Joint COVID-19 Response Legislative Workgroup

Teleconference Meeting

THIS MEETING WILL
BEGIN SHORTLY

October 28, 2020
10:00 a.m.

Agenda Overview - Vaccines

(10:00 a.m. - 10:07 a.m.)

I. Opening Remarks

II. Briefing from University of Maryland Medical System

III. Briefing from BIO/Pharma Representatives

IV. Briefing from Maryland Department of Health

V. Briefing from Baltimore City Health Commissioner

VI. Closing Remarks

Briefing from Univ. of MD Medical System

(10:07 a.m. - 10:40 a.m.)

- Kristin Bryce, SVP & Chief External Affairs Officer
- David Marcozzi, MD, MHS-CL, FACEP
  COVID-19 Incident Commander
  Associate Professor and Associate Chair of Population Health
- Wilbur H. Chen, MD, MS, FACP, FIDSA
  Professor of Medicine
  Chief, Adult Clinical Studies Section
- Limited Questions and Answers

CVD·GLOBAL HEALTH

CENTER FOR VACCINE DEVELOPMENT AND GLOBAL HEALTH

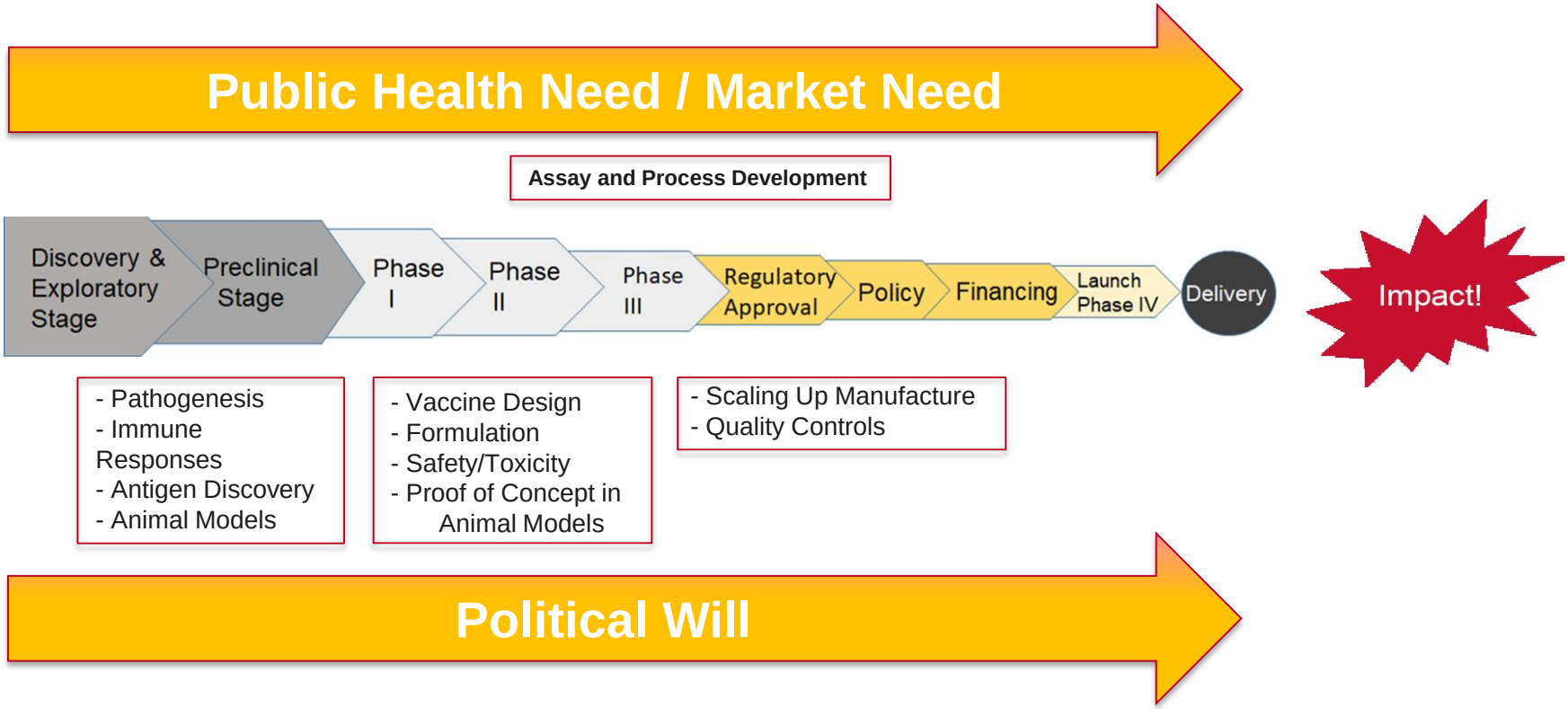
UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE
CENTER FOR VACCINE DEVELOPMENT
AND GLOBAL HEALTH

Maryland General Assembly
Joint Covid-19 Response Legislative Workgroup

Wilbur H. Chen, MD, MS, FACP, FIDSA
Professor of Medicine
28 October 2020

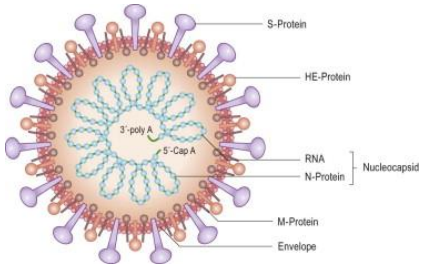
UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE
CENTER FOR VACCINE DEVELOPMENT
AND GLOBAL HEALTH

Vaccines and Therapeutics Development

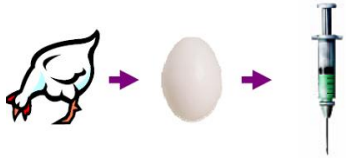


Vaccine “Platforms”

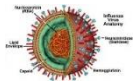
Spike Protein →



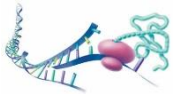
Traditional Approach



Newer Approaches



Live attenuated



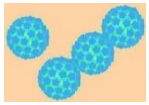
Recombinant

Cell Culture

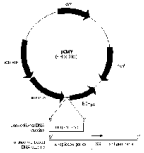
Adjuvants

Future Approaches

DNA/mRNA



Virus-like particles and Virosomes



Virus vectored

Leading COVID-19 Vaccines

- Pfizer, BNT-162 (mRNA)
- Moderna, mRNA-1273 (mRNA)
- AstraZeneca/Oxford, ChAdOx1 nCoV-19 (virus vector)
- Johnson&Johnson, Ad26.COV2-S (virus vector)
- Novavax, NVX-CoV2373 (nanoparticle/adjuvant)

- Inovio, INO-4800 (DNA)
- Sanofi Pasteur/GSK, (rSpike/adjuvant)

~180 COVID-19 Vaccines in development*

* as of 23 October 2020; https://www.bioworld.com/COVID19products

Licensure Pathway of COVID-19 Vaccines

Phase 1 – Safety (n=100)

Phase 2 – Safety and Immune Responses (n=100s to 1000s)

Phase 3 – Safety and **Efficacy** (n=10,000s)

U.S. FDA: Guidance for Licensure of COVID-19 Vaccines

- Populations – generalizable, including high-risk populations
- Efficacy:
  - prevent symptomatic, lab-confirmed infection
  - if possible, prevent more severe infections (e.g., respiratory or kidney failure)
- Statistics – minimum 50% efficacy

What can (and cannot) be evaluated?

Safety

- Injection site reactions
- Systemic reactions
- Common adverse events
- Rare, but serious adverse events

Efficacy

- Prevent symptomatic illness caused by COVID-19
- Not designed to assess asymptomatic infections
- Medical Complications
- Hospitalizations
- Deaths

Vaccine Policy & Implementation

- Limited Supply Allocation
  - Prioritization to Highest Risk Populations (HCW, essential workers)
  - Maximization of Utility (maximum benefit)
  - Equitability & Ethics framework
- National Guidelines vs. local jurisdictional flexibility
- Logistics - Access & Delivery
- Message of Public Health Value

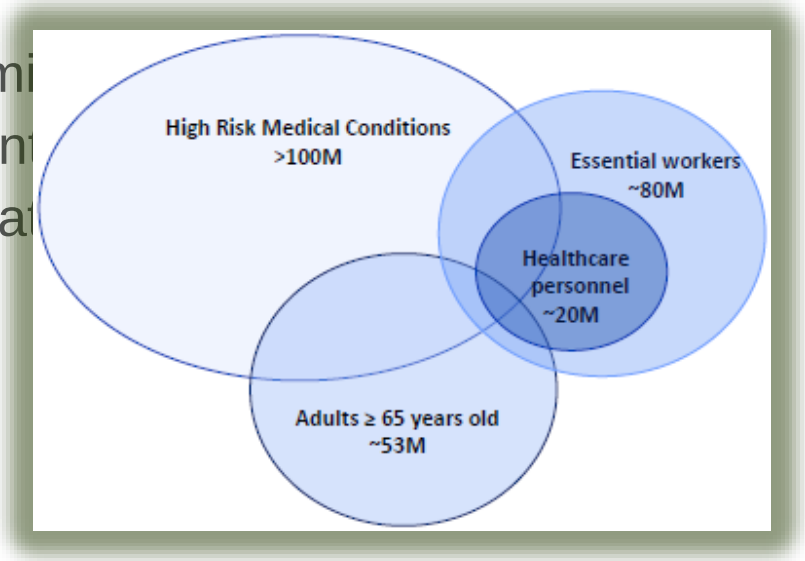
Pfizer -70°C
Moderna -20°C
AZ, J&J, SP/GSK, Novavax 4°C

❖ Maximize benefits, minimize harms, equity, justice, fairness, transparency, evidence based, feasible implementation

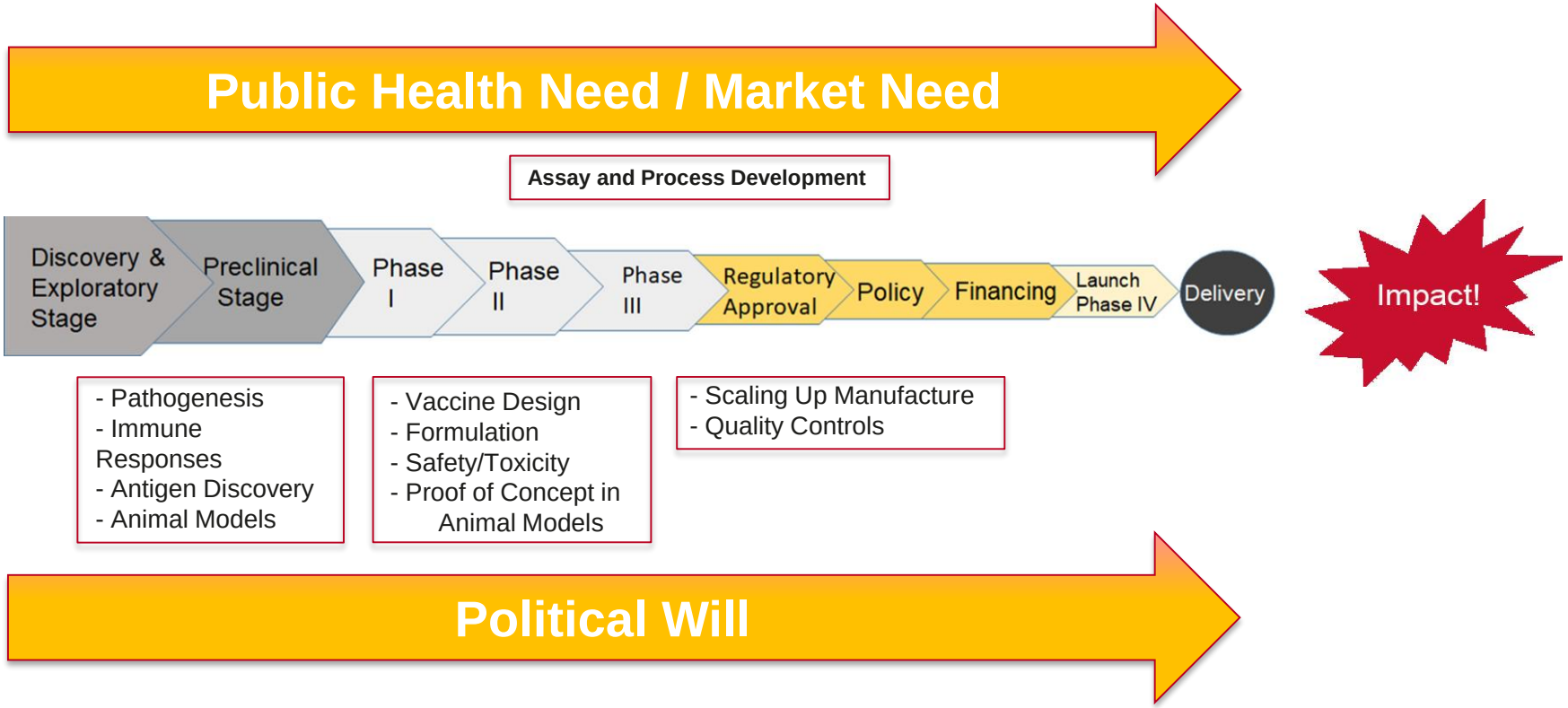
Population Risk Groups (in U.S.)

- Healthcare personnel, 20 million
  - Hospitals, longer-term care facilities, outpatient, home health, pharmacies, EMS, public health
- Essential workers, non-healthcare, 60 million
  - Food & agriculture, transportation, education, energy, water & wastewater, law enforcement
- Older Adults ≥65 yrs, 53 million
- High Risk Medical Conditions, >100 mi
- Special populations: children, pregnant
- Communities of color & disproportionat

Total U.S. population ~330 million

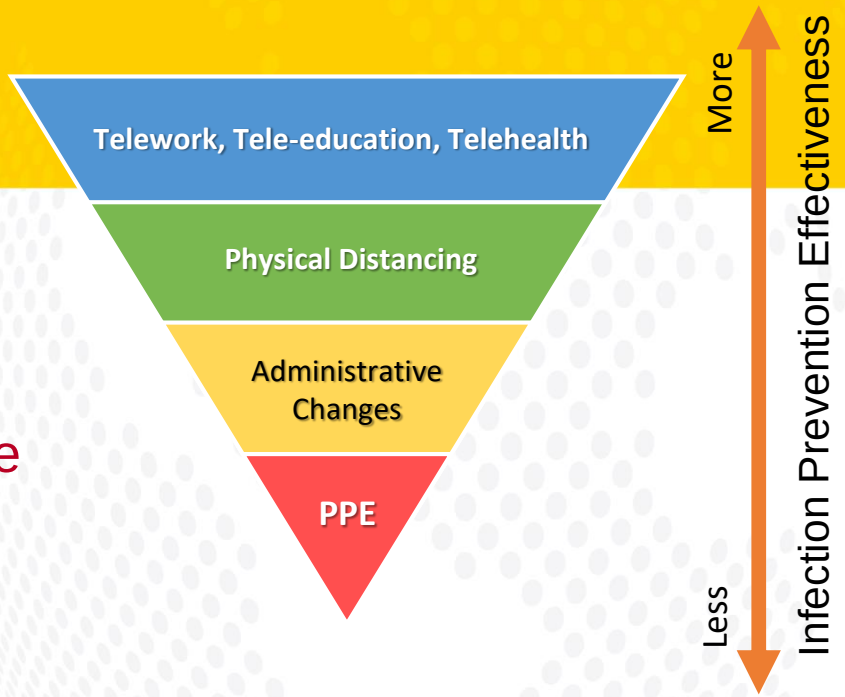


Vaccines and Therapeutics Development



Reminder:

- annual influenza vaccination
- keep all vaccinations up to date
- maintain healthy diet
- exercise



UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE
CENTER FOR VACCINE DEVELOPMENT AND GLOBAL HEALTH

UMMS-UMB Unified Command
Vaccine Considerations
October 28, 2020

CVD·GLOBAL HEALTH

CENTER FOR VACCINE DEVELOPMENT AND GLOBAL HEALTH

Maryland General Assembly
Joint Covid-19 Response Legislative Workgroup

Testimony from

David Marcozzi, MD, MHS-CL, FACEP
Associate Professor
University of Maryland School of Medicine

COVID-19 Incident Commander
University of Maryland Medical System

Maryland Coronavirus Response and Recovery Task Force

CVD·GLOBAL HEALTH
CENTER FOR VACCINE DEVELOPMENT AND GLOBAL HEALTH

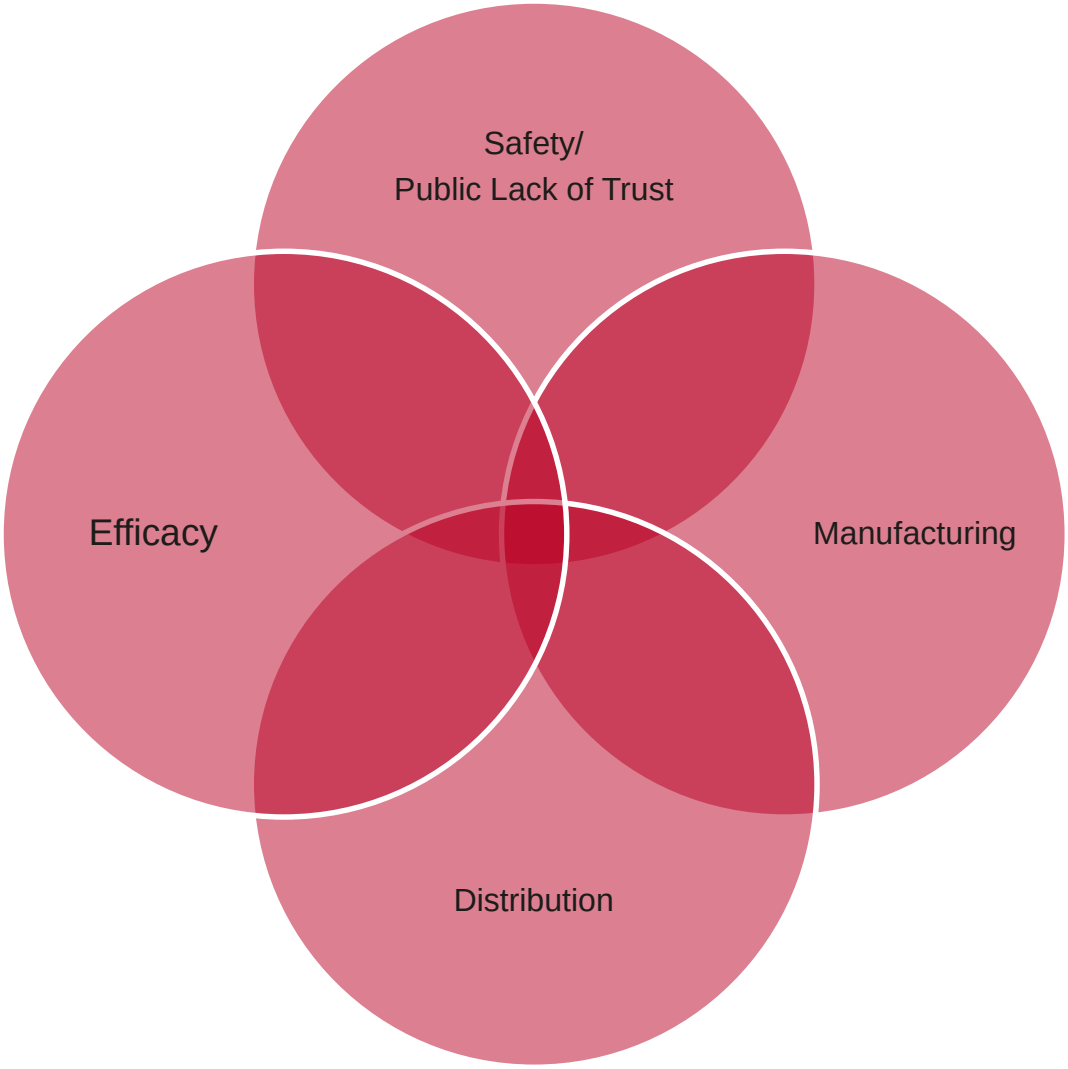
UMMS-UMB Unified Command

- A joint crisis management structure governing all COVID-19 related activities within our academic health system, bridging state-of-the-art science with optimal healthcare delivery
- Our ‘Stronger as a System’ approach transfers patients and shares resources and staff to assure the right care at the right time for all our patients while maintaining a protected workforce

General Considerations

- Entering a high-risk period
- Following public health guidance now is critical
- Other issues:
  - Testing
  - Contact tracing
  - Surge capacity
  - Personal Protective Equipment
  - Workforce shortages
  - PPE fatigue
  - Mental health
- Vaccine

Vaccine Considerations



The Trust Challenge

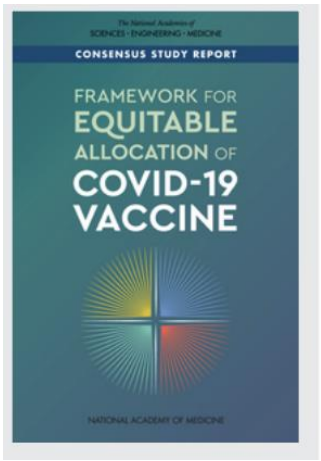
In a recent Goucher College poll of 1,002 Maryland adults between September 3 and October 4:

Half of Maryland residents surveyed that they would not take a federally approved COVID- 19 vaccine today even if it was offered free.

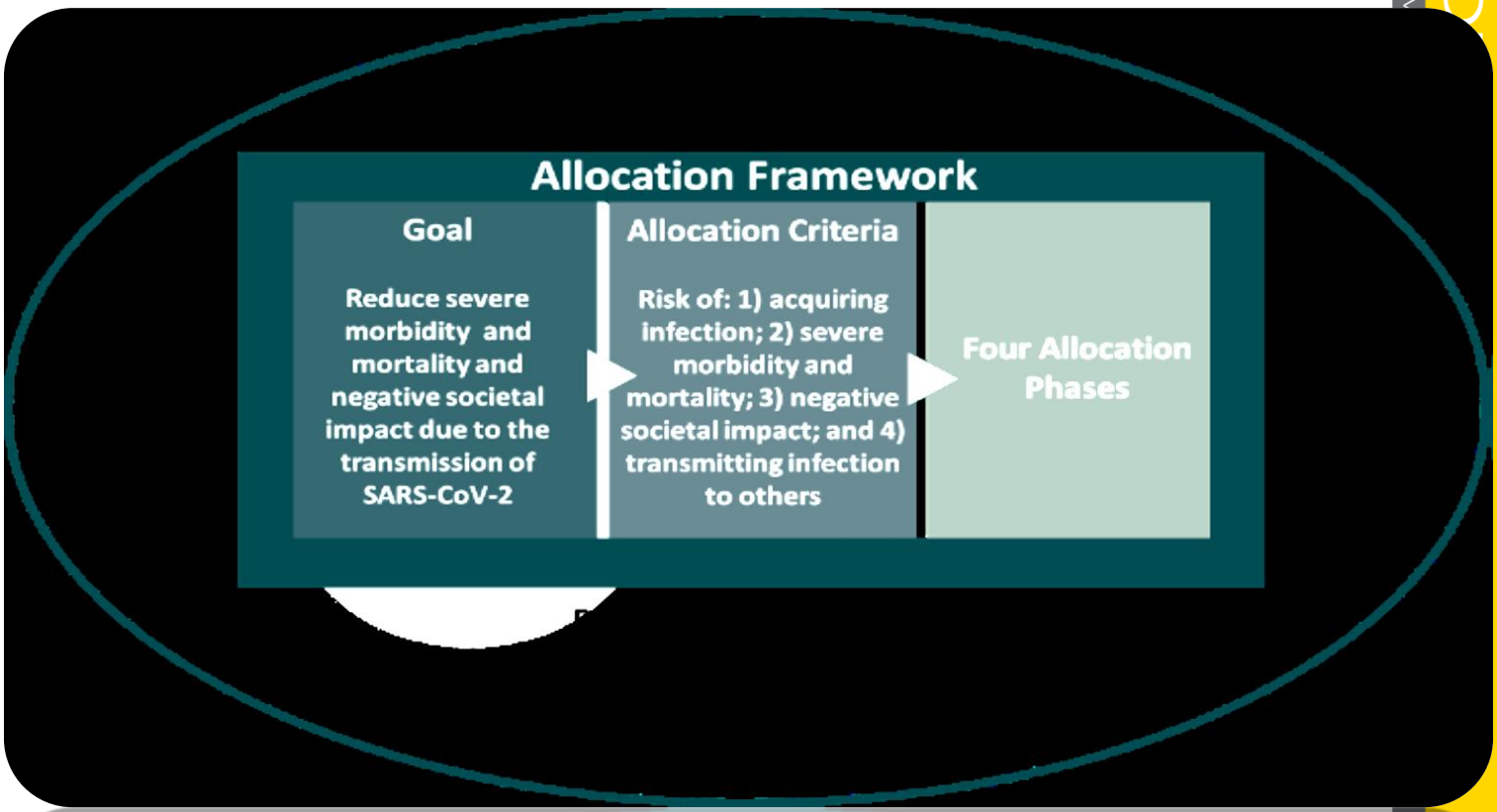
Vaccine Preparation Work Group Issues

- Workforce/Patient Prioritization
- Population/Community health efforts
- Information Technology
- Logistics/Supply Chain
- Public health education/Communications

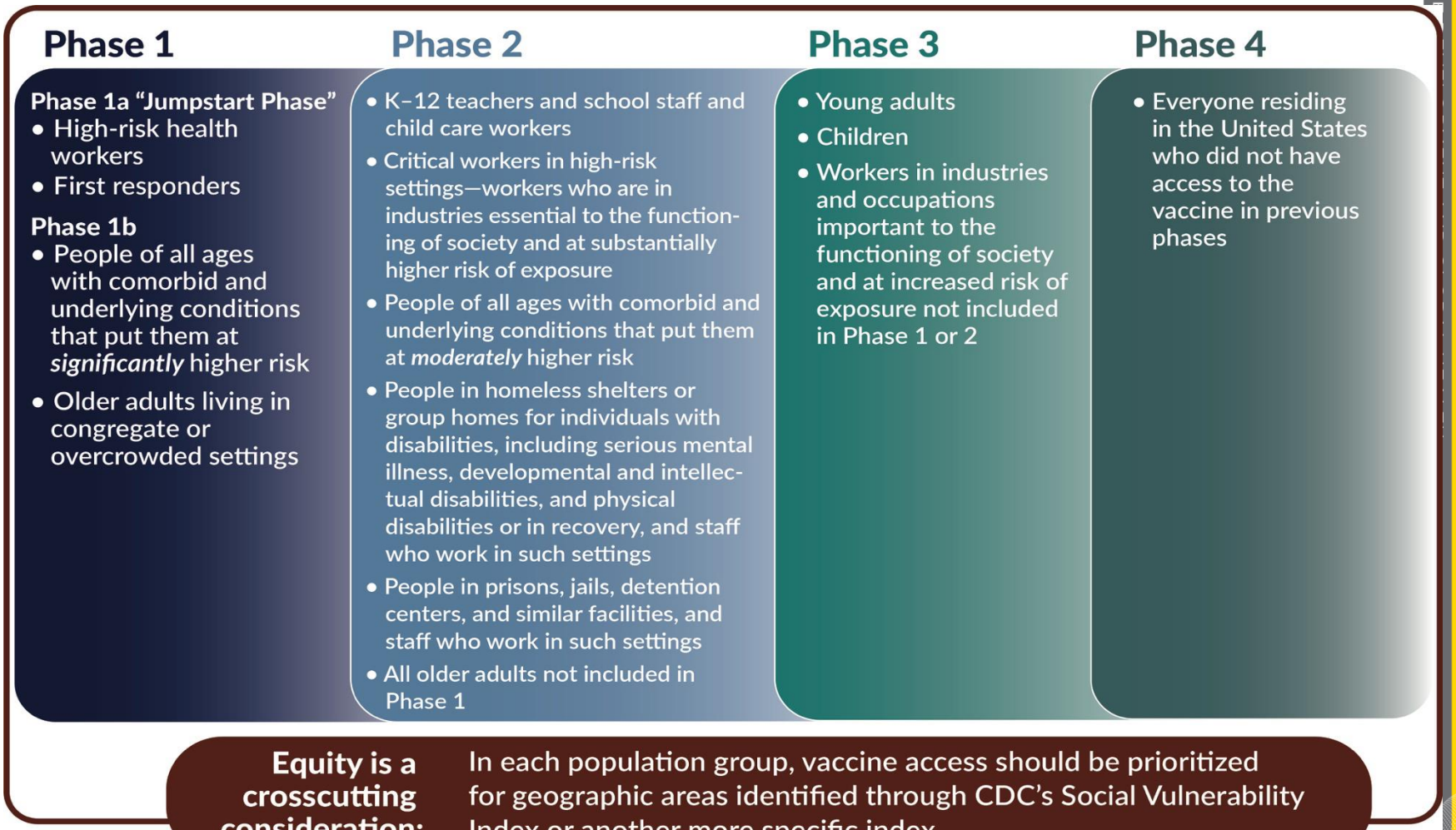
a



l Academies of Science, ering and Medicine (NASEM)



Four Allocation Phases



Workforce Considerations

- Prioritization of workforce based on NASEM recommendations
- Develop distribution plan for hospitals
- Develop operational construct for vaccination

Patient and Community Efforts

- In coordination with MD plan
- Ongoing planning considerations:
  - Outpatient/Inpatient- Inpatient will have overlap with outpatient considerations
  - Community Distribution- support established efforts and build new administration sites as requested

Information Technology

- Utilize IT to assist with registering, tracking, ordering, documentation and data reporting requirements
  - ImmuNet, PrepMod, etc
- Assuring linkages with hospitals' EHR will improve operational efficiencies
  - Inpatient
  - Outpatient
  - Community

Logistics/Supply Chain

- Define logistics requirements
  - Cold chain storage
- Procure ancillary equipment for internal and external vaccine administration

Public Health Education/Communications

- Public reservations for vaccine acceptance
- Community survey ongoing
- Share results
- Promote public health education and a communications campaign to dispel myths/misinformation and build trust and confidence in the vaccine
  - Internal and external

Summary

- UMMS-UMB Unified Command continues to guide our academic health system's efforts to optimally prepare for and respond to this crisis
- Vaccine distribution and administration will be based on a solid framework that will support a successful mass vaccination campaign
- Collaboration with state and all partners will be key as we move forward to address this next phase of the pandemic
- Education and communications to all stakeholders will be the foundation for outreach and success
- Vaccines don't save lives – vaccinations do!

Briefing from BIO/Pharma Representatives

(10:40 a.m. - 11:10 a.m.)

- Phyllis Arthur, Vice President
  Infectious Diseases & Diagnostic Policy
  Biotechnology Innovation Organization
- Dr. Rick Nettles, Vice President of Medical Affairs
  Janssen Pharmaceutica
- Christie Bloomquist, Vice President for Corporate Affairs
  AstraZeneca
- Limited Questions and Answers

Phyllis Arthur

Vice President

Infectious Diseases & Diagnostic Policy

BIO

Development and Implementation of COVID-19 Vaccines

Phyllis Arthur

VP, Infectious Diseases & Diagnostics Policy

October 28, 2020

Clinical & Preclinical Stage Vaccine Pipeline

BARDA / DoD funding
Jointly developed
OWS funded

Viral Vector

MERCK THEMIS
深圳市免疫基因治疗研究院
SHENZHEN GENO-IMMUNE MEDICAL INSTITUTE
Johnson & Johnson
康希诺生物 CanSinoBIO
Gamaleya Research Institute
AstraZeneca
UNIVERSITY OF OXFORD

Viral Inactivated

MERCK
Pavi
国药山西 SINOPHARM
sinovac

RNA[1]

SANOFI
TranslateBIO
PrEPBiopharm
BIONTECH
Pfizer
moderna
(support from NIH, CEPI)

DNA

INOVIO
Beijing Advaccine Biotechnology

Cell Based

ARCHIVEL farma
Baylor College of Medicine
symvivo

Recombinant protein

medicago
gsk
SANOFI
gsk
NOVAVAX
Creating Tomorrow's Vaccines Today
(support from CEPI)

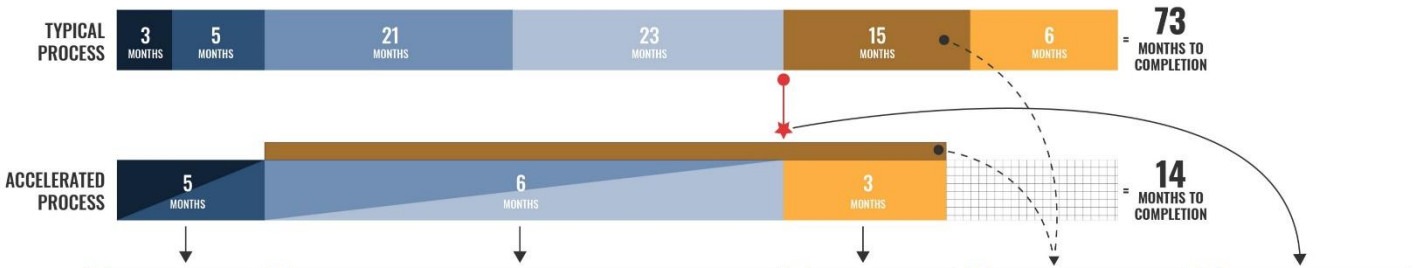
Source: Biomedtracker, Biocentury, BIO Industry Analysis
1. PrEP Biopharm vaccine dsRNA, all others mRNA
Oxford, Astrazeneca: ChAdOx1. Symvivo: bacTRL-Spike. Baylor College: BCG tuberculosis vaccine.
Sinopharm with two vaccines in phase 1 trials (one beginning Apr 12 the other Apr 27)

Bio Biotechnology Innovation Organization

Info as of Oct 25, not exhaustive

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.

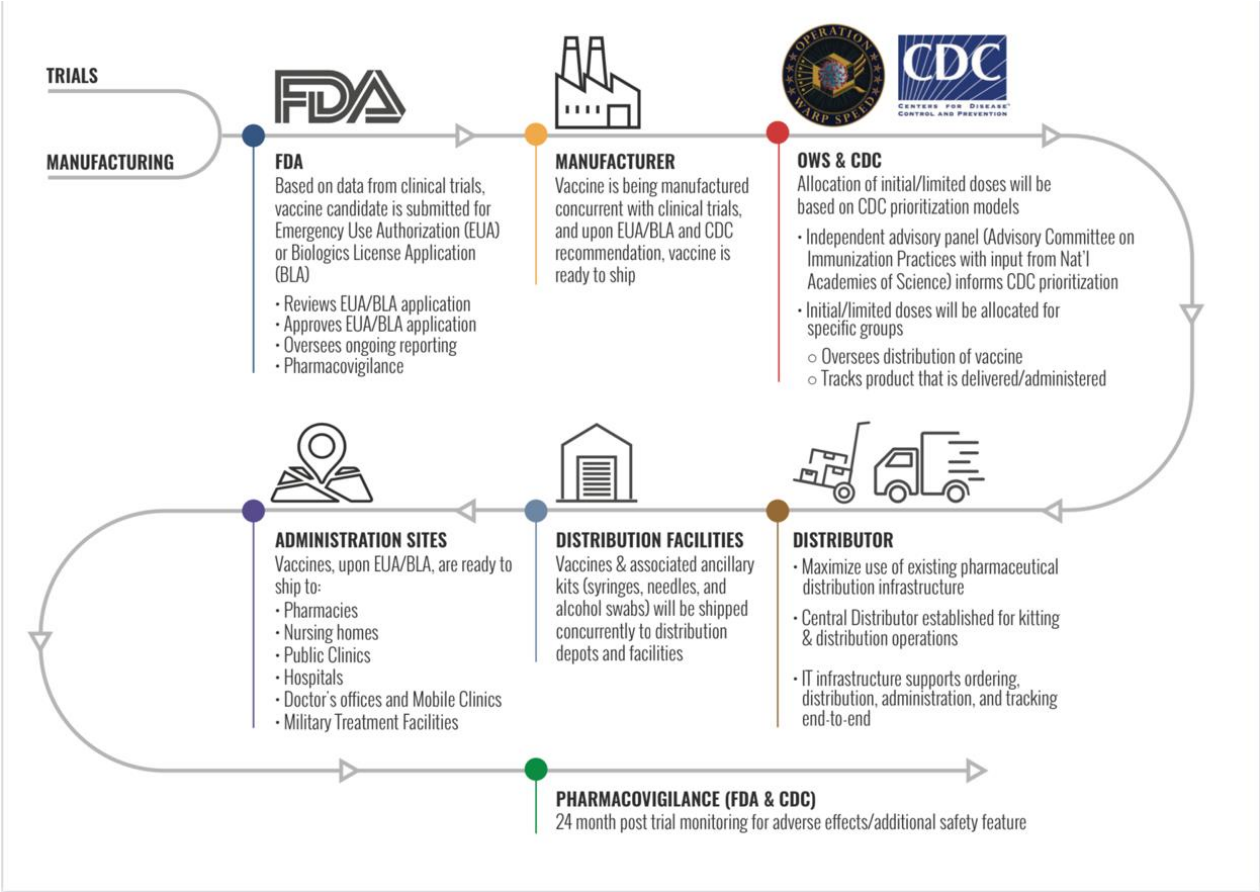
5

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

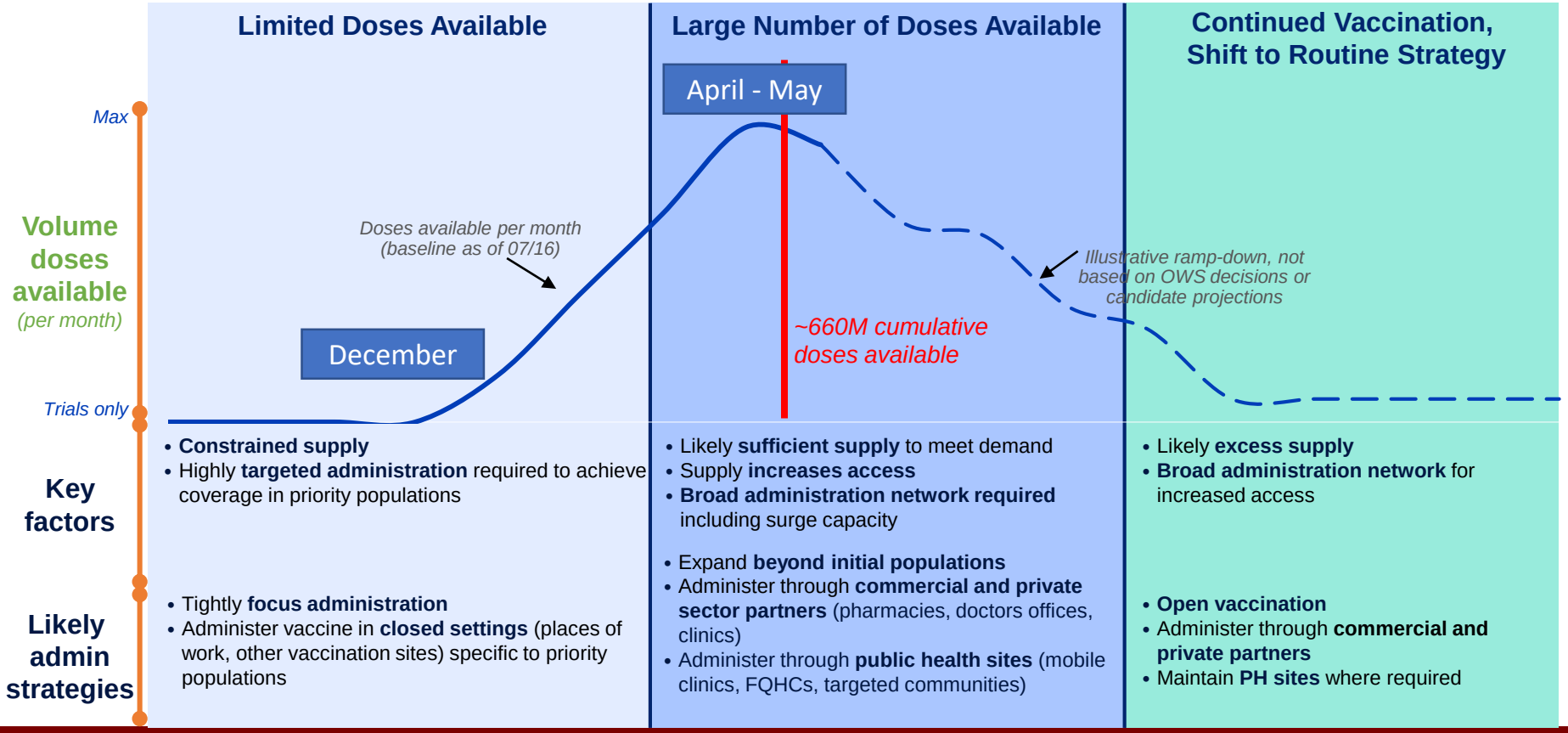
- Providing continuous safety and efficacy data collected in large Phase III clinical trials.

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

Path to Distribution of Vaccines



Distribution will adjust as volume of vaccine doses increases



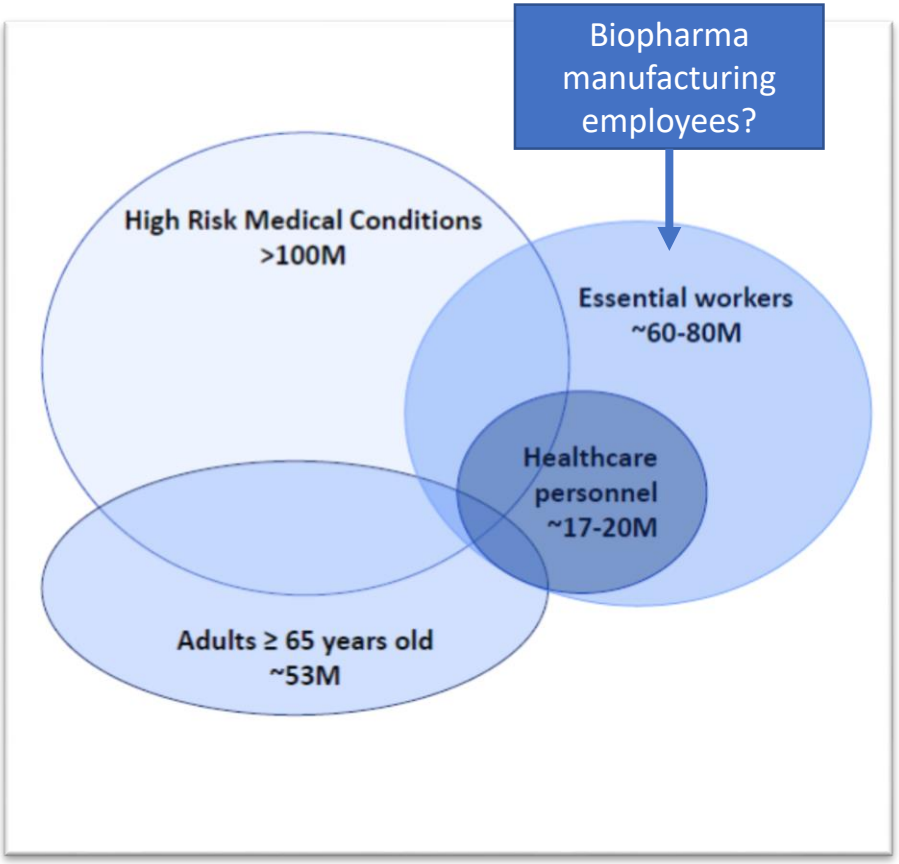
Illustrative scenario for planning purposes; will be adapted based on the clinical / manufacturing information on all OWS candidates and vaccine prioritization

30 SEPT 2020

ACIP Prioritization Framework

Groups prioritized for early phase vaccination

- ❑ Overlapping groups with significant heterogeneity
- ❑ Communities of color are significant portion of each population
- ❑ Accounts for > half of U.S. adults
- ❑ Framework informed by National Academies and Johns Hopkins frameworks



Dr. Rick Nettles
Vice President of Medical Affairs for Janssen
Johnson & Johnson

Christie Bloomquist
Vice President for Corporate Affairs
AstraZeneca

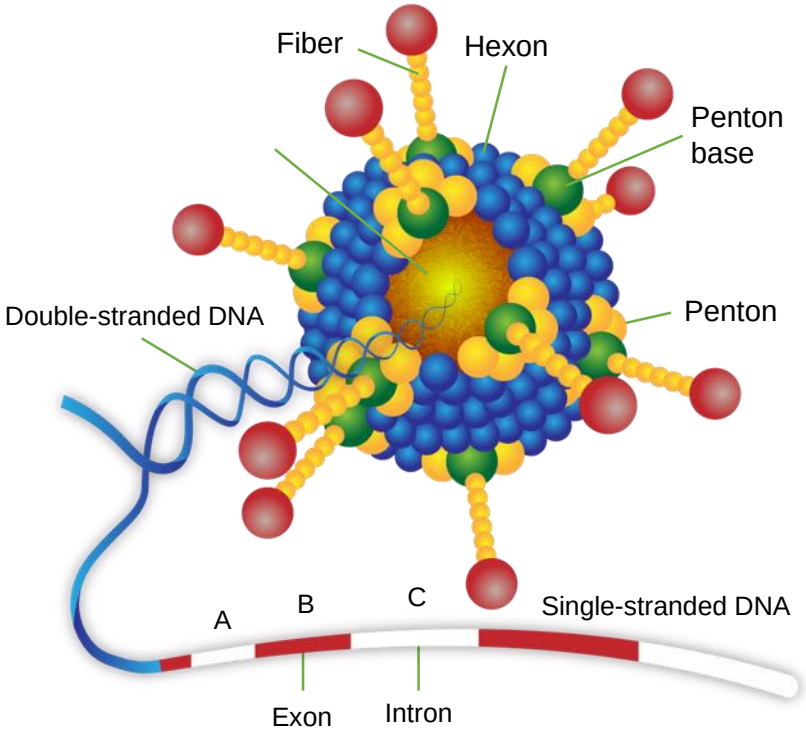
AstraZeneca response to COVID-19: Vaccine & Antibody development

Christie Bloomquist, Vice President,
Corporate Affairs, North America

October 28, 2020

AZD1222 (ChAdOx1 nCoV-19): the technology

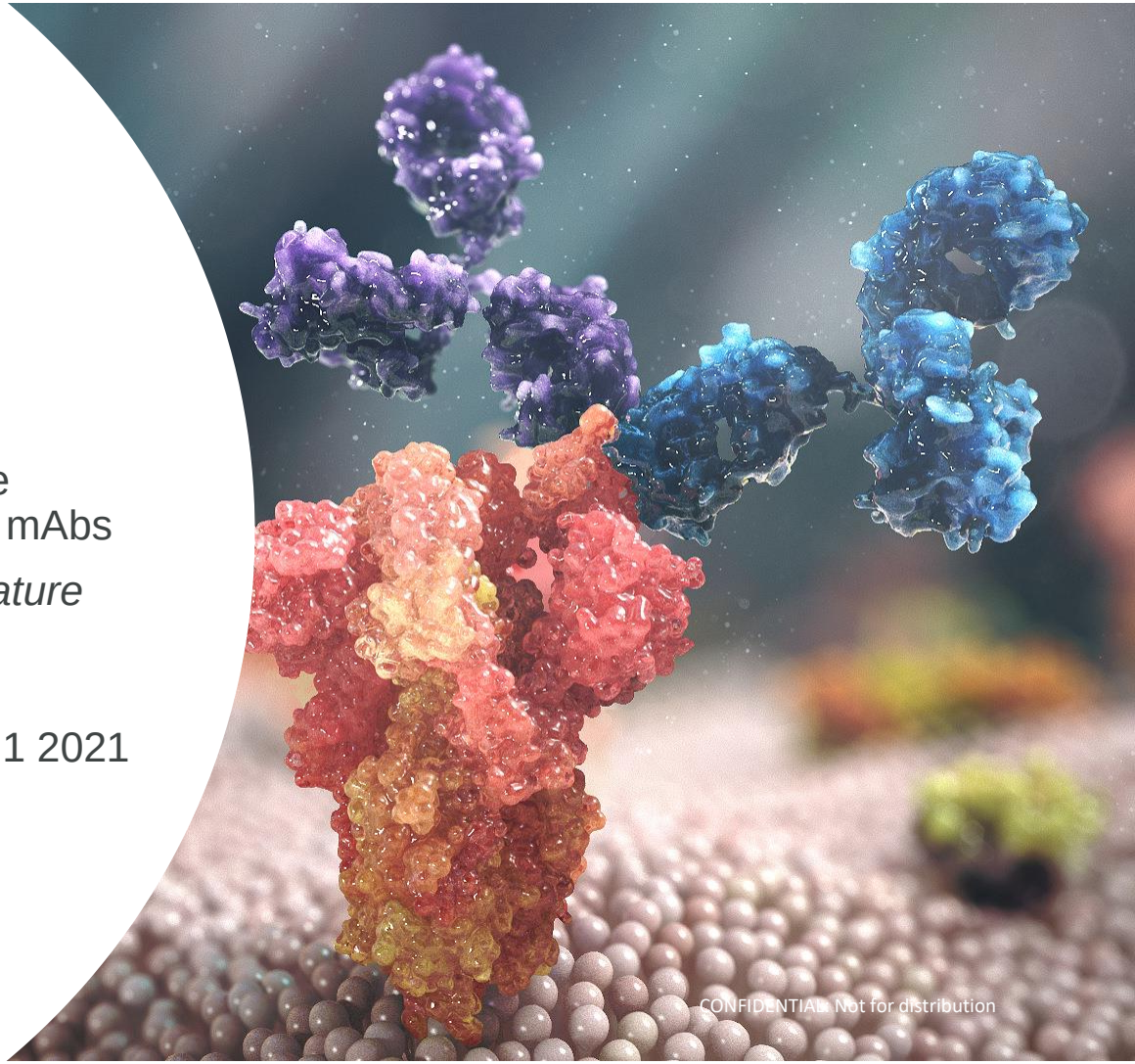
- Based on existing recombinant simian adenovirus vector (ChAdOx1)
  - Non-replicating
  - Avoids issues with pre-existing immunity to human adenoviruses
  - Induces strong B and T cell responses after single vaccination
  - Early clinical safety
- Contains genetic material of the SARS CoV-2 spike protein



NHP MERS study: van Doremalen *et al.,* Science Advances DOI: 10.1126/sciadv.aba8399
Phase I MERS trial: Folegatti *et al.,* Lancet ID DOI: 10.1016/S1473-3099(20)30160-2

Long-acting antibody (LAAB) combination

- Targeting the SARS-CoV2 spike protein as a combination of two mAbs
- Pre-clinical data published in *Nature* by Zost et. al, 2020
- UK Government agreement in principle of 1 million doses by H1 2021
- Phase I trial started in Aug



US Government Agreements

AZD1222 (Vaccine) Agreement

- Working with the US government on an over a $1B commitment to support development, production and delivery of COVID-19 vaccine AZD1222
- Phase III clinical trial with 30,000 participants began this summer and with a pediatric arm to follow
- At least 300M doses of AZD1222 will be made available at no profit during the pandemic:
    - First 100 million doses as early as January 2021
    - Additional 200 million doses in 2021.
- US supply manufactured in the US by a combination of AstraZeneca and partners

AZD7442 (LAAB) Agreement

- $486m from DoD/BARDA for the development and supply of AZD7442, building on previous $25m investment
- Investment covers two Phase III trials that will enroll over 6,000 adults for the prevention of COVID-19 and ~4,000 adults for the treatment of COVID-19 infections
- Deal supplies 100,000 doses to the US government by December 2020
- US Government has option to buy up to 1 million doses in 2021 under separate agreements
- Federal government will supply doses at no cost

Briefing from MD Dept. of Health

(11:10 a.m. - 11:40 a.m.)

- Robert R. Neall, Health Secretary

  Dr. Jinlene Chan, Acting Deputy Secretary, Public Health Services

- Limited Questions and Answers

- Contact:

  Webster Ye

  webster.ye@maryland.gov

Maryland
DEPARTMENT OF HEALTH

Maryland COVID-19 Vaccination Plan Briefing to the Joint COVID-19 Legislative Workgroup

Robert R. Neall, Secretary
Jinlene Chan, M.D., Dep. Sec. (Act.), Public Health Services
Maryland Department of Health

October 28, 2020

The information in this presentation is current as of October 28, 2020, unless otherwise noted, and subject to change.

COVID Vaccine Planning Basics

- Maryland's mass COVID-19 vaccination planning efforts have been underway with our federal partners since Spring 2020
- The plan is a draft and will evolve as more information becomes available
- The US Centers for Disease Control and Prevention (CDC) will be the central distributor for vaccines
  - New information is coming from the federal government on a continual basis
  - There are several vaccine products in development and several likely candidates for the first vaccine out of the gate

Maryland
DEPARTMENT OF HEALTH

Pending Considerations

- Need more information from the federal government on distribution, cost-sharing, federally-provided supplies
- No vaccines have been approved by the FDA yet. As vaccines receive emergency use authorization, they will be reviewed by the Technical Advisory Group
- Health care providers are currently registering with the State to administer COVID-19 vaccine. Local health departments, hospital systems, and pharmacies will also be key partners for vaccine administration

Planning for Vaccination Response

The Maryland COVID-19 Vaccination Plan:

- The Plan is based on the CDC COVID-19 Vaccination Interim Playbook for Jurisdiction Operations
- Planning will evolve as the federal government releases information, including recommendations from the CDC Advisory Committee on Immunization Practices (ACIP) regarding priority groups

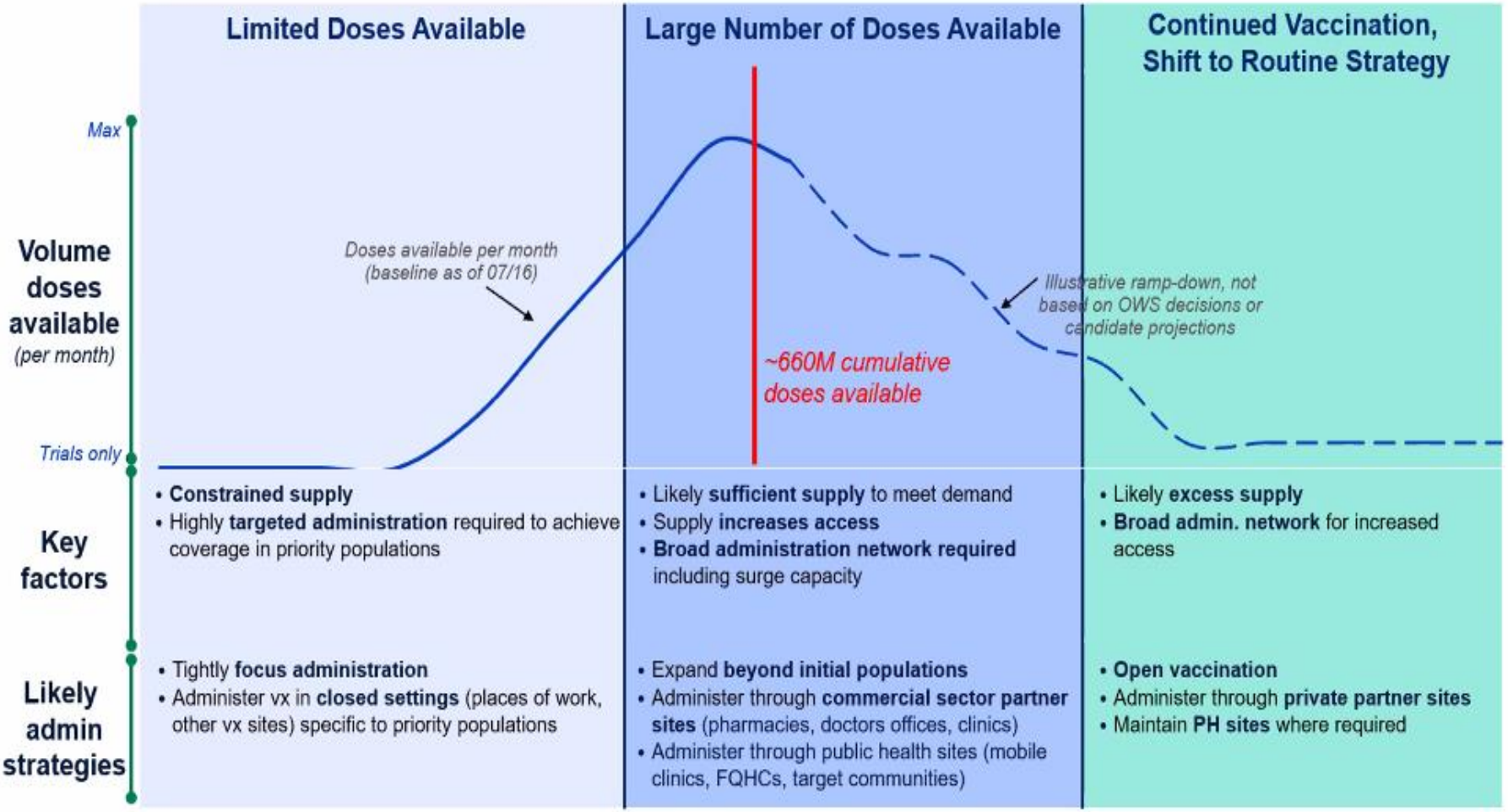
Maryland
DEPARTMENT OF HEALTH

Phased Approach

- Phase 1
  - Vaccination of critical populations (will be aligned with ACIP guidance once available)
  - Limited availability of vaccine
  - Waiting on CDC to notify the State of vaccination supply and distribution
- Phase 2
  - Begins when Phase 1 targets have been met
  - Vaccination of the general public
  - Vaccination efforts continue until every Marylander who wants a vaccine is able to get one

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

Distribution will Adjust as volume of vaccine doses increases, moving from targeted to broader populations reached (phased approach)



Maryland DEPARTMENT OF HEALTH

Plan Components

Key Components of the Plan:

- Provider Enrollment
- Vaccine Ordering and Distribution
- Vaccine Administration
- Communication and Outreach

Provider Enrollment

- Providers interested in administering COVID-19 vaccine will register with the MDH immunization information system, ImmuNet. MDH is currently enhancing its systems to handle the added influx of users and information
- MDH will work through partners to encourage providers to enroll to ensure that there are sufficient vaccination providers in the State to reach all Marylanders

Maryland
DEPARTMENT OF HEALTH

Vaccine Ordering and Distribution

- Registered providers will place their COVID-19 vaccine orders in the ImmuNet system
- Vaccine will be shipped directly to the provider from CDC's distributor
- MDH will work with providers to track inventory and administration of vaccine and to ensure that if two doses are required, people receive same product each time

Vaccine Administration

- The State will work with federal partners, local hospital systems, local health departments, and pharmacies to administer vaccine to Phase 1 priority groups
- Once vaccine is widely available (Phase 2), Marylanders will be able to receive vaccinations through their health care provider or at a pharmacy (similar to a flu shot)
- Eventually, any Maryland resident that wants to be vaccinated will be able to receive a vaccine
- Health equity considerations are crucial to ensure access across all populations

Phase 1 Priority Groups

*Subject to change based on final ACIP recommendations

	Target Population	Estimated US population size	Estimated MD population size (2% of US pop)
Phase 1	High Risk Health Care Workers	16,119,000	322,380
	First Responders	2,603,00	41,260
	Older adults in congregate or overcrowded settings	2,158,000	43,160
	Judiciary		4,320
	People in Prisons, Jails, Detention Centers and Staff		54,460
	People with Comorbid and Underlying Conditions that put them at *Significantly* higher risk	19,500,000	390,000

Maryland DEPARTMENT OF HEALTH

Communication and Outreach

Communication and Sharing of Information is key to the success of the COVID-19 Vaccination Program

- Some groups may be more hesitant to vaccinate than others
- Messaging will need to provide facts about the vaccine(s), instill confidence, and encourage vaccination
- Outreach efforts will need to be culturally competent and take into account the needs of different populations throughout the state

Maryland
DEPARTMENT OF HEALTH

Community and Stakeholder Involvement

- Two advisory groups are being established to provide guidance and recommendations to the State as COVID-19 Vaccine efforts progress:
  - Technical Advisory Group
  - Stakeholder Advisory Group
- As planning continues, the stakeholder community will be involved in feedback on ongoing planning and outreach efforts

Briefing from Balt. City Health Commissioner

(11:40 a.m. - 12:00 p.m.)

- Letitia Dzirasa, MD
  Commissioner of Health
  Baltimore City Health Department
- Limited Questions and Answers
- Contact:

  Nicholas Blendy

  Nicholas.Blendy3@baltimorecity.gov

Closing Remarks

- Check Hearing Schedule on Maryland General Assembly website for committee meetings

- Next meeting TBD