COVID Vaccine Overview

December 2020

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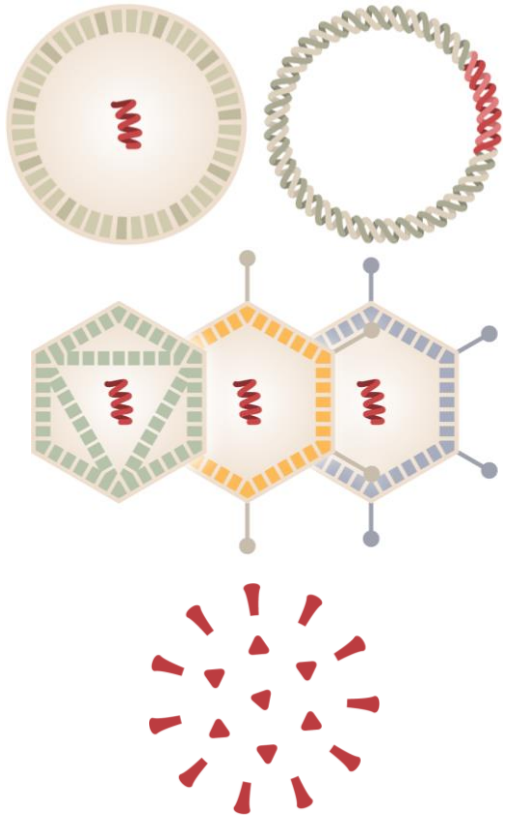
EMORY HEALTHCARE

Promising SARS-CoV-2 Vaccines

Goal: Have immune system learn to recognize COVID proteins so it can quickly fight the virus

- mRNA Vaccines (DNA)
  - Moderna
  - Pfizer/BioNTech

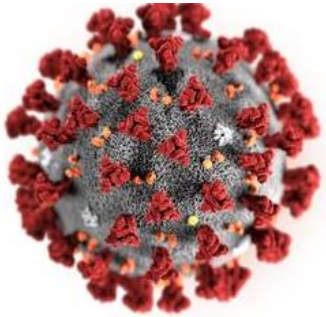
  } Both applied for EUA
- Viral Vector Vaccines
  - AstraZeneca/Univ of Oxford (chimpanzee adenovirus)
  - Janssen/Johnson & Johnson (human adenovirus 26)*
- Protein-Based Vaccines
  - Novavax*
  - Sanofi*



*Anyone interested in participating in an ongoing vaccine trial can volunteer here: https://www.coronaviruspreventionnetwork.org/
Resource: https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

How Does an mRNA Vaccine Work?

- The red protrusions on the surface of the virus = spike proteins
- The vaccine contains the temporary genetic instructions messenger RNA (mRNA) for how to make a spike protein
- Your cells use those instructions to make spike proteins
- Your immune system then learns how to recognize the spike protein and makes antibodies to it, so that it will also react to a coronavirus particle in the future



mRNA COVID Vaccines: Pfizer/BioNTech

- >43,000 participants randomized to placebo vs vaccine (2 doses given 3 weeks apart)
  - 1st American trial to enroll children (as young as 12)
  - 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds

- November 2020
  - Efficacy Analysis of 170 cases of COVID-19
  - Emergency Use Authorization (EUA) application filed

Pfizer Efficacy and Safety

- Efficacy >95%:
  - 162 cases in the placebo group; 8 cases in the vaccine group
  - Efficacy consistent across age (>94% in adults >65), gender, race, and ethnicity
- May help to prevent severe cases:
  - 10/170 cases were severe; 9/10 were in the placebo group
- Grade 3 side effects:
  - 3.8% with fatigue after dose 2
  - 2.0% with headache after dose 2

mRNA COVID Vaccines: Moderna

- COVE study: >30,000 participants (including here at Emory/Grady)
  - >7,000 over the age of 65
  - 42% with high-risk chronic disease (severe obesity, diabetes, heart disease)
  - 11,000 (37% of study participants) from communities of color

- November 2020:
  - Efficacy analysis of 196 cases of COVID-19
  - EUA application filed

Moderna Efficacy and Safety

- 94.5% efficacy:
  - 185/196 cases occurred in the placebo group
- Appeared to prevent severe cases:
  - 30 cases were severe; all of those cases occurred in the placebo group
- Grade 3 side effects:
  - 9.7% fatigue, 8.9% muscle aches, 5.2% joint aches, 4.5% headache, 4.1% pain

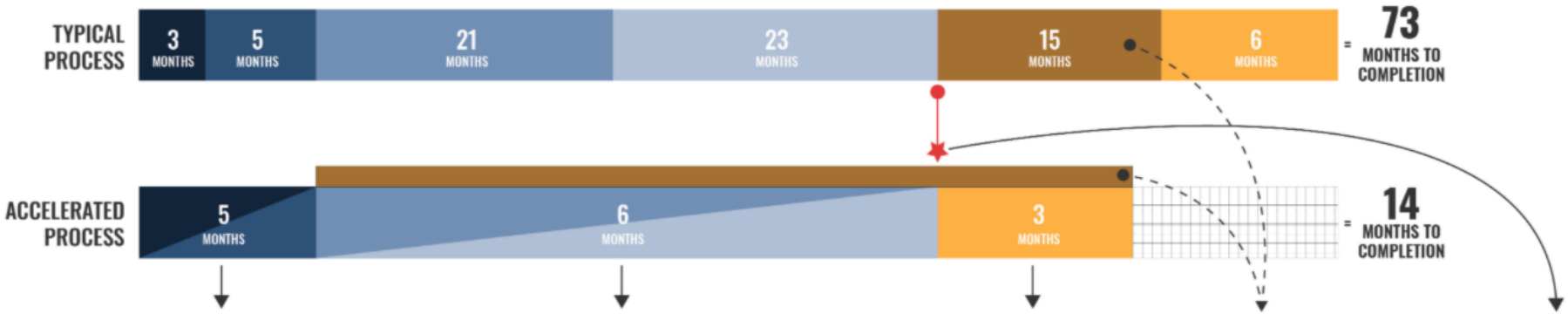
How Were These Vaccines Developed So Fast?

- The SARS-CoV-2 virus genetic sequence became available on January 10, 2020
  - Scientists were therefore able to start working before there were ever cases in the United States

- Scientific progress that occurred before the pandemic enabled quick sequencing of the viral RNA:
  - Development work in mRNA vaccine technology by BioNTech and Moderna was what allowed scientists to quickly turn the sequence into a vaccine
  - Because the vaccine includes RNA and not a killed or attenuated virus, there's no need to grow the virus in culture, which can be a difficult and time-consuming step.

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:

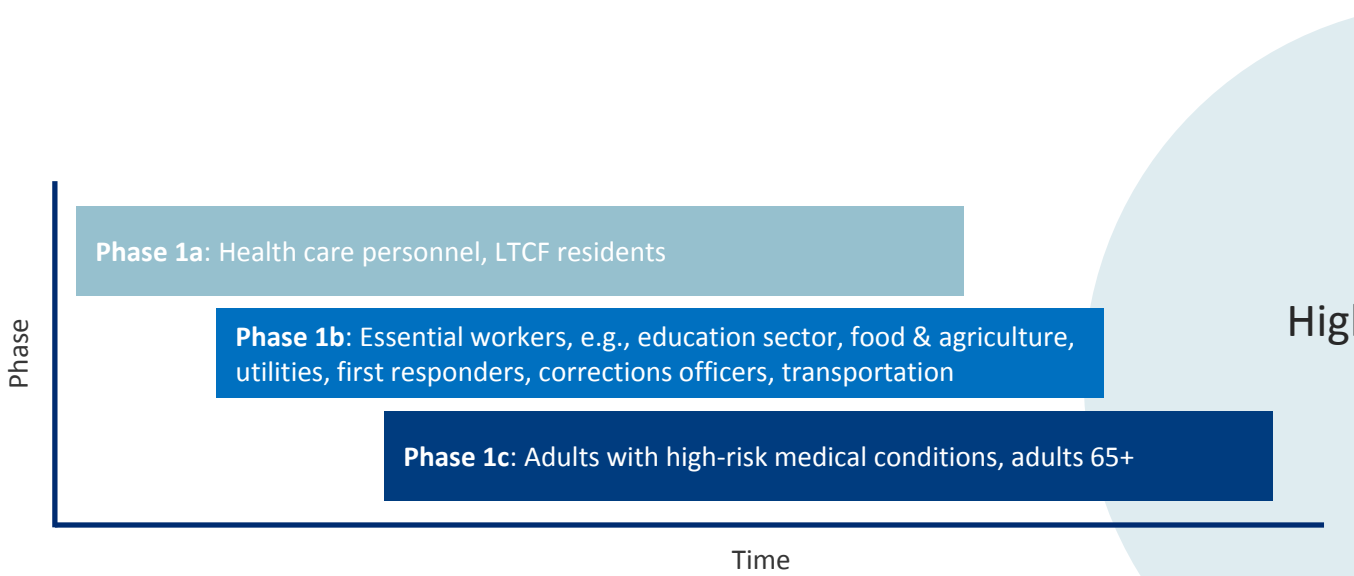
- Providing continuous safety and efficacy data collected in large Phase III clinical trials.

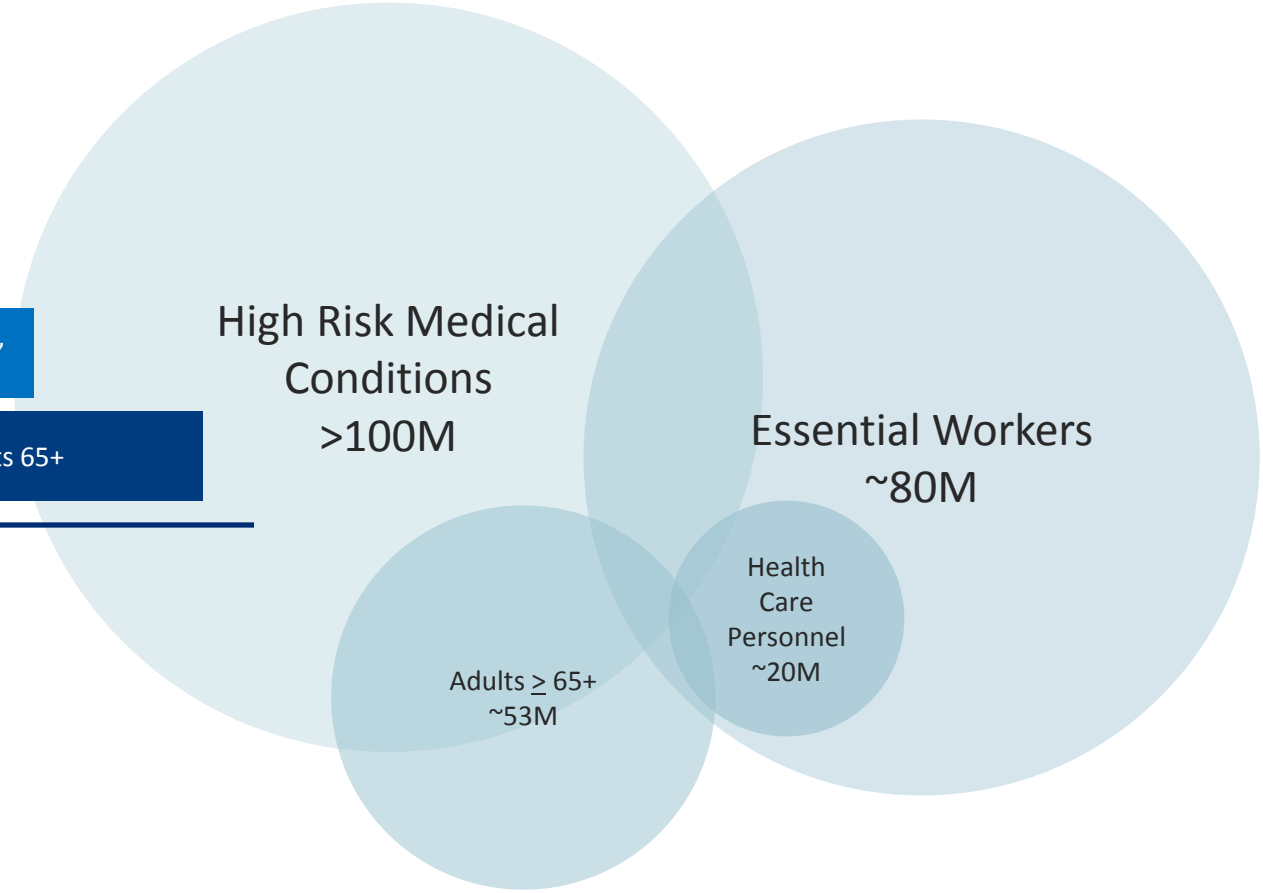
R&D + Preclinical Trials Vaccine Candidate/s Identified
Phase I Clinical Trials
Phase II Clinical Trials
Phase III Clinical Trials
Manufacturing
Distribution

Expected Timeline for Availability

- FDA's Vaccine and Related Biological Products Advisory Committee (VRBAC)
  - 12/10: to review data on the Pfizer-BioNTech vaccine
  - 12/17: to make recommendations on the Moderna vaccine
- The FDA will decide on Emergency Use Authorization (EUA) for each vaccine after the corresponding VRBAC meeting
- Emory could receive initial vaccine allocation as soon as mid-December
- We expect that we will eventually have enough to vaccinate all EHC HCWs, but that the initial allocation will be limited and will be prioritized among groups of HCWs following State and Federal guidelines

Proposed Groups for Phase 1 Vaccination





Resource: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html

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How Is This Vaccine Different Than the Flu Vaccine Distribution?

- Must follow federal and state guidelines and requirements for prioritization and distribution

- Different administrative requirements, including consent, GRITS notification to state within 24 hours and administration of vaccine cards/materials

- Logistically different in terms of administering vaccine:
  - Flu vaccine is widely available and easy to distribute and store
  - COVID vaccine must be scheduled because we expect to receive significantly fewer doses than employees in initial shipments
  - The mRNA vaccines require two doses and special, low-temperature storage and handling

Emory Healthcare Staff and Patient Safety

Staff safety

- The greatest risk observed from our employee data is what occurs/exposure outside of work, not within our facilities
- While we know that our PPE is effective in preventing COVID transmission, we may have additional opportunities to decrease risk to staff:
  - Those in roles where they may interact with unmasked patients at their presentation to care without clinical PPE
  - Those who may have increased risk of COVID acquisition because of the number of people (patients and other staff) they need to interact with in very close proximity in order to provide clinical care on a daily basis

Patient safety

- Maintaining healthcare capacity so that even during a COVID surge, we have staff and providers available to provide excellent clinical care to patients with both COVID and other life-threatening conditions without delays
- Ensuring that providers and staff who work with vulnerable long-term care facility patients, especially those in residential facilities with increased nursing needs, have a decreased likelihood of bringing the virus into these facilities

Q&A

How is EHC Prioritizing Who Receives the Vaccine?

- We are committed to ensuring all EHC staff have access to the vaccine based upon 1) federal/state regulations, and 2) supply availability
- It's likely that the first shipment we get in December will be a smaller amount, so we will plan to vaccinate in prioritized groups
- Considerations:
  - Staffing in a surge to ensure patient safety
  - Patient exposure risk in long-term care facilities
  - Staff exposure and transmission risk
  - Reassurance about safety/tolerability
  - Timing relative to work schedule

The Vaccine Is Two Doses, Do I Have To Take Both?

- Yes – the data for how well the vaccines work is based on having both doses
  - We don't know whether the vaccine would work as well (or at all) with a single dose

- It is incredibly important that anyone who receives the first dose is committed to complying with the second dose
  - We will work during scheduling to make sure you have both appointments and get reminders

What Are the Side Effects?

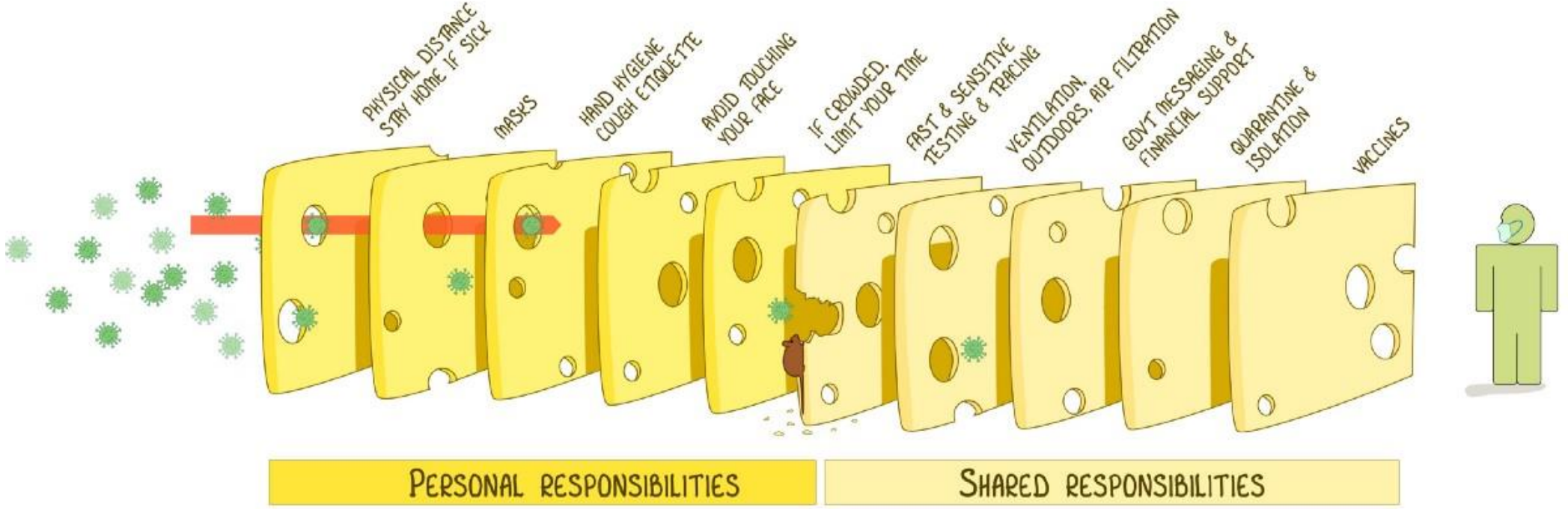
- The most common side effects are:
  - Fever
  - Headache
  - Fatigue
  - Muscle aches/joint pain
- Usually short-lived
- No serious/life-threatening adverse events reported with either of the mRNA vaccines in initial studies

If I Am Vaccinated, Can I Stop Wearing A Mask?

- NO. Getting a vaccine series does NOT mean one can stop wearing a mask, eye protection or stop social distancing practices. No vaccines are 100% effective.
- We will continue to follow PPE protocols in patient settings; as well as masking, eye protection, social distancing in our daily lives for the foreseeable future.
- We also do not know if the vaccines prevent carriage or asymptomatic infections.

The Swiss Cheese Respiratory Virus Pandemic Defence

Recognising that no single intervention is perfect at preventing spread



Each intervention (layer) has imperfections (holes).
Multiple layers improve success.

Ian M Mackay
virologydownunder.com
With thanks to Jody Lanard, Katherine Arden & the Uni of Qld
Based on the Swiss cheese model of accident causation, by James T Reason, 1990
version 3.0
update: 24oct2020

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