Advisory Committee to the Director (CDC)

May 11, 2023

9:00 AM – 3:00 PM

Closed Captioning: https://www.streamtext.net/player?event=12247MeetingAdvisoryCommitteeDirector
Event ID: 12247

Welcome, Roll Call

David Fleming, MD

ACD Chair

Agency Updates

Nirav D. Shah, MD, JD

Principal Deputy Director, Centers for Disease Control and Prevention

Discussion

Health Equity Workgroup

Monica Valdes Lupi, JD, MPH

Co-Chair

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 on Task Area 3 adopted by ACD during February 2023 ACD Meeting.
- HEW members met with CDC SMEs to understand direction for the new Office of Health Equity and CDC's policies and practices regarding appropriations, funding, and community engagement
- Task Area 1 and 2 are complete, and HEW is recommending for implementation by CDC.

TASK AREA 1

Task Area 1 Guiding Principles

- Ensure systems and processes are created and followed so that community perspectives lead and communities are meaningfully included throughout the decision-making process.
- Build on strengths that match solutions to each community, rather than employing the same solutions for all. Communities invariably have many strengths and are resilient.
- Health equity efforts cannot be myopic. Health equity across the lifespan is influenced by intergenerational and multigenerational experiences of trauma along with racism, ableism, sexism, classism, homophobia, and trauma.
- To achieve long-term positive change, routinely assess, map the effects, and intervene on the drivers of health equity on the health and well-being of affected populations and center on the principle that community development and sustained investment will yield positive impacts in the community.

Additional details in full report

Proposed Action Steps for *Task Area 1*

Action Step 1

CDC should take specific steps to build and strengthen its relationship with underserved communities and community-based organizations (CBOs) that support them.

- Create an external council/process to provide advice and perspective from diverse communities to the new Office of Health Equity and to CDC as a whole.
- Engage in a near-term process with CBOs to solicit their perspective and advice on the challenges of working with CDC and receiving funding from CDC, either directly or through sub-grants from STLT health organizations.
- Include diverse community and CBO perspectives in the membership of its Advisory Committees that serve Centers, Institutes, and Offices (CIOs).

Additional details in full report

Proposed Action Steps for *Task Area 1*

Action Step 1 *(continued)*

CDC should take specific steps to build and strengthen its relationship with underserved communities and community-based organizations (CBOs) that support them.

- Routinely include appropriate community and CBO perspectives in its external program reviews and public health issues meetings and convenings that engage outside partners.
- Prioritize the inclusion of "lived experience" as a potential job qualification in job announcements and position descriptions for internal staff who create and oversee public health programs.
- Develop and encourage opportunities for internal program staff to experience the realities of opportunities and challenges in underserved communities and the CBOs that support them.

Additional details in full report

Proposed Action Steps for *Task Area 1*

Action Step 2

CDC should engage with state, tribal, local, and territorial (STLT) public health agencies to identify and implement best practices to build and strengthen relationships between STLT public health agencies and underserved communities and the CBOs that support them.

- Provide leadership in better connecting with communities, as in Proposed Action Step 1 above, and encourage appropriate similar action by STLT public health agencies.
- Identify and implement ways to harmonize practices and expectations across CDC programs and grants to optimize community engagement and involvement at the STLT level.

Additional details in full report

Proposed Action Steps for *Task Area 1*

Action Step 2 *(continued)*

CDC should engage with state, tribal, local, and territorial (STLT) public health agencies to identify and implement best practices to build and strengthen relationships between STLT public health agencies and underserved communities and the CBOs that support them.

- Work with STLT public health agencies and community partners to identify best practices for strategies and mechanisms to ensure meaningful community engagement and leadership and should encourage or require adoption of these by STLT public health agencies in relevant CDC funding streams.
- Identify and create opportunities, including funding opportunities, for enabling meaningful engagement between STLT public health agencies and communities, especially on issues relating to underlying drivers of health equity or health disparities.

Additional details in full report

Task Area 1 Overarching Principle

The critical determinant for the success of *Task Area 1* will be the recognition that meaningful "community engagement" requires more than just fostering opportunities for the community to provide input and instead requires community agency in the design of policy, program development, and program implementation.

Additional details in full report

Discussion and Vote

TASK AREA 2

Task Area 2 Guiding Principles

Center community and equity in policies and funding:

- Recognize the impact of political and systemic power differentials on historically marginalized communities to facilitate policy actions toward equitable culture shifts and improved public health by embracing a culture of accountability for addressing long standing inequities.
- Strengthen and increase mechanisms that create increased opportunities to provide funding directly to CBOs as opposed to the traditional “trickle down” funding dissemination approach from STLT public health agencies to CBOs.
- Identify institutional barriers that have resulted in fewer opportunities for CBOs to access CDC resources, including financial and technical assistance.

**Additional details in full report*

Task Area 2 Guiding Principles (continued)

- Examine and revise existing policies and laws for the existence of stigmatizing language and ensure that new policies exclude further stigmatization.
- Embed equity into all decision-making from the OD to the CIOs and ensure a transparent, accountable, accessible, and inclusive process to enable cross-team communication and collaboration.
- Ensure that CDC's policies, communications, and programs are offered in a person and community-centered, language-concordant, accessible, and culturally-centered manner.
- Scale equitable practices across the agency that support the allocation of resources to implement cross-cutting initiatives focused on the social determinants of health.

**Additional details in full report*

Proposed Action Steps for *Task Area 2*

Action Step 1:

CDC should immediately initiate a coordinated, agency-wide assessment of all grants, cooperative agreements, and contracts across all programs, projects, and activities (PPAs) to establish a publicly available and accessible inventory of how funding is allocated (i.e., competitive, formula-driven, etc.), to which types of organizations (i.e., STLT public health agencies, CBOs, membership organizations, etc.), and where there may or may not be restrictions in the legislative language concerning eligible grantees. CDC should also develop an inventory which identifies the names and award amounts for primary grant sub-recipients for all grants, cooperative agreements, and contracts that are awarded.

**Additional details in full report*

Proposed Action Steps for *Task Area 2*

Action Step 2:

All CDC PPAs should jointly create and put into practice a publicly accessible policy document for applicants and grantees responding to CDC Notice of Funding Opportunities (NOFOs) detailing requirements for integrating health equity processes and approaches into new or continuing applications. This document should include the elements of the HHS Health Equity Guidance for Notice of Funding Opportunities (NOFOs) and also the additional ACD recommendations derived from the HEW not contained in the HHS Guide. Activities would include requiring PPAs to conduct equity assessments in developing NOFOs and requiring all grantees to develop disparity impact statements as a condition to receiving CDC funding. These NOFO considerations should also be required for STLTs public health agency grantees as they re-grant or sub-award to CBOs in their respective communities.

**Additional details in full report*

Proposed Action Steps for *Task Area 2*

Action Step 3:

CDC should develop more equitable systems throughout the lifecycle of NOFOs, from planning and development to selection and post-award support. All programs should be required to: a) engage community partners at the earliest stages of conceptualizing a new NOFO to develop a more credible, accessible, and relevant NOFO; b) develop application evaluation criteria that take into account equity factors or considerations, including evidence of community engagement in developing the response and project budgets that reflect compensation for guidance and leadership provided by individuals with lived experience; c) improve systems for strengthening and improving the accessibility of technical assistance provided to CBOs in the pre and post-award phases; d) develop webinars and other resources that are responsive to language, accessibility, and technical issues, such as access to broadband and screen reader compatible resources, which often present challenges for developing successful applications; and e) provide longer application submission timelines to ensure meaningful opportunities to engage community partners in planning and development.

Additional details in full report

Proposed Action Steps for *Task Area 2*

Action Step 4:

CDC should strengthen project officer engagement by developing or redesigning training materials that elevate equitable grantmaking and emphasize the important roles they play in providing support to grantee partners.

**Additional details in full report*

Discussion and Vote

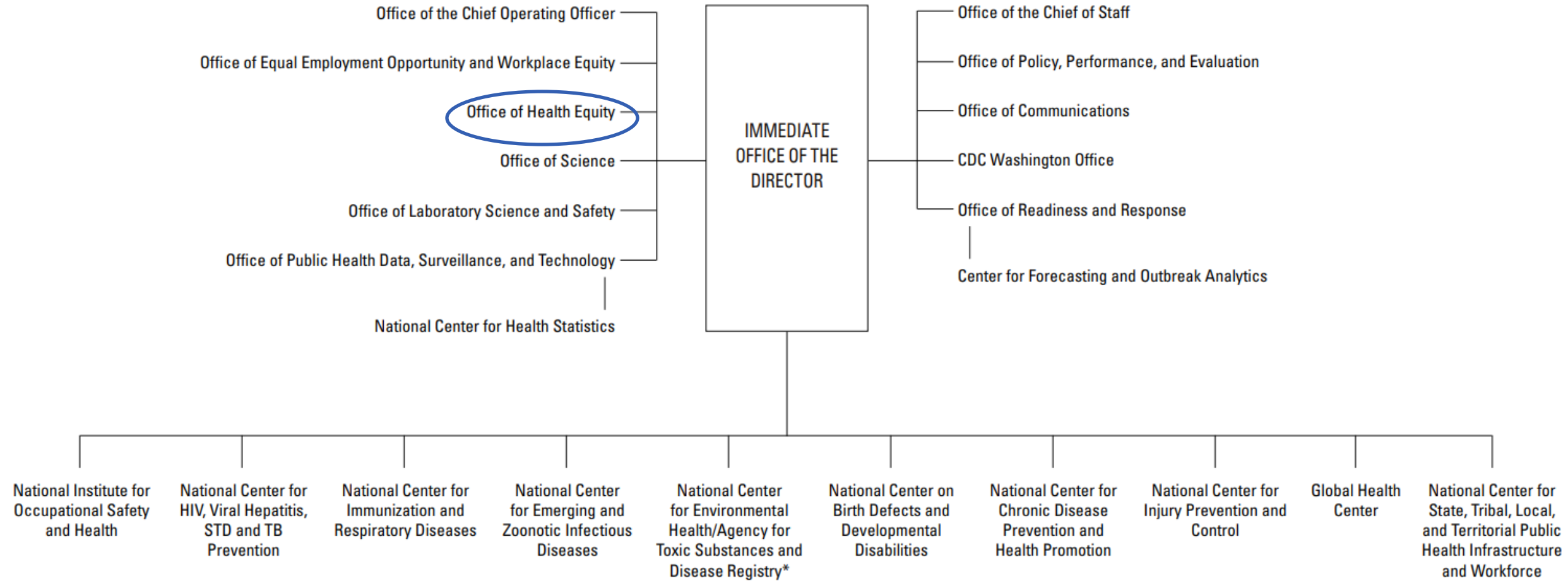
Office of Health Equity

Leandris Liburd, PhD, MPH, MA

Acting Director, Office of Health Equity, CDC

Department of Health and Human Services

Centers for Disease Control and Prevention (CDC)



Last updated February 23, 2023

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

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U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Office of Health Equity (OHE) Organizational Chart

The Office of Health Equity (OHE) is located in the CDC Immediate Office of the Director and serves as principal advisor to the CDC Director on all health equity matters domestic and global

Office of the Director

Dr. Leandris Liburd (*Acting*)

In coordination with the new Executive Governance Board, drives accountability and responsive decision-making relevant to health equity at all levels.

Office of Minority Health (OMH)

CAPT Carolina Luna-Pinto (*Acting*)

Promotes public health research, evidence-based programs, policies, and strategies to improve the health and well- being of ethnic and racial minoritized populations.

Office of Women's Health (OWH)

Dr. Pattie Tucker

Promotes public health research, evidence-based programs, policies, and strategies to improve the health and well-being of women and girls.

Office of Equitable Population Health (OEPH)

Dr. Jeff Hall (*Acting*)

Collaborates with the OMH and the OWH to develop a whole of public health approach to the populations served while contributing to and supporting the work of OHE/OD.

OHE Mission and Vision

Mission: The Office of Health Equity exists to ensure health equity is embedded in an all-of-public health approach to overcoming persistent health disparities and health inequities across a range of population groups that disproportionately experience poor health outcomes.

Vision: All people have the opportunity to attain the highest level of health possible.

Office of Health Equity Functions

OHE Strategic Priorities and Initiatives

Priorities

- **Strategy.** Develop a health equity strategy and organizational-level equity metrics for success.
- **Funding.** Create more equity in funding and NOFOs.
- **Partnerships.** Increase community engagement with populations that experience health disparities.
- **Public Health Workforce**. Build CDC's internal capacity of subject matter expertise in health equity within a workforce and workplace of diversity, equity, inclusion, accessibility, and belonging (DEIAB).
- **Science & Interventions.** Implement equitable, community-informed practices for advancing health equity in research, surveillance, programs, evaluation, emergency response/preparedness and laboratory sciences.

Selected Initiatives

- Anti-racism and Health Sprint Team
- CORE Leadership
- Committee on Women's Health
- Disability Inclusion and Accessibility Workgroup
- Diversity and Inclusion Executive Steering Committee (DIESC)
- Health Equity Communication Framing Research
- Health Equity Intervention and Action Principles
- Health Equity Science Principles
- Health Equity Leadership Network (HELN)
- Health Equity Workgroup to Advisory Committee for the Director
- Lewis and Ferguson fellowship/scholar programs
- Partnership with CMS to convene health system CHEOs; ASTHO to convene OMHs and OWHs
- Trainings (e.g. Cultural Humility)

Recent and upcoming OHE events and programs

- Power of Partnerships meeting, April 24-25
- 2023 Celebration of CORE: Making the Health Equity, Diversity, Equity, Inclusion, Accessibility, and Belonging, and Equal Employment Opportunity Connection, May 2-5 (internal)
- CDC Feature: Achievements and Milestones in CDC's Efforts to "Bake In" Health Equity
- OHE Twitter chat to celebrate National Minority Health Month
- Health Equity Learning Plan on CDC site (upcoming)

Celebrating 35 Years of Baking

HEALTH EQUITY

Into Public Health

Connect With Us!

- *Health Equity Matters:* quarterly e-newsletter that shares news, perspectives, and progress related to minority health and health equity. https://www.cdc.gov/minorityhealth/newsletter.html
- *Health Matters for Women:* monthly e-newsletter that provides information on what is happening in women's health around CDC and other agencies. https://www.cdc.gov/women/newsletter/index.htm
- *Conversations in Health Equity:* blog devoted to increasing awareness of health inequities and promoting national, state, and local efforts to reduce health disparities and achieve health equity. https://blogs.cdc.gov/healthequity/
- Engage with us on Twitter @CDCHealthEquity and LinkedIn @CDChealthequity.

Discussion

Break

Readiness and Response

Henry Walke, MD, MPH

Director, Office of Readiness and Response, CDC

Moving Forward: CDC as a Response Agency

- Implementing readiness efforts to position the agency to respond rapidly and effectively to public health emergencies:
  - Graduated Response Framework
  - CDCReady Responder Program
  - ORR Strategic Direction

Graduated Response Framework

What is the Graduated Response Framework?

- The Graduated Response Framework (GRF) is a three-level structure for improved management of CDC's public health emergency responses through better coordination and organization

- GRF allows CDC staff to manage public health responses at the right level within the agency and to transition between levels as operational needs and resource requirements change
- The GRF Concept of Operations (CONOPS) serves as a blueprint for multi-level response management
- Establishes parameters and criteria to guide response leaders and staff in operationalizing and implementing the GRF

GRF Response Levels

Agency-wide

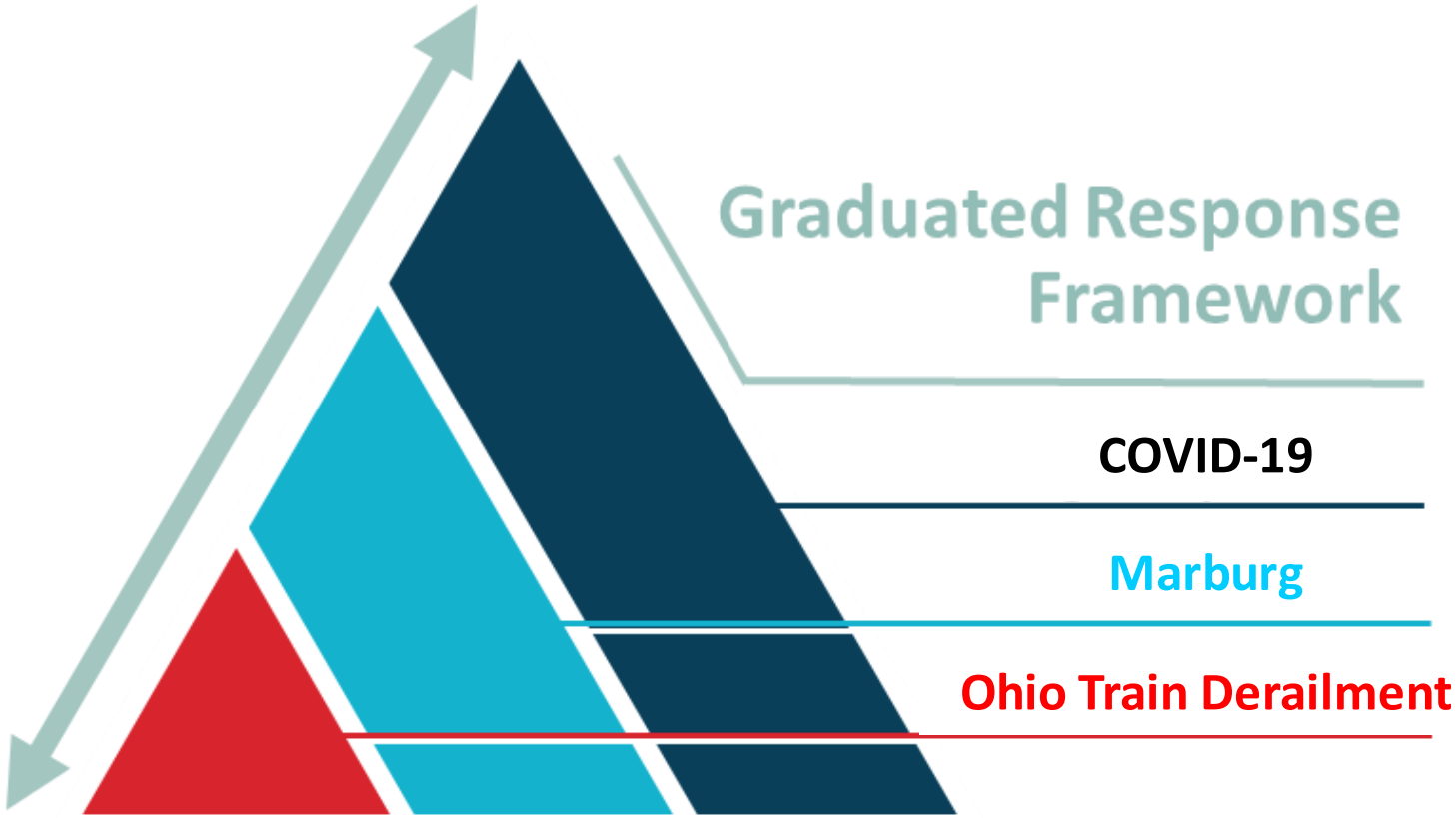
Established at the direction of CDC Director upon recommendation of PAT; response centralized in the CDC EOC

Center-led

Established at the direction of CIO Director with notification to CDC, ORR, DEO, and BSO directors and EOC; response managed within CIO(s) with some EOC coordination/support

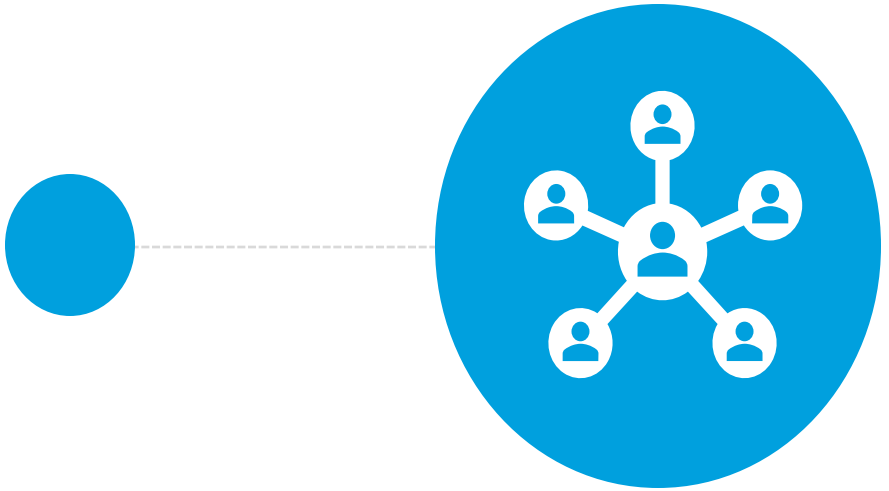
Program-led

Change in posture at the direction of Division Director with notification to EOC



GRF and CDC Partners

- **Regardless of the GRF level of a response, CDC is still responding.**
- The framework and decisions about the level at which CDC manages emergencies are internal, administrative designations.
- The level of a response should generally not affect how partners engage with the agency.



CDCReady Responder

What is CDCReady Responder?

A CDC-wide initiative that will improve how the agency identifies and prepares staff ahead of public health emergencies.

Key Aims

- Build and expand pools of pre-qualified, available responders
- Recruit and include staff not already connected to the response community
- Train staff to apply their talents to response work
- Create opportunities for staff to build new skills and professional connections

Goal:

A diverse workforce of pre-qualified, trained, and available responders to establish and sustain an emergency response.

CDCReady Responder Cadres

CDCReady RESPONDER

Response Communication

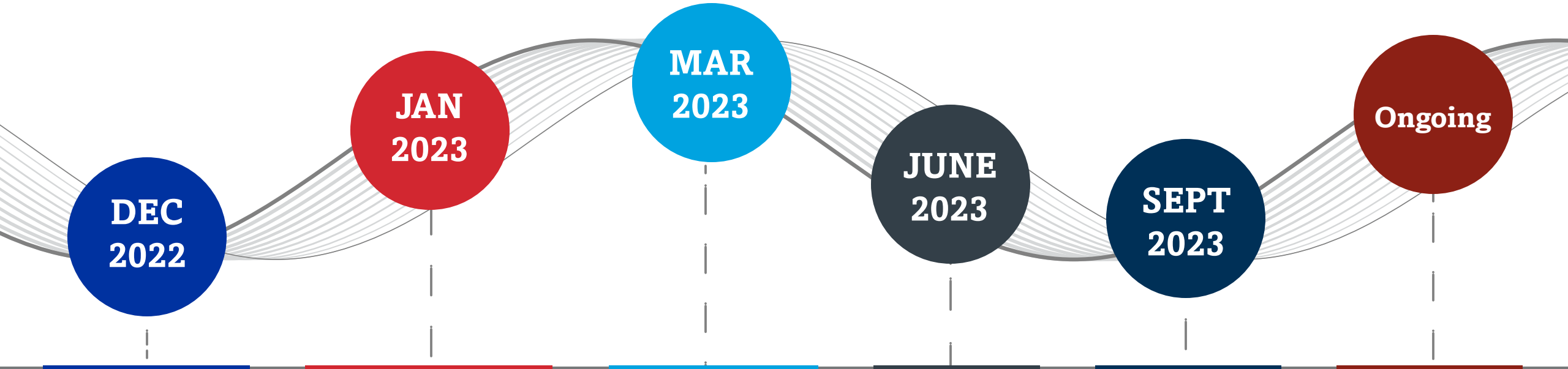
Response Leadership

Response Operations Support

Global Migration

Health Equity

Developing CDCReady Responder is an ongoing, long term, and collaborative process



Launch of CDCReady Responder

Dr. Walensky launched the CDCReady Responder program as part of the CDC Moving Forward Initiative.

First Cadre Notifications

Notified initial staff of their enrollment in the first three cadres including Response Leadership, Response Communication, and Response Operations Support.

First CDCReady Campaign Complete

Secured full enrollment of the first 5 cadres of CDCReady Responders.

CDCReady Responder Training Starts

Responder training will be launched.

Additional Cadres in Place

Launch over a dozen cadres and continue to enroll staff.

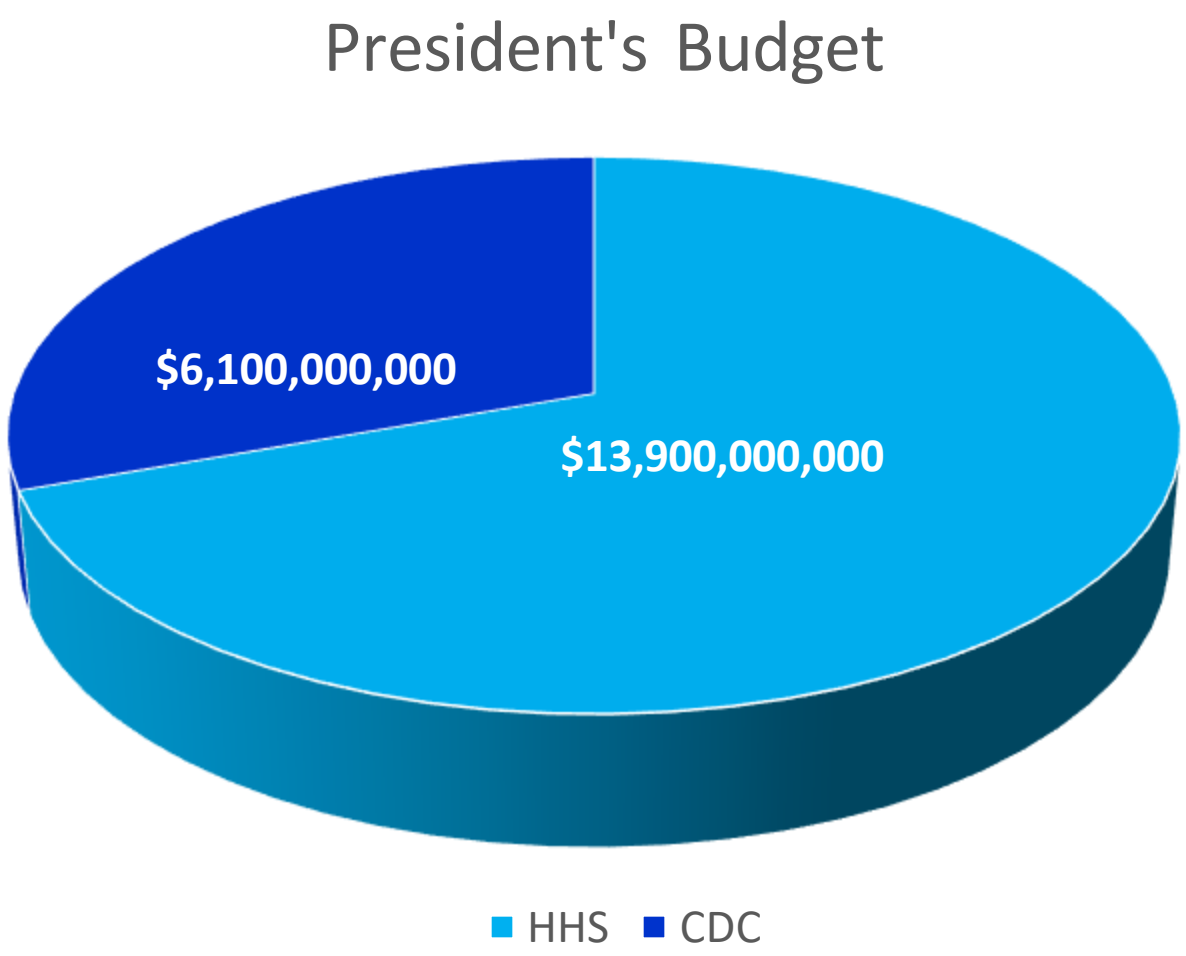
Future growth of CDCReady Responder

Continue to refine and expand cadres, build training program, and engage staff.

Congressional Updates

2006

FY24 President's Budget Proposal

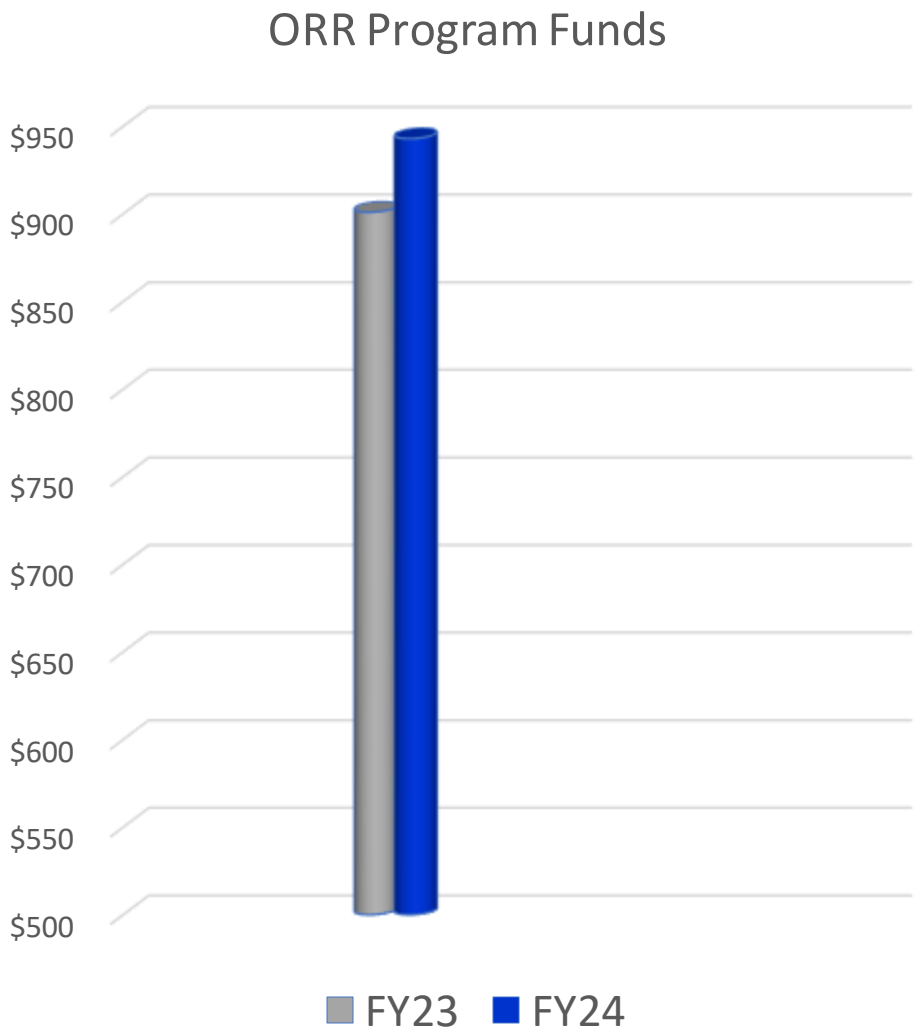


- Public Health and Social Services Emergency Fund for Pandemic Preparedness includes $20 billion in mandatory funding across HHS to prepare for pandemics and other biological threats, with **$6.1 billion allocated to CDC.**

- CDC will use these resources to:

  - ✓ Support vaccine and medical countermeasures safety and effectiveness monitoring and evaluation
  - ✓ Modernize laboratory capacity
  - ✓ Strengthen public health data systems
  - ✓ Enhance disease/pathogen agnostic surveillance capacity and capability

FY24 President's Budget Proposal



FY24 Public Health Preparedness and Response – ORR Program Funds

- $943 million, a **$38 million increase** from FY23 for domestic preparedness
- ORR will use these resources to:
  - ✓ Elevate readiness and response science
  - ✓ Prioritize populations at highest risk for adverse health outcomes
  - ✓ Enhance CDC's workforce, programs, and systems to increase CDC's readiness and response capacity and skills
  - ✓ Focus evaluations on tasks that enable ORR to take action

Discussion

Lunch

Global Health

Howard Zucker, MD, JD

Deputy Director for Global Health, CDC

Advancing Global Health Security

CDC's role in preventing and responding to the pandemics of today and tomorrow

Howard Zucker, MD, JD
Deputy Director for Global Health

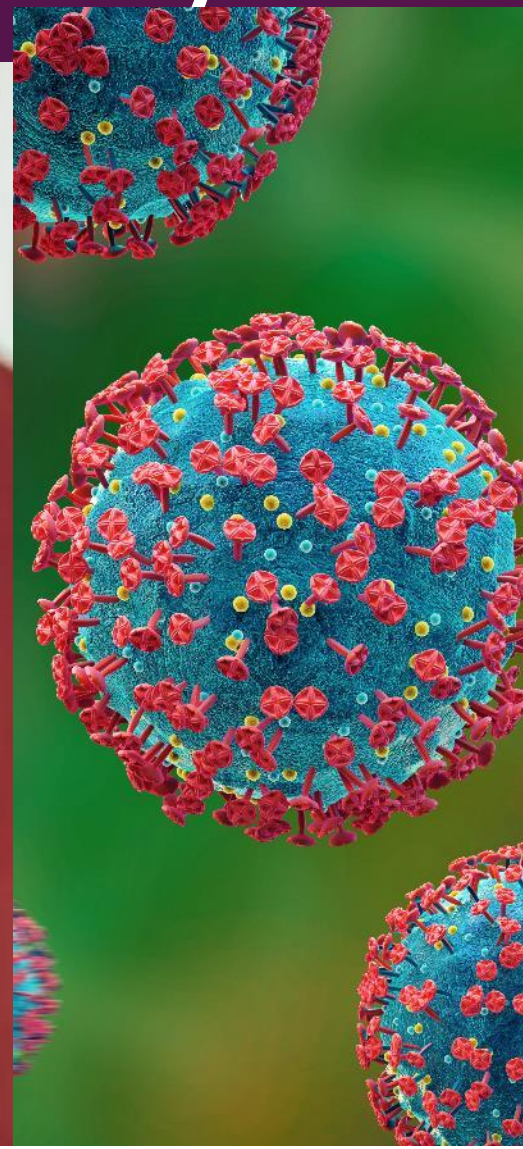
Pandemics and Outbreaks Have Shaped History

542
The Justinian Plague

1347
The Black Death

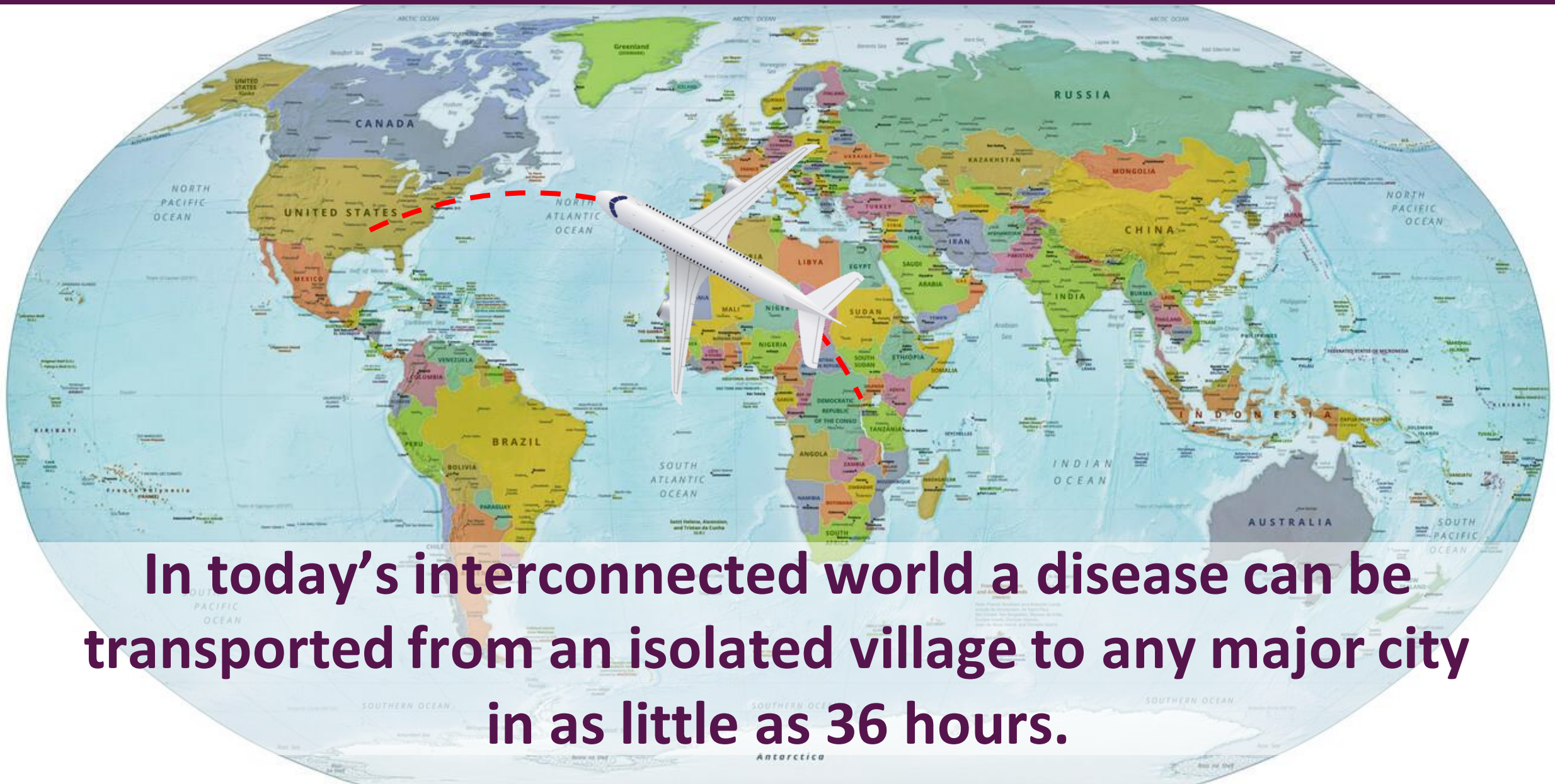
1863
Smallpox

1981
HIV/AIDS



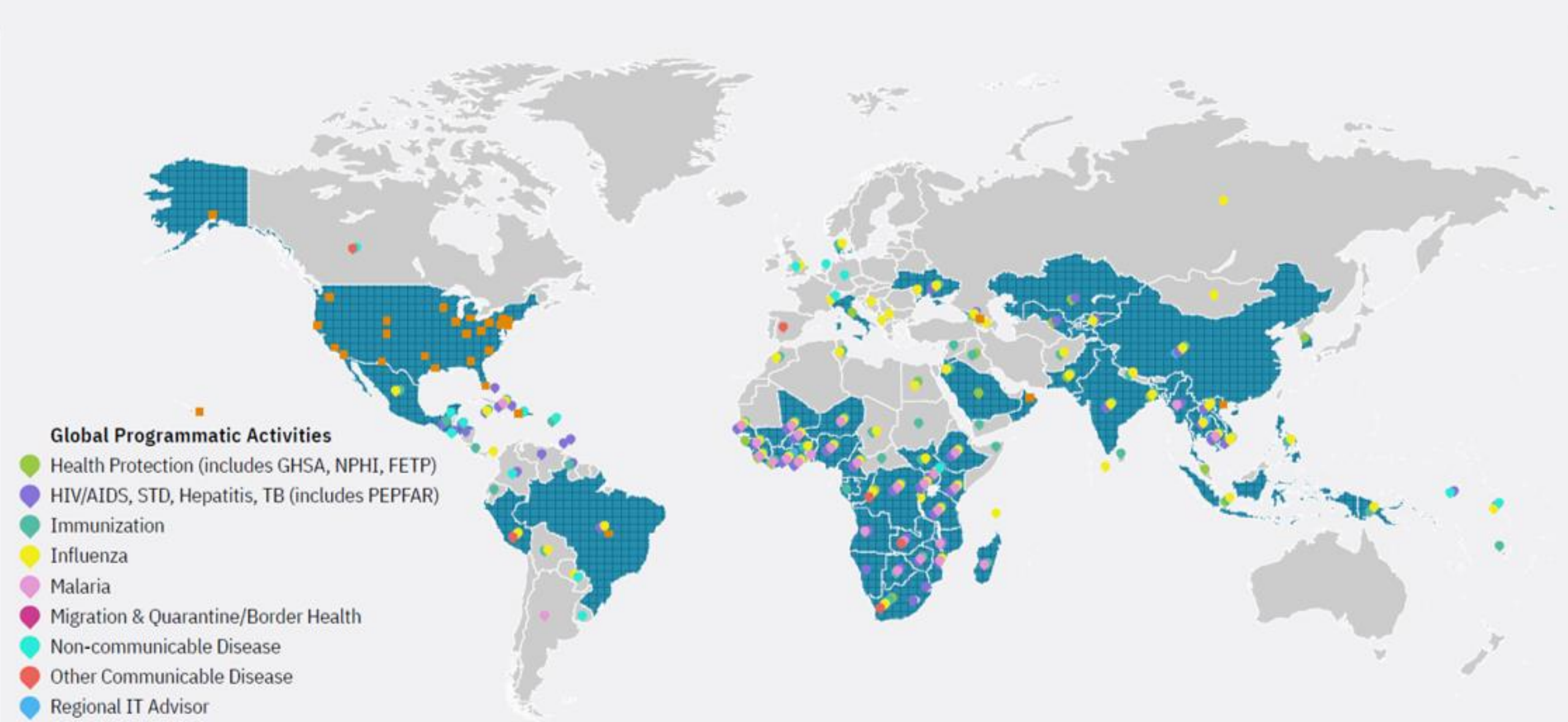
2019
COVID-19

A health threat anywhere is a health threat everywhere

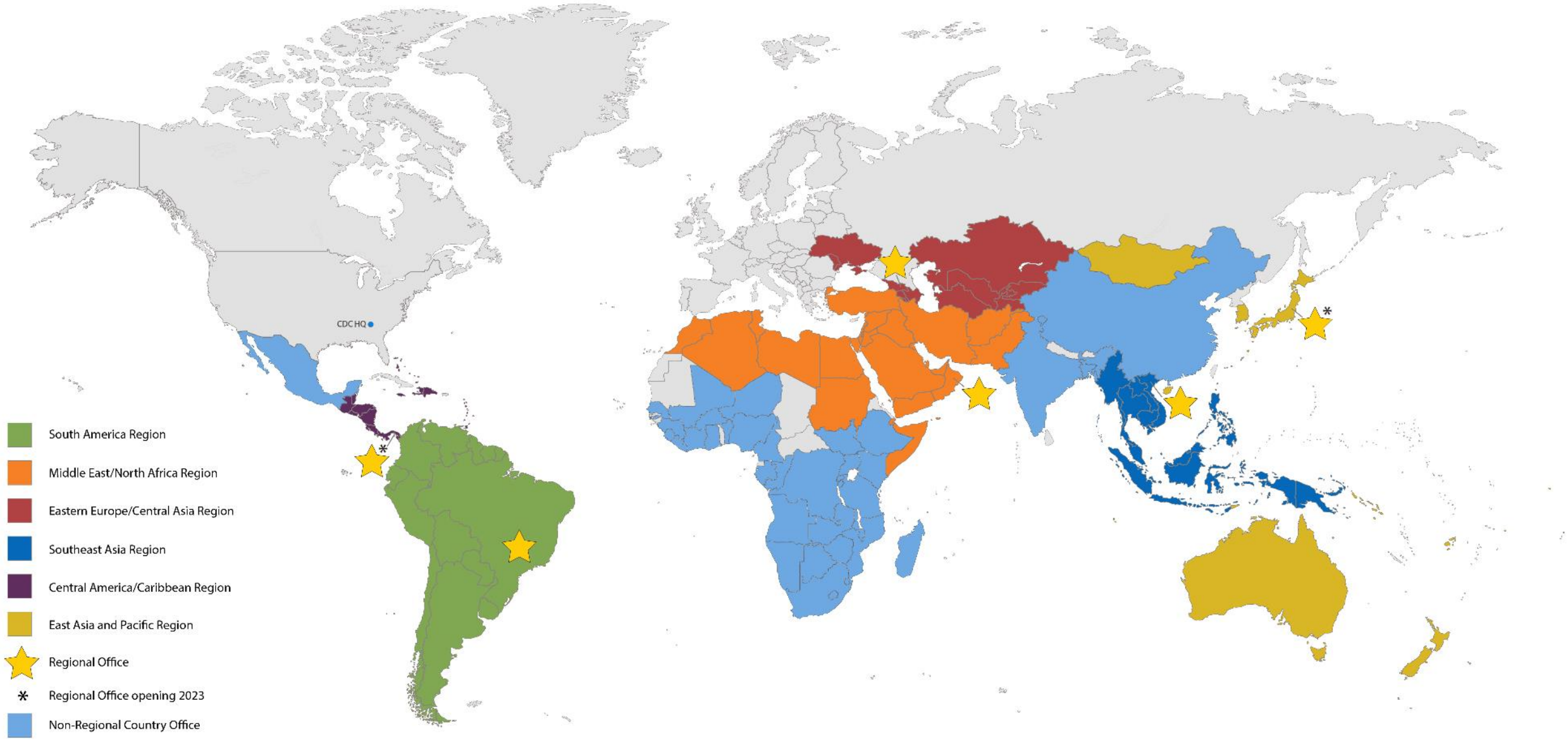


In today's interconnected world a disease can be transported from an isolated village to any major city in as little as 36 hours.

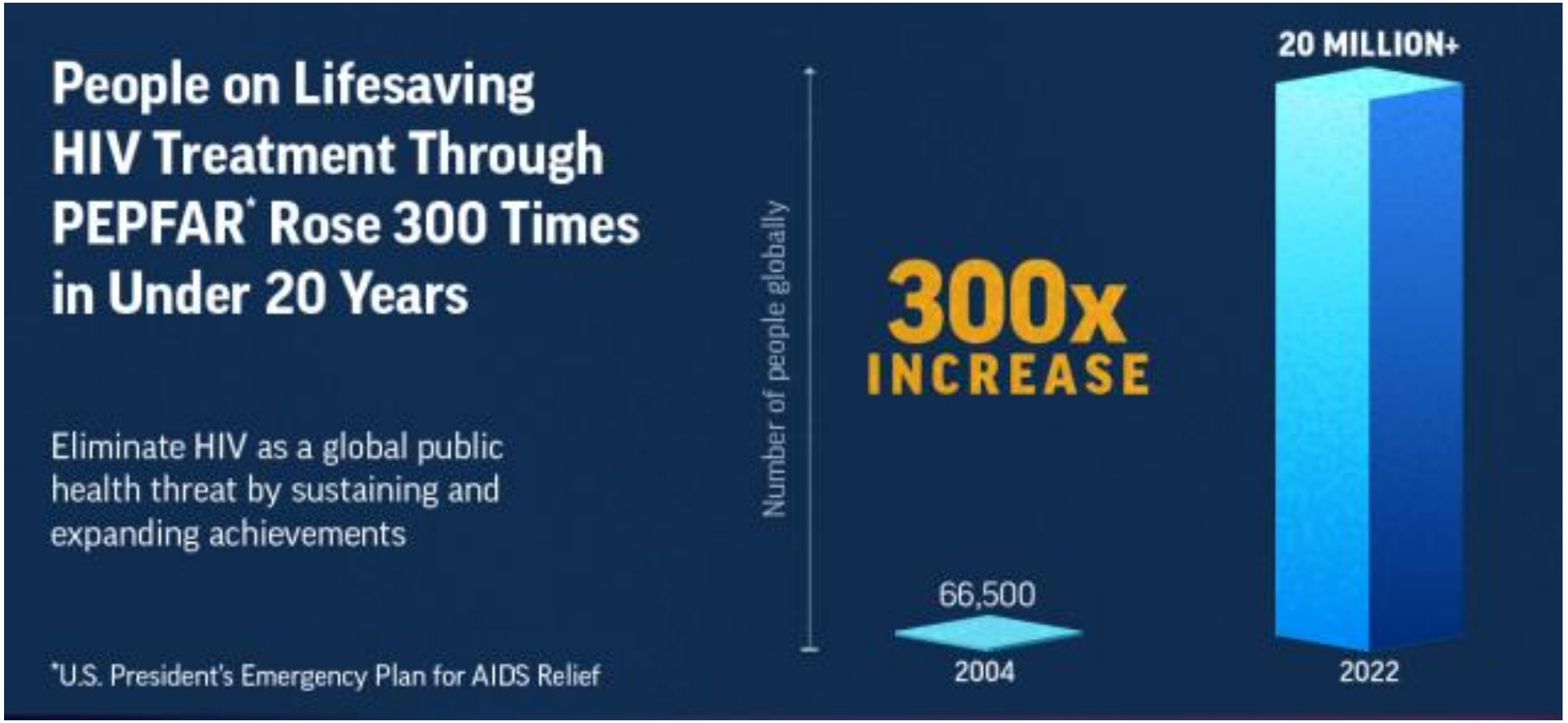
Reach of CDC's Global Health Programmatic Activities



CDC's Global Presence – Country & Regional Offices



CDC's Flagship Investments in Global Health Infrastructure



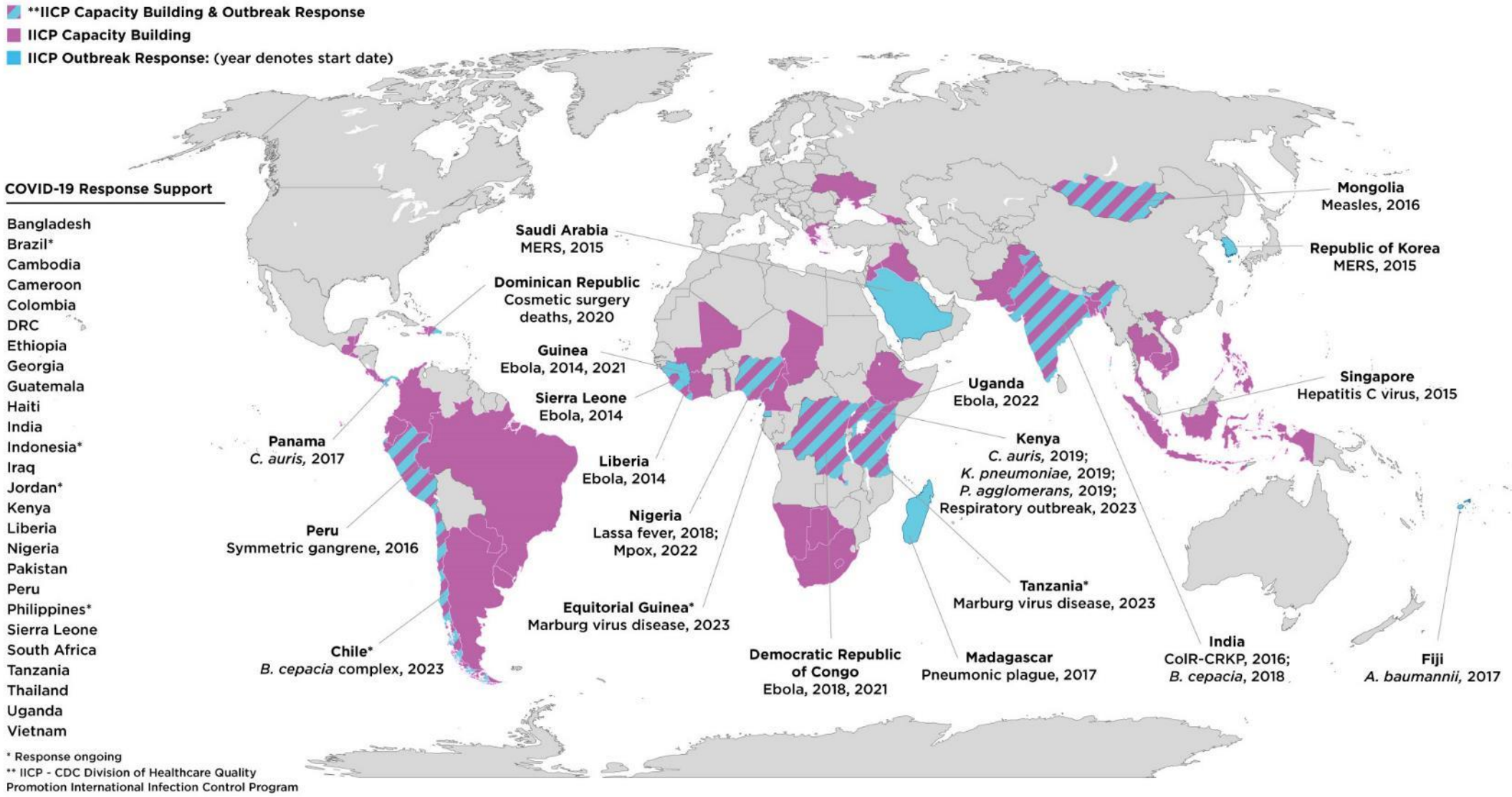
Flagship Investments in Global Health Infrastructure

INFLUENZA

OUTBREAK RESPONSE

IMMUNIZATION

Global Capacity for Infection Control and Outbreak Response



When countries are prepared and act decisively, epidemics are prevented

Global Disease Detection Operations Center

Global Rapid Response Team

Global Surveillance and Laboratory Capacity

National Public Health Institutes

Global Joint External Evaluation Tool

Field Epidemiology Training Programs

Investing in Global Health Security Infrastructure

Core Capacity Focus Areas

National and sub-national laboratory systems

Surveillance and epidemiology

Emergency management and response

Health workforce

The Pandemics that Didn't Happen

2009

H1N1 & Influenza A on cruise ship

2018-2019

Yellow Fever in Brazil

2021

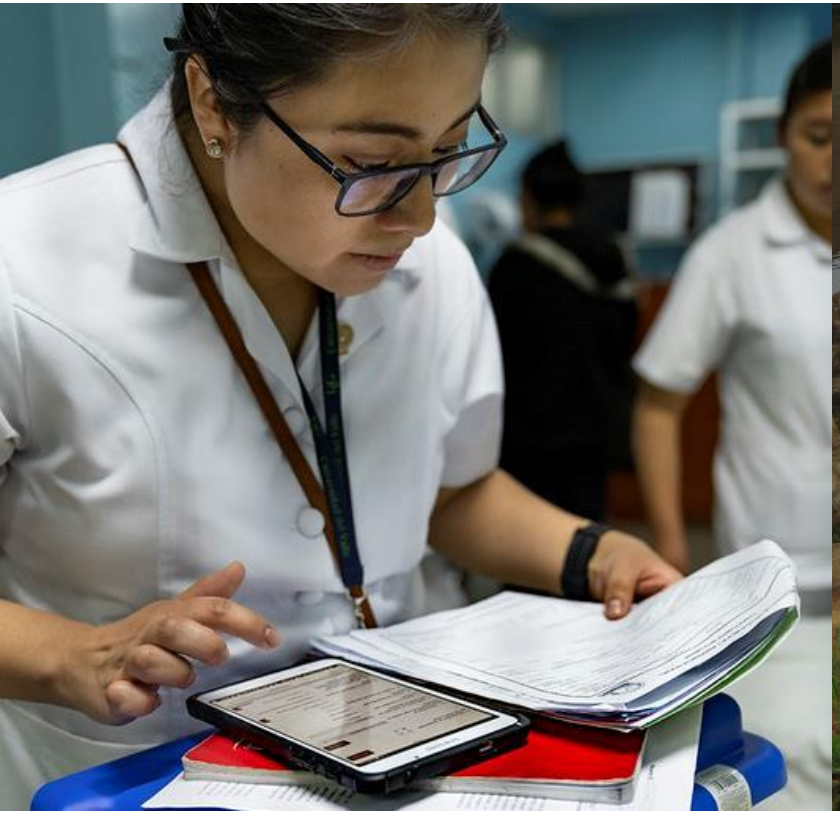
Ebola in Guinea

2021

Cholera in Burkina Faso

If we invest in global preparedness, epidemics don't have to happen

More than 70% of the world remains underprepared to prevent, detect, and respond to a public health emergency.



Investments Today Build a Safer and Healthier World Tomorrow

$16 trillion
estimated COVID-19 losses world-wide

vs

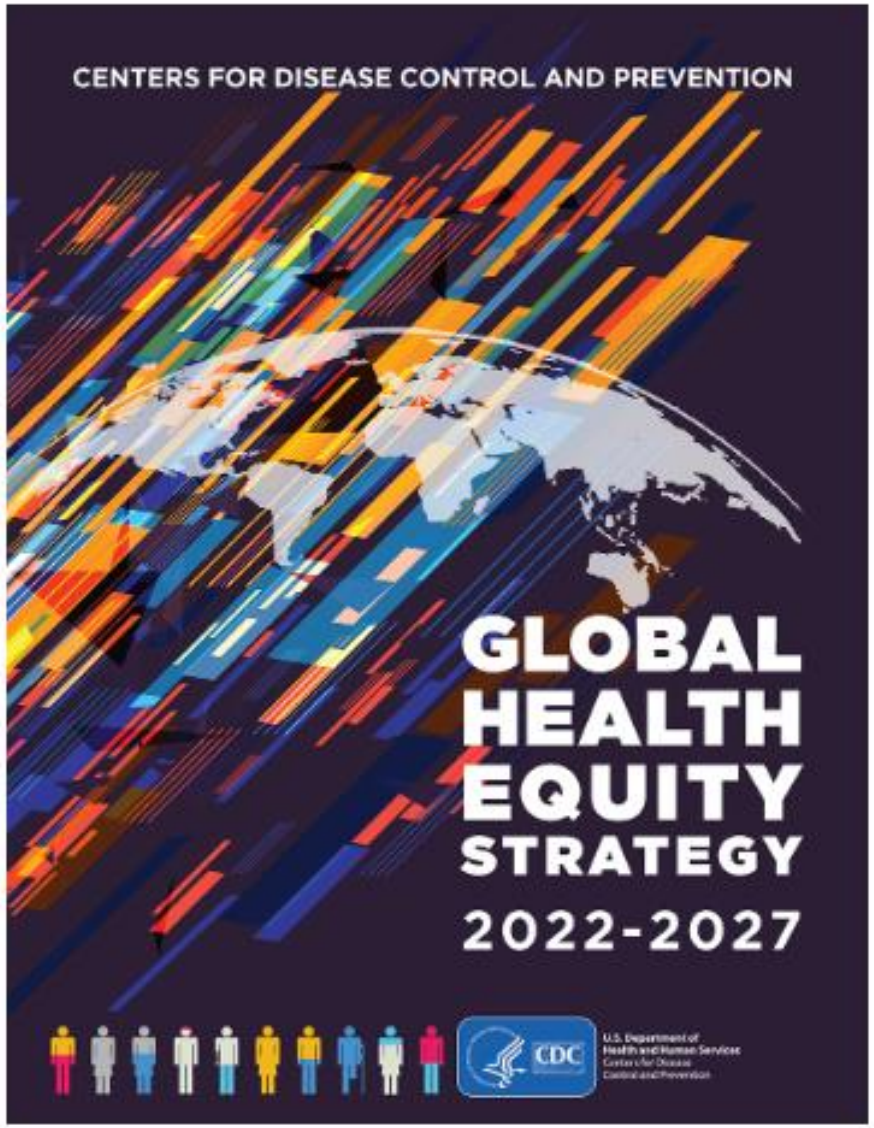
$124 billion
5-year epidemic preparation costs

$4.62 trillion
3-year COVID-19 spending by 43 USG agencies

vs

$4.5 billion
estimated annual global expenditure increase for pandemic preparedness

Health security cannot be achieved without health equity

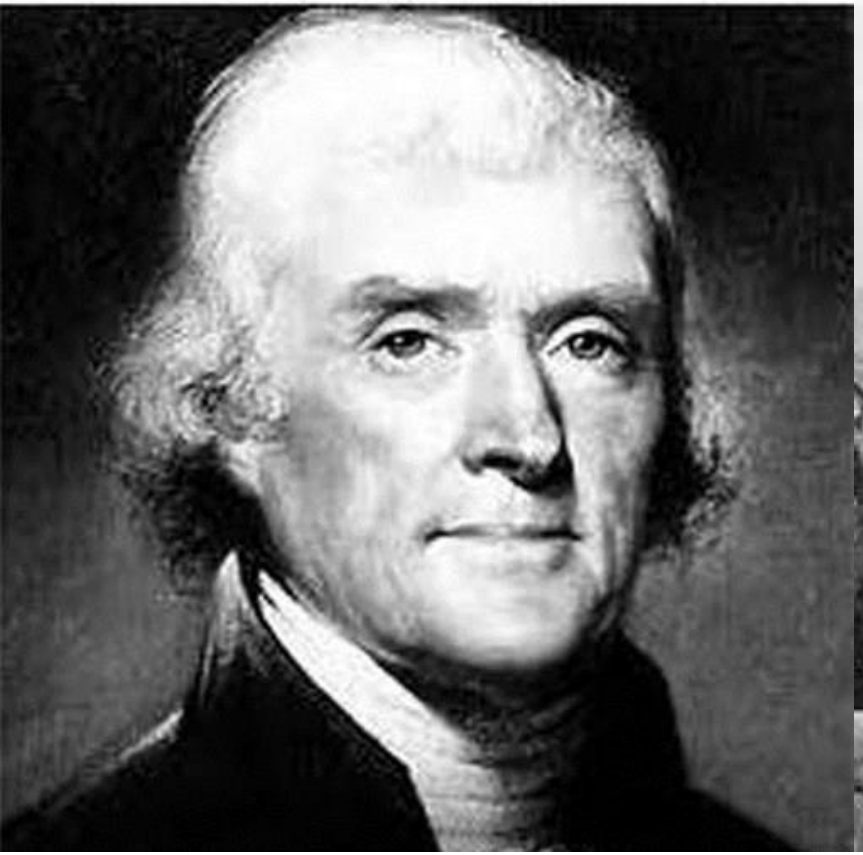


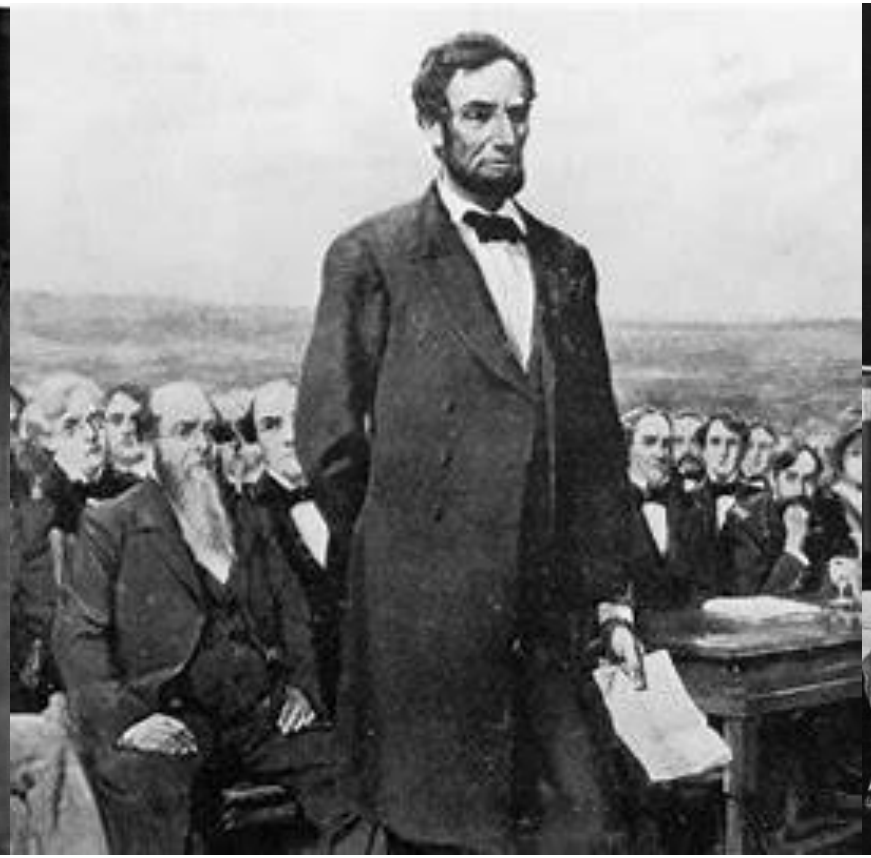
Guiding Principles for Implementing Health Equity into CDC's Global Work

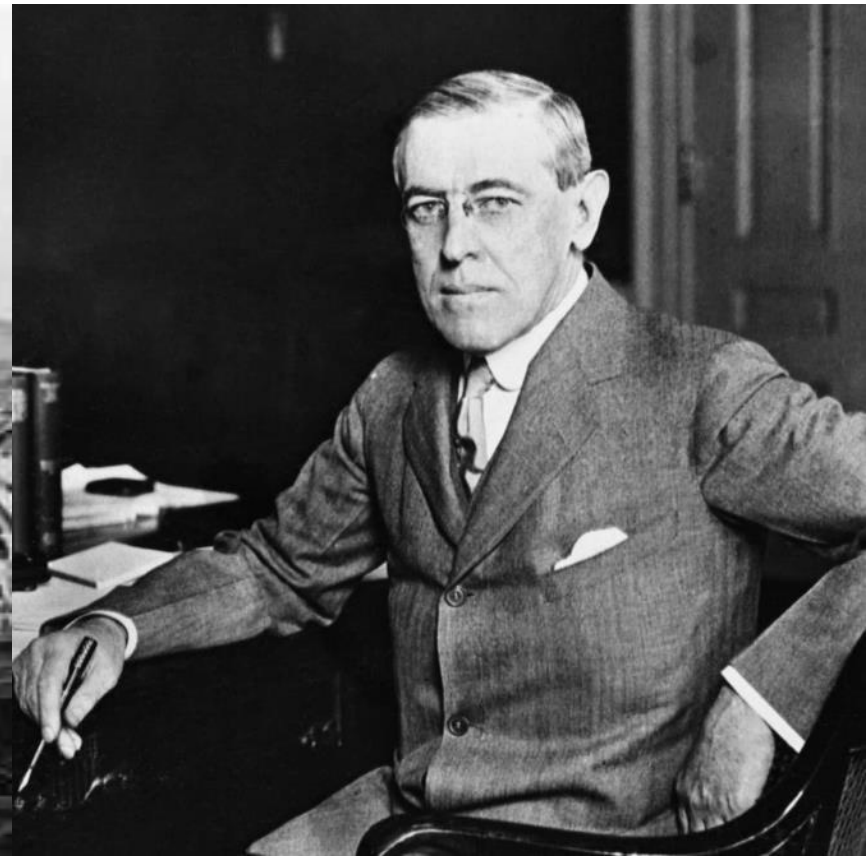
CDC Global Health Equity Strategy 2022-2027 | CDC

Diseases won’t stop, and neither can we

Pandemics and Outbreaks Will Continue to Write History







"An attention to health should take the place of every other object." *- Thomas Jefferson*

Discussion

Data and Surveillance Workgroup

Nirav R. Shah, MD, MPH

Co-Chair

The DSW has been asked to propose actions on TOR #4: Workforce

Agenda for today

- Review the priority areas addressed in the workforce memo
- Review core recommendations against each priority area
- Discussion

Three Priority Areas to Addressing Epidemiology, Public Health Data Science and Informatics, and Information Technology Workforce.

Bottom line up front

- To deliver a modern, responsive public health data infrastructure and to advance health equity, the Centers for Disease Control and Prevention (CDC) and state, tribal, local, and territorial (STLT) public health agencies need to build a workforce that includes staff appropriately trained in epidemiology, public health data science, and information technology (IT).

To achieve that goal, we propose the following priority areas

- Assess **workforce needs** to support the Data Modernization Initiative (DMI) including identifying the range of skills needed, the size of the workforce gap, and a prioritized roadmap to meet short and medium-term needs
- Assemble a cohesive **workforce training** strategy aligned with identified needs and work with the private sector and academia partners to build programs that enable upskilling, recruitment, and retention
- Issue **guidance on the use of dedicated data infrastructure funds** including how funds may be used to support the epidemiology, public health data science, and IT workforce

Proposed action steps for priority area 1: workforce shortage

The CDC should:

- **Endorse updating the public health informatics competencies** by partner organizations (PHII/UW)
- **Sponsor a landscape assessment** of the gap in skills/capabilities and staffing to deliver DMI in the short-term and medium/long-term based on the updated competencies
  - Collect data from STLTs and relevant state agencies (e.g. state OIT) to **inform specific workforce KPIs and goals** (e.g., workforce size/efficiency)
  - Inform workforce training strategy and funding guidelines (priority areas 2 and 3)
- Based on the assessment and in consultation with STLTs/other partners, **put together example workforce models for DMI** including **RACI charts**, and **clear role descriptions**, and **reviewed salary levels** to support medium to long-term workforce development
  - As part of this exercise, potential solutions including **public/private combined workforce** and **shared resources across state lines** should also be explored by referencing successful models from other agencies (CMS/HHS)
  - **Reimagine public health IT coordinator roles** at the state level to build leadership capabilities to oversee workforce coordination and executive change management
- **Act on the short-term workforce gaps** identified via the assessment with STLTs by:
  - Initiating a process to understand how best to **place CDC technical assistance teams to STLTs** over a sustained period of time
  - Sponsor the **establishment of systematic training-in-place programs** for core public health informatics skills needed in the short term
- Support workforce capacity building over the medium and long term via innovative avenues, such as the **creation of a shared workforce with hospitals and academic institutions** and **placement of mid-career academics/professionals**
- Develop a program to **highlight and celebrate front-line public health heroes in the fields of informatics and data science/data modernization** to support recruitment and retention

Proposed action steps for priority area 2: workforce training

The CDC should:

- **Sponsor an evaluation of the landscape of public health data and informatics training** available today to identify gaps to meet needs identified in priority areas 1
  - Work with the Office of the National Coordinator for Health Information Technology (ONC) to understand existing efforts
  - **Identify core KPIs** for training program development and operations
  - Address integration of health equity related measurement and strategies into public health programs
- **Create a consistent strategy for public health data workforce training** including a framework of training programs linked to professional development paths identified for priority area 1
  - Evaluate the possibility of creating **regional Centers of Excellences (CoEs) and online communities of practice** to support knowledge transfer
  - Explicitly include components that will **increase diversity in the public health workforce**
- **Support the creation of new public health informatics training programs** within CDC/STLTs, including accreditation/certification programs, leveraging the existing curriculum developed in academia/industry, and referencing other successful governmental programs.
- **Create practical training programs for academic trainees** in public health and relevant informatics fields with an exit into CDC/STLTs as pipelines for the future workforce
  - Consider working with other agencies to champion incentives such as loan forgiveness for students
  - Consider expanding centrally funded paid fellowships and internships building upon existing CDC programs
- **Evaluate the viability of building academic training grants** similar to other successful governmental grant programs (e.g., RO1 grants/T15 programs) to increase engagement with academic trainees

Proposed action steps for priority area 3: fund use guidelines

The CDC should:

- **Issue specific fund use guidelines informed by the workforce shortage and training gap assessments** to incorporate input from frontline staff
- Clarify that existing grants/contracts including the Epidemiology and Laboratory Capacity (ELC) and data infrastructure grants **can be used towards creating a data modernization workforce** that includes:
  - Using the funding to conduct a **workforce gaps assessment**
  - **Specific leadership roles** identified in priority area 1 (e.g., Chief of Public Health Informatics/Data Modernization Lead) and their responsibilities within STLTs and within the state governance structure
  - **A team** that oversees data interoperability, bidirectional exchange, and data use agreement
- Evaluative and **issue guidance on how states could share public health informatics resources** to support regional alignment and establishment of regional CoEs
- **Issue guidance on how DMI funding should be used across different programs within STLTs** to ensure a cohesive informatics workforce can be formed at the department level

Discussion and Vote

Special thanks to Yutong Liu for preparation of this material

Break

Laboratory Workgroup

Joshua Sharfstein, MD and Jill Taylor, PhD

Co-Chairs

Term of Reference #1

As the national reference laboratory for ID diagnostics, CDC is sometimes the laboratory of last resort for testing specimens that may have been stored in less-than-acceptable conditions, may be an unusual specimen type, or may contain less-than-acceptable volume. These specimens would not meet requirements for acceptable specimens and, adhering to CLIA regulations, CDC would have to reject them. In so doing, rare or difficult-to-obtain specimens can be rejected, whose results could have a meaningful impact on public health, including identifying pathogens responsible for rare or novel diseases.

Questions:

- Considering CLIA requirements, should CDC support investigation of unknown infectious agents or diseases using less-than-acceptable specimens, when acceptable specimens are not available?
- If so, how should an appropriate disclaimer be worded regarding result interpretation that acknowledges the specimens are outside validated parameters

Discussion Process

The Laboratory Workgroup (LW) met virtually:

- Tuesday April 4 with CDC staff to provide history:
  - Examples of specimen scenarios, including where CDC did not test samples outside of usual parameters (such as different types of specimens or different temperatures)
- Tuesday, April 11 to discuss the response

LW Conclusion 1:

The CDC should offer laboratory testing for unknown, rare, important, and/or difficult to diagnose infectious agents, even under less than ideal circumstances.

- The unique role that public health laboratories, including the CDC's CLIA-certified laboratories, play in testing for pathogens of public health significance.
- The negative impact on patient care and public health if specimens not meeting routine acceptance criteria are not eligible for testing.

LW Conclusion 2:

Based on best practices of large clinical and public health reference laboratories, it should be possible for CDC to perform this critical testing, and still meet the regulatory requirements of CLIA. This will require:

- Change in some processes at CDC
- Policy discussions with CMS

#1: Perform broad validations of pathogen detection and quantification assays

- Multiple specimen types
- Validate the impact of multiple pre-analytic variables **beyond the ideal state**
- Derive data to support specimen acceptance for specimens of varying volume, temperature, time in transit, matrix, and collection device
- Document this validation data in detail

#2: Develop and document a process for referral to Clinical Laboratory Director

- Document, in the standard operating procedure, the criteria for which specimens not meeting the routine acceptance criteria, are escalated to a CLIA-qualified laboratory director for evaluation.
- The laboratory director will determine whether the test's validation data can reasonably be understood to mean that technically accurate and clinically useful results can be obtained from testing such specimens.

#3: If the sample cannot be tested at CDC

- If a CDC Clinical Laboratory Director determines that the laboratory cannot test a particular specimen accurately, but another laboratory is able to do so, the agency should have a documented procedure for sending the specimen to the outside laboratory for testing.

#4 Develop a explanatory statement for the provider on the report

- Each CDC Clinical Laboratory should develop a written policy on additional interpretive comments that may be appropriate to include on the laboratory report, based on the specific context of the specimen being tested.

#5: Continuous quality improvement & Documentation

- Each CDC Clinical Laboratory should review its records regularly to determine the main reasons for rejection of specimens received, and use this information to improve their validation criteria or processes
- Document the roles of the Clinical Laboratory Directors

#6 Proposed Action

CDC should divide its diagnostic testing across multiple CLIA-certified laboratories with an individual CLIA-qualified Laboratory Director responsible for the diagnostic testing in each Center-level CLIA-certified laboratory.

#7: Initiate a Regulatory Policy Discussion with CMS

- Discuss with CMS senior leadership
- If necessary, engage with HHS senior leadership
- Consider partnering with the Association of Public Health Laboratories for the CMS discussion

If inter-Agency alignment on the interpretation of CLIA regulations proves difficult, the LW recommends that CDC engage with HHS and CMS executive leadership. It is essential that an acceptable solution is found, so that CDC can perform this critical function.

Discussion and Vote

Closing Remarks

David Fleming, MD

ACD Chair

Adjourn