Advisory Committee to the Director (CDC)

February 7, 2023

10:00 AM – 3:00 PM

Closed Captioning: https://www.streamtext.net/player?event=11942MeetingAdvisoryCommitteeDirectorFeb2023
Event ID: 11942

Welcome, Roll Call

David Fleming, MD

ACD Chair

Overview of Recent Developments

Rochelle P. Walensky, MD, MPH,

Director, Centers for Disease Control and Prevention, and Administrator,
Agency for Toxic Substances Disease Registry

Discussion - Walensky

Data and Surveillance Workgroup

Julie Morita, MD and Nirav R. Shah, MD, MPH

Co-Chairs

Update on ACD Recommendations Submitted to HHS

Three Priority Areas to Improving Essential Data Exchange between Health Care and Public Health Systems

1) Define the Minimal Data Necessary for Core Public Health Data Sources
2) Establish Public Health Data Systems, Standards, and Certification
3) Establish Data Use Agreements and Frameworks

Define the Minimal Data Necessary for Core Public Health Data Sources

CDC, in consultation with STLT partners, and with input from healthcare and federal agency partners, should:

- Develop, publish, and regularly update a list of data elements that constitute the minimal data necessary for disclosure to CDC for public health activities, including response activities
- Work with STLT partners to develop a list of data elements that constitute the range of data necessary for disclosure to STLTs for the same core data sources.

Establish Public Health Data Systems, Standards, and Certification

CDC, in collaboration with STLT partners and the Office of the National Coordinator for Health Information Technology (ONC), should

- Develop and implement a coordinated phased approach to certification which should start with expanded guidance for public health criteria, moves to requirements, and ultimately advances to certification.

Establish Data Use Agreements (DUA) & Frameworks

CDC, in coordination with STLT partners, should:

Establish a proactive approach to DUAs, and streamline the process, seeking to provide language on protecting individual privacy, and addressing other concerns like the use and re-release of data, consistent with laws applicable to each party, respectively.

Data Surveillance Workgroup Recent Areas of Focus

1) Data Science and Information Technology Workforce

2) Sustained Funding Challenges

Data Science and Information Technology Workforce (1 of 2)

1) **Presentation by Dr. Pattie Simone, Director of Scientific Education and Professional Development, CDC**
   - Challenges identified
   - Workforce shortage
   - Workforce training needs

2) **DSW member priorities**
   - Focus on State, Territorial, Local and Tribal (STLT) workforce
   - Leverage academics and private sector

Data Science and Information Technology Workforce (2 of 2)

1) Workforce shortages

- Need to quantify staffing needs
- Supplement workers through partnerships with private sector, academia, healthcare
- Better understand the public sector's capabilities vs what's best suited for academia / healthcare / private sector

2) Workforce training needs

- Define competencies
- Enhance training programs for future worker and existing worker
- Supplement workers through partnerships with private sector, academia, healthcare

3) Next Steps

- Identify priority areas for ACD to consider

Sustained Funding Challenges

1. **Current funding and anticipated funding cliff**

2. **DSW needs to better understand**
   - Existing funding
   - Funding approaches for enterprise services and resources (i.e. cloud services)
   - Challenges experienced by STLTs
   - Other federal agency or other sector models for sustainability

3. **Next Steps**
   - Infrastructure grant update by Center for Surveillance, Epidemiology, and Laboratory Services
   - Epidemiology and Laboratory Capacity (ELC) grant update by Division of Preparedness and Emerging Infections
   - Funding challenge updates from ASTHO/CSTE, NACCHO, Health Information and Management Systems Society (HIMSS)

Discussion – Data & Surveillance Workgroup

Public Health Infrastructure Grant

Leslie Ann Dauphin, PhD

Director, National Center for State, Tribal, Local and Territorial Public Health Infrastructure and Workforce (proposed)

Public Health Infrastructure
is made up of the **people, services, and systems** needed to promote and protect health in every U.S. community

Recognizing Public Health Infrastructure Gaps Only After a Crisis – 1 of 3

1988 (HIV/AIDS Epidemic)
The Future of Public Health, Institute of Medicine

2002 (9/11 and anthrax attacks)
The Future of Public Health in the 21st Century, Institute of Medicine

2022 (COVID-19)
Historically Unprepared, Senate Homeland Security and Government Affairs Committee

"Our **current capabilities for public health actions are inadequate**…The necessary **public health capacity** to cope with the immediate, enduring, and impending threats to health cannot… be turned on and off as particular health problems arise and receive attention…. **[H]ealth status will fall short of the achievable if public health is not strong**."

Recognizing Public Health Infrastructure Gaps Only After a Crisis, 2 of 3

1988 (HIV/AIDS Epidemic)
The Future of Public Health, Institute of Medicine

2002 (9/11 and anthrax attacks)
The Future of Public Health in the 21st Century, Institute of Medicine

2022 (COVID-19)
Historically Unprepared, Senate Homeland Security and Government Affairs Committee

"Under the glare of a national crisis, policy makers and the public became aware of…an **insufficient and inadequately trained public health workforce**, **antiquated laboratory capacity**, a **lack of real-time surveillance** and epidemiological systems…and **communities without access to essential public health services**."

Recognizing Public Health Infrastructure Gaps Only After a Crisis, 3 of 3

1988 (HIV/AIDS Epidemic)
The Future of Public Health, Institute of Medicine

2002 (9/11 and anthrax attacks)
The Future of Public Health in the 21st Century, Institute of Medicine

2022 (COVID-19)
Historically Unprepared, Senate Homeland Security and Government Affairs Committee

"...multiple **systemic problems** unaddressed at the outset of the pandemic remain. These issues include **insufficient funding**, **overlapping roles**, supply chain vulnerabilities, **inadequate surveillance capabilities**, and **insufficient testing capacity**, among many others. ***These problems have been flagged by experts and oversight agencies for years yet have been largely overlooked by all branches of the federal government.***"

Two CDC Approaches

New Strengthening U.S. Public Health Infrastructure, Workforce, and Data Systems Grant

National Center for State, Tribal, Local and Territorial Public Health Infrastructure and Workforce *(proposed)*

CDC's New Public Health Infrastructure National Center

National Center for State, Tribal, Local and Territorial Public Health Infrastructure and Workforce (proposed)

Goal To strengthen the public's health through effective and efficient delivery of public health infrastructure and workforce development services

Primary Functions

Jurisdictional Support

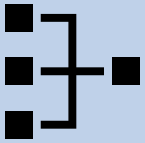
Partnerships & Technical Assistance

Workforce Development

New Public Health Infrastructure National Center

Cross-cutting Scientific Functions

Data Management

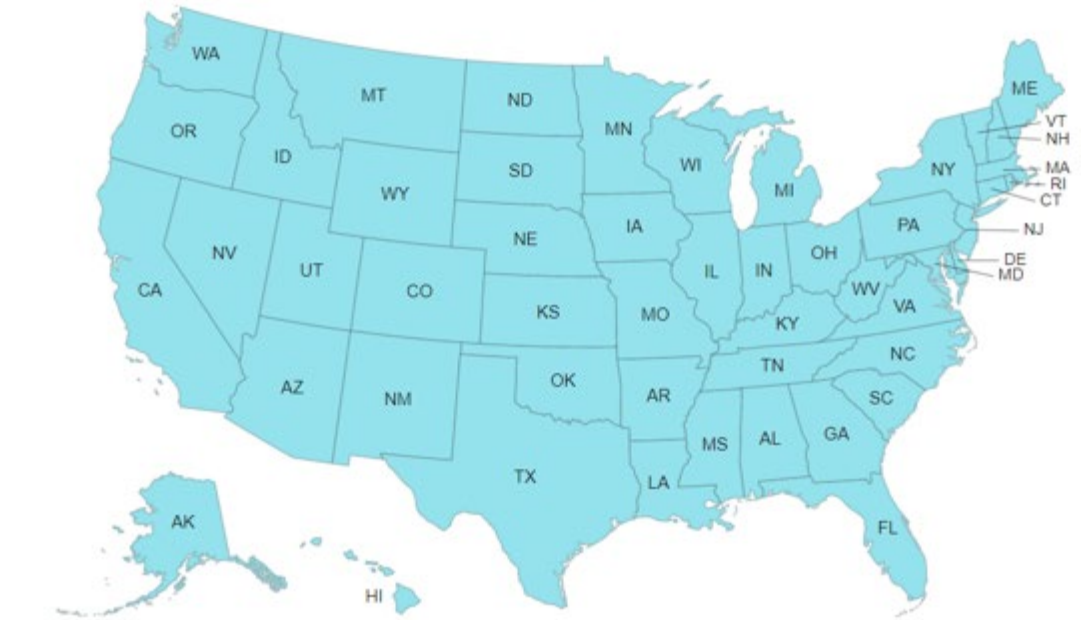


Systems & Infrastructure

Evaluation & Assessment

OE22-2203:
Strengthening U.S. Public Health Infrastructure, Workforce, and Data Systems Grant

Everyone in the United States lives in a jurisdiction that received funding under the new CDC grant



Full funding details: cdc.gov/infrastructure

Notice of Award:
November 29, 2022

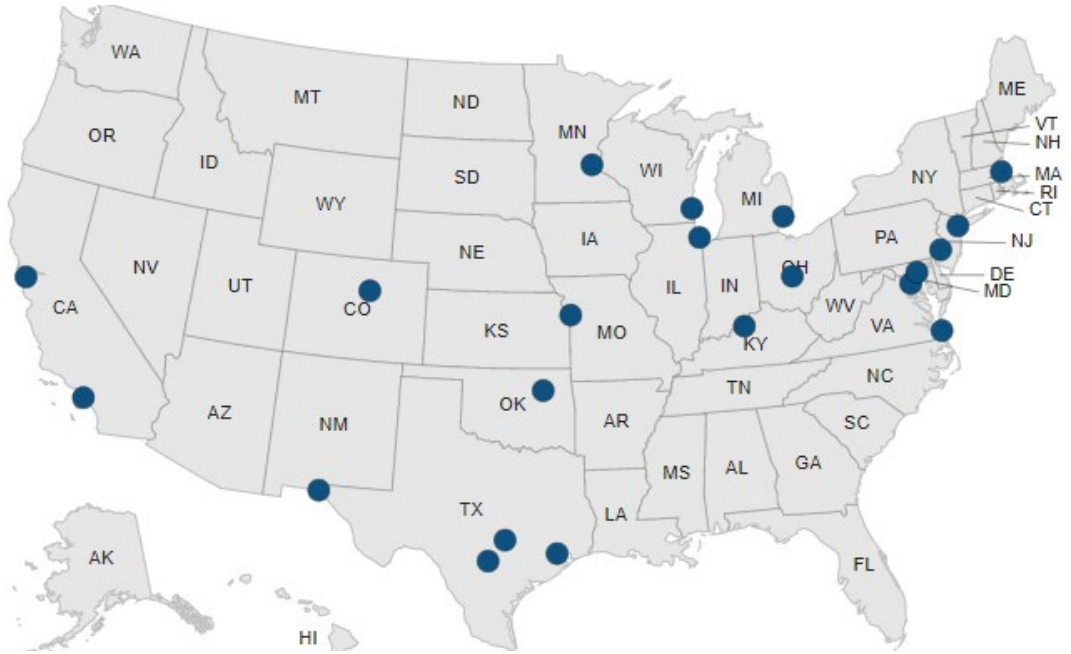
Budget period start:
December 1, 2022

Period of performance:
5 years/60 months

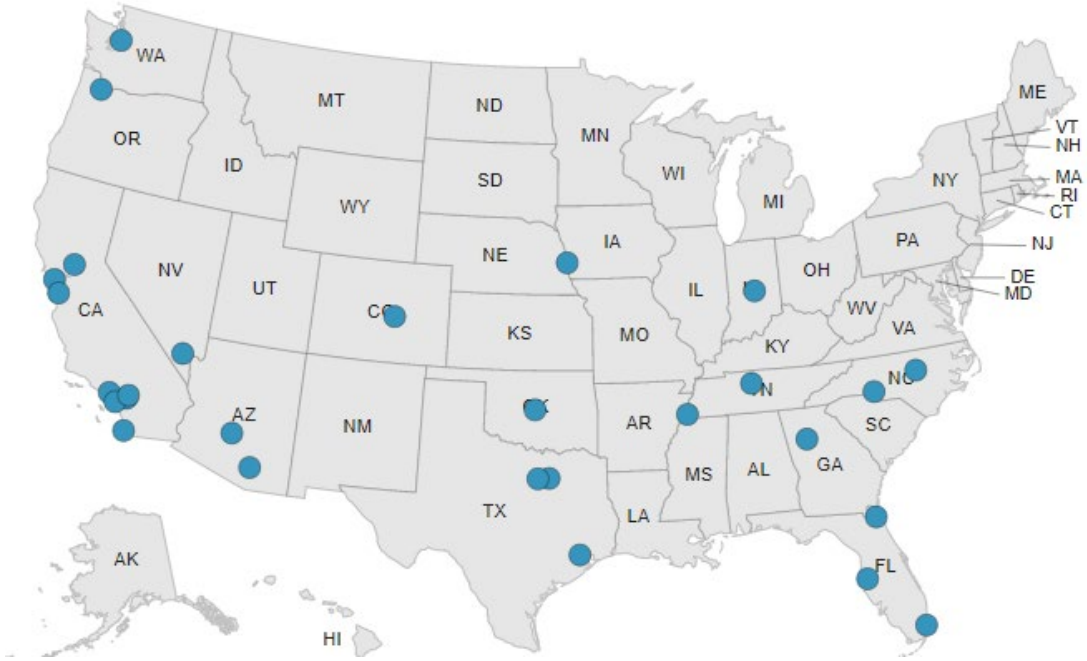
Jurisdictions Funded:
107

Partners Funded:
3

Funded Cities and Counties



Cities



Counties

Clickable Map, funding details, and more: cdc.gov/infrastructure

Grant Funding Overview

$3.2 billion awarded November 29, 2022

	Component A			Component B
	Workforce	**Foundational Capabilities**	**Data Modernization**	
Goals	Recruit, retain, support, and train the public health workforce	Strengthen systems, processes, and policies	Deploy scalable, flexible, and sustainable technology	Training, evaluation, and coordination support for grantees
Award	$3 billion	$140 million	---	$65 million
Funding Source	American Rescue Plan (ARP) Act	Public Health Infrastructure and Capacity FY 2022	--	ARP ($45M) Public Health Infrastructure and Capacity ($20M) FY 2022

Component A: Overview

107 jurisdictions received funding

- **50** States
- **22** Cities (incl. DC)
- **27** Counties
- **5** Territories
- **3** Freely Associated States

Key Strategies:

Workforce
Recruit, retain, support, and train the public health workforce

Foundational Capabilities
Strengthen systems, processes, and policies

Data Modernization
Deploy scalable, flexible, and sustainable technologies

Not currently funded

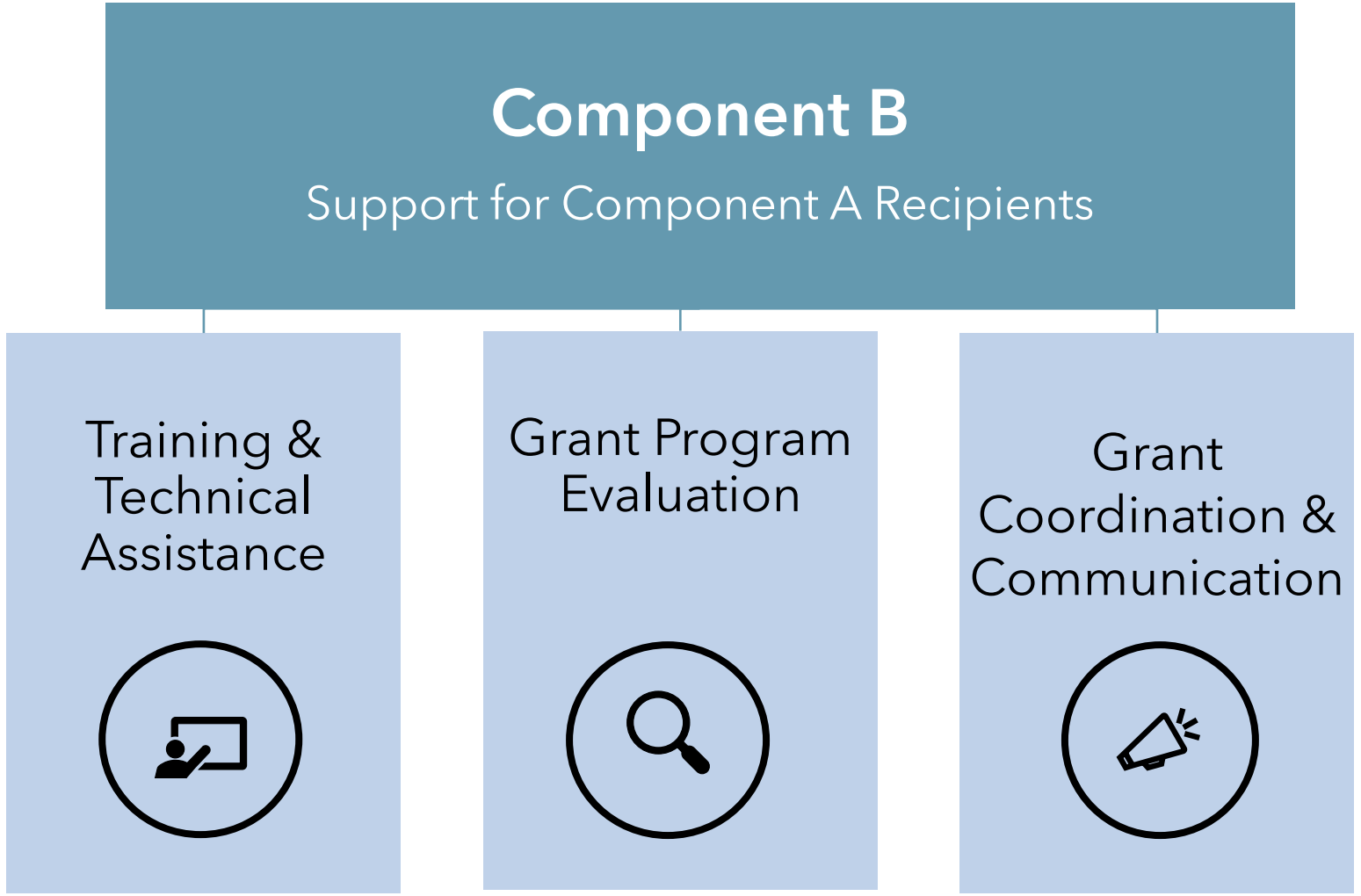
Component B: Overview

Partners:

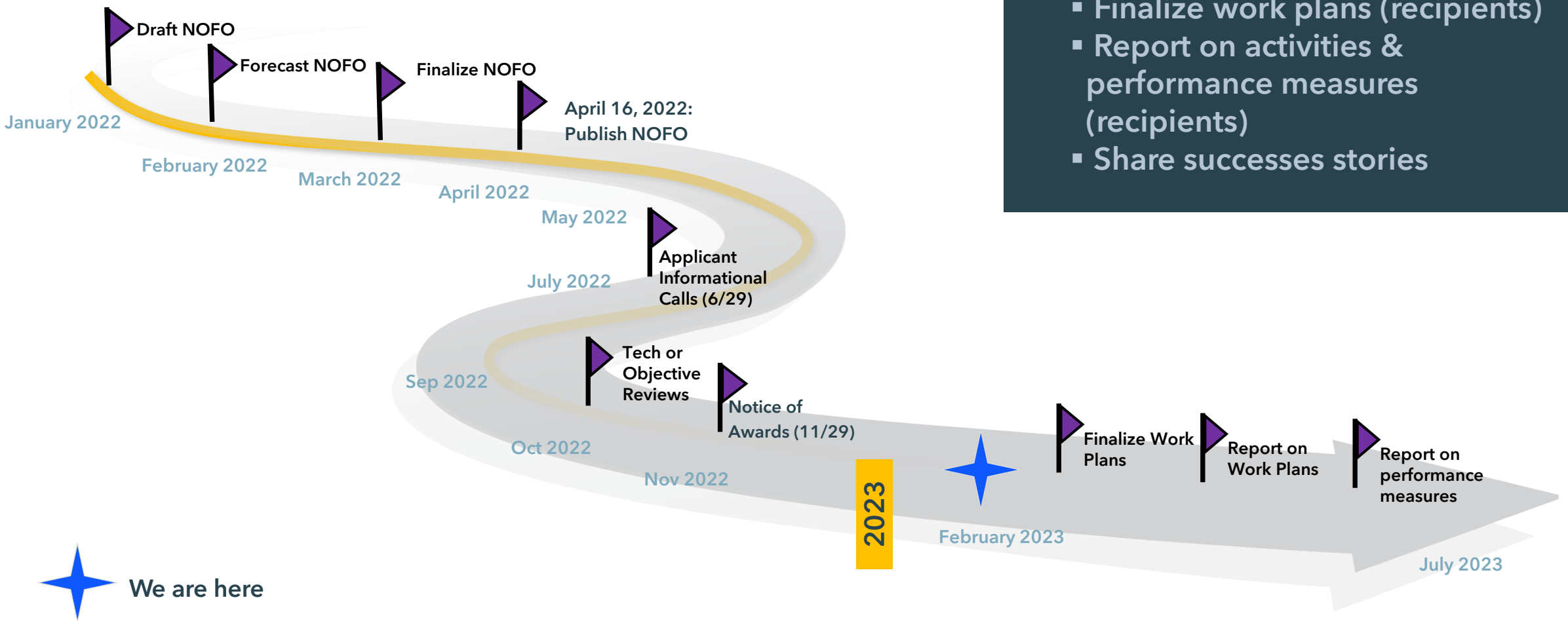
astho™

National Network of Public Health Institutes

PHAB



Grant Timeline



What's ahead…

- Finalize work plans (recipients)
- Report on activities & performance measures (recipients)
- Share successes stories

Key Outcomes

	Component A			Component B
	Workforce	**Foundational Capabilities**	**Data Modernization**	
Short-term Outcomes	Increased hiring of diverse public health staff	Improved organizational systems and processes	More modern and efficient data structure & increased data interoperability	Increased hiring & retention mechanisms available to Component A
Intermediate Outcomes	Increased size of public health workforce	Stronger public health foundational capabilities	Increased availability and use of public health data	Improved sharing of lessons learned

Recipients will achieve these key outcomes by the end of the period of performance

Evaluation

Evaluation and performance measurement will allow us to:

- Track progress towards key outcomes
- Document successes and challenges
- Drive continuous improvement
- Build evidence for interventions

We will also **leverage data from existing** assessments including:

- Association of State and Territorial Health Officials (ASTHO) Profile
- National Association of County and City Health Officials (NACCHO) Profile
- Public Health Accreditation Board (PHAB) Assessments
- Public Health Workforce Interests and Needs Survey (PH WINS)

Performance measure reporting will **complement other evaluation data and case studies**, along with ongoing workplan progress and financial reporting

Performance Measures for Evaluation

Draft examples include, but are not limited to:

- Number of **positions filled** and retained
- **Staff retention** rate
- Proportion of public health staff who **report satisfaction** (with their job, organization, workplace environment, pay, and job security)
- Number and type of **quality improvements** to organizational systems & processes
- Percent of recipients who **apply for accreditation/reaccreditation** during grant period
- Percent of **recipients accredited** by Public Health Accreditation Board (PHAB)

Discussion Questions

- How can we help to reduce the burden on US jurisdictions that receive funding from CDC?
- What would be most helpful to demonstrate progress given the flexible nature of the grant?
- How do we build support for sustainment?
- How will the grant work with other sources of CDC state and local funding?

Discussion - Dauphin

Health Equity Workgroup

Daniel Dawes, JD and Monica Valdes Lupi, JD, MPH

Co-Chairs

HEW Membership

Co-Chairs:

- Daniel Dawes, JD
- Monica Valdes Lupi, JD, MPH

ACD Members:

- Adaora Alise Adimora, MD, MPH
- Michelle A. Albert, MD, MPH, FACC, FAHA
- David Warren Fleming, MD
- Cristal A. Gary, MPP
- Lynn R. Goldman, MD, MS, MPH
- Rachel R. Hardeman, PhD, MPH
- Rhonda M. Medows, MD
- Julie Morita, MD
- Octavio Martinez Jr., MD, MPH, MBA, FAPA

Public Members:

- **Philip Alberti, PhD.** Association of American Medical Colleges
- **David Brown, MBA.** YMCA
- **Nafissa Cisse Egbuonye, PhD, MPH.** Black Hawk County Public Health (Iowa)
- **Cary Fremin, BS.** Dot Lake Village Council, Dot Lake Village
- **Delmonte Jefferson, BS.** Center for Black Health & Equity
- **Maria Lemus, BA.** Visión y Compromiso and Network of Promotoras & Community Health Workers
- **Mysheika Roberts, MD, MPH.** Department of Public Health - Columbus, Ohio
- **Bonnielin K. Swenor, PhD, MPH.** Johns Hopkins University Disability Health Research Center
- **Paula Tran, MPH.** Wisconsin Department of Health Services
- **G. Robert Watts, MPH, MS.** National Health Care for the Homeless Council

TASK AREA 1

Enable and assure the meaningful involvement of communities in agency decision-making, the development of health equity policies, program implementation, and evaluation.

ACD Lead: Daniel Dawes

David Brown

Delmonte Jefferson

Maria Lemus

Bonnie Swenor

Bobby Watts

TASK AREA 2

Align, and restructure as necessary, CDC policies, resource allocation, and program practices so as maximize the ability for staff and partners to address health inequities in their day-to-day work.

ACD Lead: Monica Valdes Lupi

Nafissa Cisse Egbuonye

Octavio Martinez

Rhonda Medows

Julie Morita

Mysheika Roberts

Paula Tran

TASK AREA 3

In concert with communities, take immediate and decisive action to expand, embed, and integrate approaches to measure and influence drivers of health equity across all public health programs.

ACD Lead: David Fleming

Ada Adimora

Michelle Albert

Philip Alberti

Cary Fremin

Rachel Hardeman

Updates

- HEW report conceptually approved during the November 2022 ACD Meeting
- HEW next steps include:
  - HEW members will work to provide additional specificity for recommended actions for Task Areas 1 and 2.
  - Task Area 3 complete and HEW will recommend for implementation by CDC.

Vote on Action Steps for *Task Area 3 (1 of 2)*

1) CDC should immediately initiate a coordinated, agency-wide approach to identify and implement measures of underlying drivers of equity and health equity in ways that make them accessible and useful to communities and public health programs.*
   - CDC should lead a process to synthesize the current state-of-the-art of measurement of upstream drivers of health equity.
   - CDC should initiate a process with key partners and stakeholders to assess the feasibility of, and opportunities for, developing and using field-tested and consistent methods and measures across programs and jurisdictions.
   - CDC should assure the development of indicators that includes asset and solution-based measures of individual and community equity and health equity.
   - CDC should focus special attention on identifying and developing measures that can be timely, locally available, and as granular as possible.
   - CDC programs should promote, and enable through program funding, the incorporation of measures of health equity into the monitoring and evaluation of all public health programs.

Additional details in full report

Vote on Action Steps for *Task Area 3 (2 of 2)*

2) CDC should immediately initiate a coordinated, agency-wide approach to develop and integrate strategies to influence the effects of drivers of health equity across the entire range of its public health programming.*
   - CDC should align and integrate the internal organization and leadership of its Health Equity and Social Determinant of Health activities to assure coherence and synergy of approaches.
   - CDC should promote and enable across all program funding the routine assessment and mapping of the effects of the drivers of health equity on the health and well-being of affected populations.
   - CDC should promote and enable across all program funding, identifying and incorporating strategies to improve project outcomes by modifying the most important and influenceable dynamics identified in the assessments above (in bullet #2 above).
   - CDC should assure that this suite of promoted and funded strategies routinely includes asset-based approaches directed at individual, as well as system, policy, and environmental drivers of health equity, including civic engagement strategies.
   - CDC should assure that measurement of these efforts and their effects are routinely incorporated into project and program evaluation.

Additional details in full report

Areas for additional specificity – *Task Area 1*

- Current rules, policies, and practices related to community engagement and community participation
  - Options for community engagement and input: FACA, other advisory boards, listening sessions, other types of committees
  - Ways for communities to contribute to decision-making and practices
  - Understanding and influencing authorizing language limitations

Areas for additional specificity – *Task Area 2*

- Current business practices and administrative rules that guide resources and funding mechanisms for community-based organizations
  - Assessment of current status of CBO/community funding
  - Understanding competitive vs. formula driven funding
  - Opportunities to scale exemplars: 2103 Health Equity, SDoH, Ryan White
  - Identification of business practice/structural barriers limiting community funding
  - Understanding mechanisms for technical assistance and capacity building support for CBOs

Discussion – Health Equity

Lunch

Laboratory Workgroup

Joshua Sharfstein, MD and Jill Taylor, PhD

Co-Chairs

Laboratory Workgroup Presentation Outline

- Background
- Findings
- Proposed Action Steps

Laboratory Workgroup Purpose

Provide advice and work products for the ACD,CDC regarding the effective implementation of CDC agency-wide laboratory quality improvements across the agency to meet CDC's goal of ensuring the agency's laboratories maintain a gold-standard level of quality using advanced laboratory science.

Laboratory Workgroup Members

- **Angela M. Caliendo, MD, PhD, FIDSA, FAAM**, Brown University, Executive Vice Chair, Department of Medicine, Alpert Medical School
- **David Fleming, MD,** University of Washington School of Public Health, Clinical Associate Professor
- **Alberto Gutierrez, PhD,** NDA Partners, LLC, Partner
- **Paul B. Kimsey, PhD, MA,** California Department of Health, Deputy Director; Director, State Public Health Laboratory
- **Grace Kubin, PhD**, Texas Department of State Health Services, Director, Laboratory Services Section
- **Ruth Lynfield, MD,** Minnesota Department of Health, State Epidemiologist, Medical Director
- **Robin Patel, MD(CM), D(ABMM), FIDSA, FACP, F(AAM),** Mayo Clinic, Professor; Director, Infectious Diseases Research Laboratory; Co-Director, Bacteriology Laboratory
- **Jennifer L. Rakeman, PhD**, Cephid, Senior Director, Medical Affairs, Public Health Programs
- **Daniel D. Rhoads, MD**, Cleveland Clinic, Microbiology Section Head
- **Tim Southern, PhD, MS, D(ABMM),** South Dakota Department of Health, Public Health Laboratory Director
- **Denise Toney, PhD (HCLD),** Commonwealth of Virginia, Department of General Services, Laboratory Director, Division of Consolidated Laboratory Services
- **Jay K. Varma, MD**, Weill Cornell Medical School, Director, Cornell Center for Pandemic Prevention and Response
- **Scott Zimmerman, DrPH, MPH, HCLD (ABB)**, Lab Corp, Vice President, Department of Science & Technology

Term of Reference #5

In the fiscal year 2022 congressional language, Congress requested the Office of the Secretary, HHS, 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 that should be established to mitigate future issues.

Process

- Workgroup met with experts
- Document review and analysis
- Developed report with findings and action steps

Failures in the first iteration of CDC's SARS-CoV-2 test

1) The N1 probe was contaminated by the positive control resulting in false positive results.

2) The N3 probe was poorly designed, resulting in false positive results.

3) The Quality Control step did not detect these failures before the test kit was sent to public health laboratories.

Three Failures (1 of 4)

1) Contamination of the N1 Probe

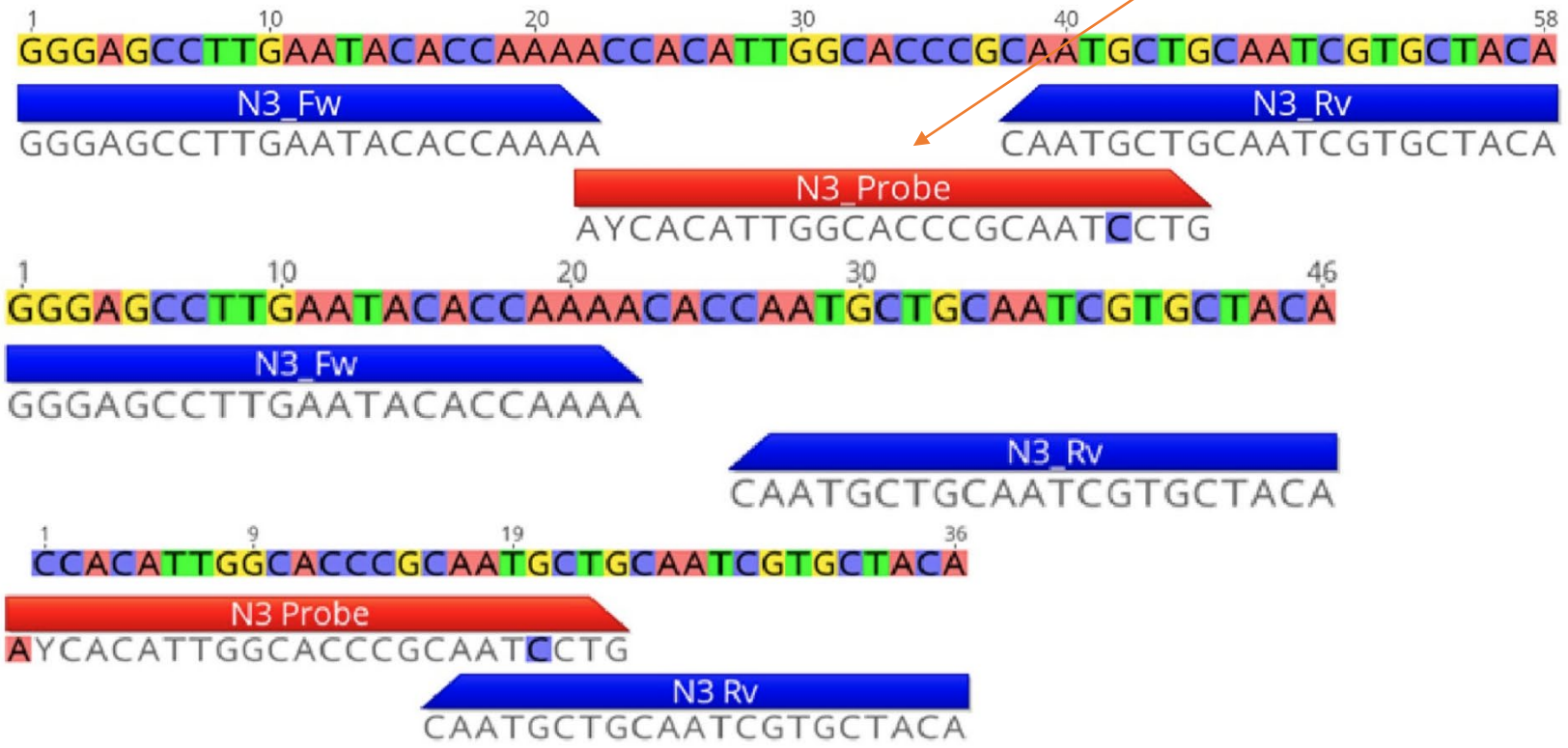
Table 2. Sequencing results of RT-PCR products demonstrated the source of false reactivity in N1 and N3 components.

RT-PCR Components[i]	Reagent Source[ii]	% Reads Mapped to Reference[iii]	% Template Contaminant[iv]	% Reads Mapped to Oligonucleotides	% Reads Involving Probe[v]
N1_pc (n = 1)	EUA-kit	96%	nd	4%	<1%
N1_fp (n = 2)	EUA-kit	nd	34% (0%)	66% (0%)	<1% (0%)
N3_fp (n = 2)	pre-EUA	nd	nd	98% (1%)	51% (2%)
N3_pc (n = 1)	EUA-kit	42%	nd	58%	<1%
N3_fp (n = 14)	EUA-kit	nd	nd	>99% (0%)	37% (4%)
N3_fp (n = 6)	Commercial	nd	nd	94% (6%)	43% (10%)

PLOS One paper

Three Failures (continued, 2 of 4)

2) Poor design of the N3 Probe



PLOS One paper

Three Failures (continued, 3 of 4)

2) Poor design of the N3 Probe

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N3_fp (n = 6)	Commercial	nd	nd	94% (6%)	43% (10%)

PLOS One paper

Three Failures (continued, 4 of 4)

3) Failure of Final Quality Control Step

Specifically, an 'incorrect' Final Kit QC testing procedure used initially to evaluate the final EUA Test Kits was unable to detect the non-specific amplification observed with the N3 molecular target when used with samples that should be negative. When the 'correct' Final Kit QC procedure was performed, one of three NTCs (33%) was positive with the N3 molecular target, which should be negative. The available information indicates that these 33% QC failure results were accepted and the EUA Test Kits—already dispatched to the IRR—were not recalled.

CDC Root Cause Analysis

Our Question: What were the causes of the causes?

What contributed to the shortcomings of the first COVID-19 tests?

- Inadequate Planning
- Ineffective Governance
- Inadequate Quality Control, Quality Assurance, and Regulatory Oversight
- Poor Test Design Processes

Inadequate Planning

Graduated Response Framework

- Supports scale up at the Center level without a full agency-wide response since…..“most responses do not warrant a CDC Activation”

Framework lacked:

- Details relevant to test development
- Clear governance structure
- Detailed transition plan from “graduated response” to full agency activation

Lab Workgroup report

Inadequate Planning: Example of Impact

- Same lab manufactured both primers and probes for the test kits as well as the positive control despite:
  - Known risk of contamination
  - Perception that there was no reasonable alternative approach to quickly gain access to positive control

Ineffective Governance

Three labs involved in making the test, reporting to different centers.

- No point of coordination and responsibility across labs:
  - Prior to the emergency
  - During the “graduated response”
  - During the incident management agency mobilization

Ineffective Governance: Example of Impact

- Delays in understanding the scale and cause of the test issues

- IM leadership was not initially aware of:
  - Performance issues of CDC-manufactured tests
  - Quality control failures prior to distribution

Earlier understanding might have led to different decisions on test development, validation, and distribution

Inadequate Quality Control, Quality Assurance, and Regulatory Oversight

- Research and clinical lab space intermingled
- No CLIA oversight for test made for distribution
- Failed quality control came after CDC application to FDA
- No clear quality assurance system overseeing test development

What is CLIA Oversight?

- The Centers for Medicare & Medicaid Services regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
- CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, patient test management, test validation requirements, quality assurance, quality control and personnel qualifications.

Inadequate Quality Control, Quality Assurance, and Regulatory Oversight: Example of Impact

- No reliable quality management system in place to guide early response activities
  - New approach was established
  - Lack of clarity regarding critical aspects of test design, validation and manufacturing
  - Hybrid system drawing from different programs

Poor Test Design Processes

- No evidence of meaningful design control process
- No evidence that available computer models for predicting design failure were used

Poor Processes for Test Design: Example of Impact

- **Failure occurred in the design and validation of N3 probe**
  - N3 probe performance issue was not detected or addressed prior to manufacture and distribution
  - No clearly defined pass/fail threshold criteria existed for test validation
  - Despite 1 in 3 test kits failing validation, the kits were sent to public health laboratories

Break for questions #1

What Policies, Practices, and Systems Should Be Established to Address These Issues in the Future?

10 Proposed Action Steps

- CDC has made addressing challenges with its clinical laboratory enterprise an urgent priority.

- Some of our action steps overlap with moves that CDC has proposed or is in the process of advancing. Others would go further.

Leadership and Management (1 of 3)

Action Step 1: There should be a senior leader for laboratories, reporting to the CDC Director, with major responsibility and authority for laboratories at the agency. This position should be a deputy director or equivalent position within the CDC's organization.

Leadership and Management (continued, 2 of 3)

Action Step 2: The CDC should consolidate key laboratory support functions into a new Center. This Center should focus on clinical laboratory quality, laboratory safety, workforce training, readiness and response, and manufacturing.

Leadership and Management (continued, 3 of 3)

Action Step 3: The CDC should create plans for developing tests for novel public health challenges that include the governance structure to be utilized in an emergency.

Quality – 1 of 3

Action Step 4: Across CDC, clinical laboratories should be consolidated, ideally at the Division level, with cross-Center strategies to encourage collaboration with epidemiologists and basic science research laboratories. The CDC should maintain a strict separation of laboratory space and staff between clinical laboratories and basic research laboratories.

Quality (continued, 2 of 3)

Action Step 5: The CDC should create and train a robust workforce for clinical laboratories, comprised of scientists who have the education, skills, and qualifications to support and lead high-complexity laboratories.

Quality (continued, 3 of 3)

Action Step 6: The CDC should cultivate and foster a culture of laboratory quality through the adoption of a comprehensive clinical laboratory quality management system across the agency.

Break for questions #2

Test Development (1 of 3)

Action Step 7: To facilitate the rapid scale-up of testing, the CDC should involve external experts in its review and deployment process for clinical tests for pathogens with pandemic potential.

Test Development (continued, 2 of 3)

Action Step 8: The CDC should incorporate redundancy into the national responsibility for test development.

Test Development (continued, 3 of 3)

Action Step 9: To reduce the burden on the agency and support a high-quality laboratory network, the CDC should transfer the performance of selected rare tests to Centers of Excellence.

Electronic Laboratory Reporting

Action Step 10: The CDC should lead the standardization of health data collection associated with laboratory tests to improve future public health responses.

Discussion – Laboratory Workgroup

Closing Remarks

Adjourn