CDC/IDSA COVID-19 Clinician Call

November 7, 2020

Welcome & Introductions

Dana Wollins, DrPH, MGC
Vice President, Clinical Affairs & Guidelines
IDSA

- 43rd in a series of weekly calls, initiated in January by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/podcasts.

Today's Topic:

Herd Immunity & Vaccines Update

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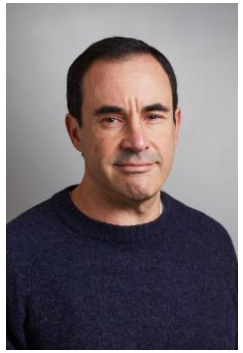
Distinguished Professor of Medicine
Division of Infectious Diseases
Emory University School of Medicine
Professor of Epidemiology and Global Health
Rollins School of Public Health of Emory University



Gregg Gonsalves, PhD
Assistant Professor, Epidemiology of Microbial Diseases
Yale School of Public Health
Associate (Adjunct) Professor of Law, Yale Law School
Co-Director, Global Health Justice Partnership
Yale Law School/Yale School of Public Health

Mary S. Hayney, PharmD, MPH, FCCP, BCPS
Professor of Pharmacy
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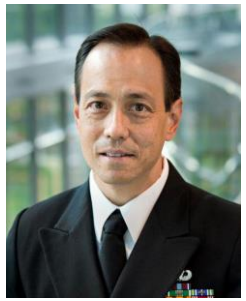
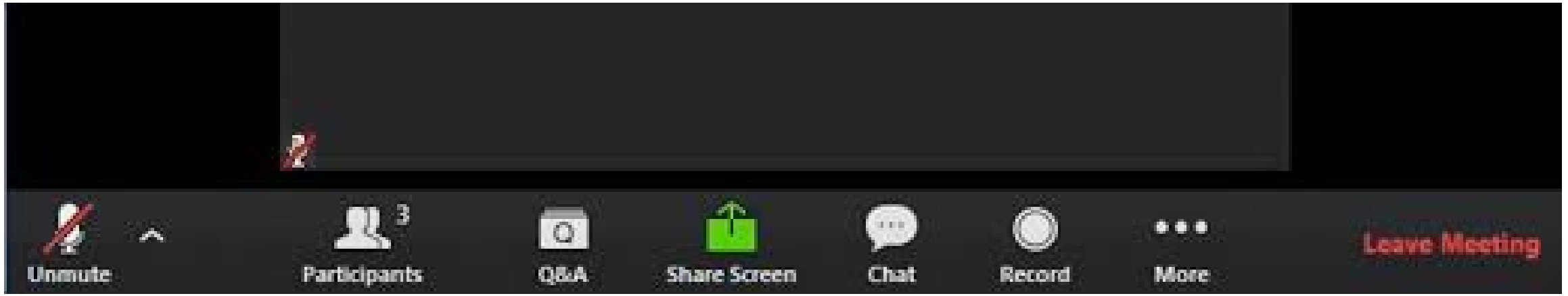


Tom Shimabukuro, M.D., MPH, MBA
Deputy Director of Immunization Safety Office
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button



Herd immunity and COVID-19

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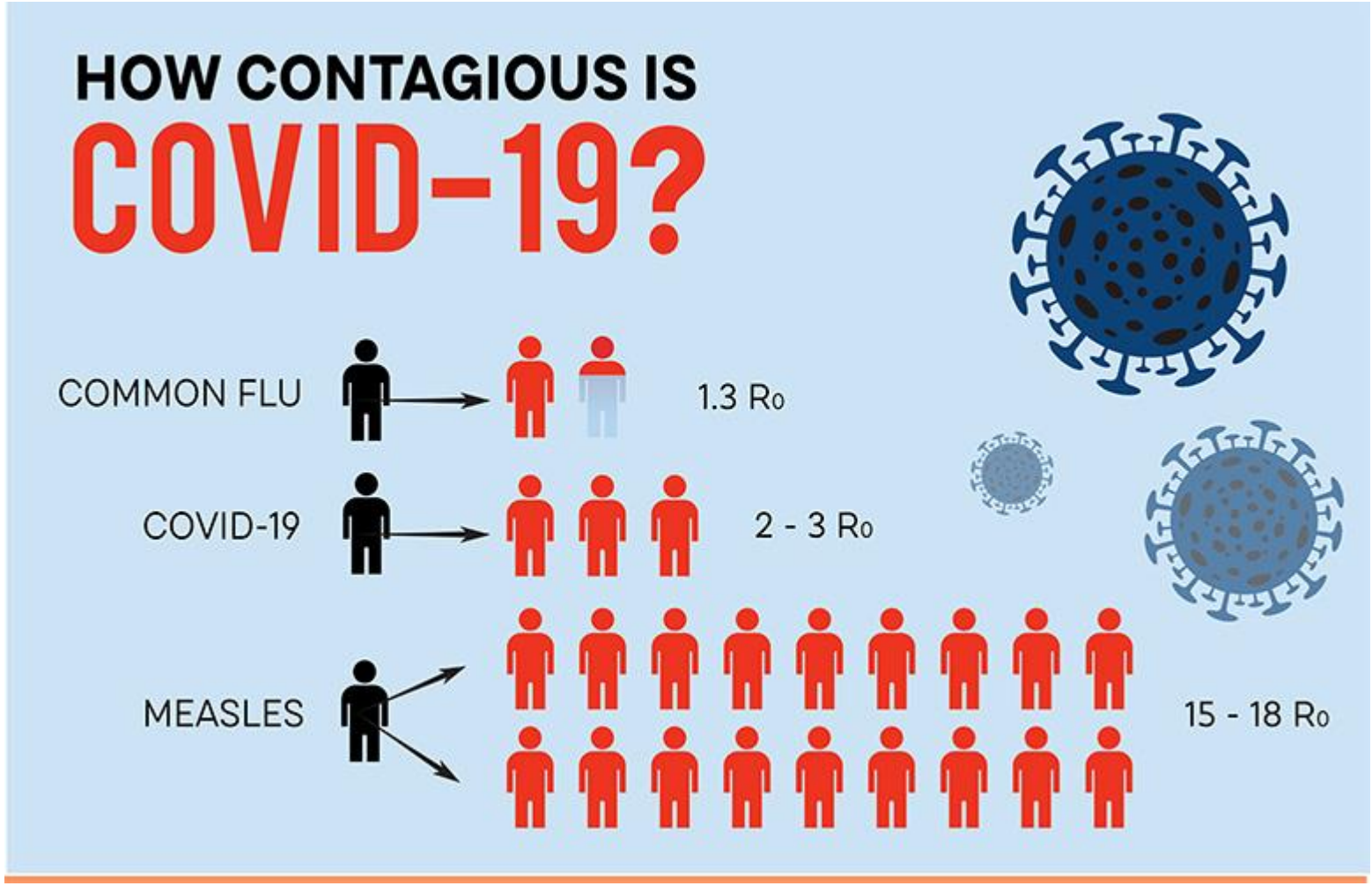
Disclosures

- Carlos Del Rio: Nothing to disclose
- Gregg Gonsalves: Nothing to disclose

Basic concepts

- R*o* = the basic reproduction number – is the average number of transmissions expected from a single primary case introduced into a totally susceptible population.
- Describes the maximal spreading potential of an infection in a population.
- Later in the epidemic preventive measures and immunity (from vaccination or disease exposure) modifies the R*o*



https://moffitt.org/endeavor/archive/the-science-behind-covid-19/

What is herd immunity?

- Also known as *indirect protection, community protection* or *community immunity.*
- Herd immunity was first used in a paper published in 1923 by Topley and Wilson
- Refers to the prevalence or proportion of immune persons in a population but often used with reference to indirect protection of non-immune persons, attributable to the presence and proximity to immune persons.
- May be achieved through vaccination or natural infection.

Herd immunity threshold

- Defined as the proportion of individuals in a population who, having acquired immunity, can no longer participate in the chain of transmission.
- Herd immunity: $R_t < 1$ even when $p = 0$ so immunity (from vaccination or disease exposure) alone makes epidemic stop

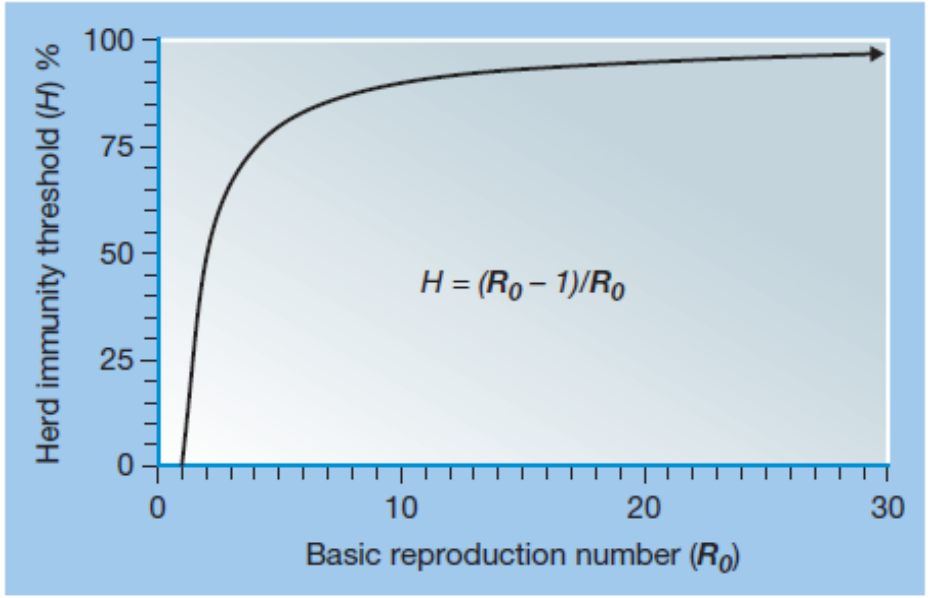


Figure 77.6. Relationship between herd immunity threshold *(H)* and basic reproduction number R_0, as in Eq. 6: $H = 1 - 1/R_0$.

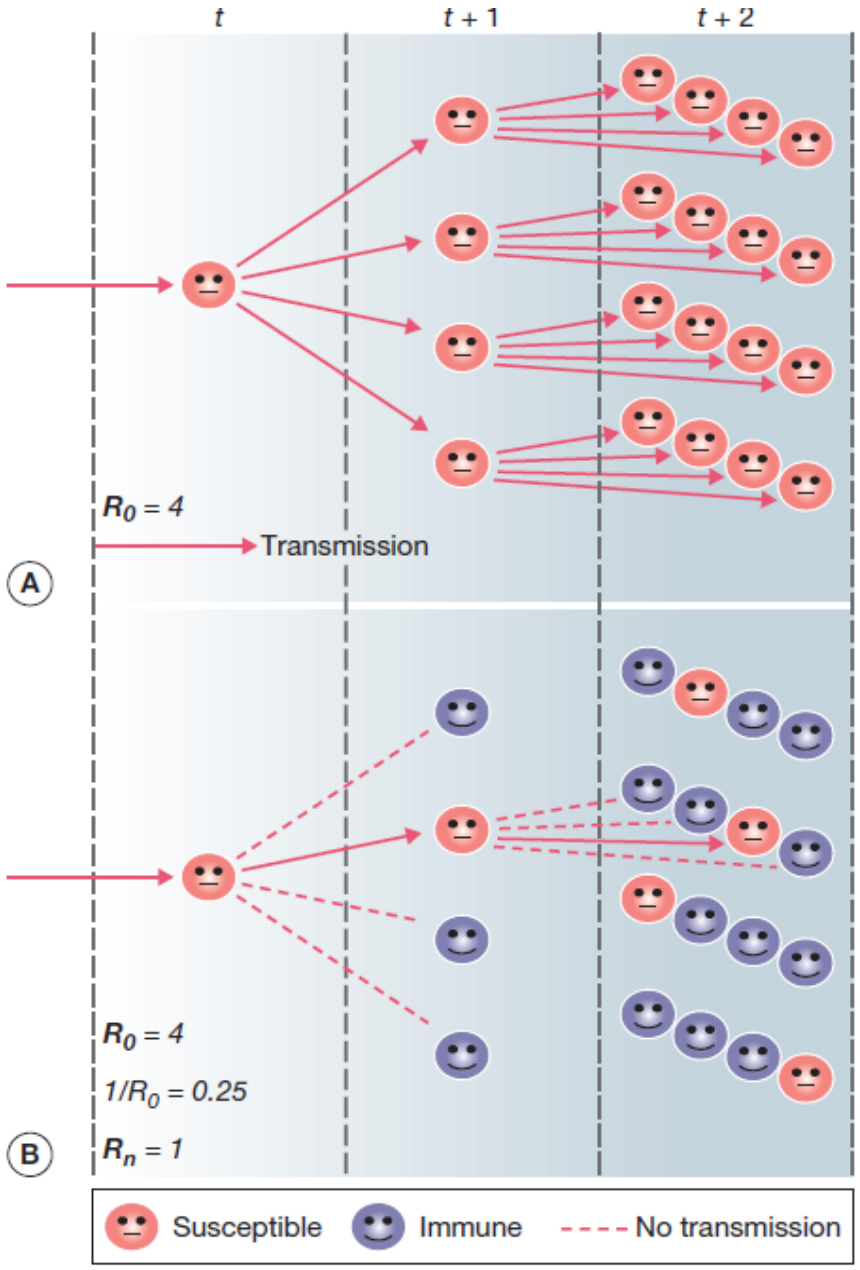
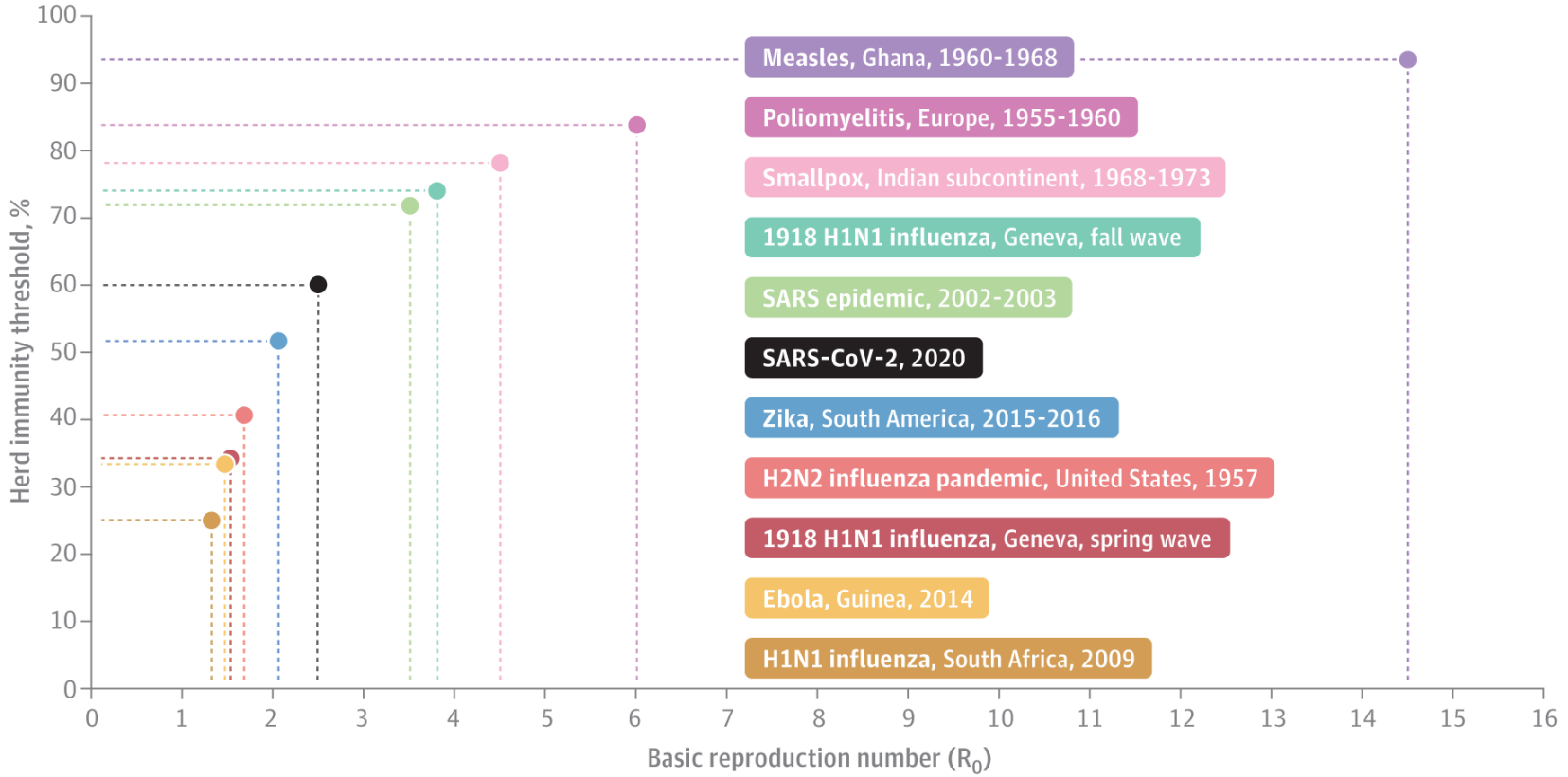


Figure 77.5. Implications of a basic reproduction number $R_0 = 4$. In each successive time (serial) interval, each individual has effective contact with four other individuals. If the population is initially entirely susceptible **(A)**, incidence increases exponentially, fourfold each generation (until the accumulation of immune persons slows the process). If 75% of the population is immune **(B)**, then on average only $S = 25\%$ of each set of four contacts lead to successful transmissions, and the net reproductive number $R_n = R_0 \times S = 1$.

From: **Herd Immunity and Implications for SARS-CoV-2 Control**

JAMA. Published online October 19, 2020. doi:10.1001/jama.2020.20892



Herd Immunity Thresholds by Disease

The locations included are the locations in which the threshold was measured.

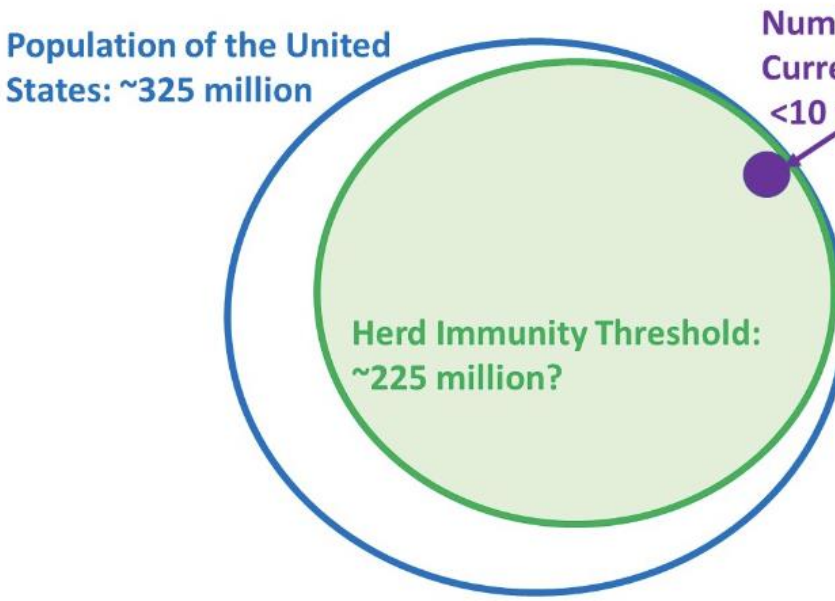
Herd immunity in COVID-19

- For COVID-19 it is estimated that 50 to 70% of the population would have to be infected to reach herd immunity.

- Herd immunity threshold = 1 – 1/R*o*.

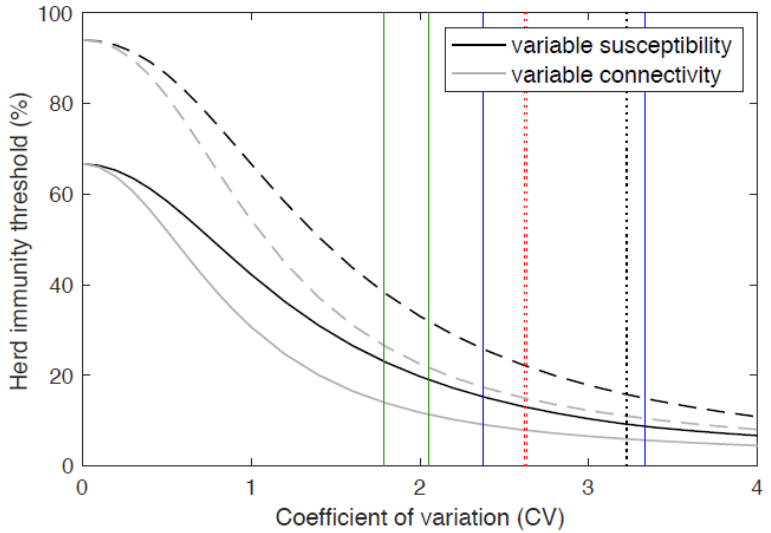
- At R*o* = 2.5, that would be 1 – ½.5 = 0.6 or 60% (R*o* = 2 to 3 so 50 – 67%).

What is the herd immunity threshold in the US?



Herd immunity threshold estimation

- Some argue that this threshold estimate is inflated, suggesting:
  - inhomogeneity in infectivity and susceptibility violate the assumptions of the simple compartment model
  - herd immunity threshold might be closer to 20%



Gomes MGM, et al. https://www.medrxiv.org/content/10.1101/2020.04.27.20081893v2

COVID-19 spreads heterogeneously

- Herd immunity theory is built on the assumption that all individuals mix randomly, that individuals are fully susceptible or fully immune and that the population is uniform.
- Strong empirical evidence suggests that COVID-19 is highly affected by heterogeneities (cluster outbreak, k-dispersion, etc.)
- At least four types of individual heterogeneities:
  - Age
  - Susceptibility
  - Social activity
  - Infectivity

CORONAVIRUS

A mathematical model reveals the influence of population heterogeneity on herd immunity to SARS-CoV-2

Tom Britton[1]*, Frank Ball[2], Pieter Trapman[1]

Britton *et al.*, *Science* **369**, 846–849 (2020) 14 August 2020

If Ro = 2.5 in an age-structured community with mixing rates fitted to social activity, then the disease-induced herd immunity can be ~ 43%

Table 1. Disease-induced herd immunity level h_D and classical herd immunity level h_C for different population structures. Numbers correspond to percentages.

Population structure	R_0 = 2.0		R_0 = 2.5		R_0 = 3.0	
	h_D	h_C	h_D	h_C	h_D	h_C
Homogeneous	50.0	50.0	60.0	60.0	66.7	66.7
Age structure	46.0	50.0	55.8	60.0	62.5	66.7
Activity structure	37.7	50.0	46.3	60.0	52.5	66.7
Age and activity structure	34.6	50.0	43.0	60.0	49.1	66.7

Table 2. Final outcome fractions infected in different groups. These values assume that R_0 = 2.5 and preventive measures are put in place such that $\alpha = \alpha_*$ just barely reaching herd immunity for R_0 = 2.5. Population structure includes both age and activity. Numbers correspond to percentages.

Age group	Low activity	Average activity	High activity
0–5 years	17.6	32.1	53.9
6–12 years	25.8	44.9	69.7
13–19 years	31.4	52.9	77.8
20–39 years	27.4	47.2	72.1
40–59 years	22.8	40.3	64.4
≥60 years	14.6	27.0	46.7

Sweden's approach to COVID-19

- Sweden refused to lock down the country.
- The architect of the strategy was state epidemiologist Anders Tegnell.
- Sweden has chosen to rely on citizens' sense of public duty and trust that they'll practice social distancing even without a host of rules meant to keep people apart.

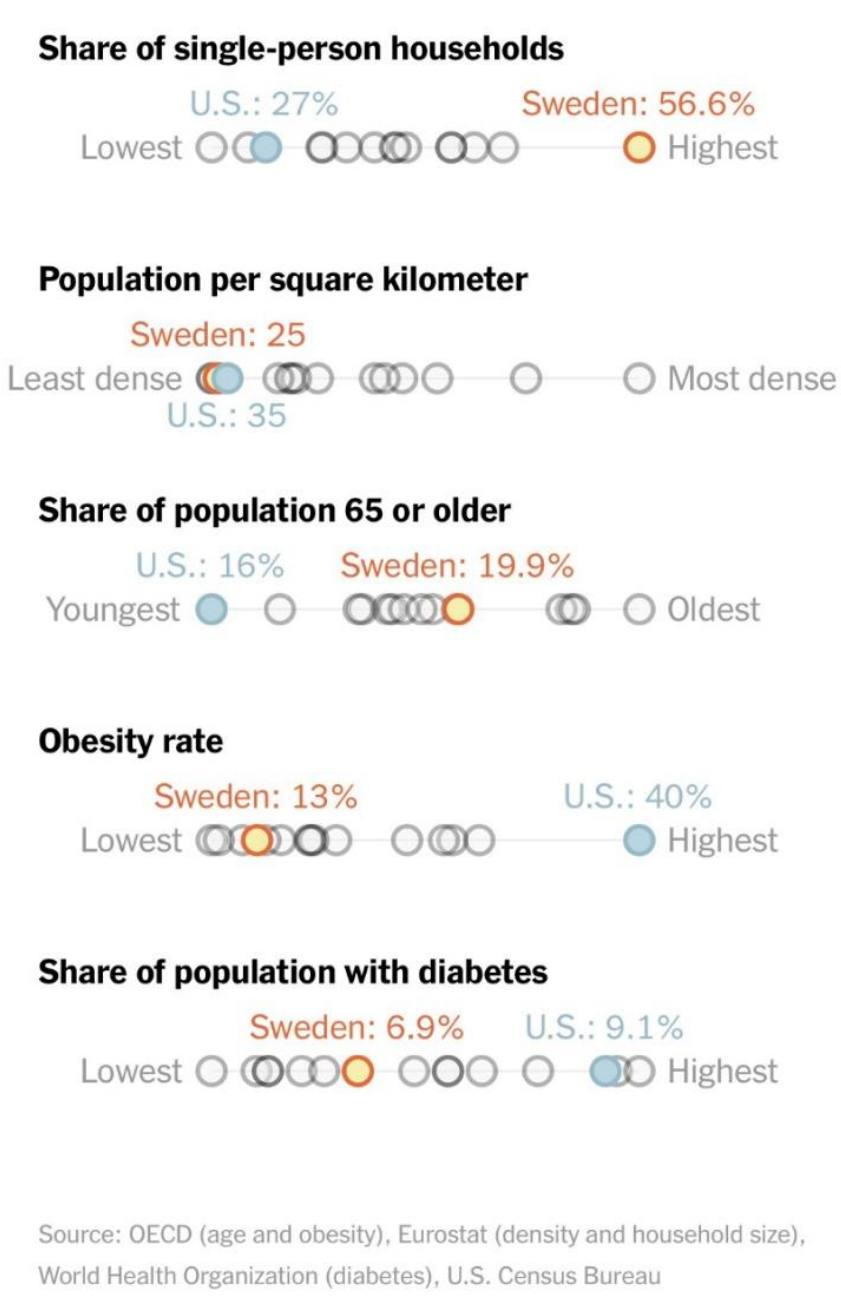
Sweden's approach to COVID-19

- Swedish authorities have not officially declared a goal of reaching herd immunity but "augmenting immunity" is no doubt part of the government's strategy or at least a consequence of keeping schools, restaurants and most business open.
- Mathematical models suggested that if ~ 40% of the population in Stockholm was infected spread of SARS-CoV-2 would stop and this would likely occur by mid-June.
- This did not happen.

Sweden's strategy is unlikely to work in the US because:

- We have less people in single person households
- Higher obesity and diabetes rates
- More individualistic approach
- Less trust in government and others

However as the US reopened this was the path we end up taking anyway.



Challenges in creating herd immunity to SARS-CoV-2 infection by mass vaccination

Roy M Anderson • Carolin Vegvari • James Truscott • Benjamin S Collyer

Published: November 04, 2020 • DOI: https://doi.org/10.1016/S0140-6736(20)32318-7 • Check for updates

- Modeling looking at the interplay between vaccine efficacy, duration of protection and proportion vaccinated in ability to achieve herd immunity.
- A large proportion of the population will need to be vaccinated to achieve herd immunity.

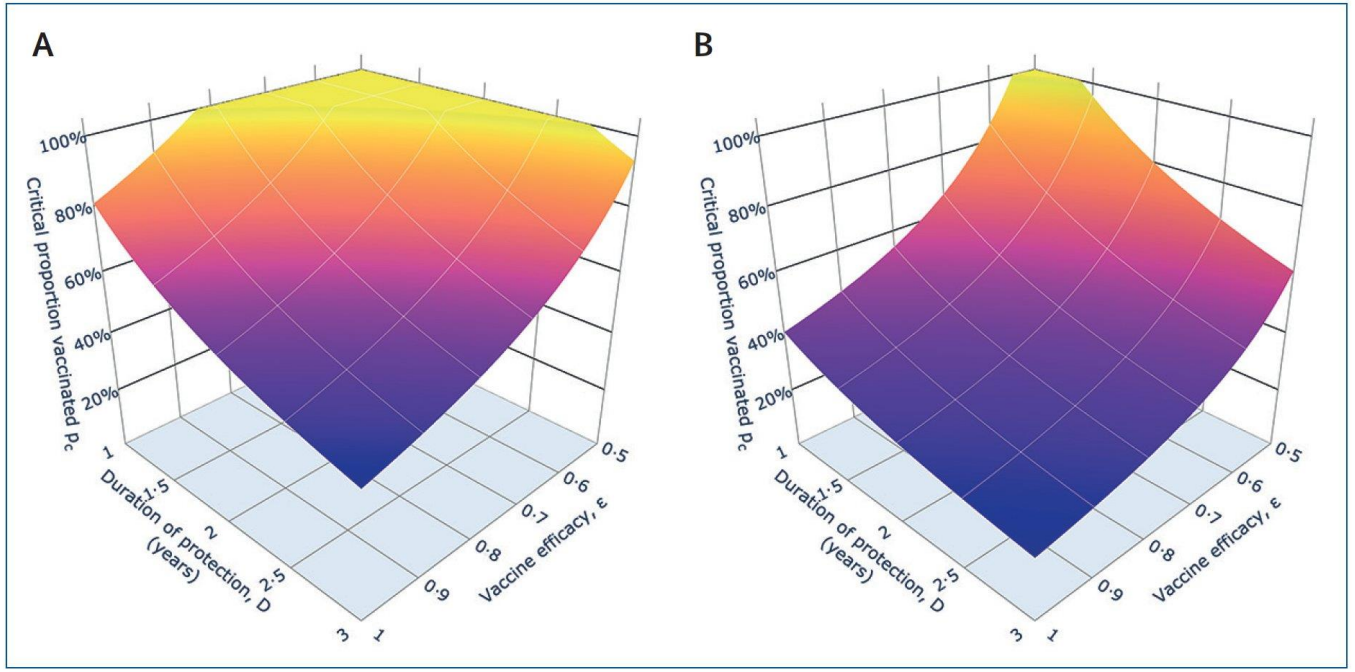
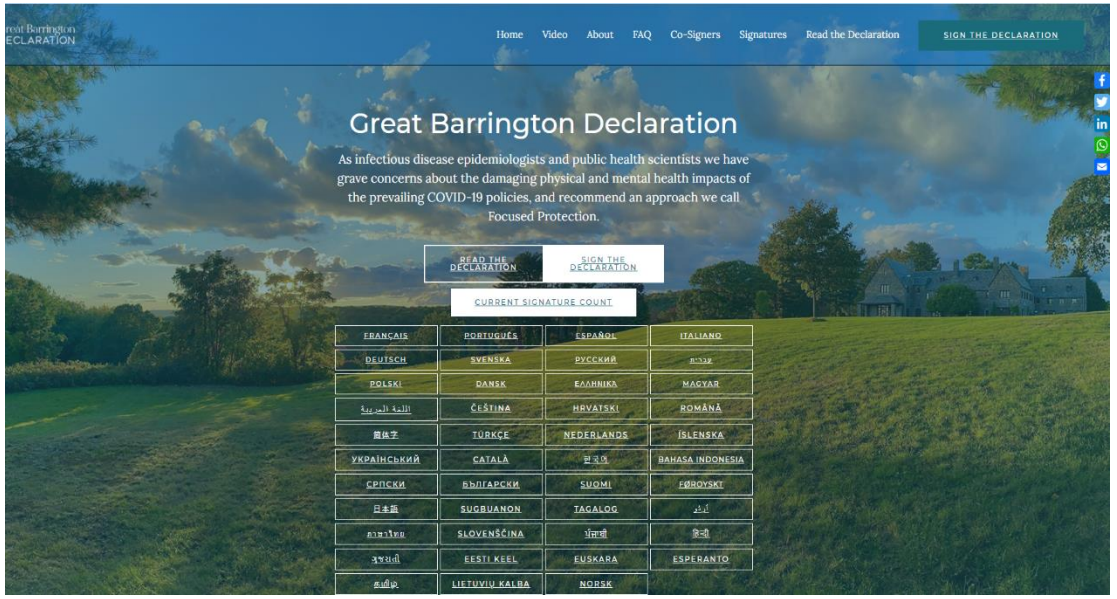


Figure: Impact of vaccine efficacy and duration of protection on what percentage of the population must be vaccinated in the first year (A) and when the system approaches equilibrium in 2–3 years under continued vaccination (B)

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32318-7/fulltext

The Great Barrington Declaration

- ✓The “Great Barrington Declaration” is released pushing for a “herd immunity” approach to the pandemic.
  - ✓*“The most compassionate approach that balances the risks and benefits … is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk”*



JOHN SNOW MEMORANDUM

MEMO ABOUT ENDORSEMENTS SIGNATORIES SIGN TRANSLATIONS

MORE THAN 6,900 scientists, researchers & healthcare professionals have now signed the John Snow Memorandum.
We vet every signature, so it may take 72 hours for your name to appear.
Thanks for your support, and please continue to share with your colleagues.

THE JOHN SNOW MEMORANDUM

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has infected more than 35 million people globally, with more than 1 million deaths recorded by the World Health Organization as of Oct 12, 2020. As a second wave of COVID-19 affects Europe, and with winter approaching, we need clear communication about the risks posed by COVID-19 and effective strategies to combat them. Here, we share our view of the current evidence-based consensus on COVID-19.

SARS-CoV-2 spreads through contact (via larger droplets and aerosols), and longer-range transmission via aerosols, especially in conditions where ventilation is poor. Its high infectivity[1] combined with the susceptibility of unexposed populations to a new virus, creates conditions for rapid community spread. The infection fatality rate of COVID-19 is several-fold higher than that of seasonal influenza[2] and infection can lead to persisting illness, including in young, previously healthy people (ie, long COVID[3]). It is unclear how long protective immunity lasts[4] and, like other seasonal coronaviruses, SARS-CoV-2 is capable of re-infecting people who have already had the disease, but the frequency of re-infection is unknown[5]. Transmission of the virus can be mitigated through physical distancing, use of face coverings, hand and respiratory hygiene, and by avoiding crowds and poorly ventilated spaces. Rapid testing, contact tracing, and isolation are also critical to controlling transmission. The World Health Organization has been advocating for these measures since early in the pandemic.

https://www.johnsnowmemo.com/

“Herd Immunity” is Not an Answer to a Pandemic

Promoting the concept of “herd immunity” as framed in a recently circulated document as an answer to the COVID-19 pandemic is inappropriate, irresponsible and ill-informed. “Community immunity,” or “herd immunity,” a goal of vaccination campaigns, should never come at the cost of planned exposure to infection of millions of additional people as well as the severe illness and preventable deaths of hundreds of thousands of people. To assert that stepping away from the vigilance needed to control the spread of this novel coronavirus and that abdication of efforts to control a pandemic that has overwhelmed health systems worldwide is a “compassionate approach” is profoundly misleading.

As an association of more than 12,000 frontline infectious diseases scientists, physicians, public health experts, and other health professionals, the Infectious Diseases Society of America and its HIV Medicine Association strongly denounce the “declaration,” released without data or evidence, that states this crisis can be controlled in the absence of critical public health measures.

As specialists committed to protecting individual and public health, we have made policy recommendations to curtail the spread of COVID-19 in keeping with the U.S. Centers for Disease Control and Prevention guidelines and well established public health principles for the control of an infectious respiratory pandemic. These include restricting the size of gatherings, maintaining safe physical distance and wearing masks in any setting where the risk of transmission exists. We recommend minimizing risks of infection by observing strict hygiene and infection control measures that include accurate and accessible testing for the virus, contact tracing and quarantine of those potentially exposed, and isolation of people who have become infected. These recommendations are made to avert preventable infections, illnesses and deaths, minimize the impacts of the pandemic on essential workers, including health care personnel, prevent rising rates of severe illness from overwhelming health care facilities and reduce the spread of disease so that businesses and institutions can safely re-open. We will continue to support those guidelines as long as the spread and impacts of the virus exceed the resources and tools needed to mitigate its threats.

Thomas File, M.D., FIDSA – President, Infectious Diseases Society of America

Judith Feinberg, M.D. – Chair, HIV Medicine Association

https://www.youtube.com/watch?v=CJ3-2j2rmAc

School of Pharmacy
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Vaccines for COVID-19

Mary S. Hayney, PharmD, MPH, FCCP, BCPS

Professor of Pharmacy

University of Wisconsin School of Pharmacy

Disclosures:

- Consultant for GSK Vaccines and Seqirus and has received research support from Dynavax, Takeda Pharmaceuticals and Sanofi.

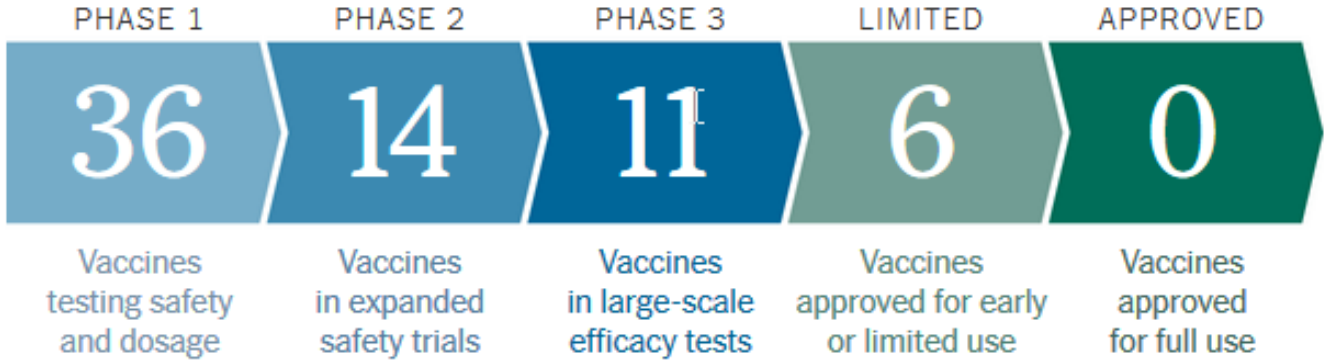
The New York Times

The Road to a Coronavirus Vaccine | Vaccine Tracker | When Can I Get One? | After the First Vaccine | Understanding Long-Term Safety

WORLD | COUNTRIES | U.S.A. | STATES | COLLEGES

Coronavirus Vaccine Tracker

By Jonathan Corum, Sui-Lee Wee and Carl Zimmer Updated November 6, 2020



November 6, 2020

Vaccine Update: Phase III clinical trials in the U.S.

- AZD1222 vaccine (AstraZeneca) announced removal of FDA hold 10/23, resuming Phase III trials
- Ad26.COV2.S vaccine (Janssen) announced lifting of safety pause 10/23, resuming Phase III trials
- BNT162b2 vaccine (Pfizer/BioNtech)
  - **42,133** participants enrolled as of 10/26/2020
  - 35,771 participants have received their second vaccination
  - 30% of U.S. participants enrolled have "diverse backgrounds"
- mRNA-1273 vaccine (Moderna): ***Enrollment Complete***
  - **30,000** participants enrolled as of 10/22/2020
  - 25,654 participants have received their second vaccination

Sources: https://www.modernatx.com/cove-study; https://www.pfizer.com/science/coronavirus/vaccine, https://connect.trialscope.com/studies/34986a8a-b779-4169-a35c-5d929149d426; https://www.reuters.com/article/us-health-coronavirus-pfizer/pfizer-says-coronavirus-vaccine-study-shows-mostly-mild-to-moderate-side-effects-idUSKBN26631T

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Bell.pdf

COVID-19 vaccines in human clinical trials – United States*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
mRNA-1273	Moderna TX, Inc.	mRNA	III	• 2 doses (0, 28d) • IM administration • 18-55, 56+ years	NCT04470427	Enrollment complete
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	• 2 doses (0, 21d) • IM administration • 18-85 years	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	• 2 doses (0, 28d) • IM administration • ≥18 years	NCT04516746	✓
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	III	• 1 dose • IM administration • 18-55, 65+	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	• Single or 2 doses • IM administration • 18-49, 50+	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II	• 2 doses (0, 21d) • IM administration • 18-84	NCT04368988	Enrollment complete
V591	Merck	Viral Vector	I/II	• 2 doses (1, 57d) • IM administration • 18-55	NCT04498247	✓

*As of October 27, 2020
**Currently on hold in US
Sources: https://milkeninstitute.org/covid-19-tracker; https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines; https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ ; https://clinicaltrials.gov/; https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Bell.pdf

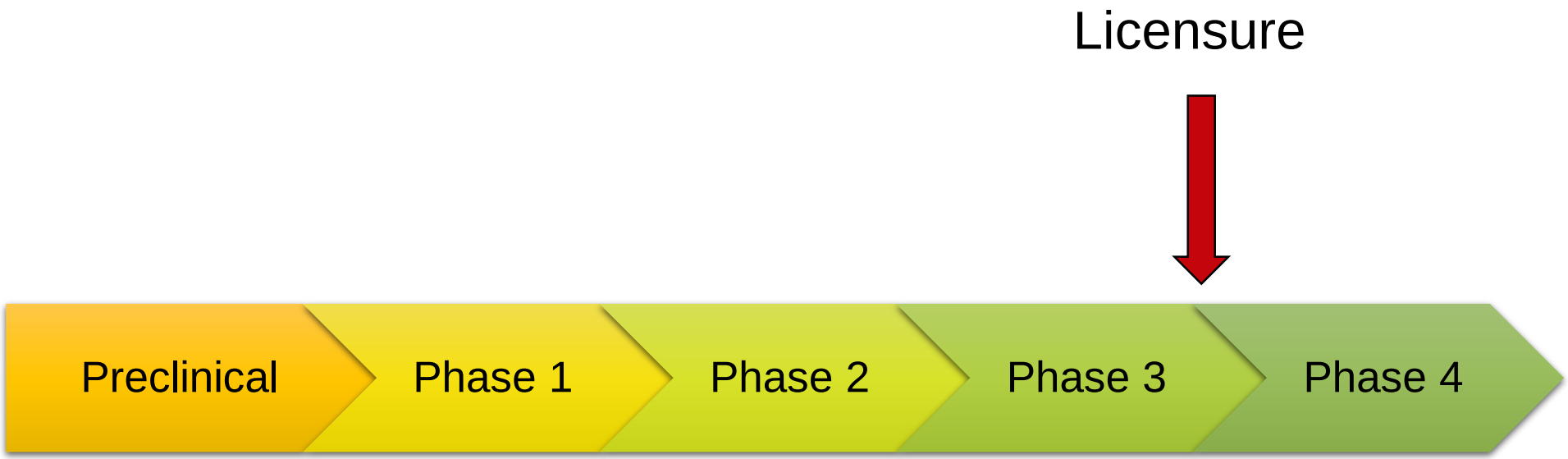
COVID-19 vaccines in human clinical trials – United States*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
AV-COVID-19	Aivita	AuDendritic cell	I/II	• 1 dose • 18+	NCT04386252	Not yet recruiting
VXA-CoV2-1	Vaxart	Viral vector (NR)	I	• 2 doses (1, 29d) • Oral tablet • 18-54	NCT04563702	✓
INO-4800	Inovio Pharmaceuticals, Inc.	DNA plasmid	I	• 2 doses (0, 4w) • SC administration/ electroporation • ≥18 years	NCT04336410	Active, not recruiting

*As of October 27, 2020
Sources: https://milkeninstitute.org/covid-19-tracker; https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines; https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ ; https://clinicaltrials.gov/; https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Bell.pdf

Vaccine Development Licensure Process



Operation Warp Speed

- Overseen by the Dept Health and Human Services and Dept of Defense
    - Diagnostics, therapeutics and vaccines
- Goal to produce 300 million doses of COVID vaccine with first doses by January 2021
- Done with investment and coordination
- Many partners—public and private
- Protocols are overseen by federal government
- No steps eliminated—steps proceed simultaneously
    - Manufacturing and filling before completion of phase 3 trials and licensure
    - Financial risk but not product risk

Transparency

- Protocols for Phase 3 trials have been released
- Nine biopharmaceutical companies, including those who are furthest along in their vaccine testing programs, signed an unusual pledge to uphold "high ethical standards and sound scientific principles," suggesting they won't seek premature government approval for Covid-19 vaccines
- Emergency Use Authorization
    - Relatively new strategy used for several diagnostic tests, PPE, devices, and medications
    - Hydroxychloroquine (EUA withdrawn) and convalescent plasma
    - Would or should it be used for a vaccine???

Vaccine efficacy

- FDA threshold 50% with confidence interval around it so VE could be as low as 30%
- Collecting cases with interim analyses planned after
    - 30+
    - 60+
    - 90+
    - 120+
    - 160+

Emergency Use Authorization (EUA)

Food Drug & Cosmetic Act, 21 USC 360bbb-3: access to unapproved drug, unlicensed vaccine, or uncleared device.

With each EUA decision, FDA weighs known and potential benefits of product against known and potential risks.

- EUAs helped speed access to COVID-19 diagnostic tests, N95 respirators, and remdesivir.
- COVID-19 vaccines: FDA prefers phase-3 studies be completed. EUA sooner could impair efficacy + safety determination.

How Can There Be Enough Information to Grant an EUA But Not License a Vaccine? Examples:

- Results are positive, but sponsor has not yet manufactured three lots that consistently meet quality checks.
- Results are positive, but FDA staff have not finished reviewing hundreds of thousands of pages of primary data.

Is EUA Status a Low-Quality or Substandard Approval? No, when supported by sufficient objective evidence.

If COVID-19 Vaccine Released via EUA, How Would Clinicians Handle It Differently?

Healthcare providers (HCPs) and potential patients must be informed:

- that HHS Secretary authorized EUA.
- of extent benefits and risks of vaccine are unknown
- of option to accept or refuse administration,
- of known and potential benefits and risks of vaccine,
- of alternatives to product and their benefits and risks.
- of consequences of refusing administration.

These facts will appear in succinct **fact sheets** that must be given to each potential recipient.

No obligation for vaccinators to collect signatures attesting that recipient understands information provided.

HHS Secretary may establish conditions related to distribution.

www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

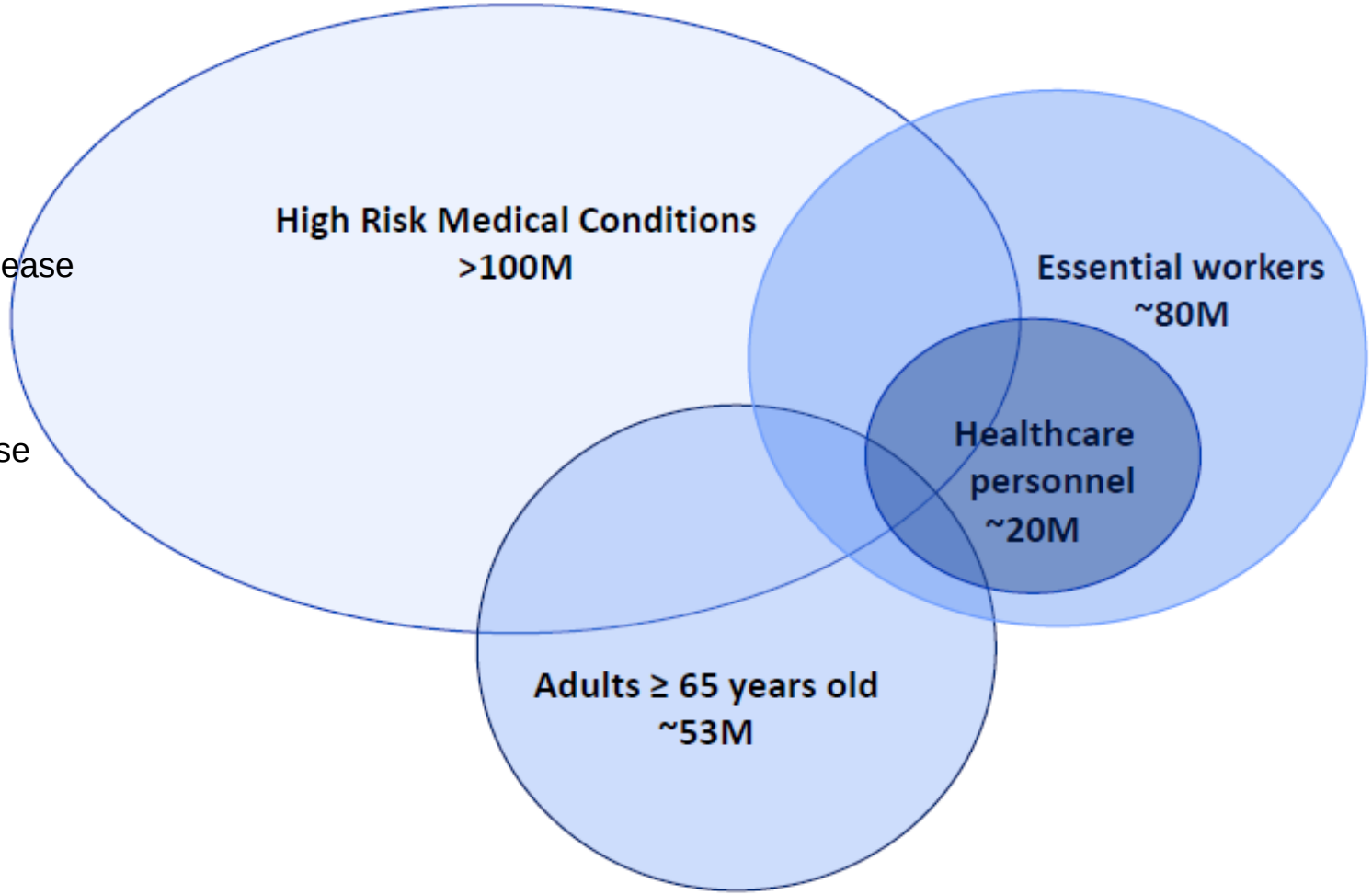
This slide is courtesy of John D. Grabenstein, RPh, PhD

COVID-19 vaccine plan

- ACIP is developing a recommendation for vaccine priority
- Maximize vaccine impact by minimizing morbidity and mortality, social and economic disruption and ensuring equity
- Preliminary plan
    - Phase 1a. Healthcare workers
    - Phase 1b. Essential workers, high risk medical conditions and age ≥65 years
- Broad network of vaccine providers, including pharmacies, clinics, public health clinics, FQHC
- Assure vaccine storage requirements

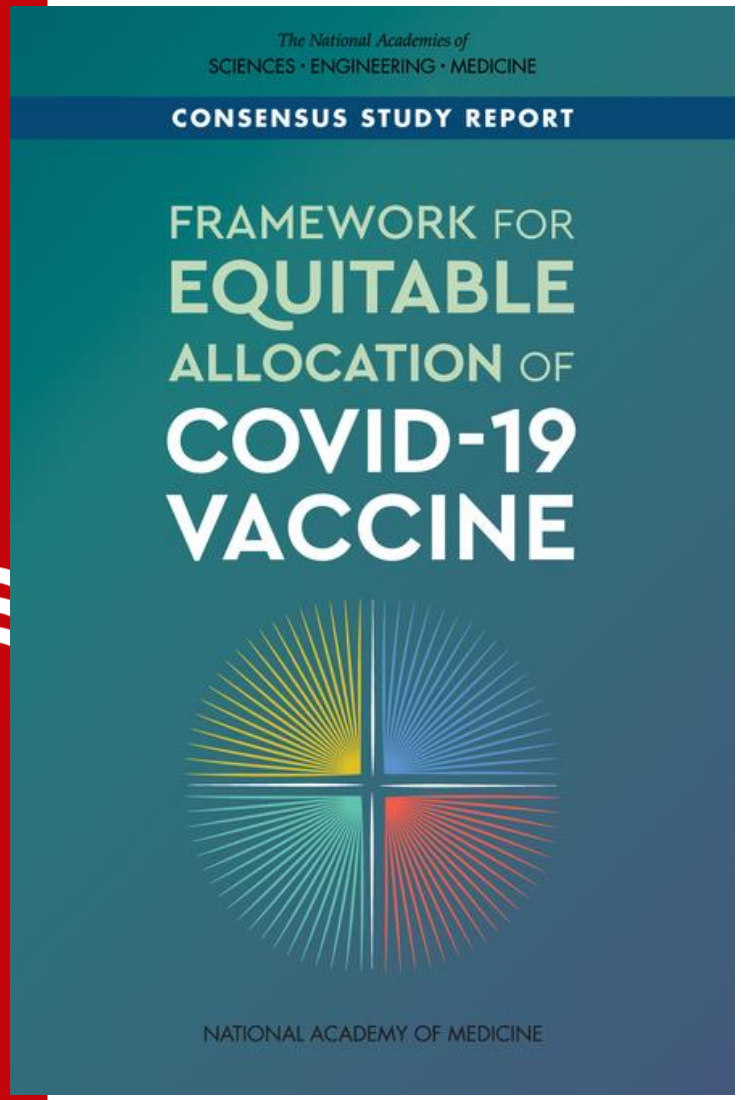
Phase 1

- Cancer
- Chronic kidney disease
- COPD
- Heart conditions
- Immunocompromise
- Obesity (BMI>30)
- Sickle cell disease
- Smoking
- Type 2 diabetes



https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html

National Academies of Sciences, Engineering, & Medicine (NASEM) releases final consensus report *Framework for Equitable Allocation of COVID-19 Vaccine*



Ethical principles: maximum benefit, equal concern, mitigation of health inequity

Risk-based criteria to set priorities to allocate vaccine.

- risk of acquiring infection,
- negative societal impact,
- severe morbidity and mortality,
- and transmitting infection to others.

Proposed phases of vaccine distribution

Phase 1a, "Jumpstart": High-risk health workers who risk exposure to bodily fluids or aerosols, first responders

Phase 1b: People with comorbid and underlying conditions at significantly higher risk; plus older adults living in congregate or overcrowded settings.

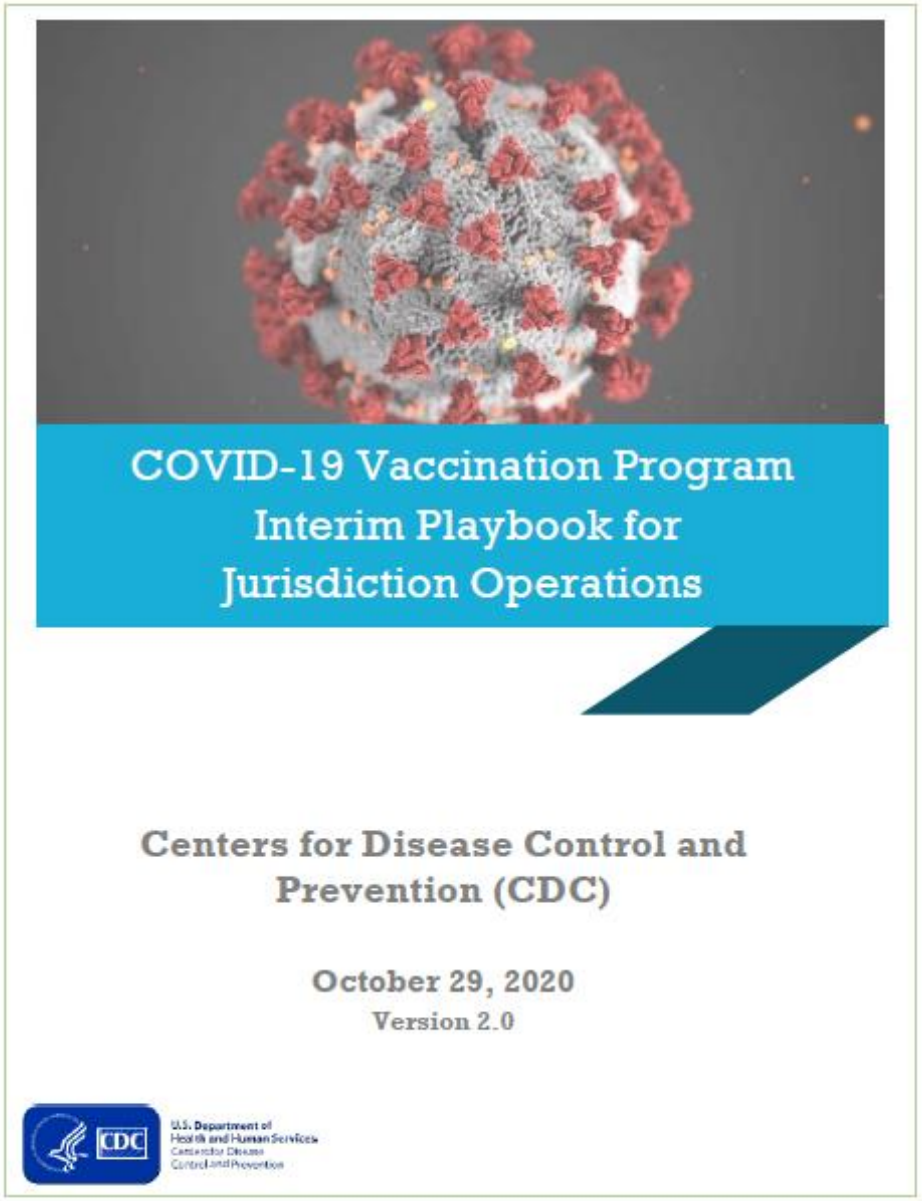
Phase 2: K-12 teachers and staff, childcare; critical workers in high-risk settings; people with comorbidities at moderately higher risk; residents and staff in homeless shelters, group homes, jails; all other older adults

Phase 3: Young adults, children, workers in roles important to functioning of society

Phase 4: Everyone residing in USA not previously mentioned

www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus. 2020 Oct 2

This slide is courtesy of John D. Grabenstein, RPh, PhD



The Playbook contains information for states, territories, and local public health and their partners to plan for the distribution of a COVID-19 vaccine. It covers many areas of vaccination program planning to ensure a comprehensive plan can be developed and implemented.

https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

COVAX—World Health Organization

- Pandemic
- Governments, global health organizations, manufacturers, scientists, private sector, civil society and philanthropy to provide innovative and equitable access to COVID-19 diagnostics, treatments and vaccines.
- The COVAX focuses on equitable access to vaccines
- About 2/3 of the world is involved

https://www.gavi.org/vaccineswork/covax-explained

Questions

- So many
- Timing of completion of Phase 3 trials
- Appropriate and transparent data sharing
  - FDA uses advisory panels
  - ACIP will make recommendations for use
- Public acceptance
- Research should continue after EUA or licensure

Bauchner, JAMA Oct 6, 2020

Resources

- Callaway. The race for coronavirus vaccines. Nature 2020; 580: 576-7.
- Centers for Disease Control and Prevention. COVID-19 vaccination program interim playbook for jurisdiction operations. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
- COVAX explained https://www.gavi.org/vaccineswork/covax-explained

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

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team

Disclaimer and Disclosures

- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of CDC
- No Disclosures.

CDC vaccine safety monitoring for COVID-19

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)
- Clinical Immunization Safety Assessment (CISA) Project
- V-safe text monitoring active surveillance

Vaccine Adverse Event Reporting System (VAERS)

VAERS

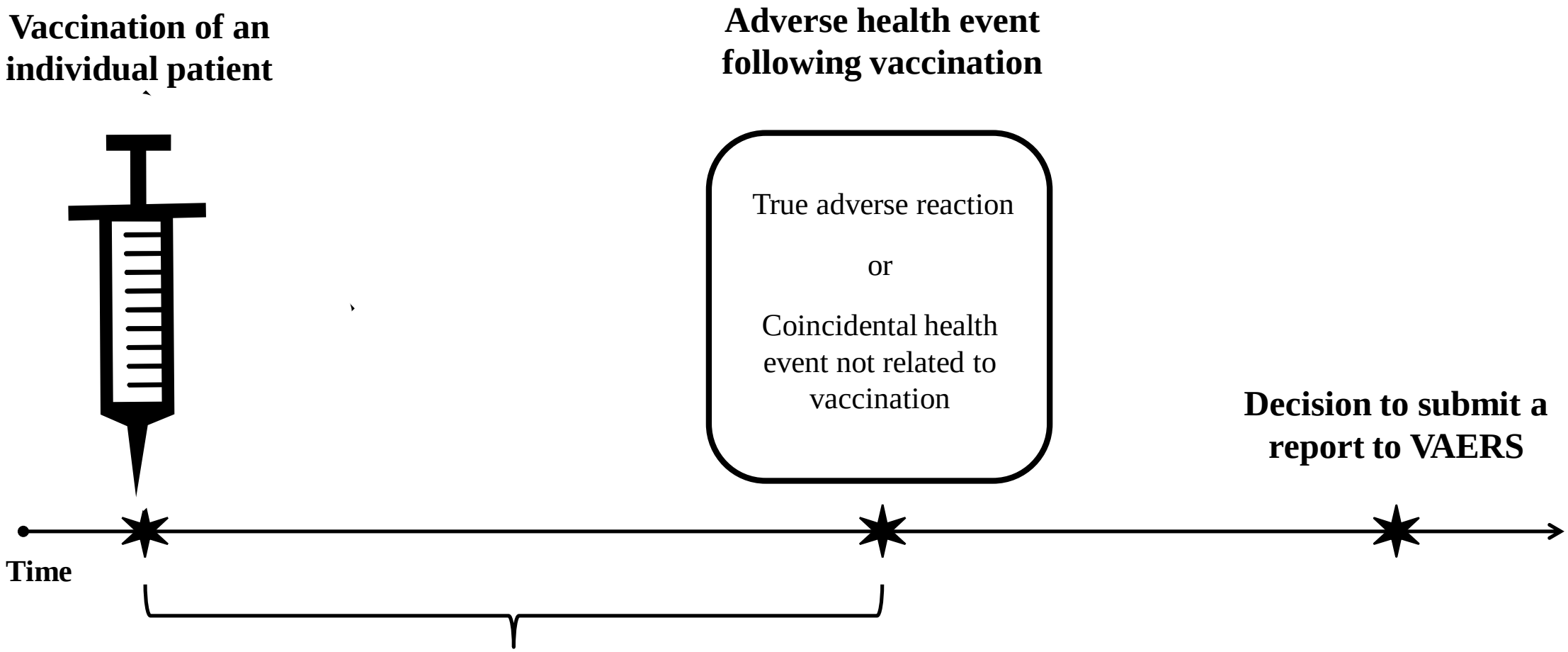
Vaccine Adverse Event Reporting System

Co-managed by
CDC and FDA

http://vaers.hhs.gov

VAERS is the nation's early warning system for vaccine safety

Example of a spontaneous adverse event report



Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

- VAERS accepts all reports from all reporters without making judgments on causality or clinical seriousness of the event
- VAERS is a signal detection or hypothesis generating system

VAERS covers the entire U.S. population

- **320 million U.S. residents** as a covered population for safety monitoring
- all ages, races, states/jurisdictions, healthy people, those with co-morbidities, etc.

- **40-50 thousand total U.S. reports** received each year

VAERS

Approaches to analyzing VAERS data

- Traditional methods
  - Clinical review of individual reports
  - Aggregate report review (automated data), e.g., case counts, frequencies of adverse event coding terms, reporting rates, reporting trends over time
- Statistical data mining methods
  - Detects disproportional reporting of specific vaccine-adverse event combinations in VAERS database

VAERS

Healthcare providers' (HCP) role in VAERS reporting

- HCPs have been CDC's longstanding partners for reporting vaccine adverse events (AEs) to VAERS
  - VAERS depends on HCPs to identify and report suspected AEs, even if they aren't sure if a vaccine caused an AE
- HIPAA permits reporting of vaccine AEs and medical documentation (e.g., medical records) to VAERS for public health purposes
- Specific guidance on VAERS reporting for vaccines authorized for use under Emergency Use Authorization (EUA) will be forthcoming

VAERS

How to report an adverse event to VAERS

- Go to vaers.hhs.gov
- Submit a report online

For help:

call
1-800-822-7967

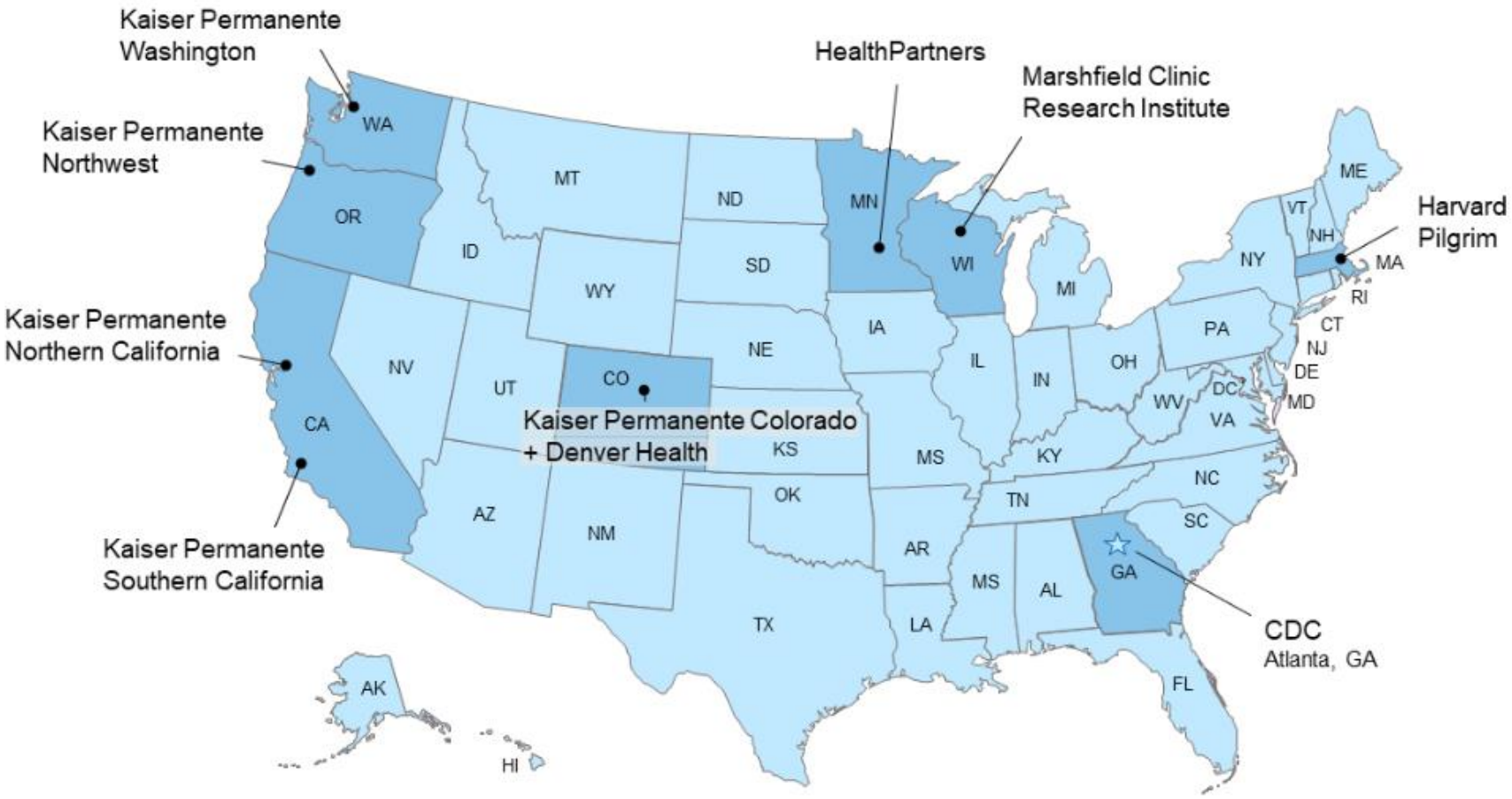
email
info@VAERS.org

video instructions
https://youtu.be/sbCWhcQADFE

Vaccine Safety Datalink (VSD): Active surveillance and research

VSD

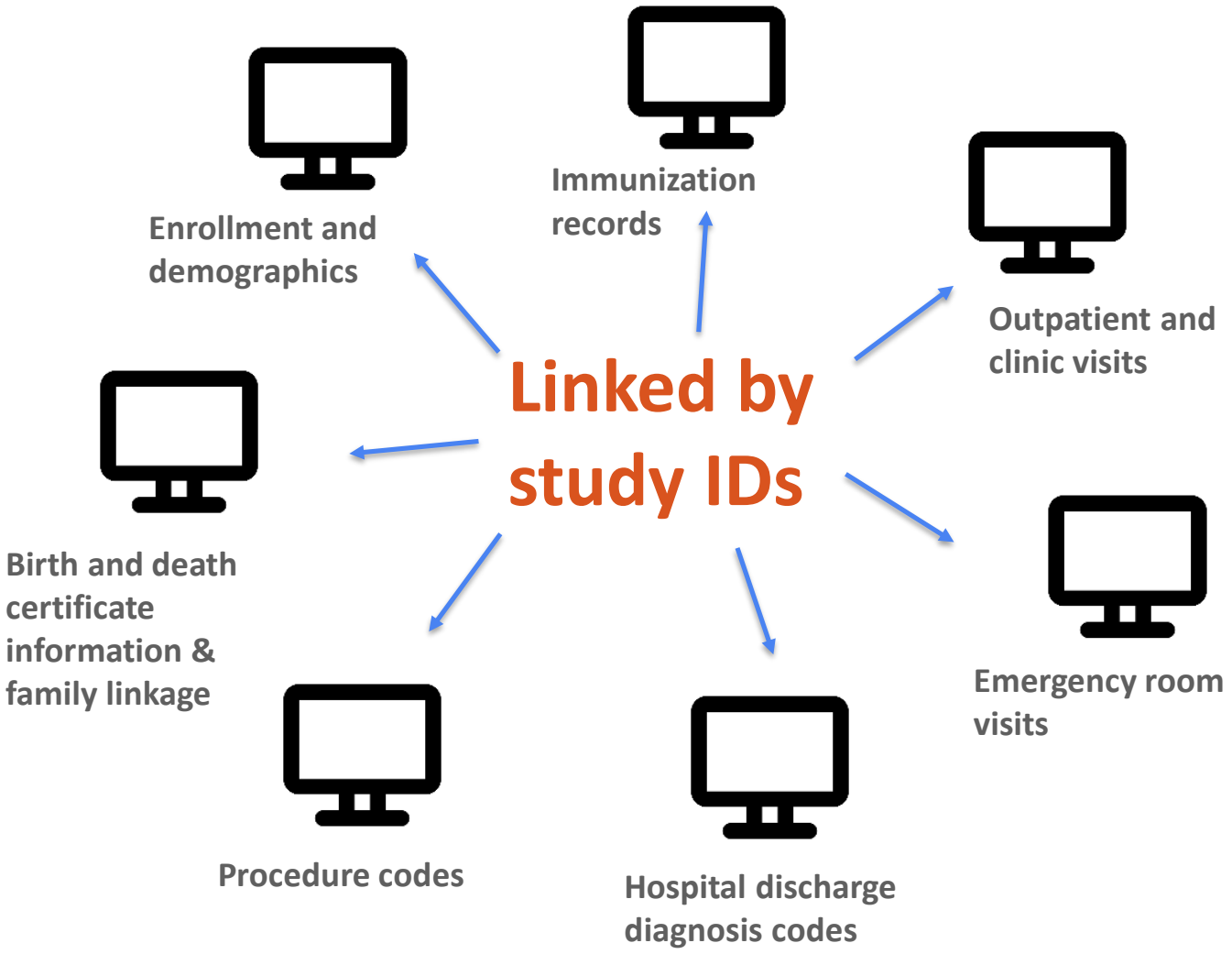
Vaccine Safety Datalink

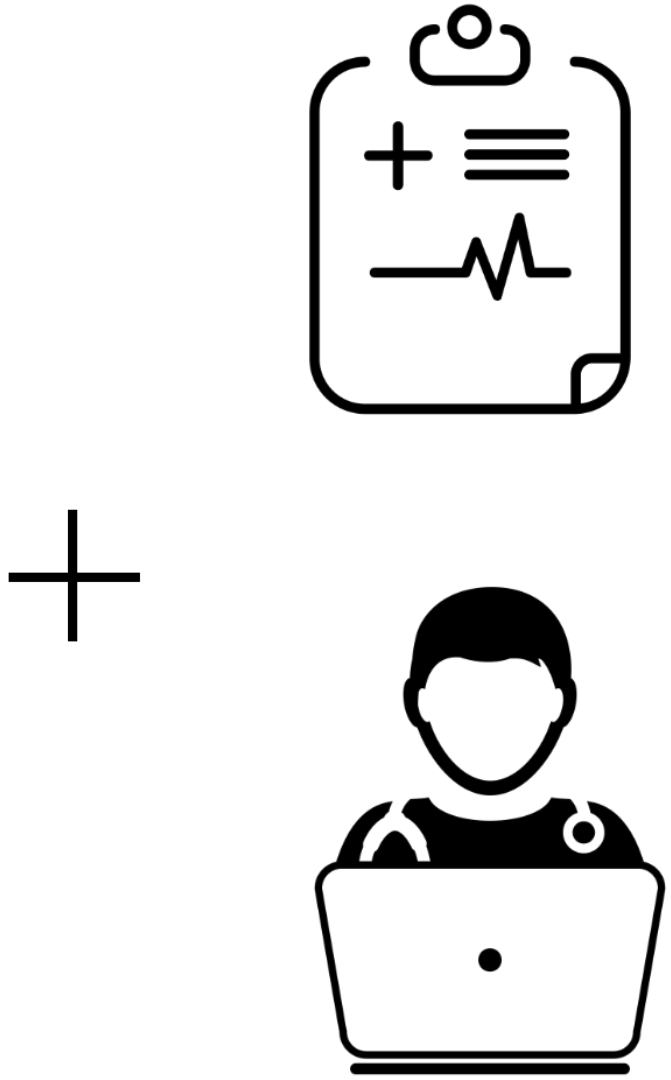


9 participating integrated healthcare organizations

Data on over 12 million persons per year

VSD electronic files + chart review





Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

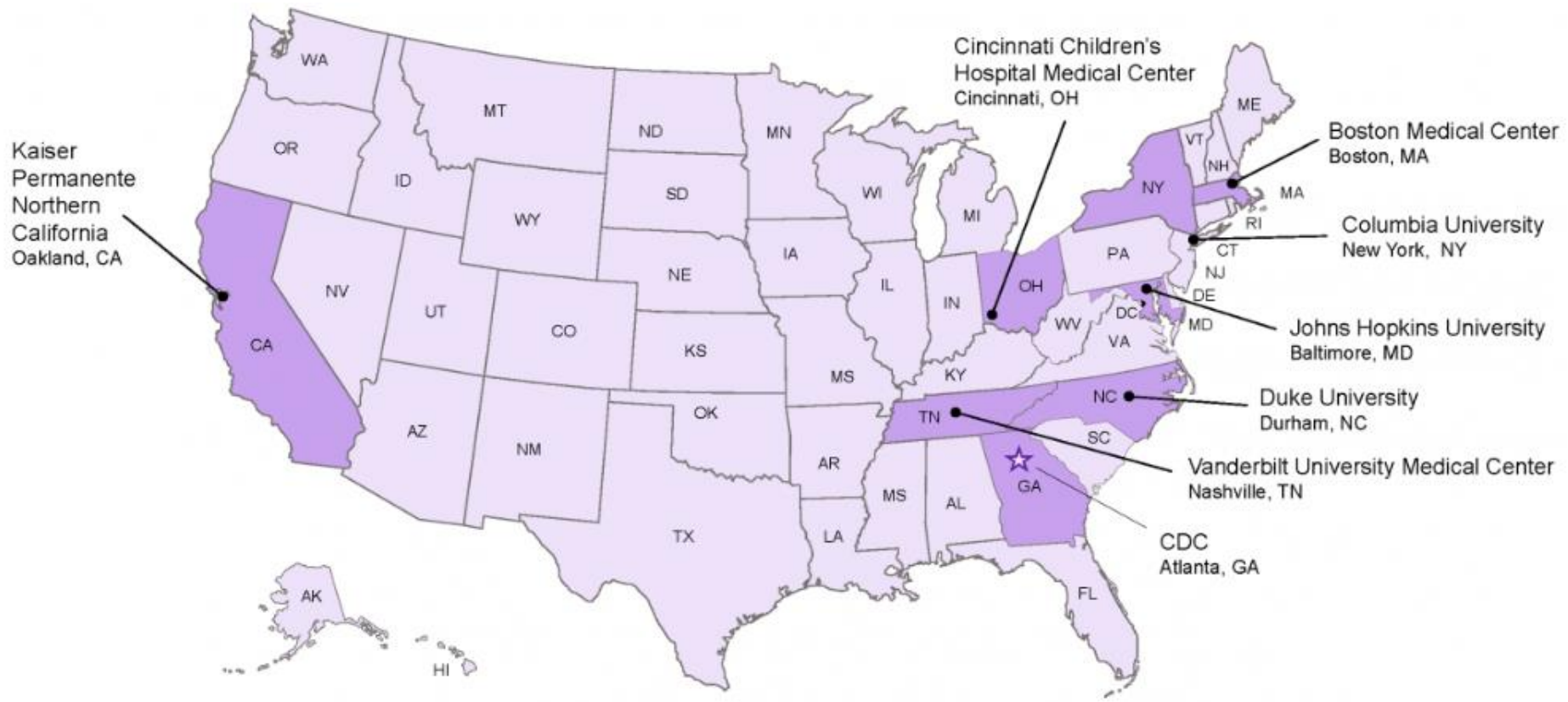
VSD planned monitoring for COVID-19 vaccine safety

- Near real-time sequential monitoring (Rapid Cycle Analysis [RCA])
- Monitoring for vaccine-mediated enhanced disease (VMED)
- Studies to evaluate COVID-19 vaccine safety during pregnancy, including fetal death and infant outcomes
- Tree-temporal scan data mining
- Projects to assess:
  - Changes in healthcare utilization during COVID-19 and impact on AE monitoring
  - Utility of smartphone technology to enhance vaccine safety monitoring
  - Multisystem inflammatory syndrome (MIS-C and MIS-A) as vaccine AEs
  - Safety in an expanded underserved VSD population
  - Knowledge, attitudes, beliefs around acceptance/refusal of COVID-19 vaccination

Clinical Immunization Safety Assessment (CISA) Project

CISA

Clinical Immunization Safety Assessment (CISA) Project



7 participating medical research centers with vaccine safety experts

- clinical consult services†
- clinical research

†More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

CISA Project consult service for COVID-19 vaccine safety

- Supports U.S. healthcare providers and health departments on complex clinical vaccine safety questions
- Assists with evaluations of patients with adverse events after COVID-19 vaccine or in making clinical decisions about administering COVID-19 vaccine to a person who may be at increased risk for an adverse event
  - Advice from CDC and the CISA Project is meant to assist in decision-making, rather than provide direct patient management
- Available to U.S. healthcare providers and health departments by contacting CDC-INFO*

*https://www.cdc.gov/cdc-info/index.html


v-safe
after vaccination
health checker

- **V-safe** is a new smart-phone based active surveillance program for COVID-19 vaccine safety
  - Uses text messaging to initiate web-based survey monitoring
  - Conducts electronic health checks on vaccine recipients
    - Daily for first week post-vaccination; weekly thereafter until 6 weeks post-vaccination
    - Additional health checks at 3, 6, and 12 months post-vaccination
  - Includes active telephone follow-up with vaccine recipients reporting an event with health impact during any health check
  - Captures information on pregnancy status and enables follow-up on pregnant women

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

Vaccine recipient

2. Clinically important event(s) reported
   - ✓ Missed work
   - ✓ Unable to do normal daily activities
   - ✓ Received medical care

v-safe after vaccination health checker

Call center

3. A VAERS customer service representative conducts active telephone follow-up on a clinically important event and takes a report if appropriate

CDC asks that:

- Healthcare providers give a one-page **information sheet*** with enrollment instructions to patients at the time of vaccination
- Healthcare providers counsel patients on the importance of enrolling in **v-safe**

*CDC will create an electronic version of the **v-safe** information sheet for printing

Summary

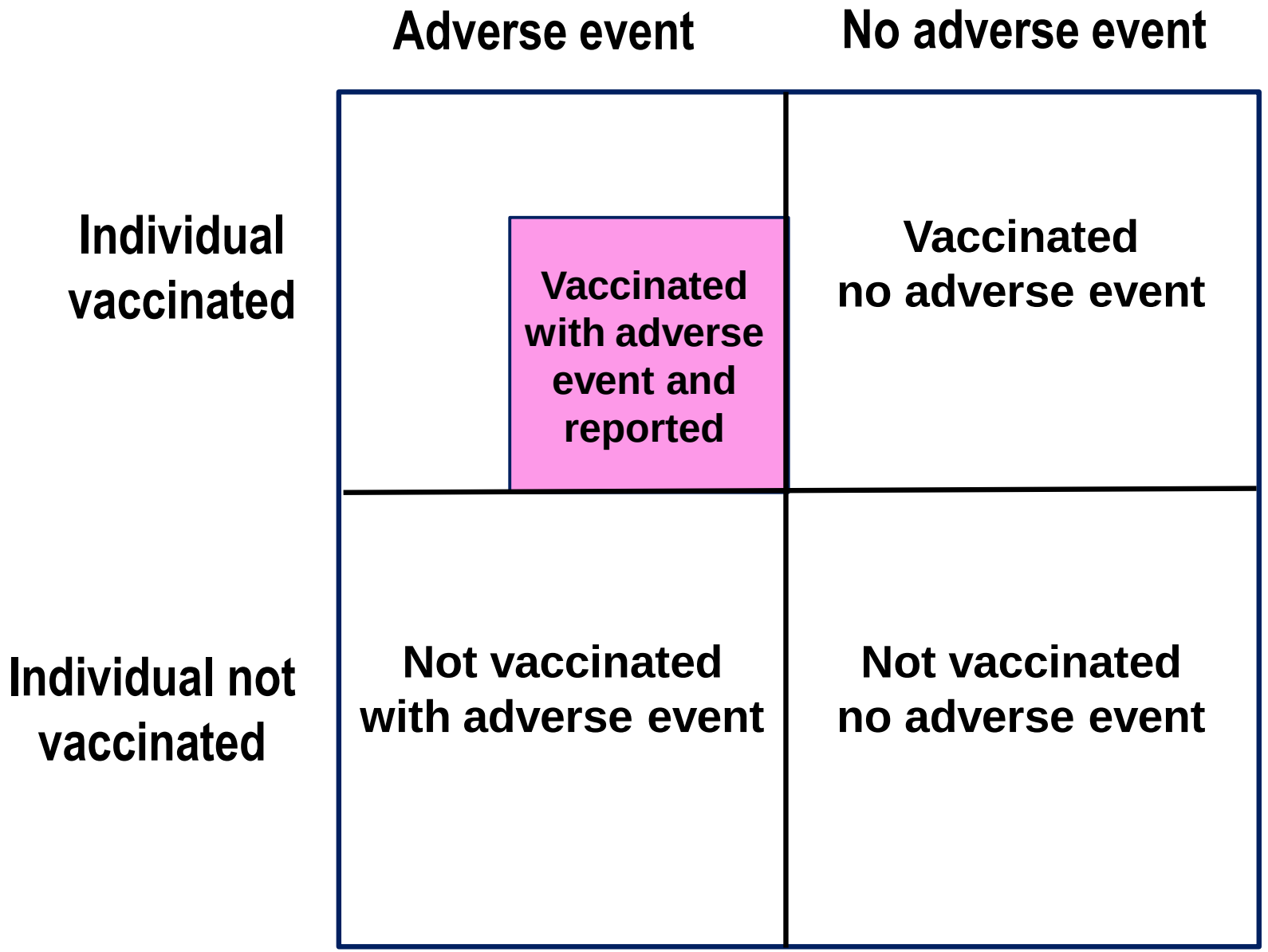
Key takeaways

- The Vaccine Safety Datalink (**VSD**), Clinical Immunization Safety Assessment (**CISA**) Project, and other planed projects are key components of COVID-19 vaccine safety monitoring and adverse event assessment
- **VAERS** is the U.S. frontline vaccine safety monitoring system
  - VAERS traditionally has provided the initial data on the safety profile of new vaccines when they are introduced for use in the population
  - Healthcare providers (HCPs) can play an important role in identifying and reporting potential AEs to VAERS: **HCPs are partners in safety monitoring**
- **V-safe** is a new smart-phone based active surveillance program
  - HCPs can play an important role in helping CDC enroll patients in **v-safe** at the time of vaccination: **HCPs are partners in safety monitoring**

Questions?

Extra slides

What's included in a spontaneous adverse event reporting database?



Preliminary list of VSD pre-specified outcomes for RCA

- Acute disseminated encephalomyelitis (ADEM)
- Acute myocardial infarction (AMI)
- Anaphylaxis
- Acute respiratory distress syndrome (ARDS)
- Convulsions / seizures
- Disseminated intravascular coagulation (DIC)
- Encephalitis / myelitis / encephalomyelitis / meningoencephalitis / meningitis / encephalopathy (not ADEM or TM)
- Guillain-Barré syndrome (GBS)
- Immune thrombocytopenia (ITP)
- Thrombotic thrombocytopenic purpura (TTP)
- Kawasaki disease (KD)
- Multisystem Inflammatory Syndrome (MIS-C and MIS-A)
- Myocarditis / pericarditis
- Narcolepsy / cataplexy
- Stroke – hemorrhagic and ischemic
- Transverse myelitis (TM)
- Venous thromboembolism (VTE)

Q&A and Discussion

Continue the conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID

We want to hear from you! Please complete the post-call survey.

Next CDC/IDSA COVID-19 Clinician Call: Saturday, November 14th.

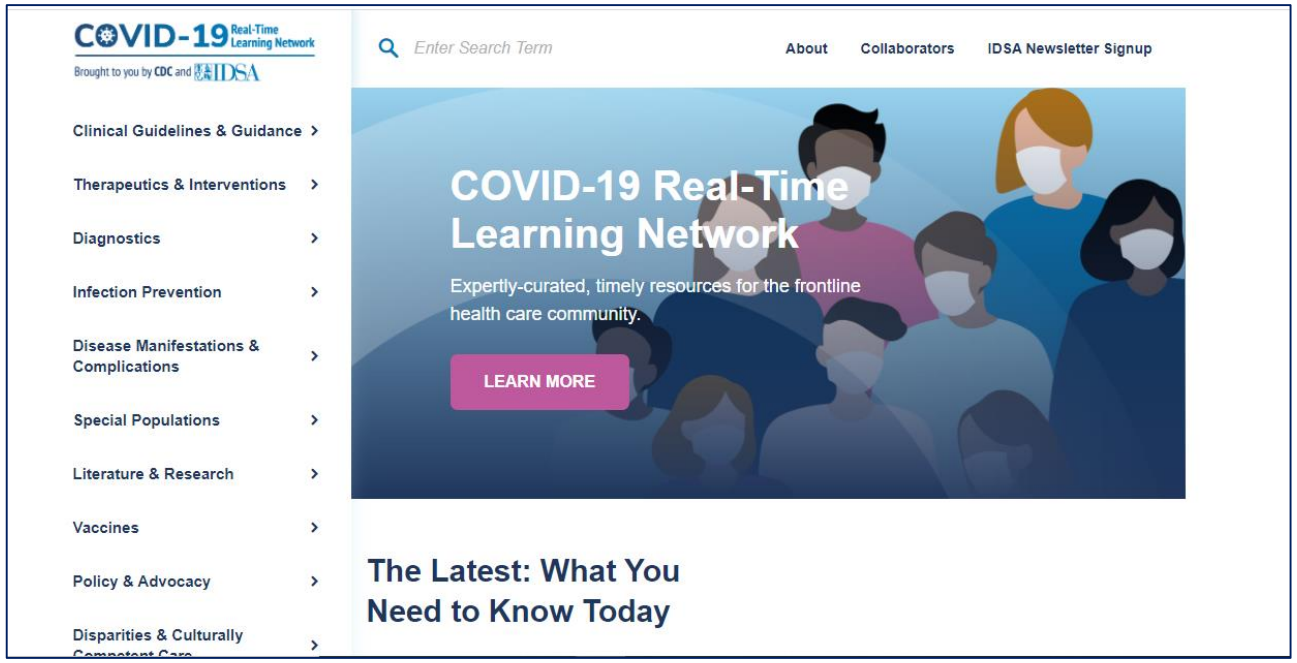
Recordings of this call and past calls are available at www.idsociety.org/podcasts

Contact Us:

Dana Wollins (dwollins@idsociety.org)

Deirdre Lewis (dlewis@idsociety.org)

COVID-19 Real-Time Learning Network



With funding from the Centers for Disease Control and Prevention, IDSA has launched the COVID-19 Real Time Learning Network, an online community that brings together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

Specialty Society Collaborators:

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Emergency Physicians
- American College of Physicians
- American Geriatrics Society
- American Thoracic Society
- Pediatric Infectious Diseases Society
- Society for Critical Care Medicine
- Society for Healthcare Epidemiology of America
- Society of Hospital Medicine
- Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org
@RealTimeCOVID19
#RealTimeCOVID19

CDC-IDSA Partnership: Clinical Management Call Support

Announcing a new service for clinicians:

FOR WHOM?

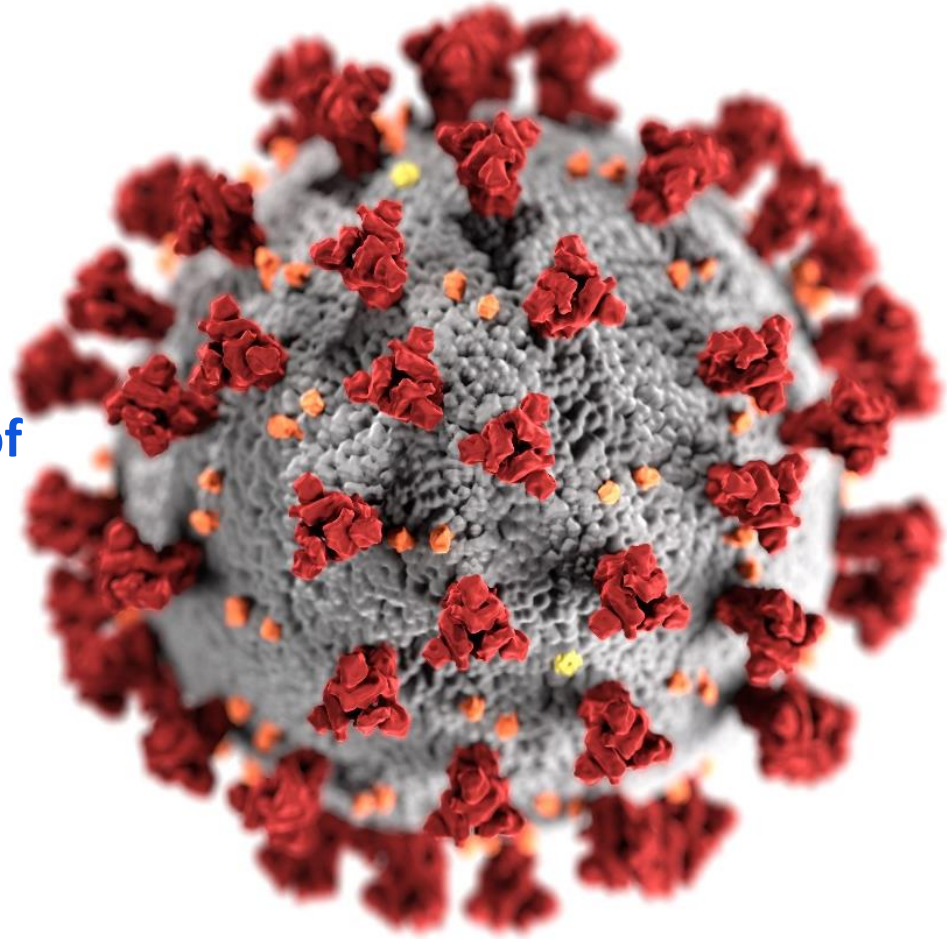
- Clinicians who have questions about the clinical management of COVID-19

WHAT?

- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form



IDSA
Infectious Diseases Society of America

cdc.gov/coronavirus