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HOUSE OF REPRESENTATIVES
COMMONWEALTH *of* PENNSYLVANIA

Virtual Hearing: CRUSHING-COVID-19

Monday, April 12, 2021 | 11 a.m.

Hosted by
State Representatives Patty Kim, Darisha Parker

11 a.m.	Amy Walker, Director of Infectious Diseases Policy ***Biotechnology Innovation Organization***
11:30 a.m.	Lisa Coen, Senior Director, Vaccines Public Affairs ***Pfizer***
	Questions from legislators

Pennsylvania House Democratic Policy Committee
"Crushing Covid-19: An update on how vaccines are helping Pennsylvania COVID-19 recovery efforts"

Monday, April 12, 2021

Testimony by
Amy Walker
Director, Infectious Diseases Policy
Biotechnology Innovation Organization (BIO)

Chair Bizzarro and members of the Democratic Policy Committee, thank you for the invitation to provide you with an update on the status of research and development of COVID-19 vaccines, therapeutics, and diagnostics. My name is Amy Walker and I am the Director for Infectious Diseases Policy at the Biotechnology Innovation Organization, or BIO.

BIO is the world's largest trade organization representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 countries. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO's membership includes developers and manufacturers of vaccines, therapeutics, diagnostics, and medical countermeasures against emerging infectious diseases, pandemic pathogens, and other health security threats. As the leading biotech trade association, BIO is working to help accelerate R&D of biotech solutions to the current pandemic, help patients weather the storm of the pandemic, and enhance US preparedness for future public health emergencies.

As you know, when a novel coronavirus emerged in late 2019, no products existed to treat or prevent this disease. In December 2020, the first vaccine was approved for use in the United States, and just four months later, more than 170 million vaccines have been administered.

The public-private partnership between the biotech industry and the U.S. government has led the global race to develop vaccines and cures to protect individuals from the novel coronavirus. Specifically, our industry is devoting our expertise, resources, and capabilities to identify science-based solutions and medical treatments to combat this threat. These efforts have encompassed unparalleled collaboration and cooperation between industry, academia, non-governmental organizations, and governments around the world. Pennsylvania is playing a vital role in the research, testing, and manufacturing of these products. A number of the biotechnology companies answering the call on COVID-19 have

research and manufacturing facilities in the state. Pennsylvania's academic institutions have laid the foundation for later stage work in partnership with biotechnology companies.

Status of the COVID-19 Pipeline

BIO has developed a suite of tools to help connect stakeholders and provide information. One such tool is a vaccines and therapeutics pipeline tracker, which cross-references information from industry databases and company public announcements. This information is available publicly for free at bio.org/covidpipelinetracker. The tracker aims to provide timely information and therefore is updated every week.

Based on our tracker, as of Monday, March 29th, more than 850 programs for COVID-19 vaccines and therapeutics were publicly announced over the past year. More than 90% of products are being developed by biotechnology companies. More than 70% of products in the pipeline have been discovered by small companies, and more than 50% have been discovered by companies based in the US.

With regard to products for COVID-19, we're really talking about three different pipelines. Of the more than 850 products in the pipeline,

- 25% are vaccines to prevent infection;
- 29% are antivirals or antibodies targeting the SARS-COV-2 virus itself; and
- 46% are treatments for secondary effects of infection.

More than 40% of all products are at clinical-stage development and they're being tested in actual people.

Many more novel technologies are being deployed and tested. More than 60% of the pipeline are biologics and vaccines, while around a third of products are traditional small molecule drugs. The products in clinical stage show a variety of modalities and technologies – ensuring that we have many shots on goal for success.

Vaccines in Record Time

Clinical trials for COVID-19 vaccines are enrolling as many or more trial participants than other vaccines to help ensure the data on safety and efficacy are robust. Phase 3 studies are being conducted using clinical trials designs that represent the gold standard in vaccines R&D – randomized, placebo-controlled, event-based trials. Last Fall, before any vaccine was under review, the Food and Drug Administration (FDA) provided guidance on the use of Emergency Use Authorizations (EUAs) that show high scientific standards are being upheld. Last September, industry leaders issued a pledge that affirmed that companies would "follow the science" and not seek FDA review until robust data has been collected through clinical trials.

The FDA has now authorized three COVID-19 vaccines for use in the United States under EUAs: mRNA vaccines from Pfizer and Moderna and Johnson & Johnson's viral vector vaccine. While vaccine research timelines were compressed during the pandemic, this speed was not at the expense of safety or efficacy. The quick pace can be attributed to a number of factors, including: building upon previous research, advances in technology, public-private partnerships and collaborations, and the shifting of priorities and resources.

Vaccines research that had been done to address previous coronavirus outbreaks of SARS and MERS are being tested against COVID-19. Learnings from work on other viruses like influenza is also being utilized in the development of COVID-19 vaccines. The vaccine technologies or platforms utilized have been tested and used in the development of other vaccines. Even mRNA, which COVID-19 is the first vaccine to be authorized using this vaccine, has been used in other ongoing clinical trials and this technology had been tested in thousands of people before COVID even came onto the scene.

Second, scientific and technological advances shortened timelines. Advances in viral genome sequencing made the underlying data on the virus available to companies more

quickly. For the 2003 SARS epidemic, it took 20 months from publication of the genetic sequence of the virus genome to development of a vaccine candidate. For SARS-CoV2 the first Phase I vaccine clinical trial began a mere three months after the genetic sequence of the virus was available. Additionally, technologies like mRNA do not rely on growing and then killing or attenuating a virus, which is subject to the timelines of natural biological processes.

Strong collaboration between US and international governments, companies, academia, non-governmental organizations, and health care worked together to form partnerships and find efficiencies. The federal “Operation Warp Speed” was started in May 2020 with the goal of having a fully tested vaccine by January 2021 and accelerating therapeutics development. This effort included partnerships with eight companies to de-risk the R&D process by providing funding for development, manufacturing, and procurement of vaccines and therapeutics. These awards are large scale: most partnerships are upwards of $1 billion.

Finally, moving staff from other projects to COVID provided more brainpower and shifting funding overcame lags that companies often face in raising funds in order to start large trials. Companies compressed timelines through parallel rather than sequential R&D and manufacturing work so that doses would be available immediately after FDA review.

Ongoing Research

In addition to the three authorized vaccines, clinical trials are continuing for additional vaccines. We will need many vaccines to meet global demand, and trials that are currently ongoing will provide information about those vaccines’ effectiveness against variant strains.

Two vaccines may be considered by the FDA soon. The AstraZeneca/Oxford viral vector vaccine is being used outside the U.S., has received a recommendation from the

World Health Orgnaization (WHO), and has been widely used across Europe, Asia, Africa, and South America. While there have been some concerns over specific side effects, many governments have determined that the rare instances of these side effects does not outweigh the benefits of the vaccine. Novavax's recombinant protein vaccine trial is fully enrolled and data from the U.S. is expected to be announced soon. Their data from the United Kingdom and South Africa showed 89.3% and 60% efficacy, respectively, with some effectiveness against the variants circulating in those countries.

In February 2021, FDA announced guidance for evaluation of vaccines to address emerging variants. Notably, FDA is not expecting companies to complete full randomized control trials. Moderna and Pfizer have both announced research of vaccines against variants. Other companies are also researching variant vaccines, as well as pan-coronavirus vaccines that may provide protection against multiple COVID-19 strains.

Pfizer's vaccine is currently authorized for individuals age 16 years and older, while Moderna's and Johnson & Johnson's vaccines are authorized for adults age 18 years and older. Pfizer, Moderna, Johnson & Johnson, and AstraZeneca all have clinical trials ongoing for pediatric populations. Additional research is also being done to examine the efficacy and safety of these vaccines among pregnant and lactating women.

As with all vaccines, ongoing monitoring of safety and efficacy will continue as long as the vaccine is in use. While the authorized and late-stage vaccines are highly safe and effective, we will be learning more about the vaccines as they are used in broader populations. COVID-19 vaccines will be monitored for safety signals using existing systems as well as new systems established specifically for COVID. One new safety monitoring system is CDC's v-safe text-based monitoring. When vaccinated, individuals will receive information about how they can register for v-safe. Enrolling in v-safe will prompt periodic check-ins asking about side effects. Reports made via text that show more severe side

effects will result in CDC follow-up and reporting to the long-standing Vaccine Adverse Event Reporting System (VAERS), if appropriate.

Conclusion

The biotechnology industry is committed to bringing safe and effective vaccines, therapeutics, and diagnostics across the finish line for people in Pennsylvania, the United States, and around the world. While we work toward getting vaccines to as many people as want them, remember to observe good public health - wash your hands frequently, wear a mask and social distance, and cover your coughs and sneezes.

Thank you again for the opportunity to speak to the Committee. I look forward to your questions.

COVID-19 Vaccines Update: Development and Deployment

Amy Walker
Director, Infectious Diseases Policy
Biotechnology Innovation Organization
April 12, 2021
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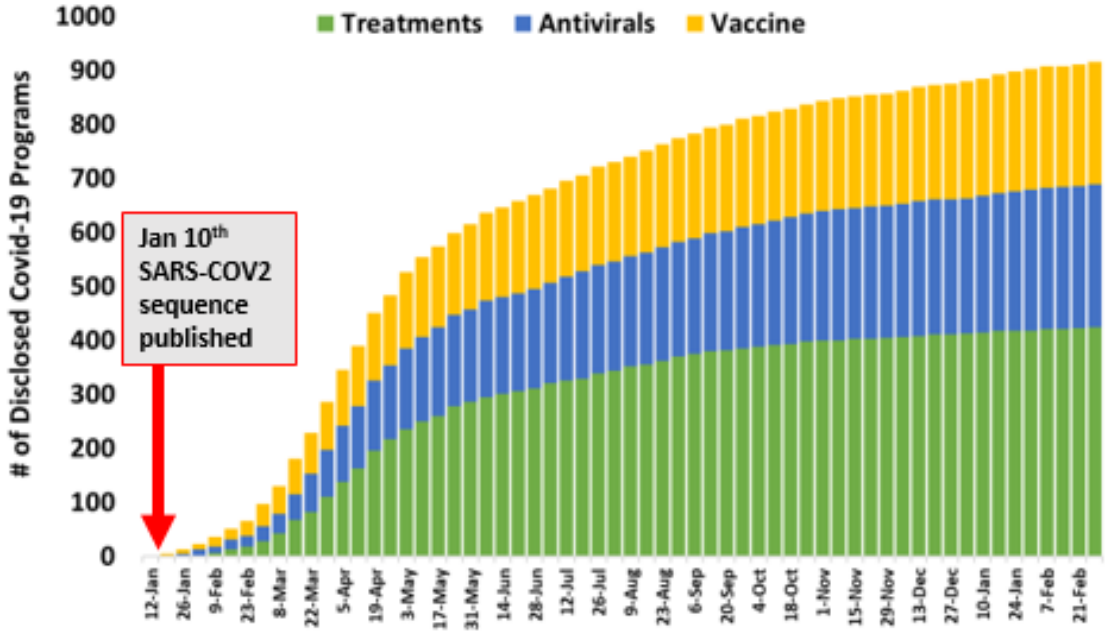
Biotechnology Innovation Organization

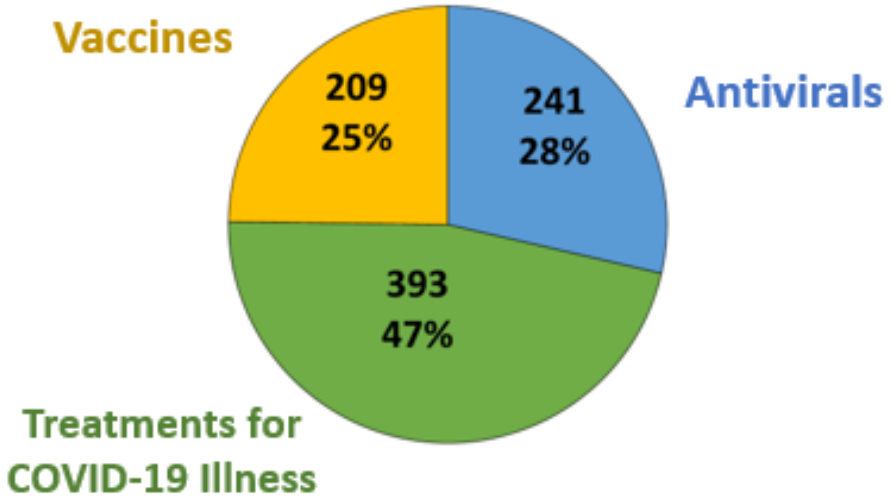
Timing of Response by Industry

***915** unique drug programs launched in 14 months*

Still Active in R&D = 843



Week of first press release announcing program

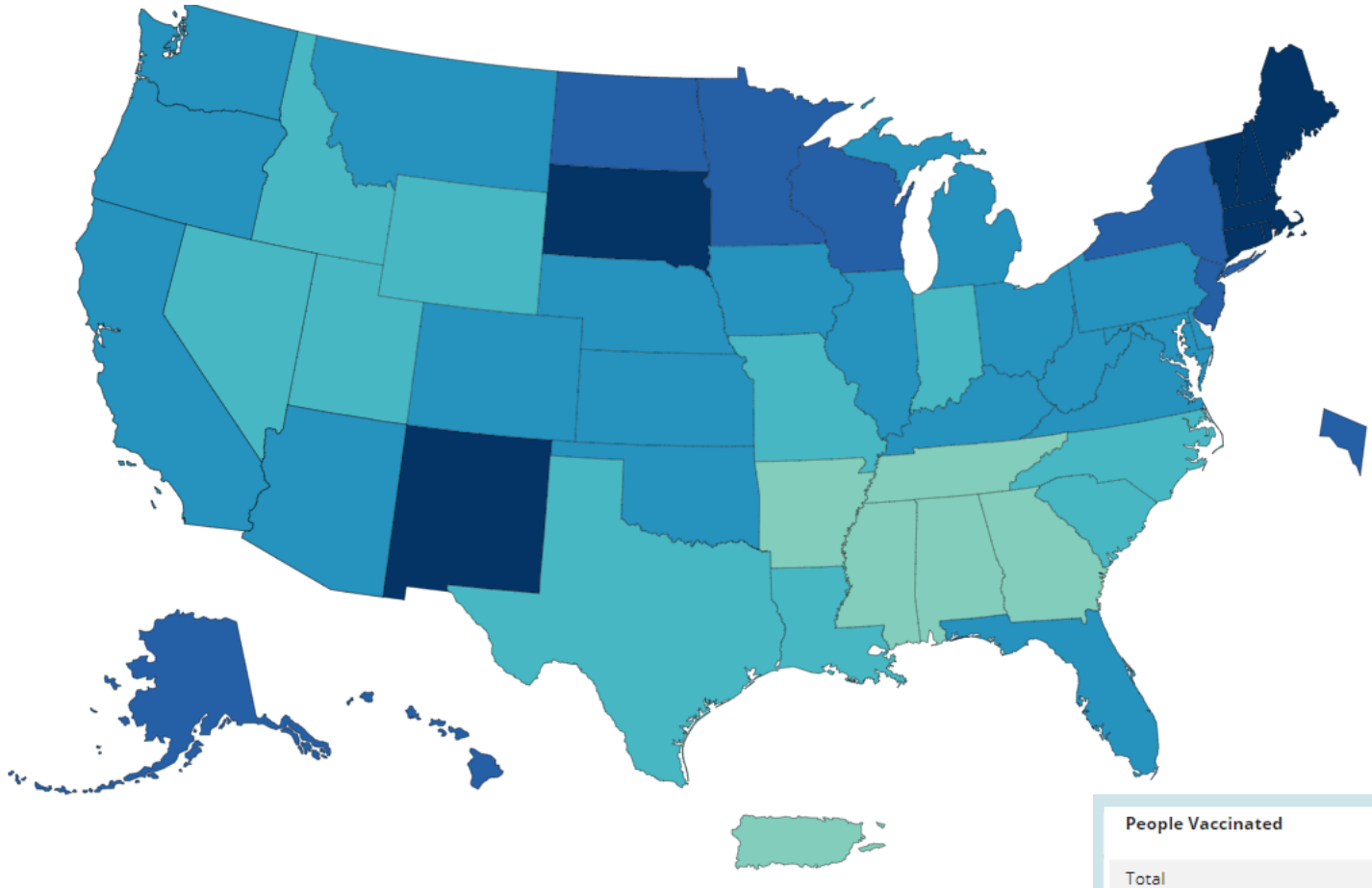


72% originated in Small Companies
51% originated in US

Weekly pipeline updates:
www.bio.org/covidpipelinetracker

Updated March 9, 2021

Biomedtracker, Biocentury, BIO Industry Analysis



Total Doses Administered per 100,000

No Data | 0 | 1 - 45,000 | 45,001 - 50,000 | 50,001 - 55,000 | 55,001 - 60,000 | 60,001+

Total Vaccine Doses

Delivered	225,294,435
Administered	171,476,655

Learn more about the distribution of vaccines.

Territories

GU | AS | RP | FM | MP | MH | VI

Federal Entities

BoP | DoD | IHS | VHA

* Data for Federal Entities are presented here and are also incorporated into the respective jurisdictional totals

People Vaccinated	At Least One Dose	Fully Vaccinated
Total	109,995,734	64,422,618
% of Total Population	33.1%	19.4%
Population ≥ 18 Years of Age	109,408,066	64,286,560
% of Population ≥ 18 Years of Age	42.4%	24.9%
Population ≥ 65 Years of Age	41,793,053	31,413,778
% of Population ≥ 65 Years of Age	76.4%	57.4%

CDC | Data as of: Apr 07 2021 6:00am ET | Posted: Apr 7 2021 1:35PM ET

Source: https://covid.cdc.gov/covid-data-tracker/#vaccinations
Data as of Wednesday, April 7, 2021

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 avi
国药山西 SINOPHARM
sinovac

RNA[1]

SANOFI
TranslateBIO
PrEPBiopharm
BIONTECH
Pfizer
moderna
messenger therapeutics

DNA

INOVIO
POWERING DNA MEDICINES
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 April 8, 2021, not exhaustive

COVID-19 Vaccines in Development for SARS-CoV2

Company/ Candidate	Vaccine type	Phase	Product characteristics	Trial characteristics	Recruiting status
Pfizer / BioNTech	mRNA	3	2 doses (0, 21 days) IM -20 degrees C (-70 degrees C preferrable)	44,000 12-85 years of age	EUA authorized Dec 11, 2020
Moderna	mRNA	3	2 doses (0, 28 days) IM -20 degrees C	30,000 18-55, 56+	EUA authorized Dec 17, 2020
Johnson & Johnson	Viral vector (non-replicating	3	1 dose / (separate 2 dose trial) IM 2-8 degrees C	60,000 / 30,000 (US) 18-55, 65+	EUA authorized Feb 27, 2021
AstraZeneca / Oxford	Viral vector (non-replicating)	3	2 doses (0, 28 days) IM 2-8 degrees C	30,000 18+	Phase 3 completed
Novavax	Recombinant Protein subunit	3	2 doses (0, 21 days) IM 2-8 degrees C	30,000 18+	Phase 3 enrollment completed
Sanofi Pasteur / GSK	Recombinant Protein subunit	2	1 or 2 doses IM 2-8 degrees C		Phase 2 enrollment completed
Inovio	DNA	2	2 doses (1, 28 days) ID w device 2-8 degrees C		Completed
Medicago	Recombinant Protein subunit	2	2 doses (0, 21 days) IM 2-8 degrees C		Phase 2 enrollment complete

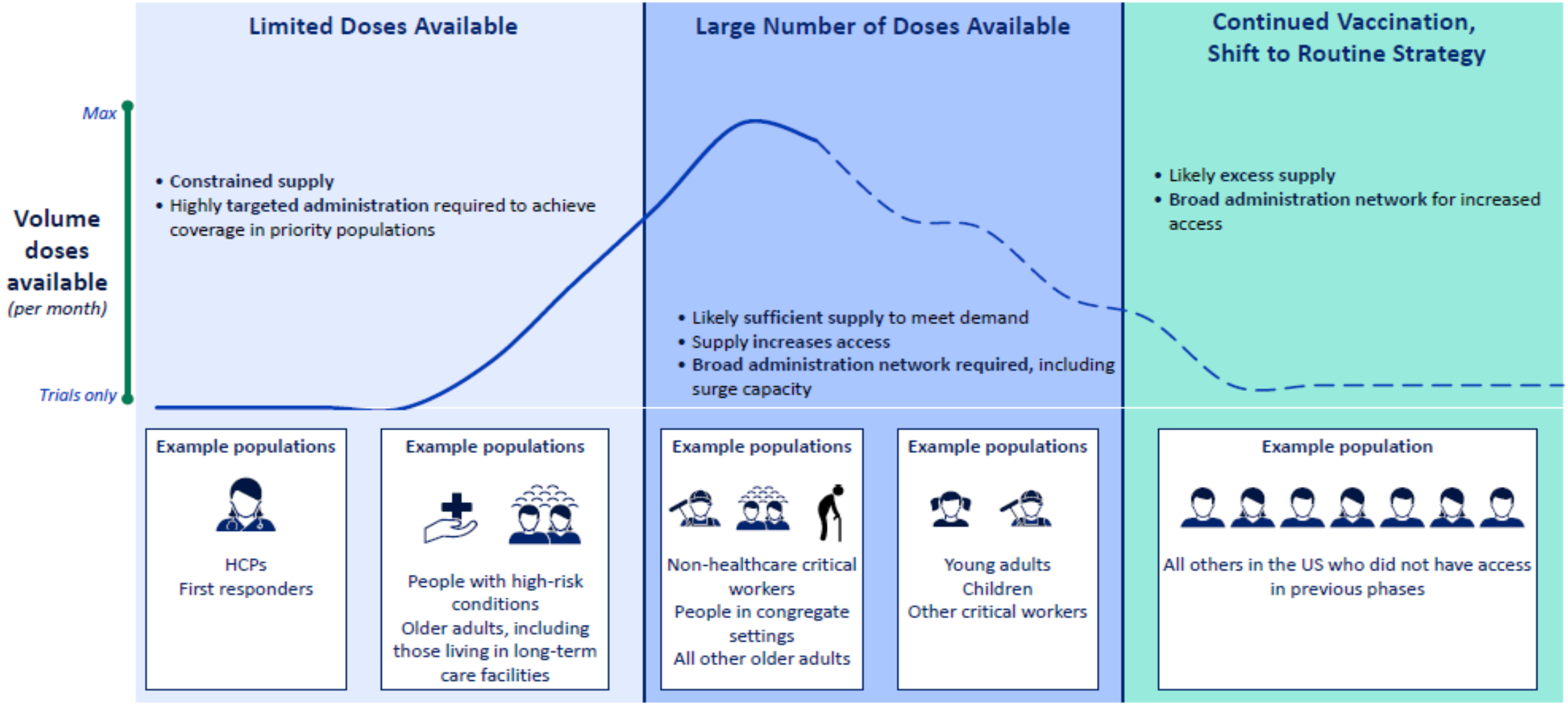
Source: Company websites and public presentations

The Speed of COVID-19 Vaccine Development

- Unprecedented pace of development **without sacrificing efficacy and safety**
- Clinical trials were larger than with other vaccines (30,000 - 40,000 people)
- *Like Building a House:*
  - Existing foundations
    - Years of research on other viruses
  - New technology
    - Leverage new science to develop vaccines – no need for the virus to grow
  - Strong collaboration
    - FDA, academia, companies, doctors all working to do more together
  - Extra and prioritized resources
    - Companies moved staff to COVID from all other projects

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

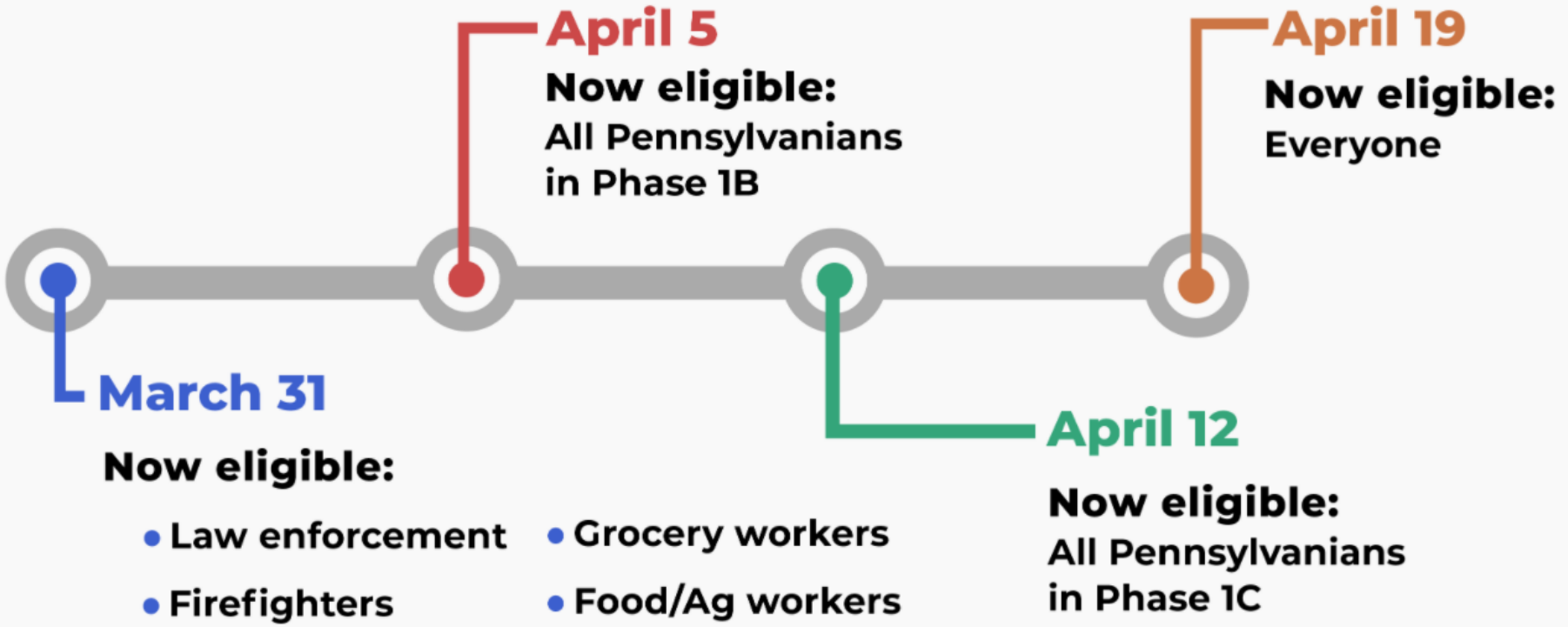
Distribution will adjust as volume of vaccine doses increases



Illustrative example populations; final prioritization to be decided by ACIP

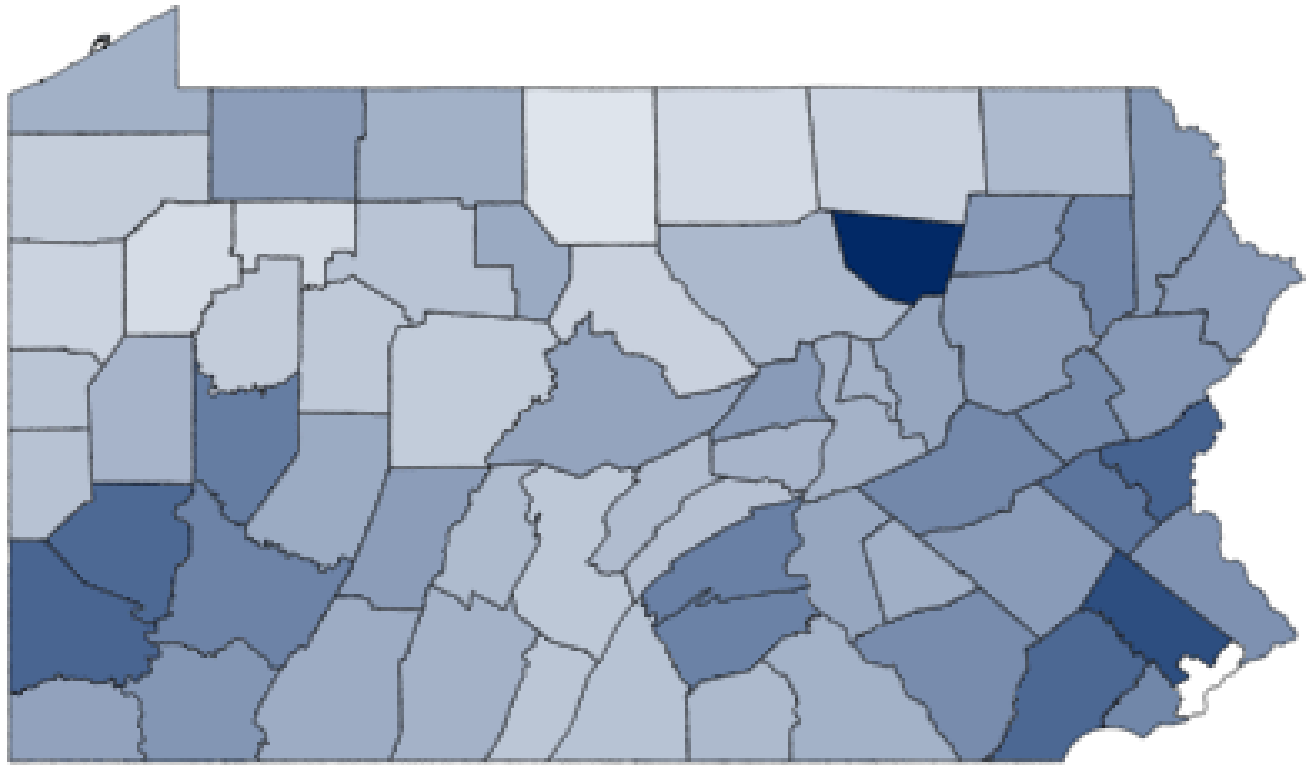
Source: CDC ACIP

Vaccine Rollout Timeline



All Pennsylvanians will be eligible to be vaccinated by **April 19**. Learn more about what each phase means.

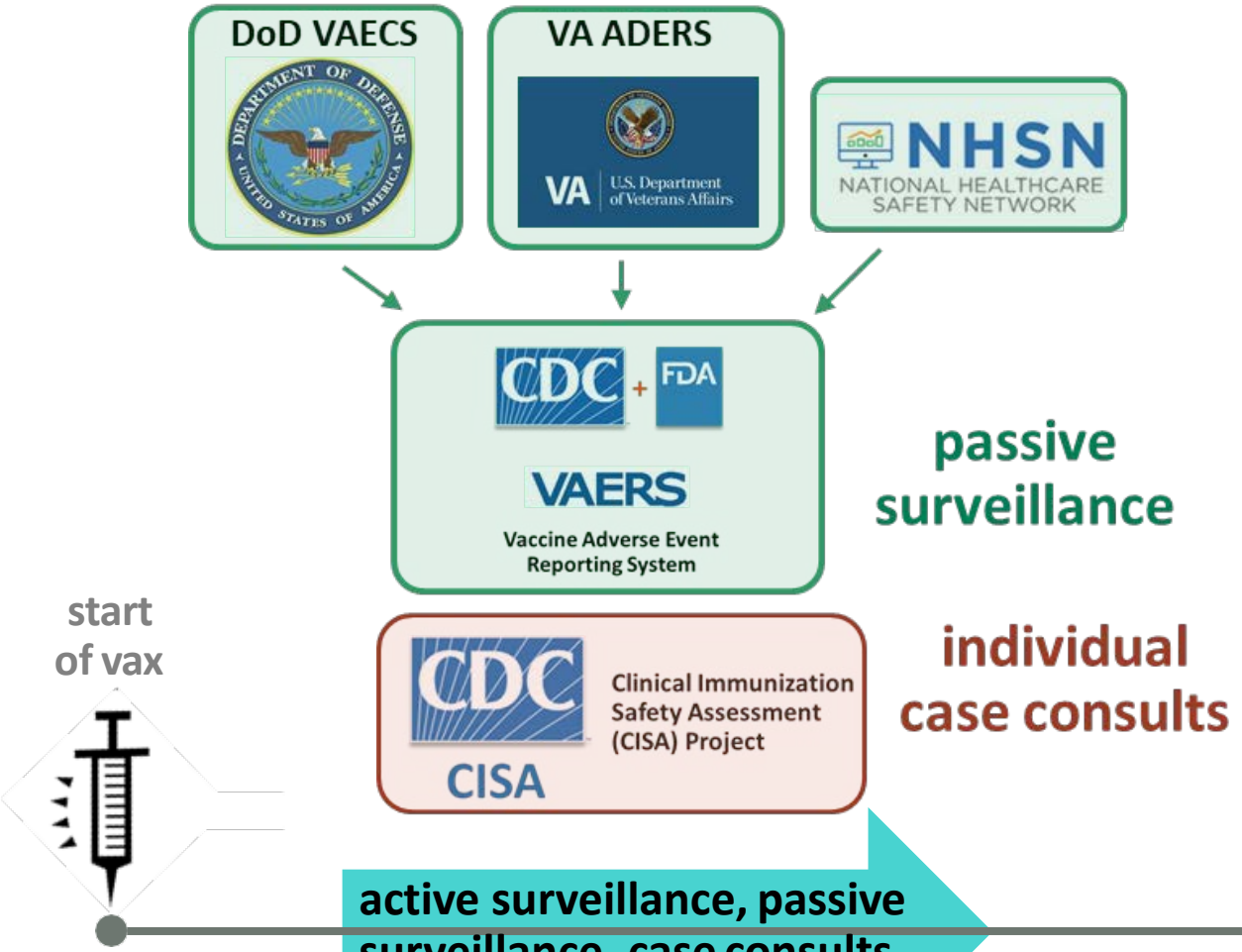
Rate per 100,000 Residents Who Have Received Partially Covered Vaccinations, by County

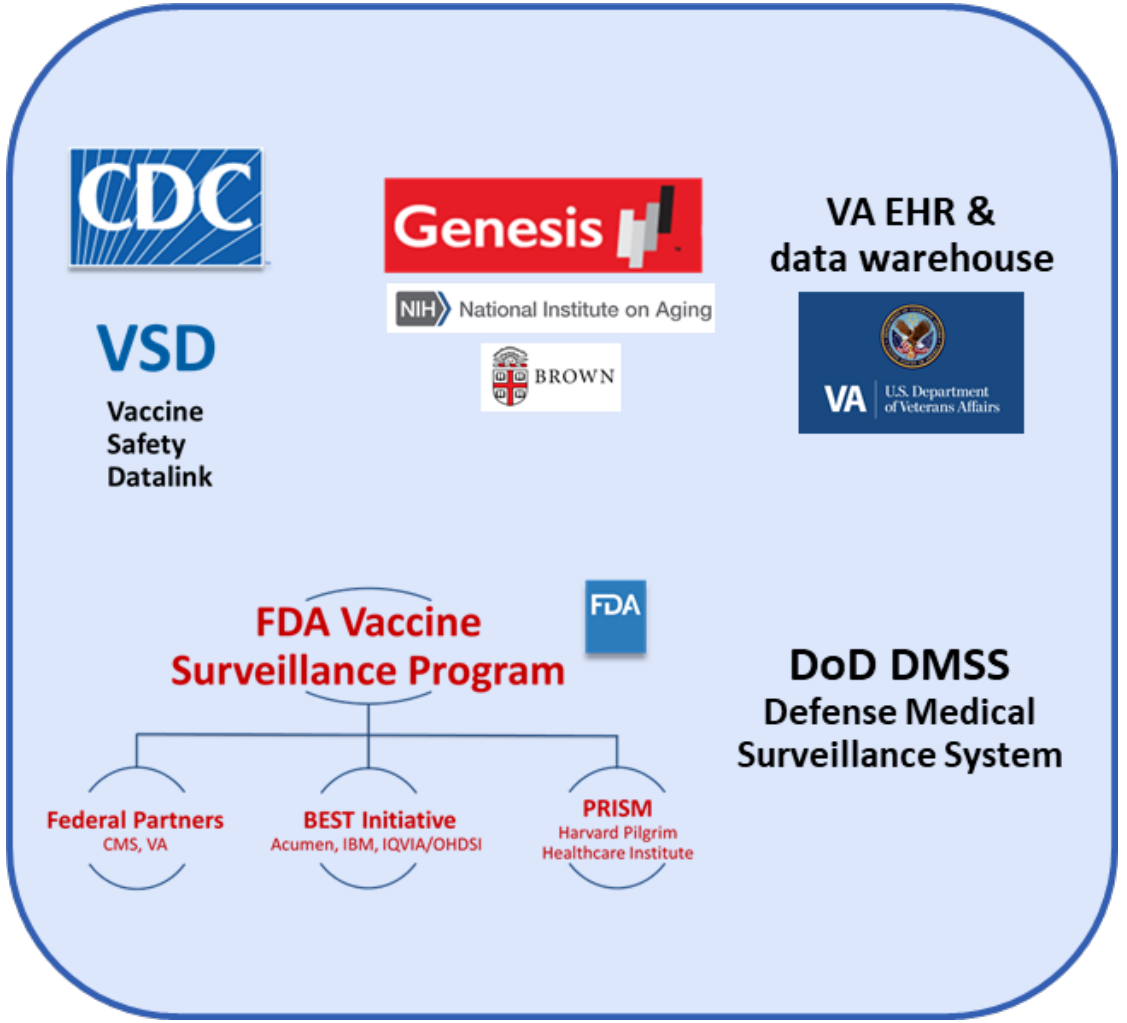


Vaccinations Administered	
Partial vaccinations administered	3,723,884
Full vaccinations administered	2,073,705
Total vaccinations administered	**5,797,589**

Source: https://www.health.pa.gov/topics/disease/coronavirus/Vaccine/Pages/Dashboard.aspx
Data as of Wednesday, April 7, 2021

Ongoing Monitoring Will Provide More Information on COVID-19 Vaccine Safety





large-linked database monitoring

safety monitoring timeline

Source: CDC

1. text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

   vaccine recipient completes web survey

This Photo by Unknown Author is licensed under CC BY-SA

Vaccine recipient

2. clinically important health impact reported
   - ✓ missed work
   - ✓ unable to do normal daily activities
   - ✓ received medical care

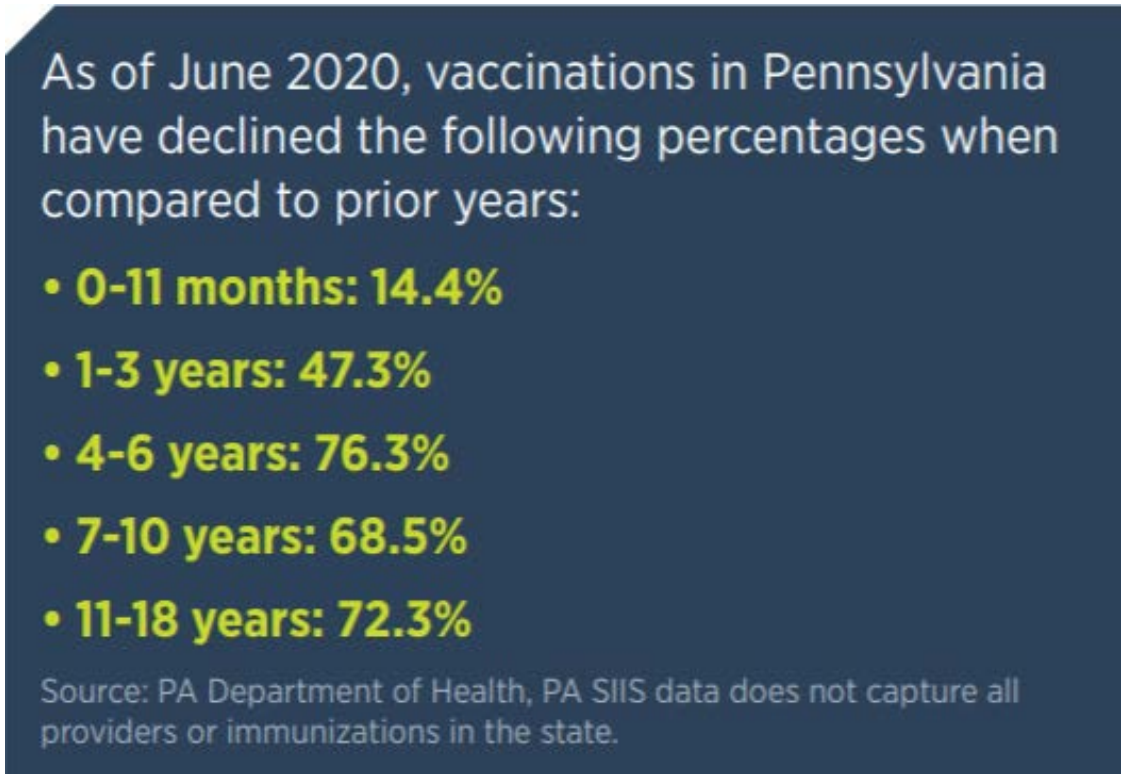
v-safe℠ after vaccination health checker

Call center

This Photo by Unknown Author is licensed under CC BY-SA

3. a VAERS customer service representative conducts active telephone follow-up on a clinically important event and takes a report if appropriate; also reminds about second dose at proper interval

Declines in Routine Immunization – *Risking Infectious Disease Outbreaks on top of COVID-19*

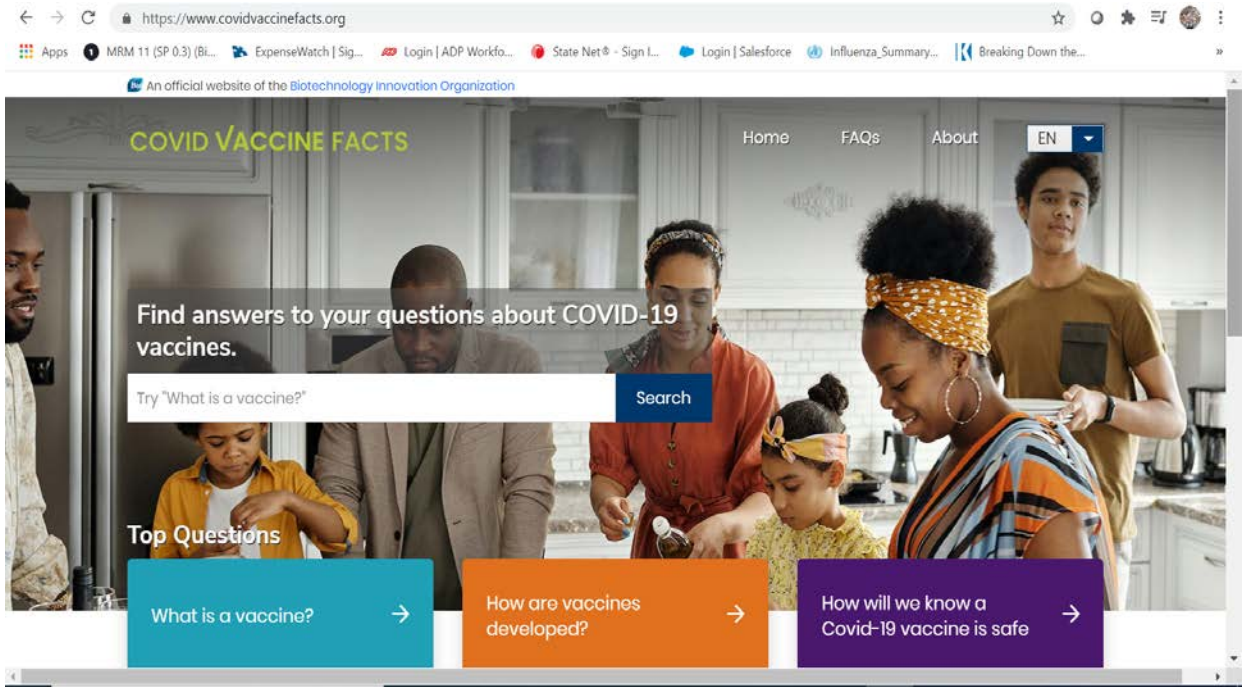


- CDC estimates that vaccination coverage declined in all childhood milestone age cohorts except for birth-dose hepatitis B coverage during the pandemic
- A study by Avalere found that adolescent and adult vaccination rates declined between 41%-53% from March-August 2019 to March-August 2020

https://www.papartnerships.org/wp-content/uploads/2020/09/Immunizations-Fact-Sheet.pdf
https://www.cdc.gov/mmwr/volumes/69/wr/mm6920e1.htm
https://avalere.com/insights/how-covid-19-has-impacted-us-adolescent-and-adult-vaccine-utilization

BIO Resources

- COVID Vaccine Facts: https://www.covidvaccinefacts.org/



- COVID Pipeline Tracker: https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker

- BIO COVID website: https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus

COVID -19 RESOURCES

- **CDC – COVID-19 Vaccination Communication Toolkit**
  https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
- Pfizer's EUA website www.cvdvaccine-us.com
- BIO's COVID-19 vaccine information website: www.covidvaccinefacts.org
- Here is a link to the new advocacy organization to help build COVID-19 vaccine confidence: www.covidvaccineproject.org
- New resource from the Association for Immunization Managers - Microsoft Word - mRNA Talking Points.docx (ymaws.com)
- Additional resources from Vaccinate Your Family - Information and Resources on COVID-19 and COVID-19 Vaccines | Vaccinate Your Family
- **CDC – Vaccinate with Confidence**
  https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html
- **Immunization Action Coalition**
  https://www.immunize.org/
- **Pandemic Resources – Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals and Patients**
  https://www.fda.gov/health-professionals/coronavirus-disease-2019-covid-19-resources-health-professionals
- **WHO Improving Vaccination Demand and Addressing Hesitancy**
  https://www.who.int/immunization/programmes_systems/vaccine_hesitancy/en/
- **American Academy of Pediatrics**
  https://www.aap.org

ONE-PAGERS

- **Talking to Family and Friends About COVID-19 Vaccination (English)**
- **Health Disparities in the Context of COVID-19 (English)**
- **Health Disparities in the Context of COVID-19 (Spanish)**
- **Older Americans are Disproportionately Impacted by COVID-19 (English)**
- **Older Americans are Disproportionately Impacted by COVID-19 (Spanish)**
- **About the COVID-19 Vaccine Education and Equity Project (English)**
- **About the COVID-19 Vaccine Education and Equity Project (Spanish)**
- **COVID-19 Vaccine Education and Equity Project Q&A**

INFOGRAPHICS

- **Vaccine Approval in the United States (English)**
- **Vaccine Approval in the United States (Spanish)**
- **Vaccines Are Essential to Preventive Care and Public Health**
- **Examples of Lifesaving Vaccines Throughout History**