Storage and handling – refrigerators, freezers, digital data loggers (temperature control)

Addressing new Data Systems and Federal Reporting Requirements

- Federal Government is building new data infrastructure for COVID-19 vaccine
- State immunization reporting systems will need to connect to these
- Key part of infrastructure planning and preparedness
- Information continues to be rolled out by CDC

Information Technology/Data Processing Systems

NMDOH Immunization (IZ) Program

- New Mexico State Immunization Information System (NMSIIS)
- Vaccine Tracking System (VtrckS)
- Internal registration mobile app (public health offices)

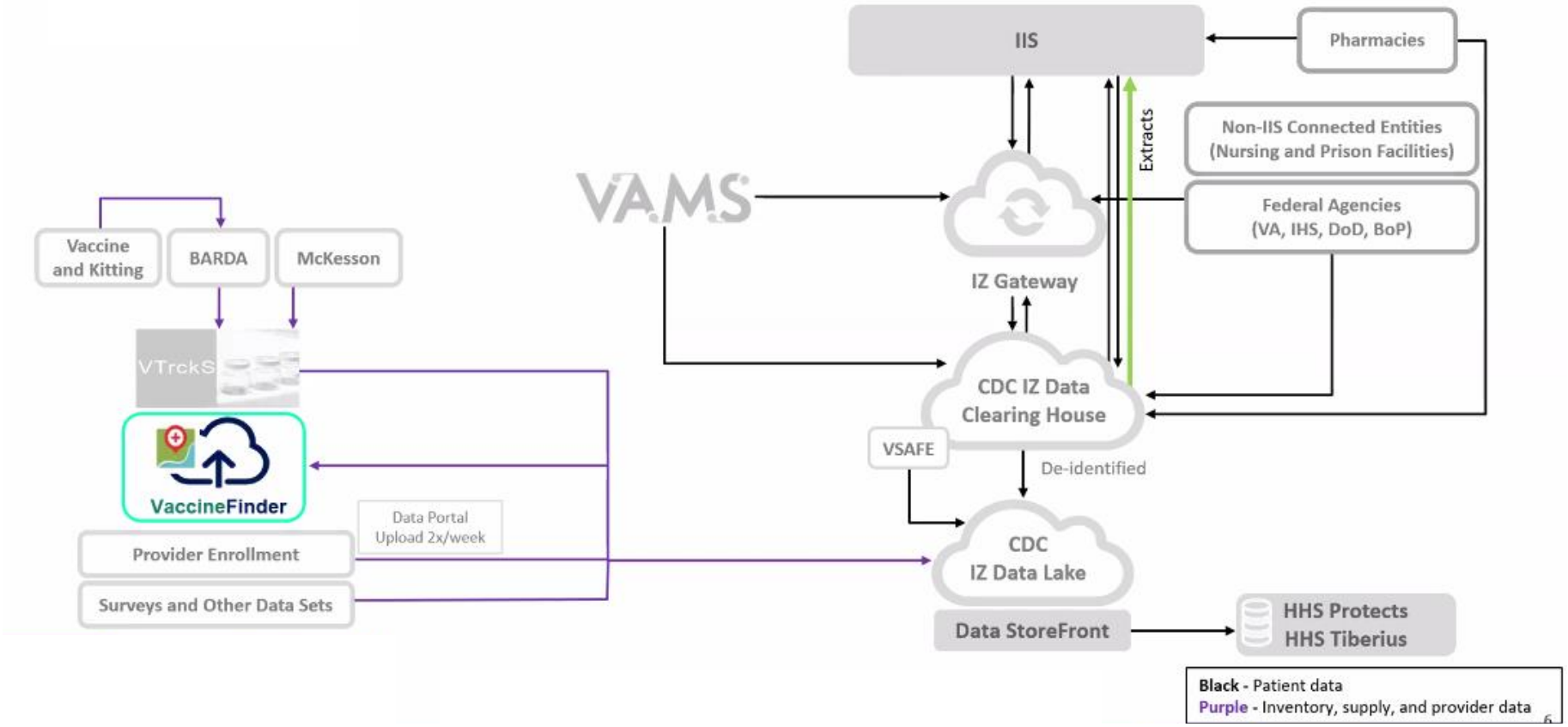
Federal Systems

- Vaccine Finder (New requirement)
- Vaccine Administration Management System (VAMS) (New system)
- Tiberius (New system described below)

Department of Health Vendor

- Real Time Solutions (gathering more specific NM data - sample below)

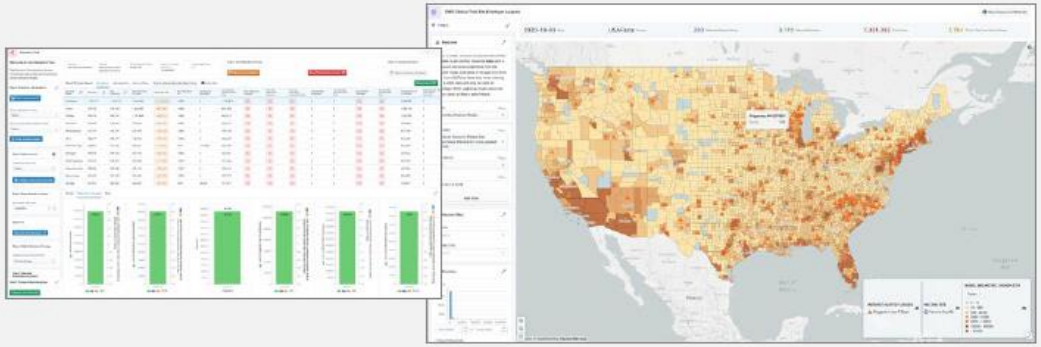
Data Architecture for COVID-19 Vaccine



Adapted from CDC Presentation October 2020

Tiberius Overview

- Tiberius (or Protect-OWS) is the Operation Warp Speed (OWS) instantiation of HHS Protect
- Provides a COVID-19 vaccine distribution planning, tracking, modeling, and analysis ecosystem to support the OWS mission
- Integrates data sources from Federal agencies, State and Local partners, private sector partners, and open data providers
- Provides flexible and near real-time data-backed applications that enable users of all types to make data-driven decisions



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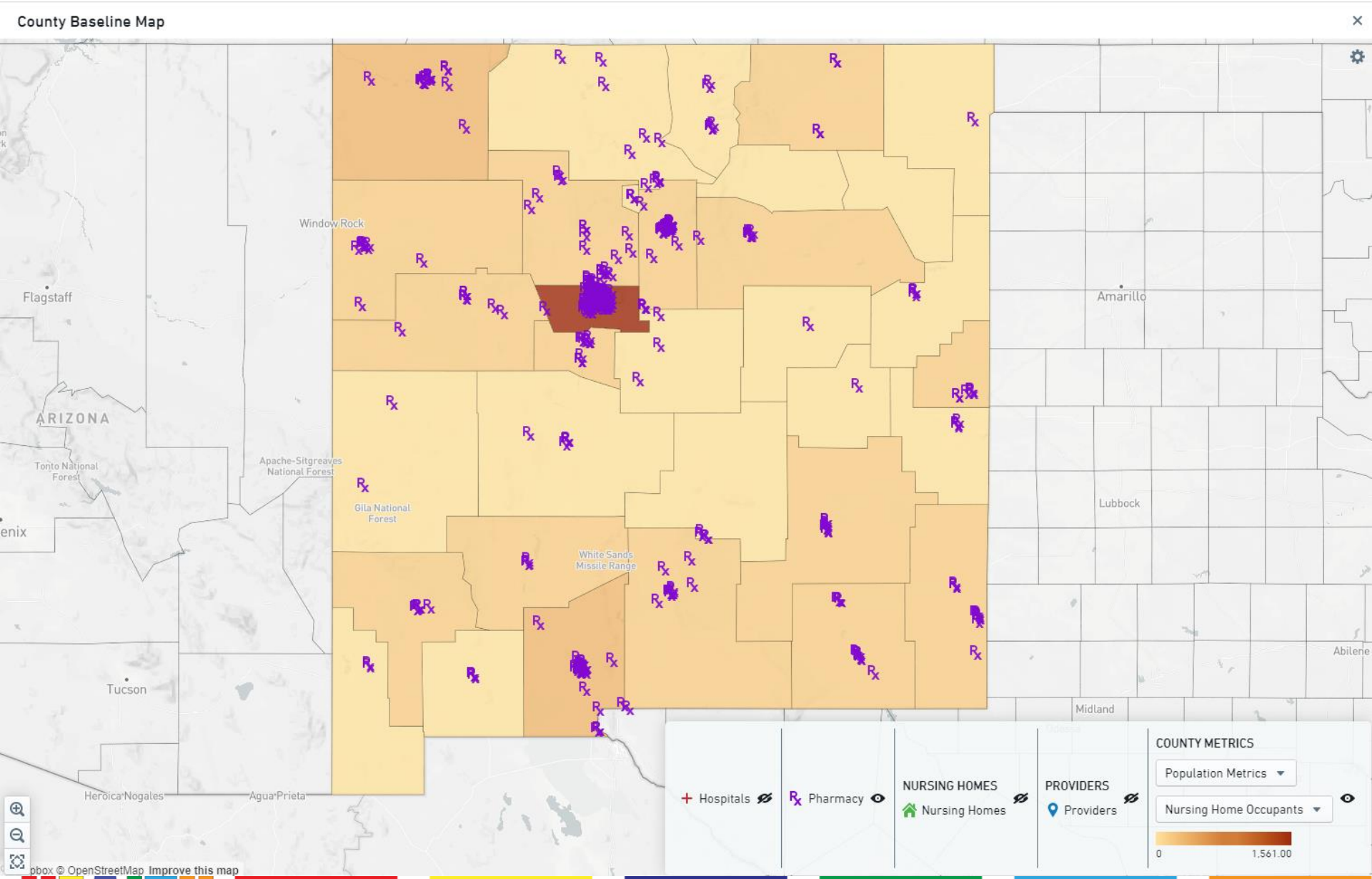

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New Mexico Department of Health

COVID-19 Vaccine Portal

CENTRALIZED
Data Gathering Hub for Vaccine Providers

FLEXIBLE
Reporting on Special Pops, LTCF, Schools etc.

UNIFYING
Ties Federal & Local efforts together

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Identifying State Capacity to Administer COVID-19 Vaccine

DOH Sent Survey to healthcare providers:

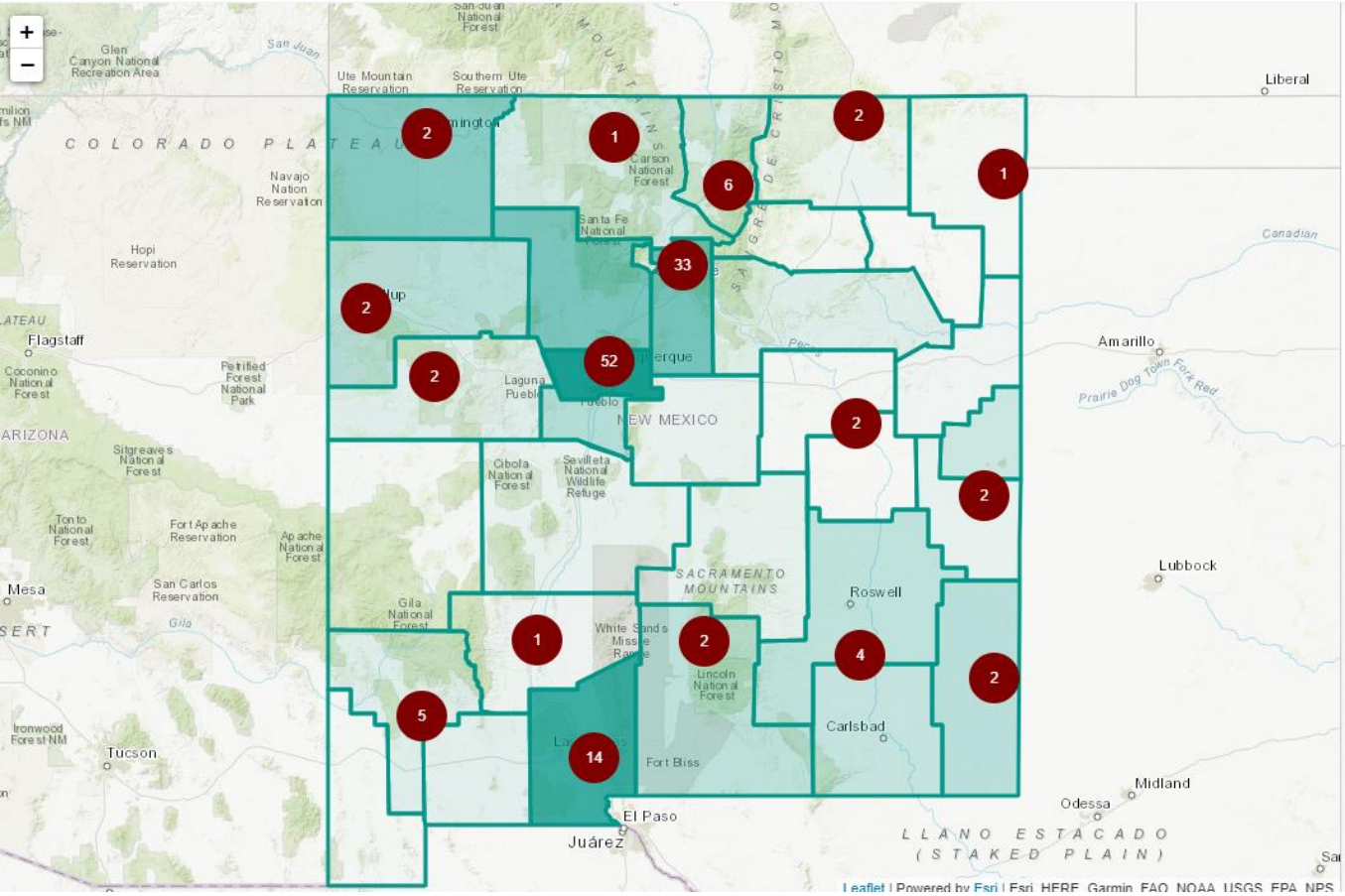
- Hospitals
- FQHC's
- LTCF's
- Pharmacies
- Other providers

Survey seeks information on vaccination capacity, infrastructure, available personnel for vaccinating & numbers of their own personnel who have high, moderate and low exposure to COVID-19 patients

New Mexico Department of Health

COVID-19 Provider Location Portal

Welcome,
Log Out



Base Layer

Population

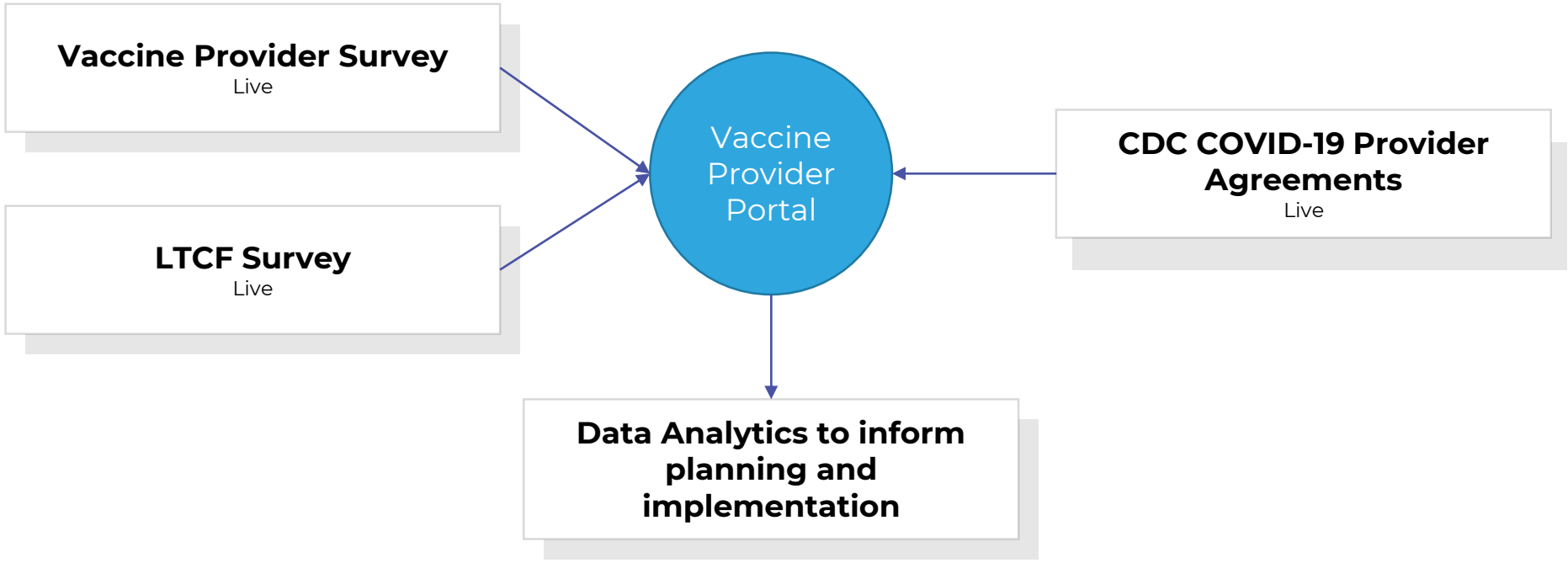
Markers

- [x] Survey Responses
- [ ] Testing Locations
- [ ] Nursing Facilities
- [ ] Assisted Living Facilities
- [ ] Intermediate Care Facilities
- [ ] Developmental Disability Providers
- [ ] DOH Care Facilities
- [ ] Flu Vaccine Providers

Rank ↓

Rank	Population
1. Bernalillo	678,216
2. Doña Ana	217,401
3. Santa Fe	149,813
4. Sandoval	145,153
5. San Juan	128,046
6. Valencia	76,064
7. McKinley	71,242

Current **Status**



CDC post-authorization/post-licensure monitoring of COVID-19 vaccines

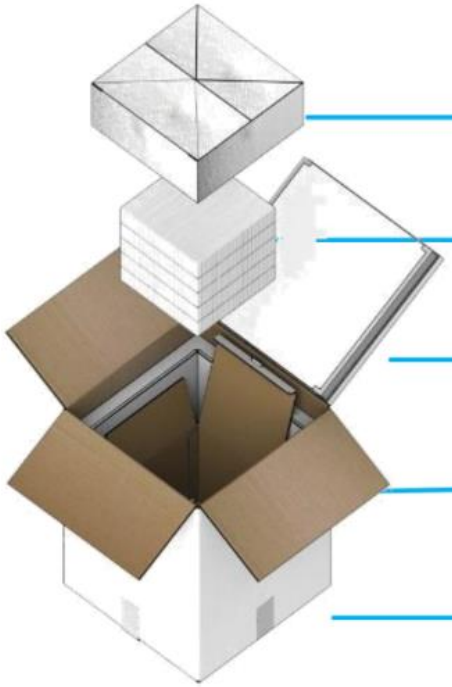
- Vaccine Adverse Events Reporting System (VAERS) – national registry to report all vaccine adverse events
  - Rapidly detects safety signals
  - Can detect rare adverse events
  - Generally cannot assess causality
- NMDOH will utilize:
  - educational materials,
  - weekly email reminders
  - Adverse events reporting module
  - COVID 19 Vaccine Webpage

Potential First Vaccine Available

Pfizer

- Ultra low temperature storage: (-70°C to -90°C)
  - Ambient (15°C to 30°C)
  - Refrigerated (2°C to 8°C)
  - Freezer (-25°C to -10°C)
  - Ultra-low Freezer (-70°C to -90°C)
- 2 doses, 21 days apart
- Minimum order of 1,000 doses (975/container)
- Earliest available vaccine might create some of the most significant logistical challenges

Ultra Low Temperature Thermal Shipper – Overview of Pack Out



ITEM	DESCRIPTION
1	DRY ICE POD
2	PAYLOAD (VIAL TRAYS)
3	INNER LID
4	PAYLOAD SLEEVE
5	OUTER CARTON

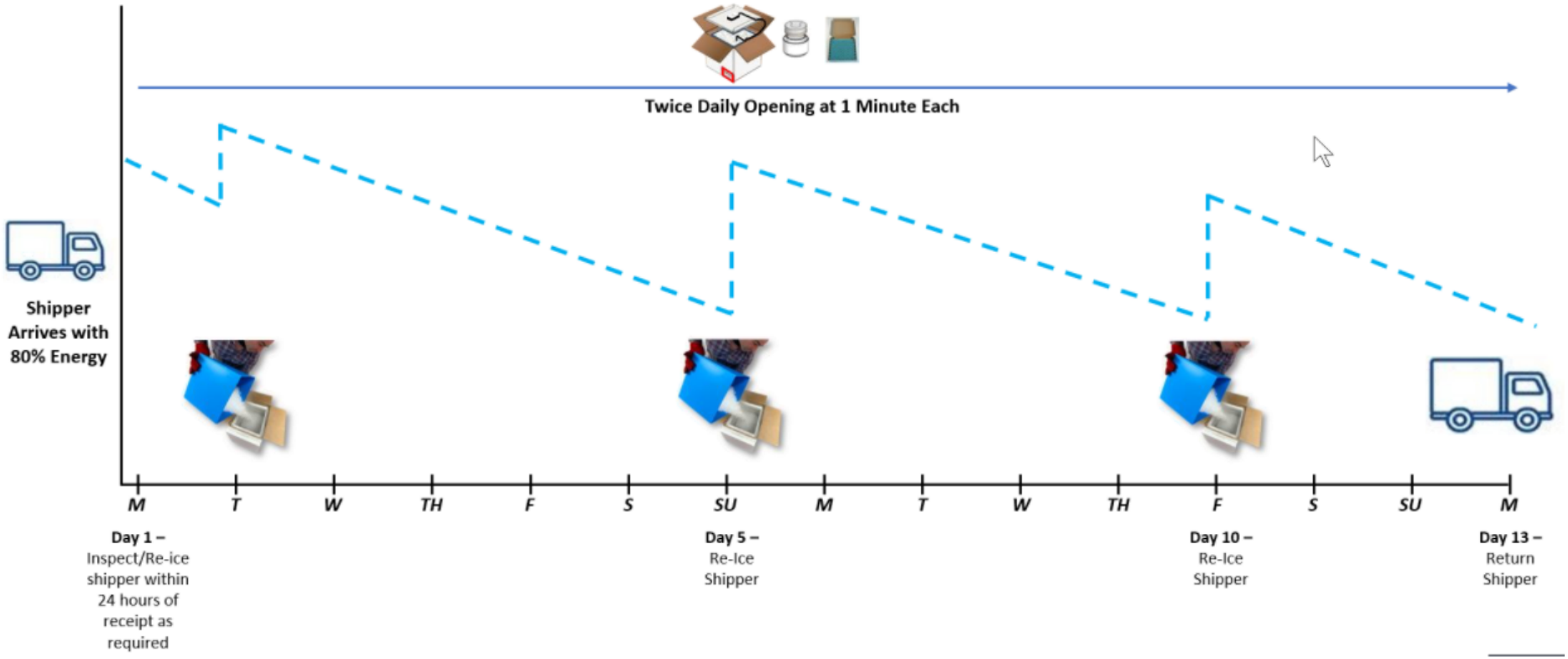
Weights and Dimensions	
Tare Weight (Inc. Dry-Ice)	8.5kg (31.5kg)
Volumetric Weight	15.0kg
Payload Space L x W x H	245x245x241mm
Shipper Dimensions L x W x H	400x400x560mm

Pfizer | BIONTECH

Diminishing Shipper Energy with Use Over Time

Handling instructions to vaccination centers

- Inspect/Re-ice shipper within 24 hours of receipt as needed as part of goods receipt process
- Re-ice every 5 days (Up to 3 times)
- Return the shipper within 10 business days



Examples of Site types for Vaccine A product

Vaccination site	Ordering assumptions			Operating assumptions				
	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per immunizer	Hours per day	Vaccines per day	Shipment model
A – large outpatient center (mass vx)	1 tray (975 doses)	Thermal box with dry-ice, 2-8CR fridge, for product estimated at site (5 days)	~500/day	10 immunizers	6 patient/hour (~10 min/Vx)	8 hours	480 vaccinations	1 tray; 2-3 times per week
B – hospital or outpatient center	1 tray (975 doses)	ULT freezer, Thermal box with dry-ice, 2-8C fridge, for product estimated at site (5 days)	Variable	4 immunizers	6 patient/hour (~10 min/Vx)	8 hours	192 vaccinations	1 tray; every week
C – large hospital with affiliated outpatient center	5 trays (4,875 doses)	ULT freezer, Thermal box,2-8C fridge, for product estimated at site (5 days)	Variable	7 immunizers (hospital outpatient clinic)	6 patients/hour (~10 min/Vx)	8 hours	340 vaccinations	1 tray; 1-2 times a week
D – outdoor parking lot vaccination hub at large retail pharmacy	1 tray (975 doses)	2-8C fridge, for product estimated at site (5 days)	~200/day	5 immunizers	6 patients/hour (~10 min/Vx)	N/A	240 vaccinations	1 tray; every week
E – mobile vaccination in targeted geographies	5 trays (4,875 doses)	2-8C fridge, for product estimated in mobile unit (5 days)	Variable	3 immunizers	6 patients/hour (~10 min/Vx)	Not specified	150 vaccinations	1 tray; every week

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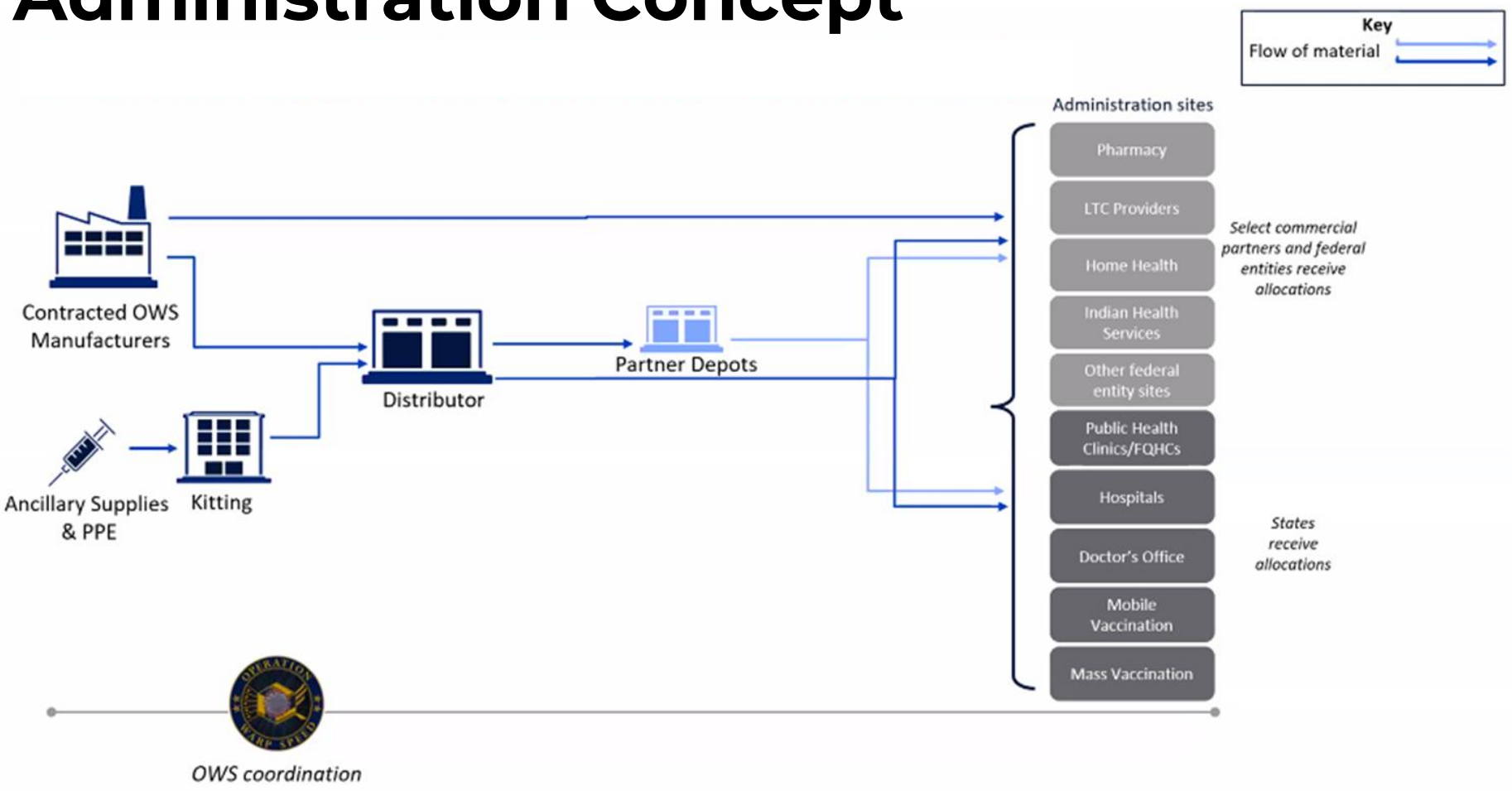
Overview of Distribution & Administration Concept



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Challenges for COVID-19 Planning

Logistical

- Vaccine
  - One vs two dose series
  - Products not interchangeable
  - Vaccine efficacy and adverse event profile in different populations
  - Varying cold-chain requirements
  - Use in children and pregnant people
  - Need for socially distanced vaccination practices
- IT
  - 24-hour reporting
  - New government IT systems

Fading Public Confidence in a Vaccine Poses a Challenge

- 58% of the U.S. public said they would get vaccinated as soon as a vaccine was available when asked earlier this month, down considerably from 69% who said the same thing in mid-August.
- That change suggests growing concern that the regulatory approval process for a Covid-19 vaccine has been politicized. But the FDA has to date continued to adhere to its scientific processes for consideration and approval of COVID-19 vaccines.
- Restoring public confidence in the safety and efficacy of the vaccines must be the top priority of our public information program

COVID-19 Communications Program

- Goal: provide clear, accurate, consistent and timely information about the NM Immunization Program
- Ensure coordination with community partners to (a) keep key stakeholders and public informed on vaccine availability and (b) develop and disseminate messaging in support of taking the vaccine
- Information is culturally and linguistically appropriate for reaching key audiences
- Expand on influenza media campaign and plan to adapt to COVID-19 Vaccine
- Development of COVID-19 Vaccine website to provide accurate and timely messaging to the public and providers

State Readiness

- Building Infrastructure to distribute and administer first doses of safe and effective COVID-19 Vaccine
- Monitoring FDA and independent scientific review of vaccine trials and approval process
- Raising questions to CDC to address gaps and gather further information
- Continually assimilating new information as it becomes available from CDC into planning
- Running statewide exercises in preparation for initial vaccine distribution
- Preparation for statewide vaccination campaign when significant vaccine will be available

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Summary

- This is a historical population-wide immunization effort
- There are many challenges, funding issues and information gaps
- Complex phased approach to reach sufficient coverage to overcome the pandemic. Must maintain COVID-safe practices in the meantime.
- Public trust in the vaccine is an essential factor, and transparency in the process is critical
- We will develop the necessary infrastructure and remain flexible in planning as new information becomes available to best prepare for COVID-19 Vaccine distribution and administration to end this pandemic

Questions?

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