Advisory Committee to the Director (CDC)

May 3, 2022

11:00 AM – 4:00 PM

Closed Captioning:
https://www.streamtext.net/player?event=4599MeetingoftheAdvisoryCommitteeetotheDirectorCDC
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

DMI Strategic Implementation Plan (cdc.gov)
We are listening...
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

Source: Public Health Surveillance Preparing for the Future (cdc.gov)
Public health must keep up with proliferating data sources

- Consumer Health Information
- Mobile Medical Devices
- Lab/Biomarkers data
- GIS & Remote Sensors
- Health Communication
- Social Media
- IoT
- Health Information Tools
- Electronic Medical and Health Records
- Genomics
- Mobile Apps
- Clinical Delivery Systems
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 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

<table>
<thead>
<tr>
<th>Monitoring Disease Burden</th>
<th>DATA COLLECTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Lab Reports</td>
<td>813M COVID-19 Tests</td>
</tr>
<tr>
<td>Case-Based Disease Surveillance</td>
<td>79M Case Reports</td>
</tr>
<tr>
<td>Emergency Department Visits</td>
<td>7.4M COVID-19 ED Encounters</td>
</tr>
<tr>
<td>Immunization Records</td>
<td>551M vaccinations administered</td>
</tr>
<tr>
<td>Virus Genomics Data</td>
<td>2.1M published sequences</td>
</tr>
<tr>
<td>Healthcare Data</td>
<td>140TB of clinical and administrative data</td>
</tr>
<tr>
<td>Hospitalization Data</td>
<td>4.6M total admissions</td>
</tr>
</tbody>
</table>

CDC COVID Data Tracker [covid.cdc.gov/covid-data-tracker]
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**

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

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

**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

**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

**Make sense of uncertainty early in an outbreak**

**Provide early warning, situational awareness**

**Get critical data for the response**

**Support policy and guidance**

**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

**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?
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**?
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

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

<table>
<thead>
<tr>
<th></th>
<th>% of Counties</th>
<th>% of Pop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>91.7%</td>
<td>92.1%</td>
</tr>
<tr>
<td>Medium</td>
<td>7.2%</td>
<td>6.5%</td>
</tr>
<tr>
<td>High</td>
<td>1.1%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

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)](https://www.cdc.gov/coronavirus/2019-ncov/cases-in-your-community/community-levels.html)
CCL Trajectory Analysis (past 5 weeks)
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
COVID-19 Surveillance Summary: Deaths

- As of April 24, 2022
  - 7-day average of daily death counts decreased 13.2% compared with previous week
COVID-19 Wastewater Surveillance

Source: CDC COVID Data Tracker: Wastewater Surveillance
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

Source: CDC COVID Data Tracker: Variant Proportions
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

Source: CDC COVID Data Tracker: Vaccinations in the US
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

Source: CDC COVID Data Tracker: Vaccination Demographics Trends; CDC COVID Data Tracker: Vaccination Demographics
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

Source: COVID-19 Vaccine Boosters | CDC; Stay Up to Date with Your COVID-19 Vaccines | CDC
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

Image Source: DON'T DELAY: TEST SOON AND TREAT EARLY (cdc.gov)
Sustain Use of COVID-19 Vaccines

- Sustain use of vaccines to protect the health of individuals and communities
  - Support uptake of 4th doses (2nd 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
COVID-19 Response Activity Transition Planning

- Planning for sustainability and incorporation of COVID-19 into routine public health practice
- CDC transitioning majority of programmatic and scientific COVID-19 Response activities to long-term "homes" within the agency
- Streamlined COVID-19 Incident Management Structure (IMS) will remain activated
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

- CHIEF OF STAFF
  Sherri A. Barger, MSPH

- CHIEF OPERATING OFFICER
  Robin D. Bailey Jr., MA

- CDC WASHINGTON DIRECTOR
  Jeff Rezk, MPA

- OFFICE OF EQUAL EMPLOYMENT OPPORTUNITY
  Reginald R. Melano, MS

- DIRECTOR OF INTERGOVERNMENTAL AND STRATEGIC AFFAIRS
  John Auerbach

- ASSOCIATE DIRECTOR FOR COMMUNICATION
  Cantin (Cate) Shockley, J.D.**

- SENIOR COUNSELOR FOR STRATEGIC COMMUNICATION
  Dori Salcido

- SENIOR ADVISOR FOR DIVERSITY, EQUITY, INCLUSION AND ACCESSIBILITY
  Aletha Maybank, MD, MPH

- ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE AND SAFETY
  Jim L. Perle, MD, PhD**

- ASSOCIATE DIRECTOR FOR POLICY AND STRATEGY
  Robin M. Ikeda, MD, MPH (RADM, USPHS, RET)

- CHIEF MEDICAL OFFICER
  Mitch Wolfe, MD, MPH (RADM, USPHS, RET)

- DEPUTY DIRECTOR FOR PUBLIC HEALTH SERVICE AND IMPLEMENTATION SCIENCE
  Nathaniel Smith, MD, MPH

- Office of Minority Health and Health Equity
  Leandra Liburd, PhD, MPH, MA

- Center for Global Health
  Nathaniel Smith, MD, MPH**

- Center for Preparedness and Response
  Henry Walke, MD, MPH

- Center for State, Tribal, Local, and Territorial Support
  José T. Montero, MD, MHCO*DS

- DEPUTY DIRECTOR FOR PUBLIC HEALTH SCIENCE AND SURVEILLANCE
  Daniel Jernigan, MD, MPH (CAPT, USPHS, RET)**

- Office of Science
  Rebecca Bunnell, PhD, MEd

- Office of Laboratory Science and Safety
  Jim L. Perle, MD, PhD**

- Center for Surveillance, Epidemiology, and Laboratory Services
  Leslie Ann Dauphin, PhD**

- National Center for Health Statistics
  Brian C. Moyer, PhD

- DEPUTY DIRECTOR FOR NON-INFECTION DISEASES
  Celeste Philip, MD, MPH

- Office of Science
  Rebecca Bunnell, PhD, MEd

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  Jim L. Perle, MD, PhD**

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- National Center for Health Statistics
  Brian C. Moyer, PhD

- DEPUTY DIRECTOR FOR INFECTIOUS DISEASES
  Jay C. Butler, MD (CAPT, USPHS, RET)

- National Center on Birth Defects and Developmental Disabilities
  Karen Remley, MD, MBA, MPH, FAAP

- National Center for Chronic Disease Prevention and Health Promotion
  Karen Hacker, MD, MPH

- National Center for Environmental Health/Agency for Toxic Substances and Disease Registry
  Patrick Brayette, PhD, CHP**

- National Center for Injury Prevention and Control
  Christopher Jones, PharmD, DrPH, MPH (CAPT, USPHS)**

- National Center for Immunization and Respiratory Diseases
  Sam Posner, PhD**

- National Center for Chronic Disease Prevention and Health Promotion
  Karen Hacker, MD, MPH

- National Center for Emerging and Zoonotic Infectious Diseases
  Christopher Braden, MD**

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  Patrick Brayette, PhD, CHP**

- National Center for Injury Prevention and Control
  Christopher Jones, PharmD, DrPH, MPH (CAPT, USPHS)**

- National Center for HIV, Viral Hepatitis, STD, and TB Prevention
  Jonathan Memin, MD, MPH (RADM, USPHS)
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
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 mosquitoes that can carry malaria
For persons with bleeding disorders, monitors for select infectious agents and other abnormal factors
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
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

### True Positive Rate

- **True positive rate** or **Sensitivity** = \( \frac{TP}{TP+FN} \)

### False Positive Rate

- **False positive rate** = \( \frac{FP}{FP+TN} \)

### True Negative Rate

- **True negative rate** or **Specificity** = \( \frac{TN}{FP+TN} \)

### Positive Predictive Value

- **Positive predictive value** = \( \frac{TP}{TP+FP} \)

### Negative Predictive Value

- **Negative predictive value** = \( \frac{TN}{FN+TN} \)
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

<table>
<thead>
<tr>
<th>CLIA lab</th>
<th>Surveillance lab</th>
<th>Research lab</th>
</tr>
</thead>
</table>
| - 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 | - 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 | - 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 |
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.
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 ± 1 minute and temperature 56 ± 1°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
<table>
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<tr>
<th>Health Equity Workgroup Membership</th>
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### ACD Members

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

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

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.