

Vaccines update

September 2020

Situational overview

Current context for COVID-19 vaccination

- To date, there is no globally approved COVID-19 vaccine or specific treatment available
 - There are over 260 vaccine candidates and over 380 therapeutics candidates in consideration internationally¹
 - Limited quantities of a federally funded vaccine may become available this year under emergency use authorization (EUA)² pre approval
 - Advisory bodies including the Advisory Committee on Immunization Practices (ACIP) and the Vaccines and Related Biological Products Advisory Committee (VRBPAC) will review scientific evidence for any vaccines under EUA and provide their opinions
 - The National Academies of Sciences, Engineering, and Medicine (NASEM) have provided preliminary prioritization guidance for allocation, which will inform ACIP's recommendation to CDC's allocation guidance
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New Jersey's experience with adult immunizations

- The State of New Jersey has experience with pandemic vaccination during 2009 for H1N1
 - Routinely ~50% of the population in the state receive the flu vaccine annually (~73% of children 6 months – 17 years of age were vaccinated in the 2019-2020 flu season)
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Planning implications

- The State of New Jersey will need to plan for large scale vaccination, assuming a safe and efficacious vaccine becomes available
- To understand and inform public expectations of COVID-19 vaccine risks, benefits, and availability, the State will engage with a range of stakeholders
- Equitable access will be a primary consideration across all planning and delivery elements

¹ As of 08/27/2020

² Expedited authorization of medical products to address public health emergencies (could be issued prior to completion of Phase 3 clinical trials)

COVID-19 vaccines



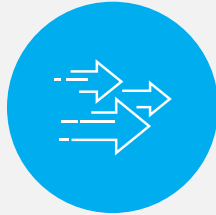
What we know

- Several vaccines are in Phase 3 clinical trials (*details to follow*)
- Initial supply will be limited, requiring allocation decision making¹
- Planning will likely be complex given the need for safeguarding, cold-chain requirements, multiple doses (e.g., spread over 3-4 weeks), and likely scale
- COVID-19 vaccine and some ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers
- Given the novel nature of the vaccine, likely under EUA, will result in varying levels of public confidence
- Every state will need to submit a vaccines rollout plan to the CDC on Oct 16th



What is likely

- FDA could issue emergency use authorization (EUA) of a coronavirus vaccine pre approval
- The federal government will likely provide guidance on prioritization but the State will need to make allocation and operational decisions
- Allotment of COVID-19 vaccine to jurisdictions will be based on multiple factors, including populations recommended by the ACIP with input from NASEM, current local spread/prevalence, and vaccine availability
- COVID-19 pandemic may not resolve without community protection (herd immunity) or effective vaccination



What we don't know

- Efficacy and adverse event profile for any potential vaccines
- Likelihood of community protection through vaccination
- Actual allotment and timeline of availability or further detailed guidance

¹ CDC vaccination scenarios assume initial national availability of two likely vaccines: ~3M doses by end of October, ~20-30 doses by end of November, and ~35-45M by end of December. By January 2021 significantly more COVID-19 vaccine will be available for distribution and plans will need to evolve to address additional vaccine availability

Preliminary, pre-decisional, and deliberative. Based on input provided by State agency leaders and staff, to date, and subject to change. Content is descriptive only and is not meant to constitute legal, clinical, or policy advice.

SOURCE: CDC guidance on 8/27

Clinical phases for typical vaccine development

x Number of vaccine candidates in a particular phase as of 09/08¹

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers with adults first.

Phase 1

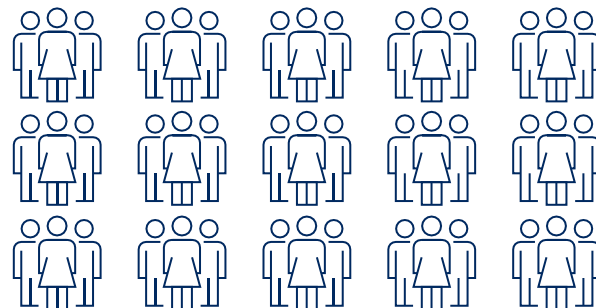


20-100 healthy volunteers

- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

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Phase 2

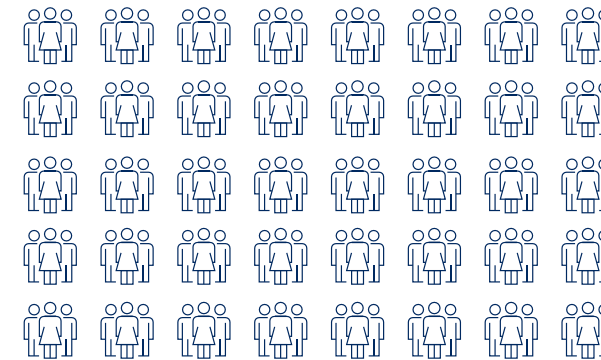


Several hundred volunteers

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccines?

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Phase 3



Hundreds or thousands of volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

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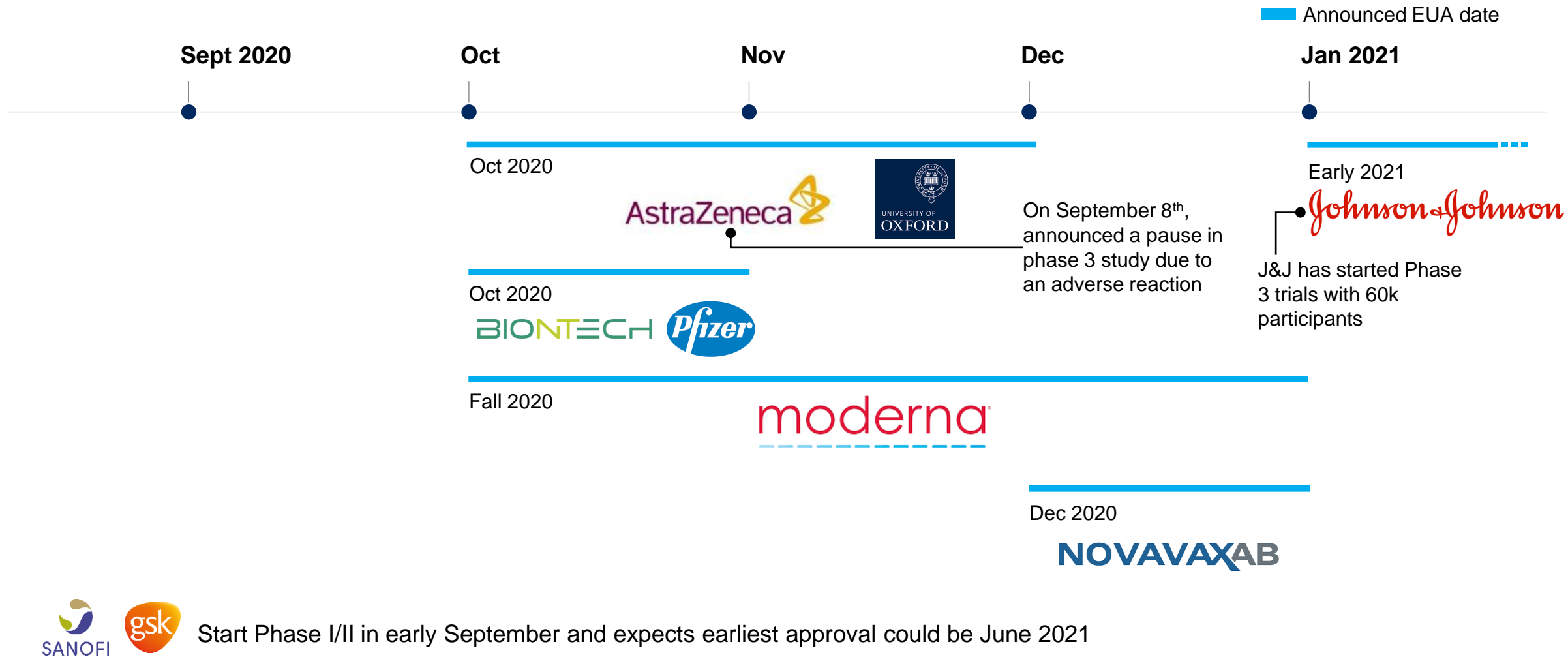
FDA could issue an emergency use authorization (EUA) of a coronavirus vaccine (could be prior to completion of Phase 3 clinical trials)

¹ 5 vaccines approved for limited use in China, Russia and UAE before full results of Phase 3 trials








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SOURCE: FDA; press releases

Developers who have announced potential for emergency use authorization in late 2020 and/or early 2021 in the US



Additional details on leading vaccine candidates

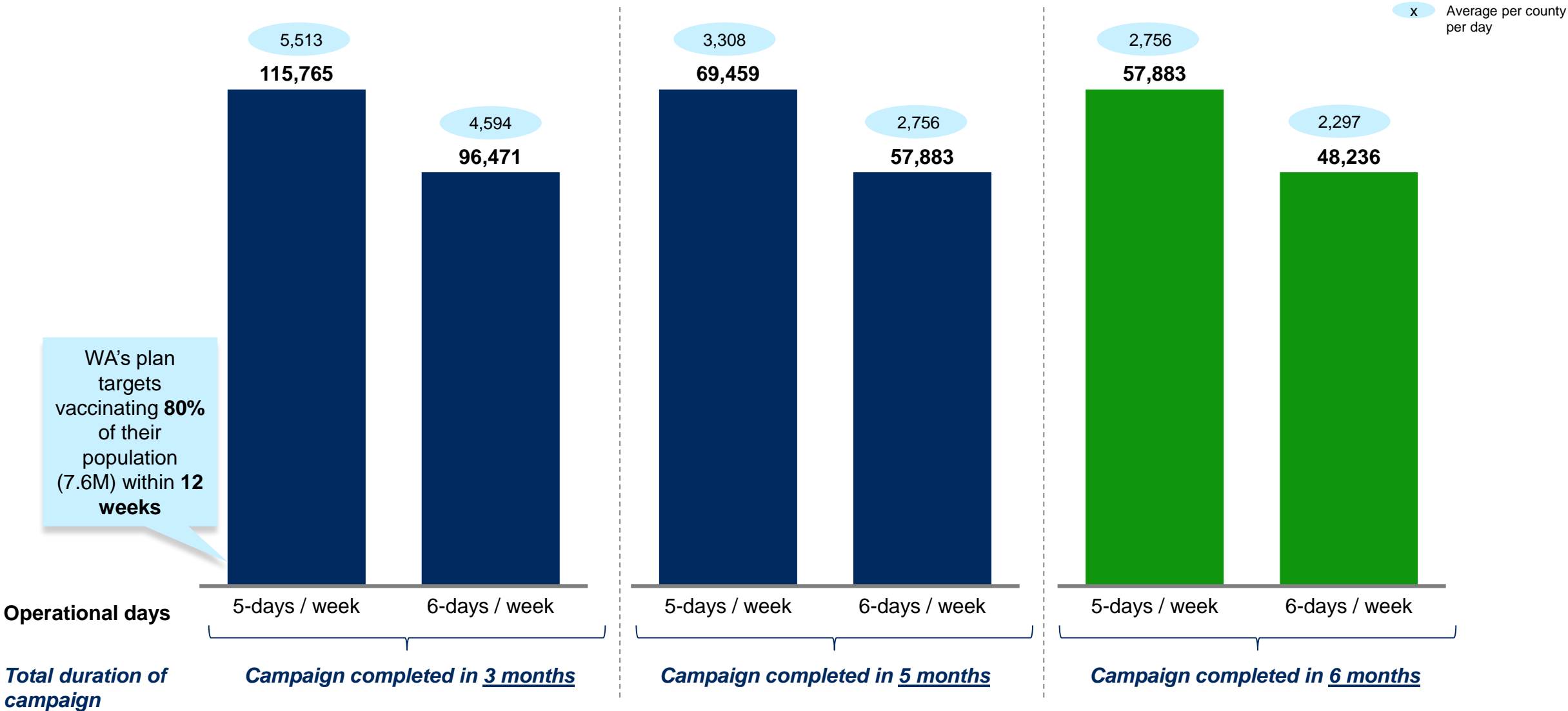
		<u>Vaccine type</u>	<u>Clinical trial status</u>	<u>EUA possible date</u>	<u>Doses¹</u>	<u>Storage and handling</u>	<u>US Gov. contracted doses</u>
ModernaTX USA		mRNA	Phase 3	2020 Oct?	2 doses	Ship: -20°C POC ² : 2-8°C	100 million
BioNTech with Pfizer		mRNA	Phase 3	2020 Oct?	Single or 2 doses	Ship: -70°C POC: dry ice or 2-8°C	100 million
Johnson & Johnson (Janssen Vaccines)		Adenovirus vector	Phase 1	2021 Jan?	2 doses	2-8°C	100 million
Novavax		Subunit protein	Phase 2	2021 Jan?	2 doses	2-8°C	100 million
Sanofi Pasteur (with GlaxoSmithKline)		Subunit protein	Phase 1	2021 Jan?	N/A	2-8°C	100 million
CureVac		mRNA	Phase 1/2	2021 Jan?	2 doses	N/A	N/A
Univ. of Oxford³ with AstraZeneca		Adenovirus vector	Phase 2/3 Phase 3	2020 Sep? 2021 2Q	Single or 2 doses	2-8°C	300 million

Recent update

¹ Information as of 8/22/2020
² Point of Care (e.g., clinic, pharmacy)
³ Jenner Institute

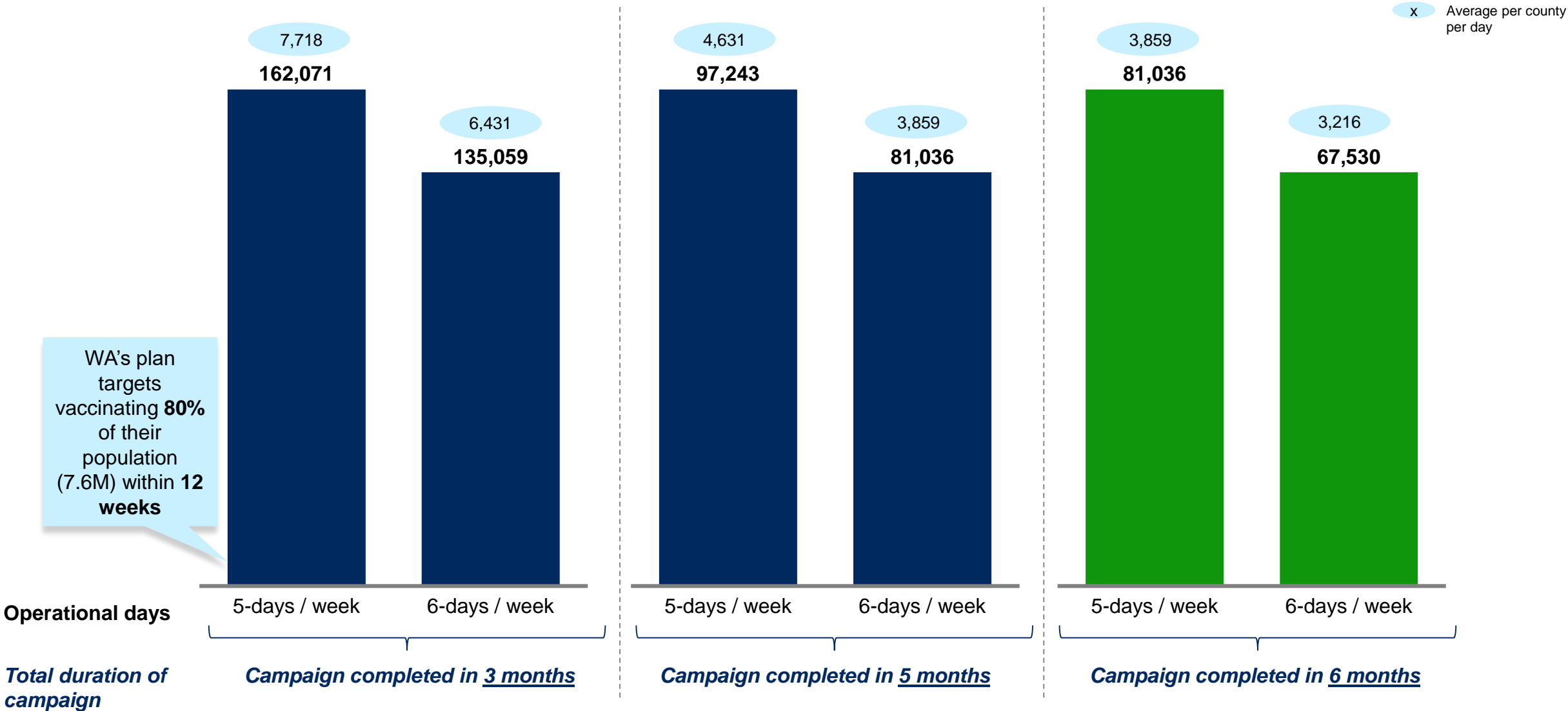
Number of doses that will need to be delivered per day to 50% of NJ residents (only adults)

Doses that need to be dispensed per day (when a sufficient supply of doses to meet demand)



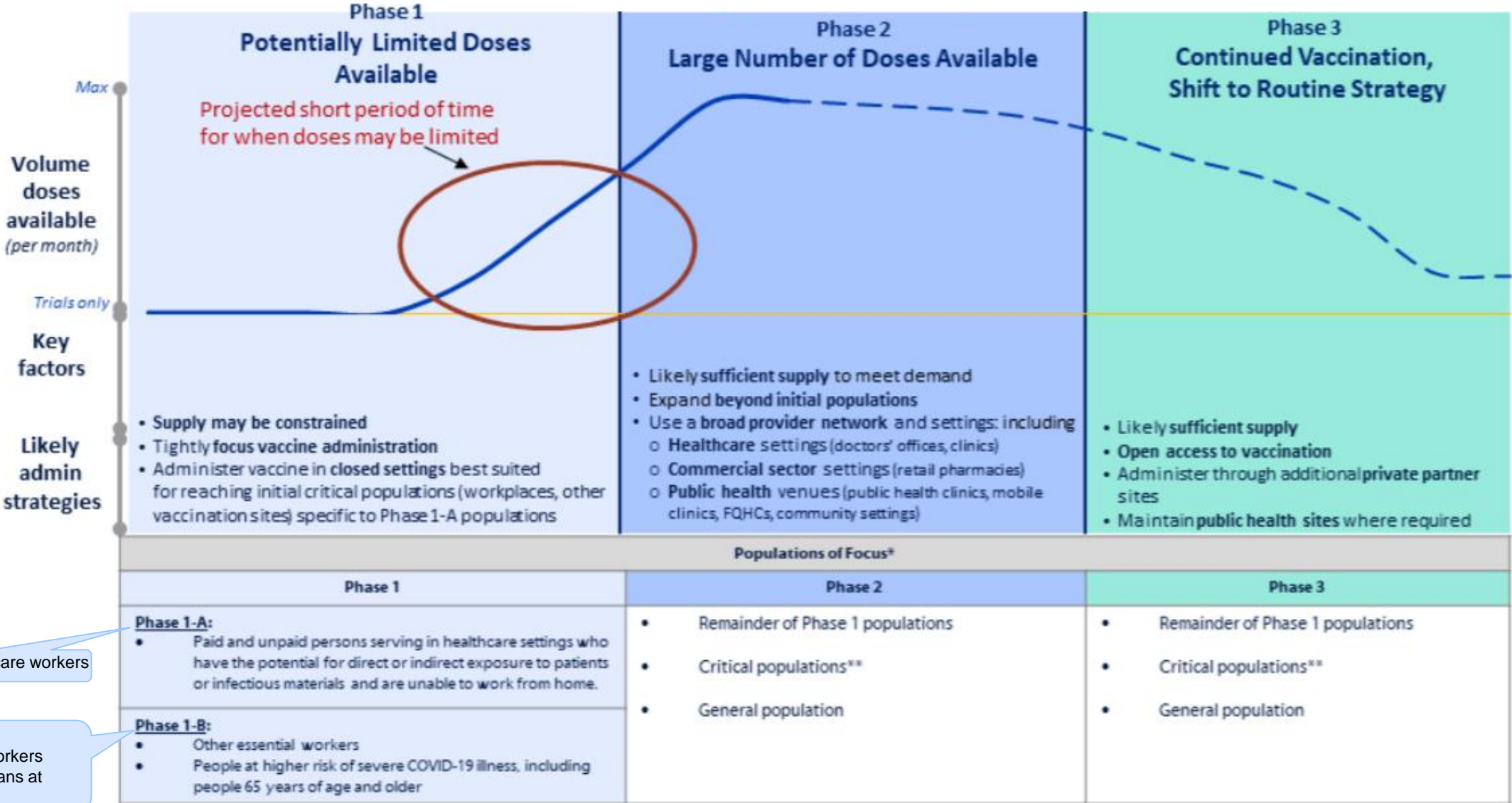
Number of doses that will need to be delivered per day to 70% of NJ residents (only adults)

Doses that need to be dispensed per day (when a sufficient supply of doses to meet demand)



NOTE: Assumes 2 dose vaccine

CDC guidance – Phasing from Vaccination Program Interim Playbook for Jurisdiction Operations (9/16)



17-20M¹ healthcare workers

60-80M¹ critical infrastructure workers
 >100M¹ Americans at higher risk

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 1 NJ proportion based on 2.77% of total US population would be ~470k-554k for healthcare workers, 1.66-2.22M critical infrastructure workers, and >2.77M residents at higher risk

COVID-19 Response Sustainability Planning: Department of Health responsibilities

 Deliverables to follow

Testing	Contact tracing	Emergency preparedness	Vaccines	Long-Term Care
Testing strategy	CT recruiting	Monitoring disease progression	Logistics and PODS delivery	Long-term care quality and safety
NJ access strategy / operations	Onboarding / training	Broader surveillance management	Federal interoperability, IT, data flow management and surveillance	Emergency response to COVID in LTCs
Vulnerable population testing coordination	CT workforce effectiveness management	Reopening guidance	Specific population planning	LTC policies and reopen guidance
County testing sites	CT efficacy	Safeguarding effectiveness	Enabling policy	Facility licensing and inspections
Testing vendor management	Digital contact tracing strategy	Rapid response team	Public confidence	Implementation of Manatt recommendations
Third party testing management	Digital contact tracing development	Stockpiling / procurement of essential resources	Strategic communications	Data / IT
State-led testing / sample collection	Support services integration	Regional collaborations	Analytics and reporting	
Lab – major lab management	Local quarantine	Surge capacity across healthcare settings with ability to cohort	Management and administration	
Lab – public / private partnership	Medical quarantine	Workforce stabilization and readiness	Flu vaccine acceleration and general immunization	
Corporate / private sector engagement	Public awareness / communications			
Public awareness / communications	Dashboards and analysis			
Dashboards and analysis	Data / IT (CommCare)			
Data / IT (CDRSS)	Corporate / private sector engagement			

Professional Advisory Committee

PAC Health Equity Sub-committee

Epi modeling	Funding	Procurement	Vendor management	Value assurance	State / third party engagement	Data / IT	Enabling policy	Reporting
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 1 Staff training: cold chain – proper receipt, storage and temp. monitoring, inventory management, preparation and administration, transport, documentation (inventory, temp logs), emergency preparedness (e.g., power outage, storm)


Deliverables across working groups for vaccines rollout planning

Submission of rollout plan may be due early Oct¹




Logistics and PODS delivery

- Partnerships
- Cold chain management
- Static and mobile site delivery
- Local Engagement
- Vendor relationship
- Vaccine command center




Federal interoperability, IT, data flow management and surveillance

- Pandemic vaccine provider registration
- Provider call center
- Consumer registration
- Consumer call center
- Tech interfaces between providers, state, feds, consumers
- Surveillance



Specific population planning

- Population specific vaccine plans e.g., vulnerable, critical infrastructure workers, general pop



Enabling policy

- Vaccination plan for CDC
- Executive directives or other regulatory/policy tools
- Stakeholder consultation



Public confidence

- Stakeholder engagement
- Public call center
- Campaign



Strategic communications

- Relationship management
- Inbound comms management




Analytics and reporting

- Population data capture
- Analytics to inform success of implementation



Management and administration

- Workforce
- Contracting
- Budget



Flu vaccine acceleration and general immunization

- Statewide campaign
- Pilot learnings for COVID
- Support for specific populations
- Vaccine site navigation

Cross cutting elements: *Equity* *Funding*

¹ CDC has issued guidance that they will provide a planning framework to states with a deadline for submission of state plans set at 30-days from that point Preliminary, pre-decisional, and deliberative. Based on input provided by State agency leaders and staff, to date, and subject to change. Content is descriptive only and is not meant to constitute legal, clinical, or policy advice.

Preliminary range of stakeholders who may need to be engaged

	Awareness	Education	Action		
State	Government entities and their grantees State legislators NJ Legislative Black and Latino Caucus NJ Commission on American Indian Affairs Health subcommittee of Commission CEO Council (Restart) Coronavirus Relief Fund Advisory Committee on Immunization Practices	CDC/HHS Academia (Schools of public health, social work etc.) Media Maternal and Child Health consortia Office of New Americans New Jersey Immunization Network	Coronavirus taskforce DMAVA LTC associations (NJHA, Leading Age, HCA NJ) NJHA and hospitals Medical Society of NJ NJ Pharmacists Association NJ Dental Association NJ Immunization Network NJ State Funeral Directors Association YMCA state alliance	NJ Associations of Chiefs of Police (NJSACOP) EMS Council of NJ Firefighters associations of NJ Medical Transport Association of NJ (MTNJ) Consumer groups e.g., AARP Union groups Garden state equality Housing finance associations	OEM OHSP EMS taskforce National guard DoD DLA McKesson Statewide representatives for shelters
Regions	Massive public awareness campaign Legislators	FQHCs VNAs Health hubs Schools and higher education organizations Community based organization Mortuary services	LINCS (PODS) VNAs 317 providers Occupational Health for major employers		
County	Elected officials First responders	LINCS City government Home health aids County continuum of care rep	LINCS (PODS) County OEM FQHCs		
Municipality	Community groups Faith-based	LHDs Sr. Housing	LHDs (PODS)		
City (>20,000)	Urban mayors		...		
Town	Local officials Mayors	Food pantries Outreach groups	PCPs Pharmacist Harm reduction centers Community ARCH nurses HIV clinics Contact tracking workforce		

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Update on flu vaccination plans

2019 Flu season

Typical flu vaccination rate in NJ

<50%

- 19k doses of flu provided to the state through CDC for deployment through 317 sites to uninsured / under-insured adults
- 361k doses allocated through VFCs (Vaccines for Children sites)
- From Jan-Jun 2019, 801k total doses for childhood vaccine were given



2020 Flu season

Vaccination goal for 2020

70%

- 440k doses provided to the state through CDC (~22x more than 2019) for all adults (eligibility screening has been waived)
- ~434k does allocated through VFCs (20% more than 2019)
- From Jan-Jun 2019, 642k total doses for childhood vaccines were given (18% lower than 2019)
- Vaccine campaign to focus on increased importance of flu vaccine due to COVID-19 health and capacity risks

What do we need from you?



Seek knowledge and be informed



Reach out if you have questions



Work with us to develop a plan to build public confidence



Stay safe, stay healthy, ...

...and get vaccinated!