

## Advisory Committee to the Director (CDC)

May 3, 2022

11:00 AM – 4:00 PM

Closed Captioning:

<https://www.streamtext.net/player?event=4599MeetingoftheAdvisoryCommitteetotheDirectorCDC>

Event ID is: 4599



# Welcome, Roll Call

David Fleming, MD, ACD Chair



# Welcome and Highlighting of Key Issues

Rochelle P. Walensky, MD, MPH, Director

Centers for Disease Control and Prevention, and Administrator, Agency  
for Toxic Substance Disease Registry

# Data and Surveillance Workgroup

Dan Jernigan, MD, MPH

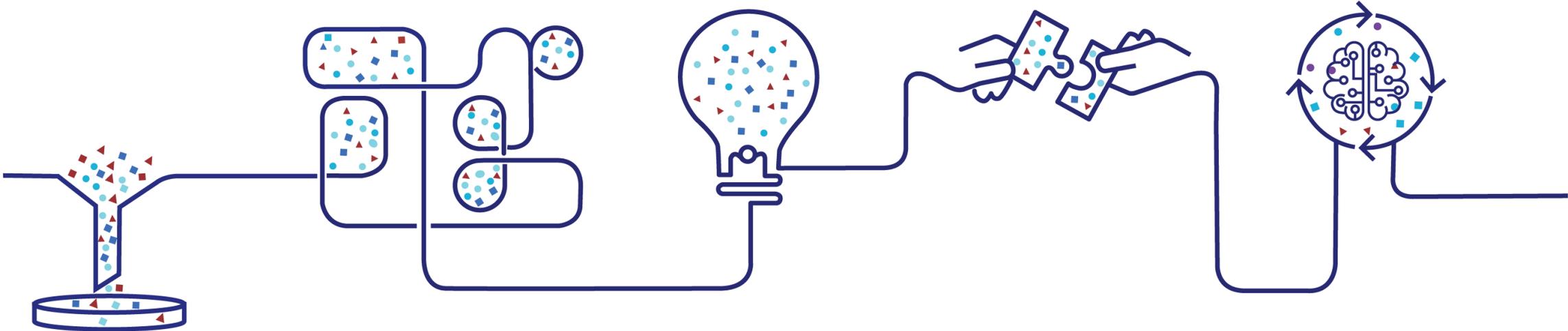
Deputy Director for Public Health Science and Surveillance



# Addressing Modernization Questions: Data and Surveillance Workgroup

**Daniel B. Jernigan, MD, MPH**  
**CDC Deputy Director for Public Health  
Science and Surveillance**

# DMI Priorities



## Build the right foundation

- Decreased burden on reporters
- Free up staff time to focus on prevention and control
- Faster data for detecting emerging threats at all levels of public health

## Accelerate data into action

- Better data integration, visualization
- Robust forecasting / modeling
- Response-ready platform

## Develop a state-of-the-art workforce

- Identify, recruit, and retain experts to generate meaningful public health insights

## Support + extend partnerships

- Better / more timely access to data within and across ecosystem
- Common tools to support STLT partners

## Manage change + governance

- Adaptive, agile approaches
- Collaboration
- Improved acquisition

# We are listening...

## Challenges and Opportunities for Strengthening the US Public Health Infrastructure

Findings from the Scan of the Literature

### VIEWPOINT

#### Modernizing Public Health Data Systems Lessons From the Health Information Technology for Economic and Clinical Health (HITECH) Act

Kushal T. Kadakia, MSc  
Google Health,  
Mountain View,  
California.

Michael D. Howell,  
MD, MPH  
Google Health,  
Mountain View,  
California.

Barriers to timely data collection and exchange hindered health departments throughout COVID-19, from fax machines creating bottlenecks for disease monitoring to inconsistent reporting of race and ethnicity. Modernizing public health data systems has become a bipartisan postpandemic imperative, with President Trump engaging the US Digital Service to improve data exchange and President Biden issuing an Executive Order

more than \$1 billion for the CDC's Data Modernization Initiative (DMI), such overdue resources means, not the ends. Policy makers need more from HITECH—which had 30-fold more funding still encountered roadblocks—to ensure data meet the needs of the public health community in turn, the US population.

#### Lessons From HITECH

Like public health today, health care in 2009 partly relied on paper-based systems des



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### Back to the Future of Public Health

Julie Louise Gerberding MD, MPH

[+] Author affiliations, information, and correspondence details

## JPHMP JOURNAL OF Public Health Management & Practice

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### THE MANAGEMENT MOMENT

#### Modernizing Our Nation's Public Health Information System: Toward an Integrated Approach

Singletary, Vivian JM, MBA; Richards, Chesley L. Jr MD, MPH; Ross, David A. ScD; O'Carroll, Patrick M. MPH; Baker, Edward L. MD, MPH

Outline

Download

Review > BMC Public Health. 2014 Nov 5;14:1144. doi: 10.1186/1471-2458-14-1144.

### A systematic review of barriers to data sharing in public health

Willem G van Panhuis<sup>1</sup>, Prama Paul, Claudia Emerson, John Grefenstette, Richard Wilder, Abraham J Herbst, David Heymann, Donald S Burke

Affiliations + expand

PMID: 25377061 PMCID: PMC4239377 DOI: 10.1186/1471-2458-14-1144

Free PMC article

## Charting a Course for an Equity-Centered Data System:

Recommendations from the  
National Commission to Transform  
Public Health Data Systems

OCTOBER 2021



Public Health Data Systems Task  
Force 2021  
Report to the Health Information  
Technology Advisory Committee

# CDC's structure creates strengths and challenges for DMI



CDC has 100+ surveillance systems providing foundational data for public health

#### Data from Healthcare Encounters

- Syndromic Surveillance
- Hospital-Acquired Infections
- Notifiable Diseases
- Vital Statistics

#### Risk Factors and Exposures

- Behavioral Risk Factor Surveillance
- Hazardous Substances Emergency Events

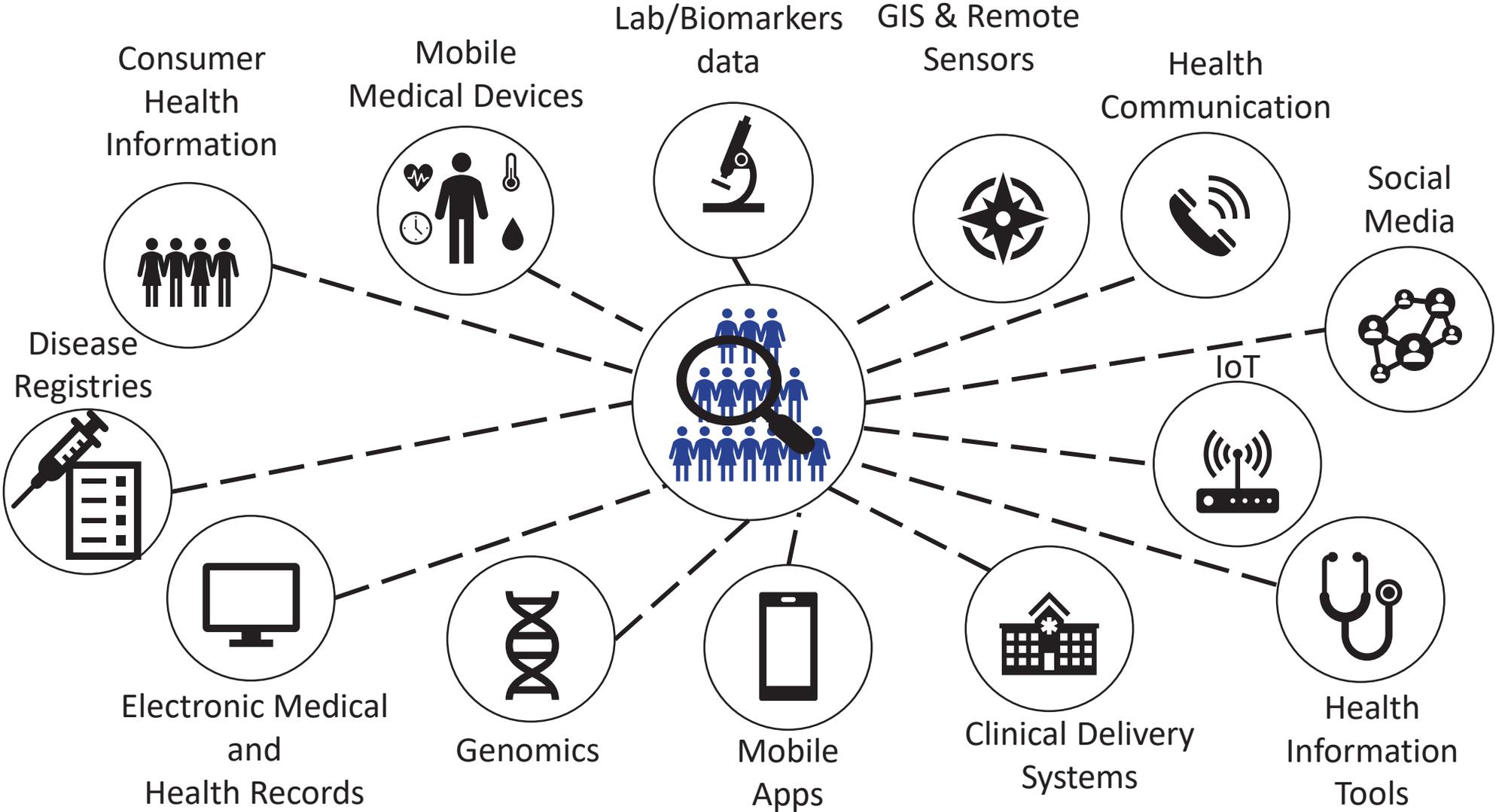
#### Non-Infectious Conditions

- Chronic Diseases
- Injuries
- Drug Overdose
- Environmental

#### Infectious Disease

- COVID, influenza
- Foodborne, waterborne, wastewater
- HIV, TB, STD
- Vector-Borne

# Public health must keep up with proliferating data sources



# Data and Surveillance Work Group Terms of Reference (TOR)

# Data and Surveillance Workgroup

**Primary Charge: To provide input to the ACD, CDC regarding potential solutions to issues and questions**

The workgroup will help to:

- Identify innovative, equitable, and promising modernization practices and approaches
- Align with the principal pillars of DMI
- Advance modern, harmonized data policies and practices
- Develop advice and recommendations to support the effective execution of DMI across the agency

# Focus Issues

## Six main areas:

- Authorities
- Data Exchange
- Forecasting & Analytics
- Workforce
- Breaking Down Siloes
- Assuring Sustainability

# Issue 1: Authorities

CDC does  
not have broad  
and direct  
authority to  
require  
data reporting

CDC receives data from 50 states and 3000+ local jurisdictions and territories.

Each jurisdiction creates their own data sharing agreements with CDC and with each other.

It is up to each city, county, and state to decide what information is collected, as well as how and when it can be shared with CDC.

# We are in a different place than we were before the pandemic

## Monitoring Disease Burden

### DATA COLLECTED

**Electronic Lab Reports**

**813M** COVID-19 Tests

**Case-Based Disease Surveillance**

**79M** Case Reports

**Emergency Department Visits**

**7.4M** COVID-19 ED Encounters

**Immunization Records**

**551M** vaccinations administered

**Virus Genomics Data**

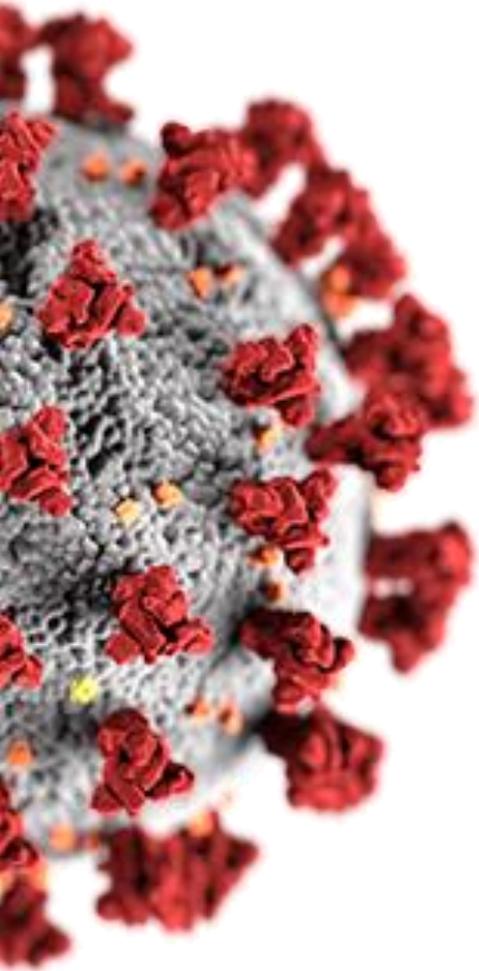
**2.1M** published sequences

**Healthcare Data**

**140TB** of clinical and administrative data

**Hospitalization Data**

**4.6M** total admissions



## Question:

How can CDC support **common approaches to data sharing** and access for public health data, particularly through supporting policy and system approaches, consistent with applicable laws and regulations, to **build trusted networks for data exchange** and **address vulnerabilities** created by variation across sectors and levels of public health?

## Issue 2: Data Exchange

Exchanging data  
is burdensome  
and time-  
consuming

Data comes to CDC in a variety of formats.

Outdated technologies at health departments are not flexible, do not use cloud, and are not scalable.

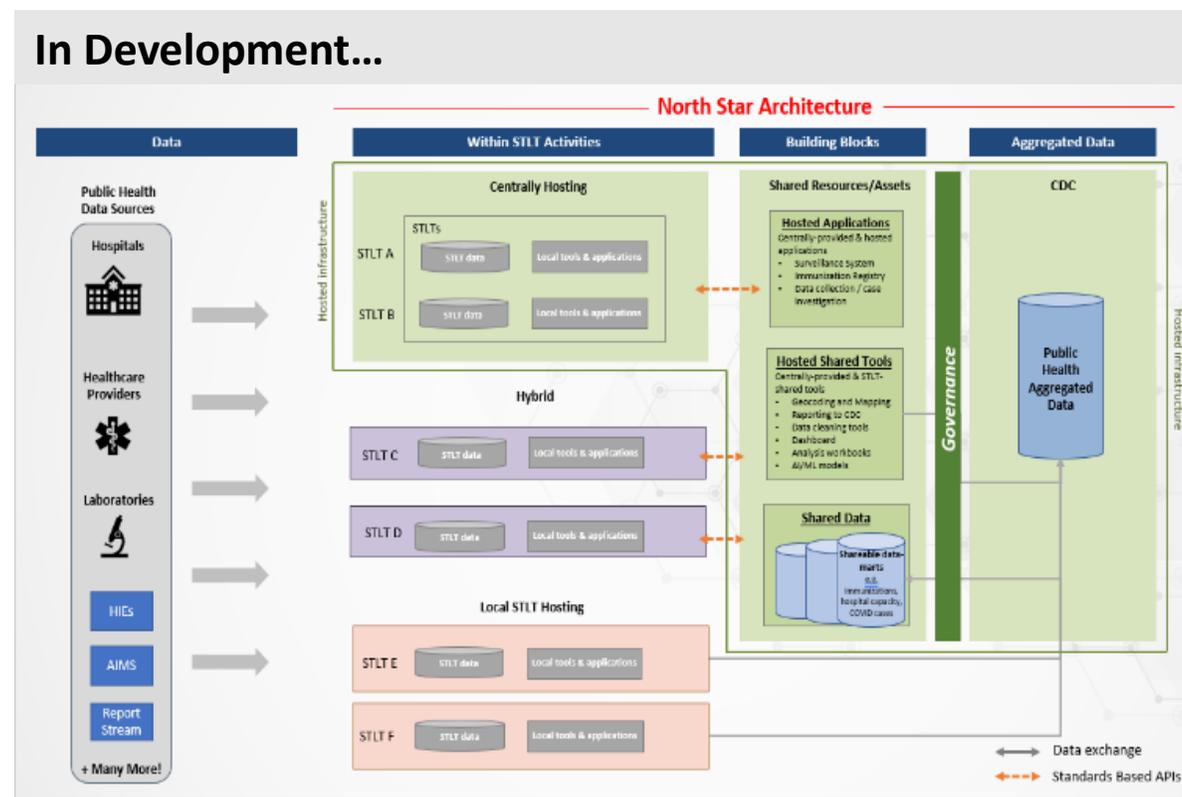
Reporting into multiple systems in different ways creates an unnecessary burden on data providers.

# What is a North Star Architecture?

The **North Star Architecture** is a joint ONC-CDC effort to help articulate a shared vision of a public health data infrastructure for STLTs to share data with each other and CDC.

Key ideas:

- **Flexible but standardized:** Offers a range of support levels to our STLT partners, depending on their needs
- **Secure cloud environment:** Offers more efficient sharing of infrastructure, applications, tools, and data
- **Collaboration and transparency:** Rules and products will be developed through joint CDC/STLT governance
- **Time and planning:** We will work on this with partners over the next two years



# Questions:

What role should **centrally hosted infrastructure and service** play in a modern public health information ecosystem?

How can the structure and use of a modern public health information ecosystem support and ensure that partners receive **added value through participation**, for example through the sharing of harmonized data to jurisdictions from CDC?

## Issue 3: Forecasting & Analytics

CDC needs better capabilities to provide real-time data for decisions

CDC's information is relied on by policymakers and individuals to make everyday and emergency decisions.

This information depends on us having the right models, forecasts, and analytics.

Better tools are needed for situational awareness, early warning, and emergency response.

# Center for Forecasting and Outbreak Analytics



Make sense of uncertainty  
early in an outbreak

## Parameter Estimates

- Assess epidemic potential and severity
- Quantify risk and timing of imported cases
- Assess risk to the homeland



Provide early warning,  
situational awareness

## Scenario models, forecasts

- Develop good-bad-worst planning scenarios; bound uncertainty
- Assess expected impact of interventions
- Produce short term forecasts



Get critical data for the  
response

## Targeted studies

- Inform resource demand projections
- Inform design and targeting of prevention measures
- Monitor vax, treatment effectiveness over time
- Identify and track variants
- Provide data to update scenarios and forecasts



Support policy and  
guidance

## Responsive analytics

- Develop & analyze custom models to inform policy and public health guidance on topics such as
  - Border controls
  - Testing, quarantine & isolation
  - Countermeasure demand
  - Vaccine prioritization
  - Surveillance design

## Question:

How should CDC prioritize advancement of **forecasting and analytic** efforts to integrate public health activities and **address health equity**?

## Issue 4: Workforce

The public health workforce is struggling to keep up

Public health needs more people and better skills to interpret the data, including more modelers and analysts.

At the state and local level, we need to find sustainable solutions for reversing the decades-long erosion of the workforce.

# CDC's workforce approach is guided by three main strategies

## Recruit & Build



- Fellowships
- New infrastructure grant
- Public Health AmeriCorps

## Train



- Data Science Upskilling
- CSTE: Data Science Team Training
- CSTE: Applied Public Health Informatics Fellowship

## Forecast



- HRSA: Public Health Workforce Research Center
- New infrastructure grant: Workforce planning

## Question:

How can CDC work with partners to support the public health enterprise by increasing access to **data science and information technology skillsets and staff** from academia and the private sector and addressing barriers to **hiring and retaining experts** in these fields?

## Issue 5: Breaking Down Siloes

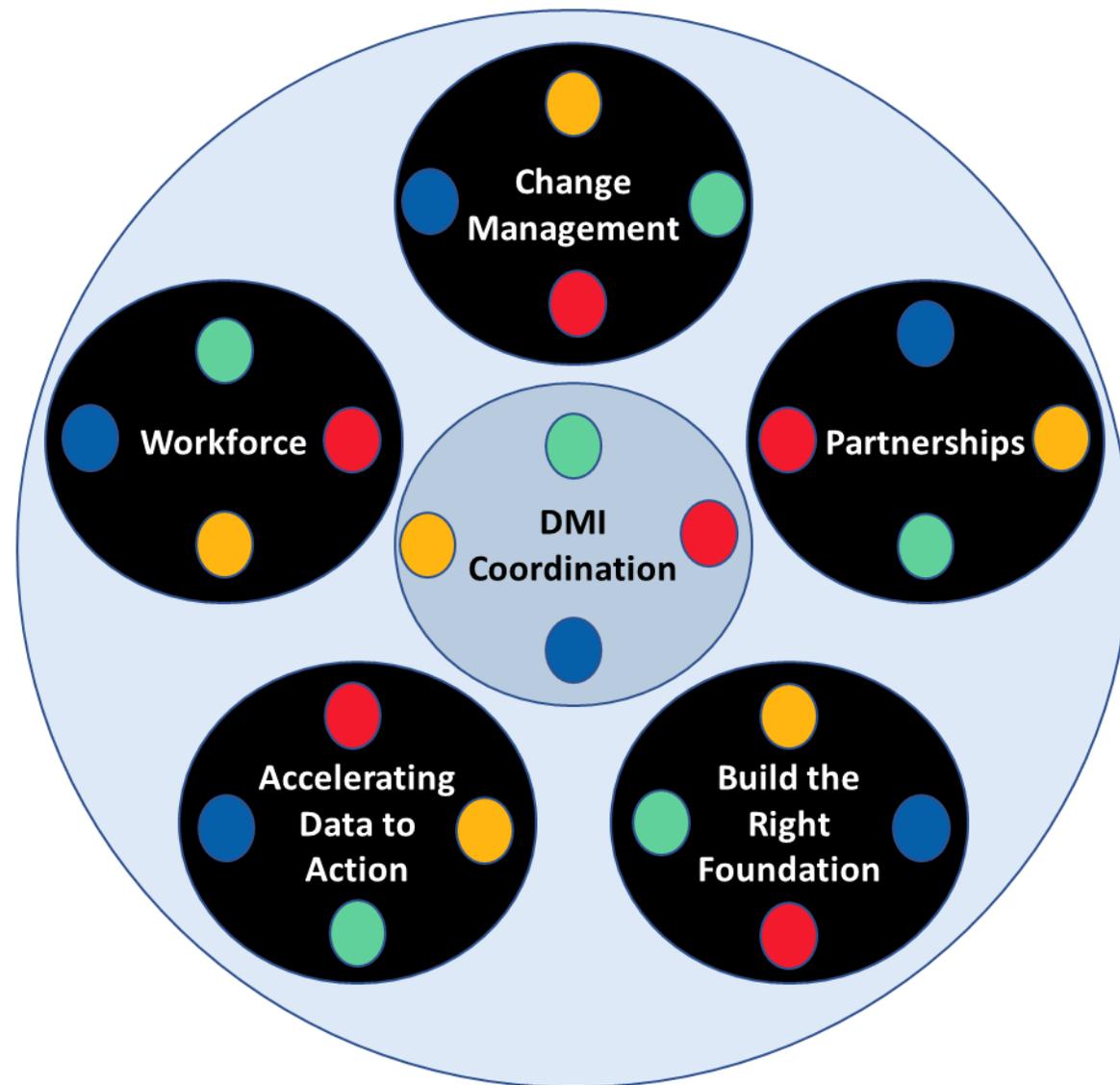
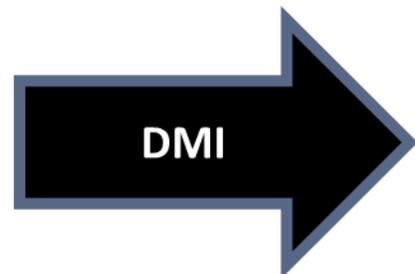
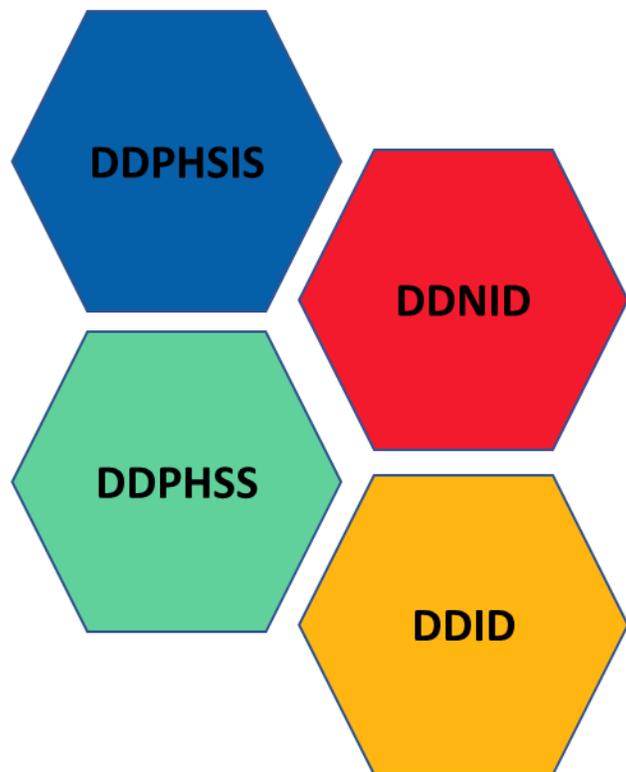
Siloed  
systems keep  
us from seeing  
the complete  
picture

Disease-specific budget lines have led to the creation of disease-specific systems across all of public health.

These systems are often proprietary and/or disconnected from one another.

Lack of cross-program connection creates burden and limits insights.

# Current CDC Structure Compared with DMI Implementation Approach



# Questions

For the next phase of DMI, what agency-wide activities would most benefit from a **coordinated, all-of-CDC approach**?

What efforts could ensure **long-term sustainability and success** in achieving modernization and supporting advancement of agency priorities like **climate change** and **health equity**?

## Issue 6: Assuring Sustainability

Current  
approaches  
are not nimble  
or sustainable  
enough

When it comes to the sustainability of our data infrastructure, we need to rethink:

- Business policies
- Practices
- Procedures

...At all levels of public health.

# The Public Health Infrastructure Grant provides a flexible mechanism to deliver additional DMI funding to jurisdictions

## WHAT?



- Provides funding to improve public health capacity and systems
- Currently supported by ARP funding and FY22 base, potential for future funding through other appropriations
- One application approach:
  - Part A: Infrastructure (health departments)
    - A1: Workforce
    - A2: Foundational capabilities
    - A3: DMI
    - A4: Physical infrastructure
  - Part B: National partners

## WHO?



- Open competition notice of funding opportunity (NOFO)
- State, local, territorial, and other qualified public health departments are eligible to apply
- Potential applicants include:
  - 50 states
  - Washington D.C.
  - U.S. territories and freely associated states
  - Large cities and counties\*
  - Public health partners
- All applications responsive to the NOFO requirements will be reviewed and considered

# Questions

How can CDC work with partners to address barriers related to **funding mechanisms, procurement, and program delivery**?

What mechanisms for assuring **sustainability of modernized systems** need to be developed and implemented?

# Data and Surveillance Workgroup: Specific Activities

Participating in sessions to consider and address the guiding questions

- Drafting a **report of the findings, observations, and outcomes**

Receiving ad hoc presentations:

- From the **CDC DMI Leadership Team** to review the aims, content, and underlying assumptions of the DMI Strategy
- From **CDC programs** on evidence-based approaches, tools, and what's driving successful implementation of data modernization activities
- On **initiatives**, both internal and external, that will impact DMI outcomes

Reviewing CDC's DMI implementation **outcomes, progress, and metrics** to provide feedback to the ACD, CDC

Providing **updates** to the ACD, CDC at each meeting

# Data and Surveillance Workgroup Terms of Reference Discussion



**BREAK**



# COVID-19 Pandemic Update

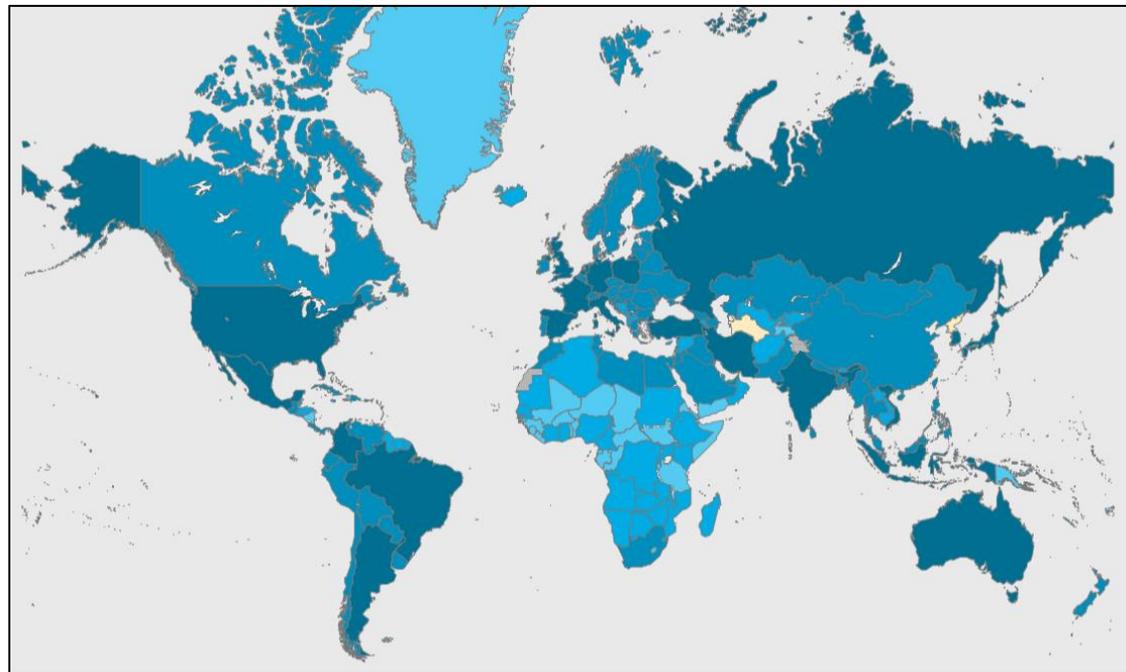
Barbara Mahon, MD

Incident Manager, CDC COVID-19 Response

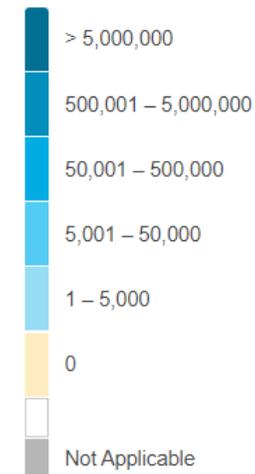


# COVID-19 Surveillance Summary: Cases

- 507,501,771 confirmed cases globally
- 6,220,390 cumulative deaths



**Total COVID-19 Cases**

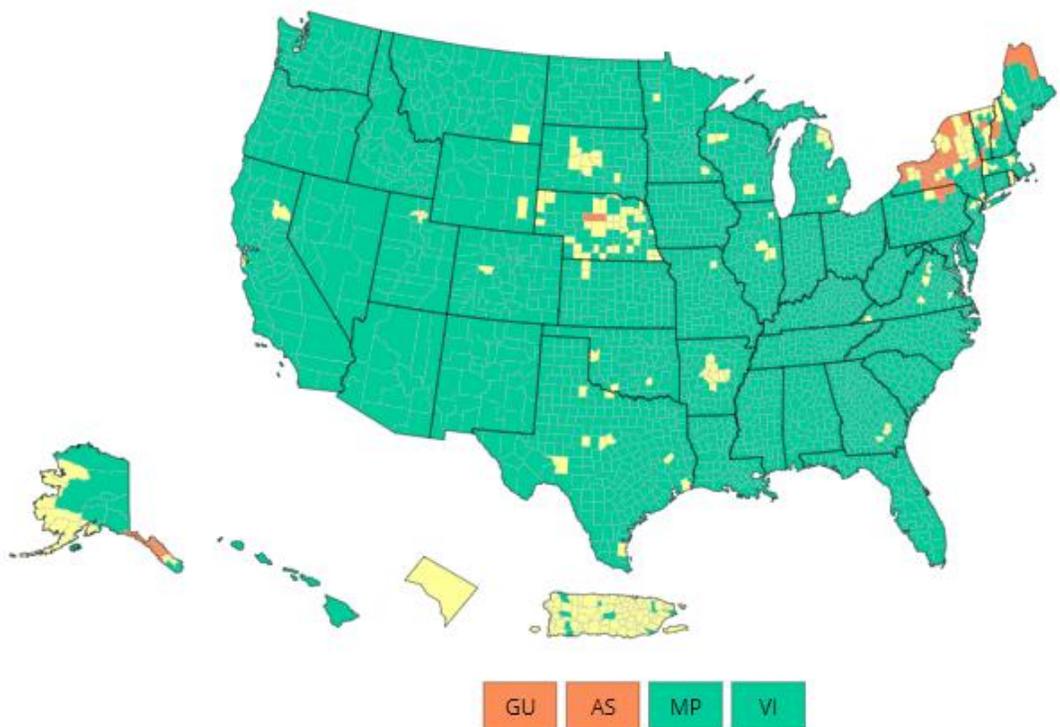


Data as of April 25, 2022

Source: [WHO Coronavirus \(COVID-19\) Dashboard](#)

# COVID-19 Community Levels (CCLs)

COVID-19 Community Levels in the US by County  
as of April 21, 2022



	% of Counties	% of Pop
Low	91.7%	92.1%
Medium	7.2%	6.5%
High	1.1%	1.4%

Time Period: COVID-19 Community Levels were calculated on Thu Apr 21 2022. New COVID-19 cases per 100,000 population (7-day total) are calculated using data from Thu Apr 14 2022 - Wed Apr 20 2022. New COVID-19 admissions per 100,000 population (7-day total) and Percent of inpatient beds occupied by COVID-19 patients (7-day average) are calculated using data from Wed Apr 13 2022 - Tue Apr 19 2022.

Source: [CDC COVID Data Tracker \(County View\)](#)

# CCL Trajectory Analysis (past 5 weeks)

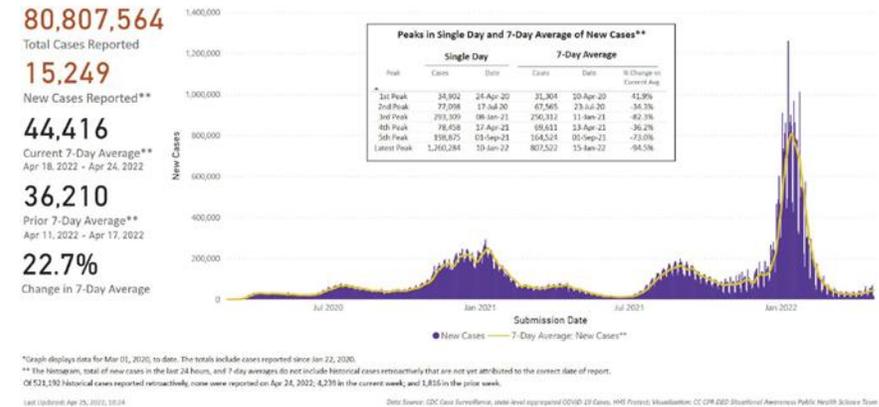


Data are Provisional Until Officially Released by the CDC - For Internal Use Only (FIUO) - For Official Use Only (FOUO) - Sensitive But Unclassified (SBU) - Not for Further Distribution

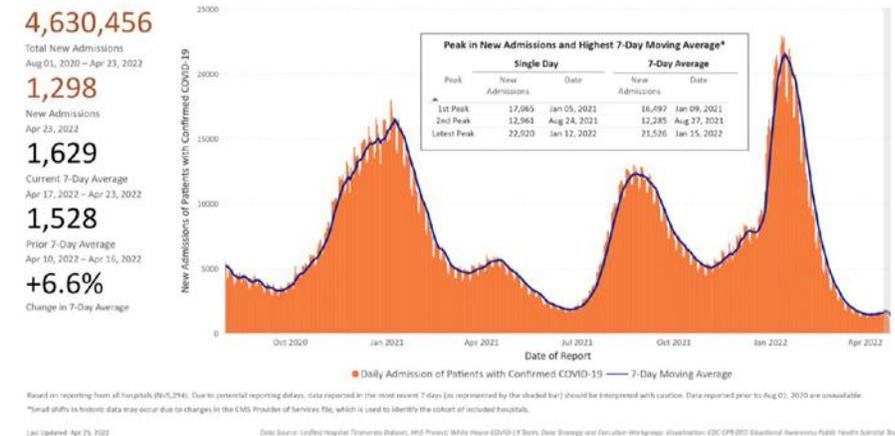
# COVID-19 Surveillance Summary: Cases and Hospitalizations

- As of April 24, 2022
  - 7-day average of daily **case counts** increased **22.7%** compared with previous week
- As of April 23, 2022
  - 7-day average of daily **new hospitalizations** increased **6.6%** compared with previous week

Daily Change in COVID-19 Case Counts, United States  
March 2020 – April 2022



New Admissions of Patients with Confirmed COVID-19, United States  
August 2020 – April 2022



# COVID-19 Surveillance Summary: Deaths

- As of April 24, 2022
  - 7-day average of daily **death counts decreased 13.2%** compared with previous week

**Daily Change in COVID-19 Death Counts, United States**  
**March 2020 – April 2022**

January 22, 2020\* - April 24, 2022

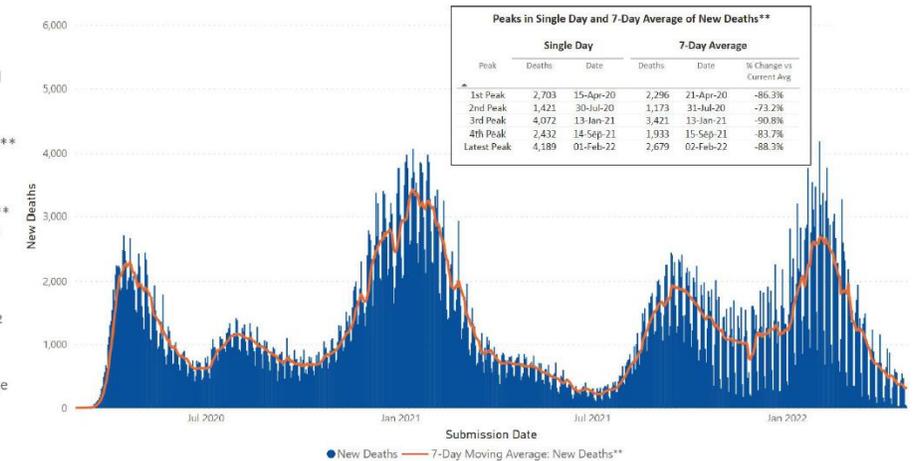
**988,707**  
 Total Deaths Reported

**28**  
 New Deaths Reported\*\*

**314**  
 Current 7-Day Average\*\*  
 Apr 18, 2022 - Apr 24, 2022

**362**  
 Prior 7-Day Average\*\*  
 Apr 11, 2022 - Apr 17, 2022

**-13.2%**  
 Change in 7-Day Average



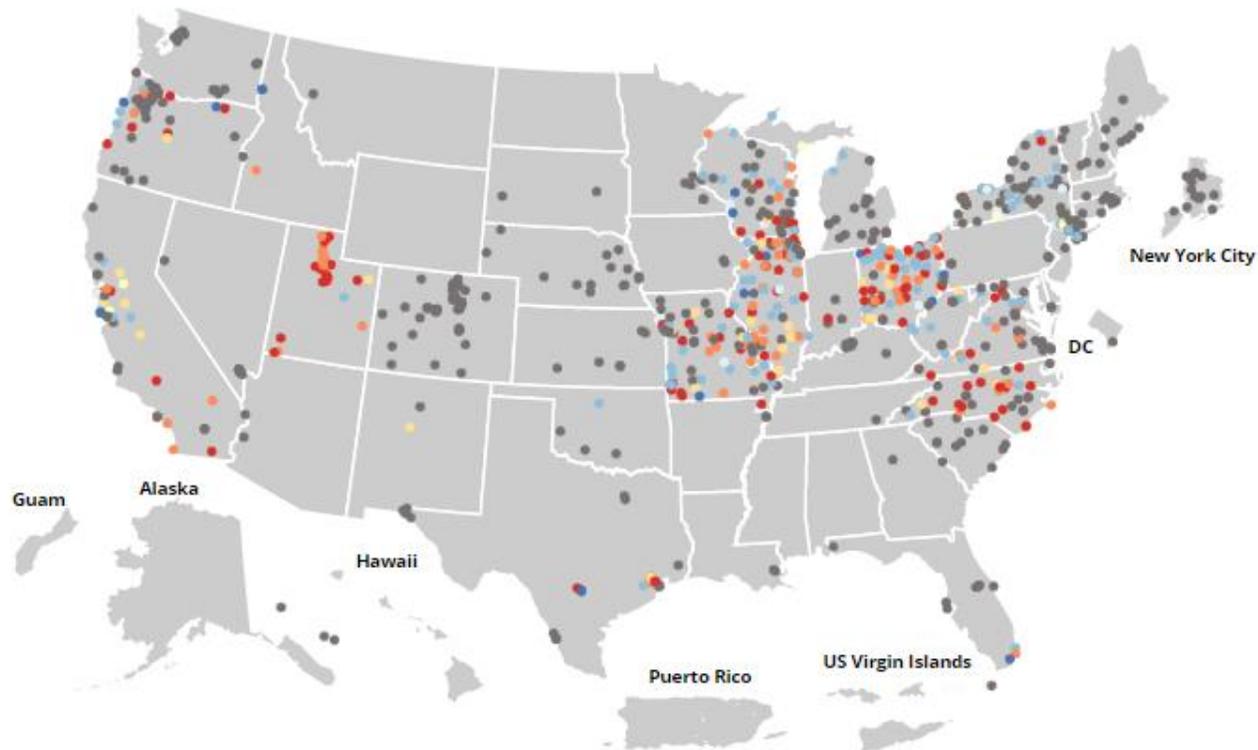
\*Graph displays data starting on Mar 01, 2020. The totals include deaths reported since Jan 22, 2020

\*\* The Histogram, total of new deaths in the last 24 hours, and 7-day averages do not include historical deaths reported retroactively. Historical deaths are still reflected in the cumulative national total. Of 21,361 historical deaths reported retroactively, none were reported on Apr 24, 2022; 178 in the current week; and 439 in the prior week.

Last Updated: Apr 25, 2022, 10:24

Data Source: CDC Case Surveillance, state-level aggregated COVID-19 Cases, HHS Protect: Visualization; CDC FPR DED Situational Awareness Public Health Science Team

# COVID-19 Wastewater Surveillance



Percent change of SARS-CoV-2 in the last 15 days by site, United States

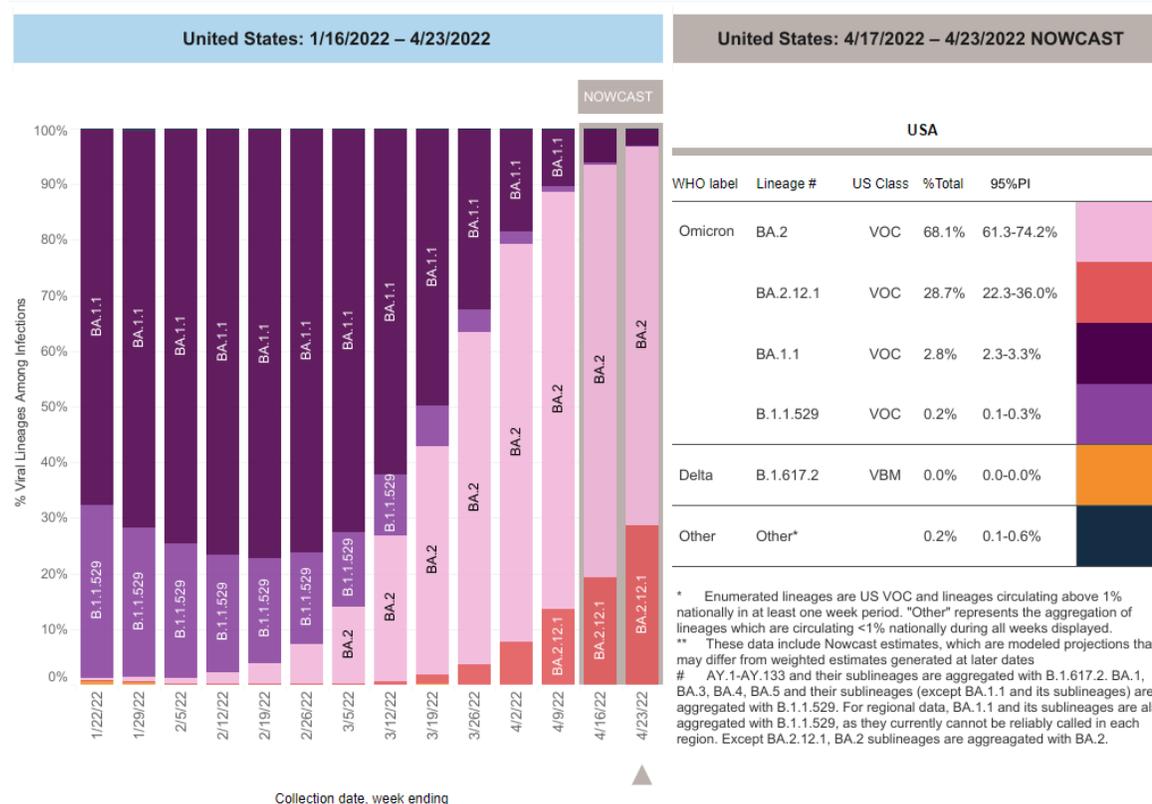
15-day % change category	Num. sites	% sites	Category change in last 7 days
- 100%	18	4	0%
- 99% to - 10%	143	30	- 26%
- 9% to 0%	16	3	- 52%
1% to 9%	14	3	- 53%
10% to 99%	60	13	- 58%
100% to 999%	107	23	- 45%
1000% or more	117	25	29%

Total sites with current data: 475

Total number of wastewater sampling sites: 845

# COVID-19 Variants

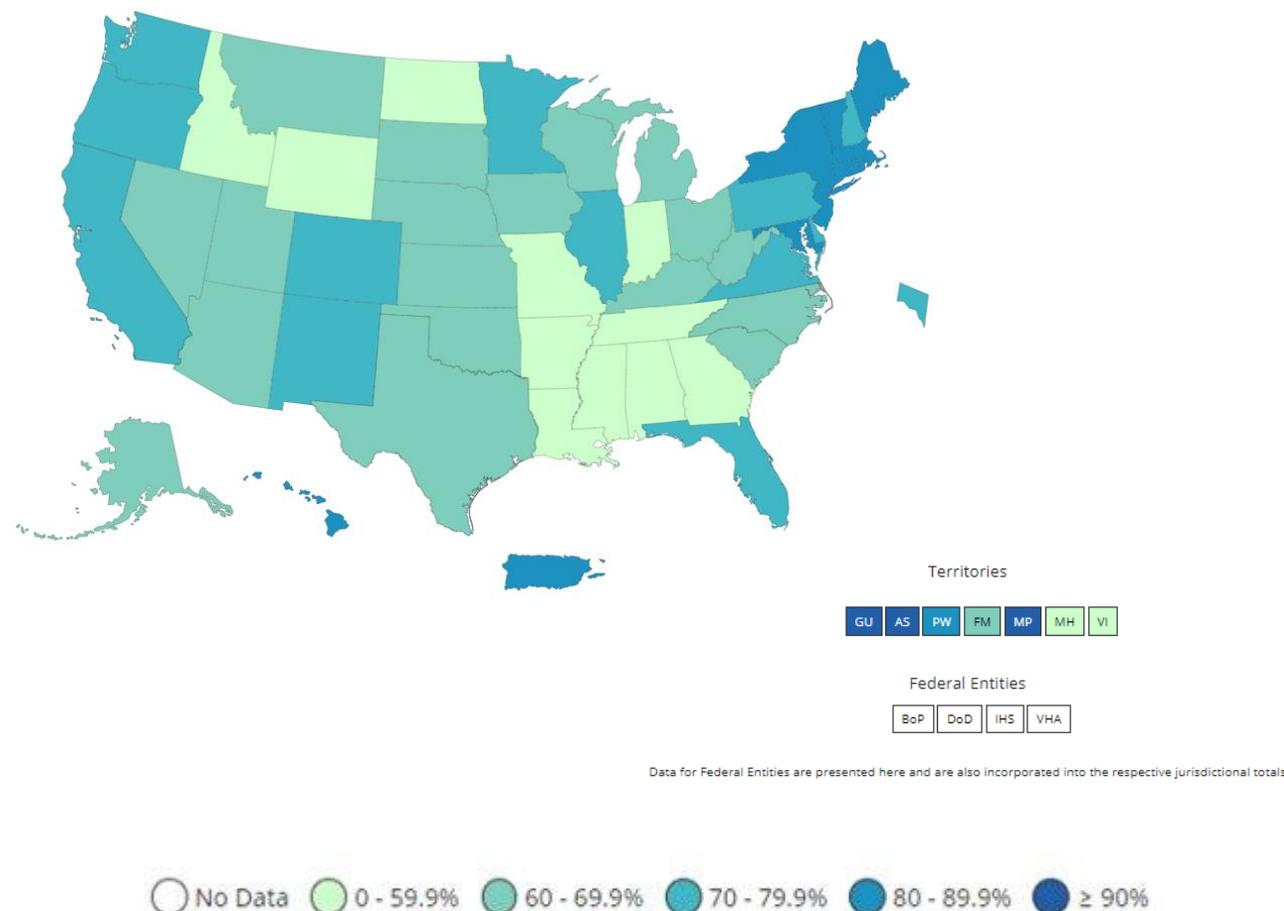
- Estimated percentage of COVID-19 variants circulating in the U.S. as of April 23, 2022
  - Omicron BA.2: 68.1% of cases
  - Omicron BA.2.12.1: 28.7% of cases
  - Omicron BA.1.1: 2.8% of cases
  - Omicron B.1.1.529: 0.2% of cases
  - Other variants: 0.2% of cases



# COVID-19 Vaccination: Domestic

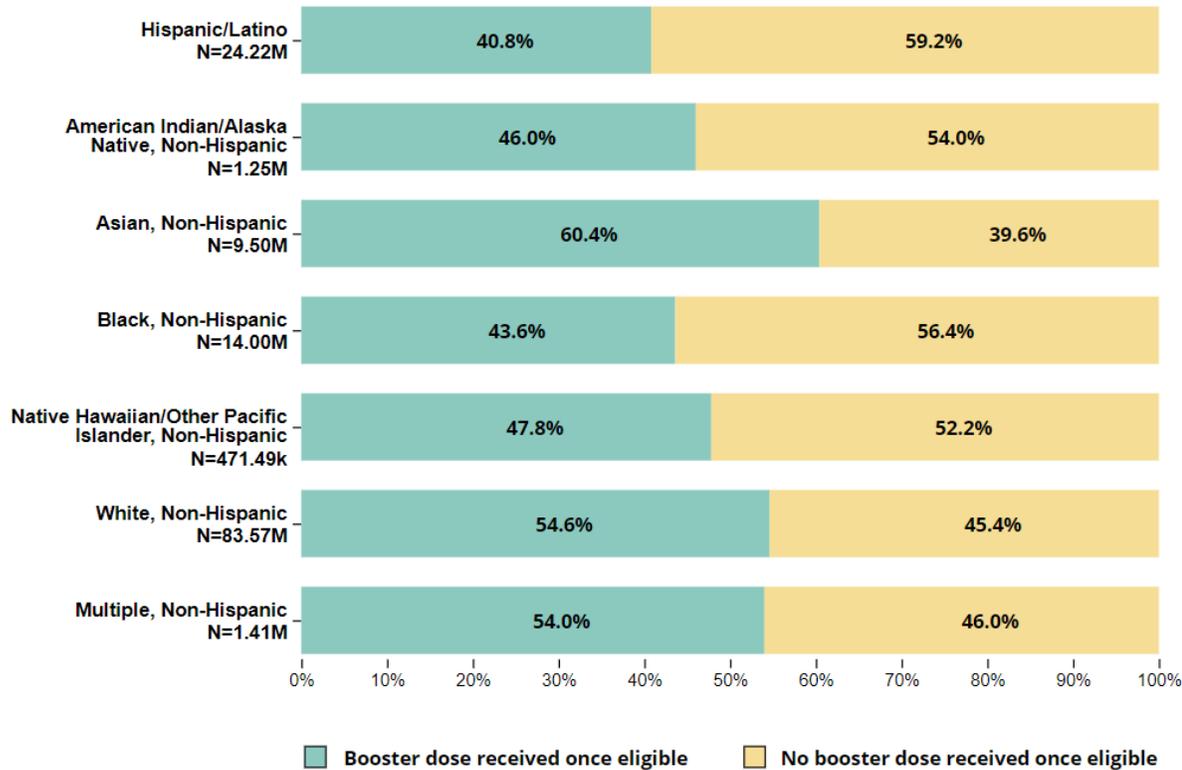
- As of April 25, 2022
  - 77.5% of US population has received at least 1 dose
  - 66.1% of US population fully vaccinated
  - 45.6% of fully vaccinated persons have received one additional dose

Percent of Population >=5 Years of Age Fully Vaccinated for COVID-19 by Jurisdiction as of April 25, 2022

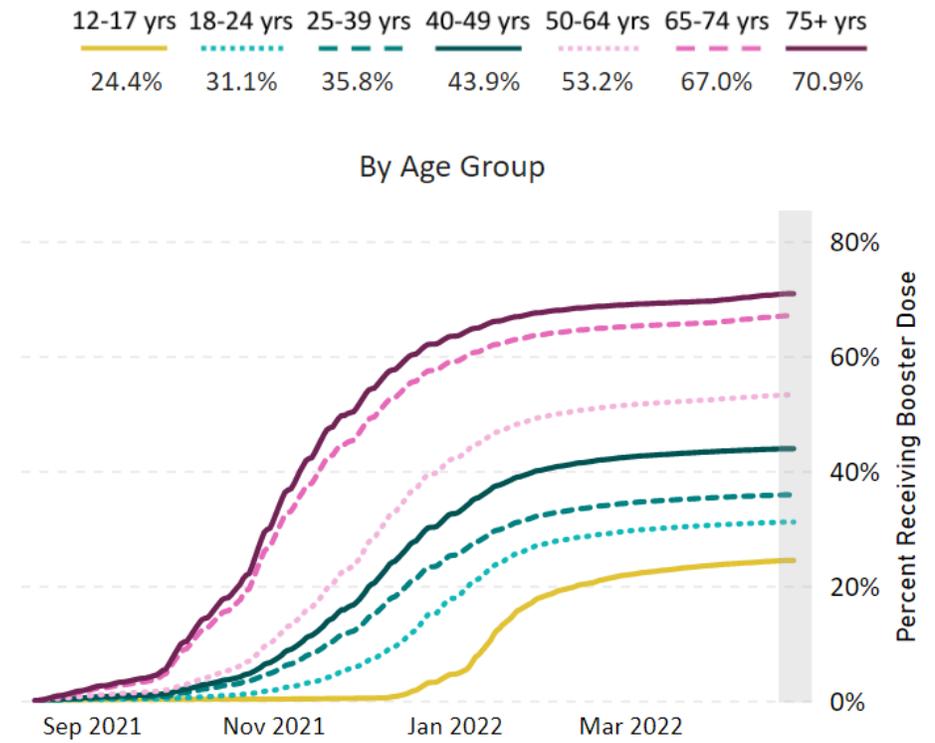


# COVID-19 Vaccination: Demographics

Percent of Population Eligible for a First Booster Dose with and without a Booster, by Race/Ethnicity, United States for 12 Years and Older as of April 25, 2022



Percent of Fully Vaccinated People Receiving a First COVID-19 Booster Dose, Age Group and Date Administered, United States for 12 Years and Older August 13, 2021 – April 25, 2022



# Second Boosters

- Who can receive a second booster?
  - Adults ages 50 years and older who received a primary series and booster of Pfizer-BioNTech or Moderna OR who first received a J&J/Janssen COVID-19 vaccine, regardless of what type of booster they received
  - Anyone who received a J&J/Janssen COVID-19 vaccine for both their primary dose and booster
- When can eligible individuals receive a second booster?
  - At least 4 months after their first booster
- What second booster product can eligible individuals receive?
  - The second booster must be an mRNA COVID-19 vaccine

# Recent COVID-19 Response Priorities and Achievements



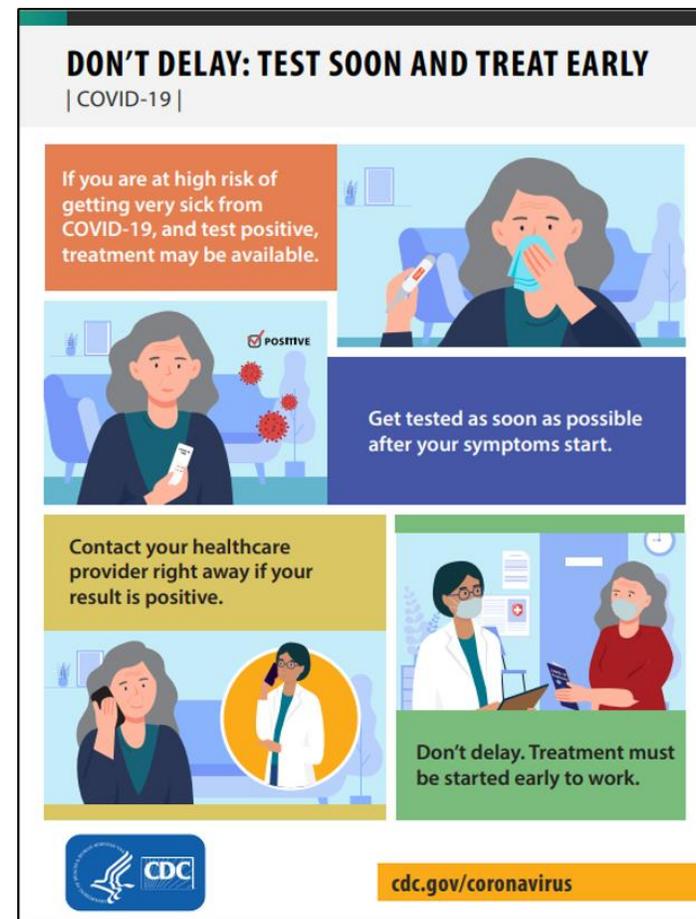
# Prioritization of Health Equity

- Strengthening ties to and addressing concerns of people with disabilities
- Assisting in identifying accessibility of therapeutics to marginalized communities
- Ensuring involvement in planning and/or responding to new developments such as travel-related mask mandates
- Reviewing impact of and/or lessons from the grants that focus on communities of color
- Planning to ensure that equity remains a priority both inside the COVID-19 Response and CDC CIOs as activities are moved to programmatic homes



# Communicating COVID-19 Risk to the Public

- Launching materials to help people, especially those at high risk, better understand their risk level and actions they can take to protect themselves
  - Planned "Know Your Risk" Tool
  - Communication of treatment availability



# Sustain Use of COVID-19 Vaccines

- Sustain use of vaccines to protect the health of individuals and communities
  - Support uptake of 4<sup>th</sup> doses (2<sup>nd</sup> boosters)
  - Improve equitable access to vaccines domestically and globally
  - Support efforts for all eligible individuals to be up to date on vaccines
  - Prepare for vaccine for children <5 years old





# Laboratory Workgroup

Jim Pirkle, MD, PhD

(Acting) Associate Director for Laboratory Science and Safety



# CDC Laboratory Quality Plan

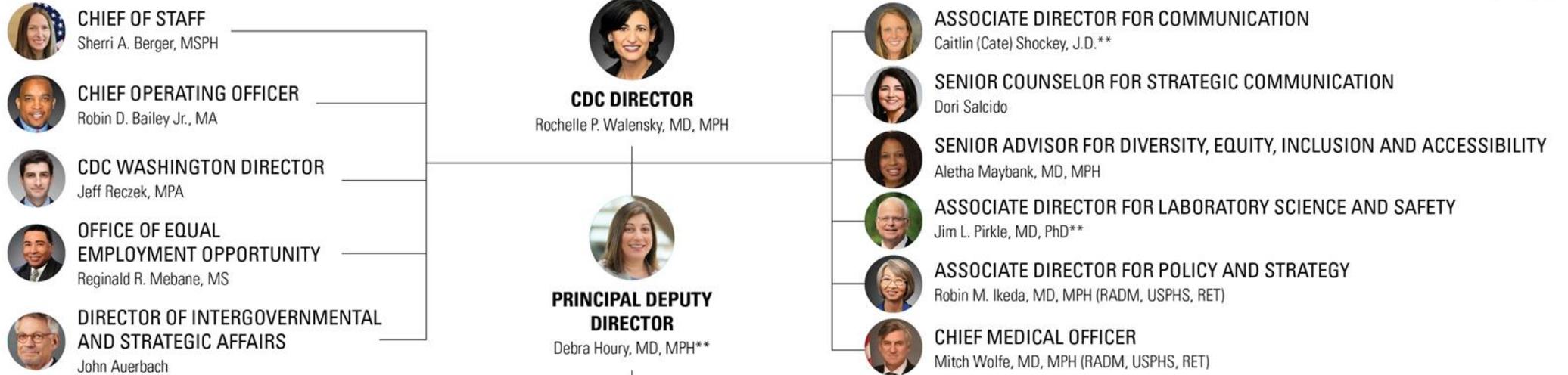
**Jim Pirkle, MD, PhD**

Associate Director for Laboratory  
Science and Safety (acting) and  
Director, Office of Laboratory  
Science and Safety (acting)



# Six CDC Centers and NIOSH have laboratories

April 18, 2022



\* ATSDR is an OPDIV within DHHS but is managed by a common director's office.

\*\* Acting position

# Public Health Role of CDC Laboratories

- To provide laboratory science that effectively supports the detection, diagnosis, treatment and prevention of disease and harmful exposures

# Common Laboratory Activities at CDC

- Analyze samples to find an unknown pathogen or toxic agent in an outbreak
- Develop better diagnostic methods for diseases and harmful exposures
- Support detection and diagnosis of infectious diseases including extremely dangerous pathogens requiring high containment laboratories
- Support surveillance of disease incidence and prevalence
- Identify vulnerable population groups at higher risk of disease or harmful exposures
- Identify risk factors that cause people to be at higher risk of disease or harmful exposures

# Common Laboratory Activities at CDC

- Serve as reference laboratories that provide quality testing to other labs
- Conduct quality assurance programs to assist state, local and other laboratories
- Provide technical assistance on performance and interpretation of diagnostic tests
- Help address treatment challenges such as antibiotic resistance
- Support research studies to better understand disease pathogenesis, transmission and virulence resulting in better public health prevention actions
- Help evaluate effectiveness of treatments or preventive actions

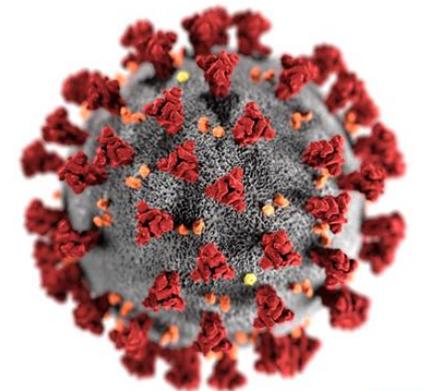
# National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

- Research and control dangerous bacterial and viral pathogens
- Outbreak response, bioterrorism response, and suspicious material identification
- Identify pathogens and diseases that other laboratories cannot
- Develop methods to detect emerging healthcare-associated infection threats, including antimicrobial resistance



# National Center for Immunization and Respiratory Diseases (NCIRD)

- Outbreak investigations and reference laboratories for respiratory and vaccine-preventable diseases
- Monitor and control influenza through global surveillance and advancing vaccine development and testing
- Develop and support use of vaccines, medical countermeasures, and diagnostics for anthrax and respiratory disease and other priority pathogens
- Detect gastroenteric and respiratory viruses, including coronaviruses
- Support the Global Polio Eradication Initiative including polio outbreak investigations



# National Center for National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

- Develop biomedical interventions and testing for HIV infections, and serve as national HIV reference laboratory including drug-resistance testing
- Develop diagnostic testing, including point-of-care testing, for sexually transmitted diseases
- Serve as national tuberculosis laboratory, strengthening vaccination strategies, testing, and understanding of drug resistance
- Serve as national reference laboratory for viral hepatitis



Ending  
the  
HIV  
Epidemic

[Learn more](#)



# Center for Global Health (CGH)

- Provides reference laboratory support for more than 50 countries including outbreak response, laboratory systems, and pathogen discovery
- Reference laboratory for diagnosing parasitic diseases
- Surveillance for malaria drug resistance
- Monitoring quality of anti-malarial drugs
- Evaluating insecticide resistance among mosquitos that can carry malaria



# National Center on Birth Defects and Developmental Disabilities (NCBDDD)

- For persons with bleeding disorders, monitors for select infectious agents and other abnormal factors



Saving Babies

# National Center for Environmental Health (NCEH)

- Measures population and individual exposures to environmental chemicals
- Assesses human exposure to chemical threat agents, toxins and radiologic threats
- Provides quality-assurance, proficiency testing, and technical assistance for state newborn screening testing for early detection of treatable diseases
- Assesses the nation's nutritional status using laboratory testing in the National Health and Nutrition Examination Survey (NHANES)
- Measures addictive and toxic substances in tobacco products, vaping products, and in the urine and blood of people who are exposed to these products
- Improves quality of laboratory measurements of state, clinical, and research partners addressing chronic diseases, nutrition status, and environmental exposures

# National Institute for Occupational Safety and Health (NIOSH)

- Test and certify respirators to ensure they meet filter efficiency standards
- Develops methods for sampling and analyzing contaminants in workplace air and in blood and urine of workers exposed to hazards in the workplace
- Conduct applied research on health hazards, safety hazards, and disaster prevention in mining
- Develop engineering controls and safe work practices for preventing work-related fatalities and work-related traumatic injuries across all industry sectors

Promoting productive workplaces  
through safety and health research



# CDC Laboratory Quality Plan

# Vision

- CDC labs operate at a gold-standard quality level
- CDC labs are at the forefront of advances in laboratory science that benefit public health

# Goals

- Excellent quality Infectious Disease (ID) lab methods with review documenting that excellent quality
- Excellent quality ID lab results that pass appropriate quality control criteria
- ID clinical labs pass external reviews with only occasional minor deficiencies

## Goals – continued

- Demonstrated effective capability to rapidly develop high-quality diagnostic tests for new high-risk pathogens under emergency conditions in collaboration with private and public health partners
- A single, excellent Quality Manual for Microbiological Labs (QMML)
- Needed scientists and sustained funding are available so labs can ensure high quality and be at the forefront of advances in laboratory science that benefit public health

# Major Constraints

- Clinical, surveillance, and research labs are commonly together – very tough constraint
- Quality must be ensured for emergency, rapid test development for tests that have high consequences for quality failure
- More than 1,700 CDC laboratory scientists in 200+ labs in multiple states/territories

# Laboratory Quality Plan

- Infectious Disease (ID) Test Review Board
- Three (3) separate Quality Management Systems for infectious, non-infectious and NIOSH laboratories
- Quality Manual for Microbiological Laboratories (QMML)
- Flexible and user-friendly quality management software
- Biennial external review of every laboratory – clinical, surveillance and research

# Infectious Disease (ID) Test Review Board

# Infectious Disease Test Review Board

- Function:
  - To review test methods developed at CDC before they are shared with external laboratories to ensure the quality of the test and the transferability of the test is suitable for intended use
- Who performs the review:
  - A panel of at least three scientists with expertise in the method science, but not involved with the test development, must recommend approval of the method to the Test Review Board who must provide final approval.

# Infectious Disease Test Review Board

- What is reviewed:
  - Diagnostic sensitivity
  - Diagnostic specificity
  - Limit of detection
  - Sample collection and stability
  - Quality control criteria
  - Successful transfer of the test to another laboratory

# Test Predictive Value

		Disease or condition present	
		Yes	No
Test results	Positive	TP True positive	FP False positive
	Negative	FN False negative	TN True negative

Positive predictive value =  $\frac{TP}{TP+FP}$

Negative predictive value =  $\frac{TN}{FN+TN}$

True positive rate or Sensitivity =  $\frac{TP}{TP+FN}$

False negative rate =  $\frac{FN}{TP+FN}$

False positive rate =  $\frac{FP}{FP+TN}$

True negative rate or Specificity =  $\frac{TN}{FP+TN}$

# Infectious Disease Test Review Board

- The ID Test Review Board began meeting in early March 2022.
- Any ID test to be shared with an outside laboratory must now go through this Board for review.

# Three Separate Quality Management Systems for Infectious, Non-infectious, and NIOSH Laboratories

# Three separate Quality Management Systems for Infectious, Non-infectious, and NIOSH Laboratories

- Allows specific quality requirements at depth needed to assure excellent quality
- Similar to separation of microbiology from clinical chemistry labs
- NIOSH has specialized laboratory functions

# Quality Manual for Microbiological Laboratories (QMML)

# Quality Manual for Microbiological Laboratories (QMML)

- One-stop resource for excellent microbiology lab quality practices like the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual is for safety. **Safety First and Quality Second.**
- QMML standards will exceed CLIA and FDA requirements
- Separate sections for clinical labs (CLIA labs), surveillance labs, and research labs.

# Quality Management System requirements *by type of ID lab*

- Test requisition
- Test records
- Test reports
- Complaints
- Security of personal data
- Sample referrals

- Sample collection, shipping, storage and handling
- Proficiency testing for tests
- Internal quality audit in years not getting external review
- Data security and backup

- Test documentation including method validation, sample rejection criteria, calibration, and quality control criteria
- NCE and CAPA
- Personnel - duties, training, competency, qualifications
- Equipment maintenance and function checks
- CMS, A2LA or CAP accreditation every 2 years

CLIA lab

- Sample collection, shipping, storage and handling
- Proficiency testing for tests
- Internal quality audit in years not getting external review
- Data security and backup

- Test documentation including method validation, sample rejection criteria, calibration, and quality control criteria
- NCE and CAPA
- Personnel - duties, training, competency, qualifications
- Equipment maintenance and function checks
- A2LA external accreditation/ review every 2 years

Surveillance lab

- Test documentation including method validation, sample rejection criteria, calibration, and quality control criteria
- NCE and CAPA
- Personnel - duties, training, competency, qualifications
- Equipment maintenance and function checks
- A2LA external accreditation/ review every 2 years

Research lab

# Quality Manual for Microbiological Laboratories (QMML)

## Ensuring excellent quality in laboratory developed tests

- Method Expert Groups (three CDC lab scientists per group) develop excellent test method quality standards for *each method type* (RT-PCR, enzyme immunoassay, serology, etc.)
- Every CDC method in that method type must meet those standards.

# Quality Manual for Microbiological Laboratories (QMML)

## Ensuring excellent quality in laboratory developed tests

- Standards include:
  - Determining diagnostic sensitivity
  - Determining diagnostic specificity – include samples likely to cross react
  - Determining limit of detection
  - Number and types of quality control samples
  - Quality control criteria including result rejection criteria
  - Sample collection and stability
  - Thorough method documentation so another lab can readily bring up the test
  - Transparent listing of all data used to evaluate method quality

# Test Documentation includes Safety Pointers Up Front

- If you are not certain about the safety of every step in this procedure, then **STOP** and consult your supervisor.
- Do not hurry – work at a steady, controlled pace.
- All steps require double gloving.
- More pointers... up to about 10

# Test Documentation includes Quality Pointers Up Front

- If you are not certain you can perform every step in this procedure at the quality level needed, then **STOP** and consult your supervisor.
- Step 4 is to heat the sample in a water bath for 30 minutes at 56°C. Heating time must be  $30 \pm 1$  minute and temperature  $56 \pm 1^\circ\text{C}$ .
- More pointers... up to about 10

# Flexible and User-friendly Quality Management Software

# Special Effort to Find User-friendly, Flexible Electronic Quality Management System (eQMS) Software

- eQMS software facilitates:
  - Document management – especially test methods and SOP
  - Identifying and tracking non-conforming events (NCE)
  - Corrective and preventive actions (CAPAs)
  - Training records
  - Competency testing
  - Equipment maintenance
  - More
- Already identified and beta-tested a promising software package

Biennial External Review of Every  
Laboratory – clinical, surveillance, and  
research

# Biennial External Review of all Laboratories– clinical, surveillance, and research

- All CLIA labs (clinical labs) must be accredited according to CLIA standards. Can use CMS inspectors, American Assoc. for Laboratory Accreditation (A2LA) or College of American Pathology (CAP).
- Surveillance and research labs will participate in an external review by A2LA every 2 years, based on quality standards in QMML.

# Laboratory Work Group Terms of Reference (TOR)

# Purpose: Laboratory Work Group (LW)

**Primary Charge:** Established to provide work products to assist the ACD, CDC in developing recommendations to CDC on agency-wide activities related to the scope and implementation of improvements to strengthen the quality of work within CDC laboratories.

The Work Group will help to identify innovative processes and systems to :

- Assist CDC labs to operate at a gold-standard quality level and remain at the forefront of advances in laboratory science that benefit public health
- Ensure CDC has demonstrated capability to rapidly develop high-quality diagnostic tests for new high-risk pathogens under emergency conditions
- Recruit and retain highly qualified laboratory scientists

## LW can provide input on:

- **CDC is sometimes the laboratory of last resort for testing specimens with less-than-acceptable or unusual specimen types.**
  - Considering regulatory requirements, when should CDC support investigation of these less-than-acceptable specimens?
  - How can results be reported with appropriate limitations in interpretation?
- **The QMML will be the primary resource for quality standards for infectious disease laboratory operation.**
  - LW review could result in insights that strengthen the manual and help to ensure that the work done in CDC infectious disease laboratories meet and maintain the highest standard of laboratory quality.

## LW can provide input on (cont.):

- **Excellent laboratory scientists are essential for high-quality, advanced laboratory testing.**
  - How can CDC recruit and retain outstanding laboratory scientists to ensure high-quality, advanced laboratory testing at CDC?
- **HHS, was directed in the 2022 federal budget agreement, to establish a Task Force to evaluate factors contributing to the shortcomings of CDC's first COVID-19 test, as well as policies, practices and systems to mitigate future issues.**
  - Will the Laboratory Quality Plan that CDC has developed address previous deficiencies and mitigate future challenges in diagnostic test development for public health outbreaks?

# Laboratory Workgroup Terms of Reference Discussion



# Health Equity Workgroup

## Co-Chairs:

- **Monica Valdes Lupi, JD, MPH - Managing Director for the Health Program at The Kresge Foundation**
- **Daniel Dawes, JD - Executive Director of the Satcher Health Leadership Institute at Morehouse School of Medicine**

# Health Equity Workgroup Membership

## ACD Members

<b>Daniel Dawes, JD/HEW Co-Chair</b> <b>Morehouse School of Medicine</b> <b>Satcher Health Leadership Institute</b> <b>Executive Director</b>	<b>Monica Valdes Lupi, JD, MPH/HEW Co-Chair</b> <b>The Kresge Foundation</b> <b>Managing Director of Health Program</b>
<b>Adaora Alise Adimora, MD, MPH</b>	University of North Carolina (UNC) School of Medicine Sarah Graham Kenan Distinguished Professor
<b>Michelle A. Albert, MD, MPH, FACC, FAHA</b>	University of California, San Francisco School of Medicine Walter A. Haas-Lucie Stern Endowed Chair in Cardiology and Professor in Medicine
<b>David Fleming, MD</b>	University of Washington School of Public Health Clinical Associate Professor
<b>Rachel R. Hardeman, PhD, MPH</b>	University of Minnesota School of Public Health Associate Professor in the Division of Health Policy & Management
<b>Rhonda Medows, MD</b>	Providence Population Health President of Population Health Management
<b>Julie Morita, MD</b>	Robert Wood Johnson Foundation (RWJF) Executive Vice President
<b>Octavio Martinez Jr., MD, MPH, MBA, FAPA</b>	Hogg Foundation for Mental Health/University of Texas (Austin) Executive Director

# Health Equity Workgroup (HEW) Background

- Began official health equity discussions during ACD orientation session in October 2021
- Published *Federal Register* Notice in March 2022
  - Solicited nominations from people with health equity; public health science and practice; public health policy development, analysis, and implementation expertise.
  - Nominees with front line and field experience at the local, state, tribal and territorial levels were encouraged to apply.
- Conducted three review rounds in March and early April 2022
  - Technical review of all the HEW nominations to ensure they were eligible for further review and ranking
  - CDC panel of health equity experts reviewed and ranked all nominations and made recommendations to the HEW co-chairs and ACD leadership
  - HEW co-chairs, Designated Federal Officer, ACD Chair, and CDC's leading health equity expert met and reviewed the highest ranked recommendations
  - Chose 10 outside experts to serve one-year terms representing various groups (disability, Alaskan Native, homelessness, LGBTQ+, corrections, local and state public health, population health)

# Health Equity Workgroup Membership

## Outside Experts

Name	Organization	Title
<b>Philip Alberti, PhD</b>	Association of American Medical Colleges	Founding Director
<b>David Brown, MBA</b>	YMCA	President and CEO
<b>Nafissa Cisse Egbuonye, PhD, MPH</b>	Black Hawk County Public Health (Iowa)	Public Health Director
<b>Cary Fremin, BS</b>	Dot Lake Village Council, Dot Lake Village	Director of Health and Social Services
<b>Delmonte Jefferson, BS</b>	Center for Black Health & Equity	Executive Director
<b>Maria Lemus, BA</b>	Visión y Compromiso and Network of Promotoras & Community Health Workers	Founding Executive Director
<b>Mysheika Roberts, MD, MPH</b>	Department of Public Health - Columbus, Ohio	Public Health Commissioner
<b>Bonnielin K. Swenor, PhD, MPH</b>	Johns Hopkins University Disability Health Research Center	Founder and Director
<b>Paula Tran, MPH</b>	Wisconsin Department of Health Services	State Public Health Officer
<b>Mr. G. Robert Watts, MPH, MS</b>	National Health Care for the Homeless Council	Chief Executive Officer

## HEW – Next Steps

- Monthly meetings planned – next in May
- CDC staff support identified
- Consideration of process including use of sub-groups and guest panels
- Goal of presenting draft report at Nov. 2022 ACD meeting
- **Immediate step:** Approve the Terms of Reference

# Health Equity Workgroup

## Terms of Reference

# Purpose

- Provide input to ACD on the scope & implementation of CDC's **CORE** strategy
- Prepare reports with findings, observations and outcomes to enhance the **CORE** strategy
- Suggest innovative and promising health equity practices
- Suggest ways to embed anti-racist policies/practices in public health programs

## **HEW - Emphasis Initially On First three Topics In TOR**

1. What will CDC need to do to be successful in CORE implementation? What are the best 3 agency-wide CORE goals & most important changes to advance CORE?
2. What are potential unanticipated barriers to CORE implementation and how can they be minimized?
3. How can CDC accelerate work on health equity at the state, territorial, local and tribal levels?

# Health Equity Workgroup

## Terms of Reference Discussion



# Wrap Up



# Adjourn

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

