Centers for Disease Control and Prevention Virtual meeting minutes

November 4-5, 2024

The Centers for Disease Control and Prevention's (CDC's) Board of Scientific Counselors, Infectious Diseases (BSC ID) held a virtual public meeting on November 4–5, 2024. In addition to Board members and CDC staff, the meeting was attended by representatives of several public health partner organizations and other members of the public (appendix). The agenda included

- Discussion with CDC Director Mandy Cohen
- Updates from CDC center directors Daniel Jernigan, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID); Jonathan Mermin, National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP); Demetre Daskalakis, National Center for Immunization and Respiratory Diseases (NCIRD); and Kayla Laserson, Global Health Center (GHC)
- Reports from the four BSC ID workgroups: Food Safety Modernization Act Surveillance Working Group (FSMA SWG); Infectious Disease Laboratory Workgroup (IDLWG); Wastewater Surveillance Workgroup (WSW); and Acute Flaccid Myelitis Task Force (AFM TF); and
- Presentation and proposal for the formation of a new workgroup on emerging threats.

Following the report from the AFM Task Force, the Board voted unanimously to sunset the taskforce due to the successful completion of its goals. The BSC ID also unanimously supported the formation of a new workgroup on emerging threats.

Welcoming Remarks and Roll Call

Dr. Lauren Meyers, BSC ID Chair, welcomed the Board members, and in particular the fifteen members for whom this was their first Board meeting. As part of the roll call process, Designated Federal Officer (DFO) Sarah Wiley instructed all members, both new and returning, to provide a brief introduction and to disclose any conflicts of interest or perceived conflicts of interest that may be relevant to the meeting. Each of the Special Government Employee members, ex officio members, and liaison representatives introduced themselves and described their multiple roles including various sources of funding for their research activities. The following potential conflicts of interest were noted:

- Dr. Angela Caliendo: Serves on advisory boards for Visby, Danaher, Cepheid, Beckman Coulter, and VintaBio.
- Dr. Tri Do: Works as a consultant for a point-of-care diagnostic startup.
- Dr. Anthony Flores: Receives funding from GlycosBio, but stated it is unrelated to the topics to be discussed.

Purpose and Goals of the Meeting

The primary goal of the meeting was to provide background information and to serve as an introductory session for new Board members to understand the programs under the BSC ID's jurisdiction, the priorities of these programs, and the type of input needed from the Board to effectively inform their work.

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Updates and Priorities

Introduction and Overview of CDC

Daniel Jernigan, Director of NCEZID, began by providing foundational information about the Centers for Disease Control and Prevention (CDC) for the benefit of new Board members.

CDC Mission

The CDC is the nation's leading science-based and data-driven public health agency, working 24/7 to protect the United States from a wide range of health, safety, and security threats. These threats include diseases both foreign and domestic, whether chronic or acute, curable or preventable, and those resulting from human error or deliberate attacks.

CDC Structure and Reach:

- The CDC employs 13,500 full-time equivalent (FTE) staff and about 12,000 contractors, with locations across the U.S. and in over 70 countries worldwide.
- It is one of 13 operating divisions within the U.S. Department of Health and Human Services (HHS) and forms part of the U.S. Public Health Service.
- CDC's annual budget is approximately \$9 billion.
- The agency uses a "One CDC" approach to health protection, emphasizing collaboration to protect health and improve lives.

CDC's director is Dr. Mandy Cohen with deputy directors managing organizational, administrative, and cross-cutting programmatic functions. CDC is divided into several major Centers, each focusing on specific areas of public health. BSC ID primarily works with the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), the National Center for Immunization and Respiratory Diseases (NCIRD), and the Global Health Center (GHC).

NCEZID Overview

Dr. Jernigan provided an in-depth overview of NCEZID's role within CDC, focusing on its primary priority of response readiness. NCEZID is the largest of CDC's programmatic centers, with approximately 1800 FTEs and over 2,000 contract staff, spread across four U.S. locations: Anchorage, San Juan, Fort Collins, and Atlanta. The Center consists of seven divisions: four pathogen-specific divisions and three cross-cutting divisions. The Center is responsible for

monitoring over 800 pathogens, including various pathogenic bacteria, viruses, parasites, prions, and algae.

Core Capabilities:

- Investing in state and local capacity through the Epidemiology and Laboratory Capacity (ELC) Program. ELC is a cooperative agreement that has provided \$43 billion in funding to state and local health departments over the past four years, primarily through COVID-19 supplemental funds. ELC support serves as the primary avenue for addressing foodborne illnesses and other routine infectious disease work.
- Advanced molecular detection and next-generation sequencing
- Vector-borne diseases, including traditional diseases and emerging ones, such as Oropouche.
- Combatting antimicrobial-resistant infections and healthcare-associated infections,
- Foodborne, waterborne, and fungal diseases
- o Malaria and other parasitic diseases
- o High-consequence pathogens such as Ebola, Nipah, mpox, and anthrax
- o Global migration health

Driving Factors for Emerging Infections

Dr. Jernigan identified several key factors driving the rise of emerging infections:

- Increasingly Crowded. The world is projected to reach 11 billion people by 2050. Approximately 80% of this growth has occurred in less developed countries. Crowded environments accelerate the spread of infectious diseases.
- **Increasingly Connected.** With approximately 3 billion people traveling internationally and the increasing use of global supply chains, diseases can spread rapidly.
- Increasingly Converging. Convergence of human and animal populations through human encroachment on wildlife habitats and bringing animal populations into urban settings through practices such as wet markets and live bird markets increase potential transmission of zoonotic diseases.
- **Conflict.** Global conflicts exacerbate antimicrobial resistance and the spread of infectious diseases such as cholera.
- Climate. Longer summers and more mosquitos affect disease risk and spread.

Emerging Infections Outbreak Examples

Dr. Jernigan discussed several emerging infections currently being addressed by NCEZID:

 Multi-drug Resistant Pseudomonas aeruginosa: Infections from contaminated medications used in long-term care facilities. Cases were detected due to CDC-support for

- antimicrobial resistance testing network at health departments, which made it possible for advanced molecular diagnostics to be used to trace the source.
- Mpox Clade 1b: An outbreak primarily in the Democratic Republic of the Congo with some
 cases in Germany. CDC is leveraging innovations with traveler-based genomic sequencing
 and wastewater surveillance to monitor and control this outbreak.
- Marburg virus disease: A rare, severe viral hemorrhagic fever (VHF), somewhat like Ebola, that was spread from bats in a mine, leading to approximately 70 cases that are contained in Rwanda. This highlights the importance of the Viral Hemorrhagic Fever (VHF) Readiness Strategy CDC is developing, which will facilitate interagency collaboration and focuses on better countermeasures.
- Lassa fever: A traveler from Liberia who had Lassa fever came to the U.S. We are following up with approximately 140 contacts of that individual to assure no additional cases.
- Dengue and Oropouche Outbreaks: There have been approximately 6,500 locally acquired cases of Dengue in the U.S., mostly in Puerto Rico, in addition to travel-associated cases.
 This response was recently expanded to include Oropouche virus, with thousands of cases this year in Cuba, which led to travelers with Oropouche returning to the U.S. We are working to improve diagnostics and better understand and characterize transmission.

Antimicrobial Resistance (AR)

- NCEZID is heavily invested in combating antimicrobial resistance (AR) through multiple strategies, including infection prevention and control, surveillance, examining antibiotic use, and promoting better vaccines, diagnostics, and therapeutics.
- Pre-pandemic investments were showing significant improvements, including an 18% reduction in deaths from 2013-2019 due to AR infections, and as of 2021, approximately 95% of hospitals met all of CDC's Core Elements of Antibiotic Stewardship. There were some declines in these measures during the pandemic, but are starting to see an encouraging return to these baselines.
- The Antimicrobial Resistance Threats in the United States, 2021-2022 report, published in July 2024, described six AR bacterial hospital-onset infections that increased by a combined 20% during the pandemic; we will update this report over the next year.
- A global effort to reduce AR-related deaths by 10% by 2030 was endorsed at the 2024 UN General Assembly.
- The estimated national cost to treat infections caused by six antimicrobial-resistant germs is over \$4.6 billion annually.
- CDC's innovations to slow AR are now the industry standard. Examples of these
 innovations include Chlorhexidine bathing as an infection control strategy,
 endpoints for decolonization therapeutics, and improvements in terminal cleaning
 of healthcare environments.

Pathogen-Nonspecific Surveillance and Technology

Dr. Jernigan highlighted several innovative new approaches that are improving the CDC's ability to detect and respond to infectious diseases:

- National Wastewater Surveillance System (NWSS): Wastewater surveillance provides
 early detection of increasing cases of an infectious disease, is independent of symptoms
 and healthcare seeking, tracks emerging health threats and variants, and complements
 other public health surveillance data. Wastewater surveillance has proven to be helpful in
 a number of public health responses.
- Traveler-based Genomic Surveillance (TGS): Provides early detection of emerging infectious threats at U.S. airports by collecting and analyzing data from eight major U.S. airports using voluntary nasal sampling, single aircraft wastewater sampling, and combined aircraft wastewater sampling. Since 2021, TGS has enrolled over 700,000 volunteer travelers from over 135 countries, targeting more than 1,400 flights every week across participating airports. TGS is currently testing for RSV, Flu A/B, SARS-CoV-2, and mpox. TGS successfully identified multiple SARS-CoV-2 variants up to six weeks ahead of other U.S. public health systems and contributed to global genomic data banks.
- Advanced Molecular Detection (AMD): Uses next-generation sequencing and bioinformatics to improve public health data systems, foster collaboration, and enhance public health responses at national, state, and local levels and with private industry.
- Emerging Infections Program (EIP): CDC's Emerging Infections Program (EIP) works to
 modernize the connection between clinical and public health ecosystems, utilize shared
 services across the EIP network, accelerate modernized infrastructure, and enhance
 interoperability and standards for systems and data exchange pathways.

Budget Overview and Challenges

Dr. Jernigan presented a chart outlining the NCEZID budget, detailing the fiscal year (FY) 2024 enacted budget and the FY 2025 President's Budget along with the U.S. House of Representatives and Senate budget marks. Despite some cuts proposed in the House for much of CDC, NCEZID's funding remains intact in the House mark, with a potential increase in the Senate mark for FY 2025. CDC also receives \$29 million via an interagency agreement with USAID for parasitic disease and malaria work.

Challenges:

- Vital innovative public health activities such as TGS, NWSS, and AMD rely heavily on supplemental funds.
- Sustainable annual funding is critical for continued readiness to address future health emergencies.

BSC Comments and Discussion

- Board members inquired about plans to expand on the TGS program to include airports in additional regions and to the southern border. Dr. Jernigan responded that the airports were strategically chosen in order to maximize the capabilities of the TGS program with the resources that were available.
- Board members asked about efforts to optimize laboratory activities and surveillance systems through integration of the portfolio of data being collected and leveraging

electronic health records. Dr. Jernigan explained that flexible funding lines and pathogen non-specific platforms would make it easier to pivot priorities to address emerging problems. He also described efforts underway to modernize collection techniques and consolidate systems across the agency. An in-depth discussion of the move toward One CDC Platform for information systems would be a good future topic for the Board. Dr. Jernigan also discussed agency efforts to work with the Trusted Exchange Framework and Common Agreement (TEFCA) to better connect healthcare and public health.

- Dr. Jernigan also discussed the importance of improving diagnostics to be able to both detect unusual cases of rare diseases and also better diagnose, and therefore rule-out more routine illnesses and ensure appropriate care for patients.
- A Board member asked about enhancing collaborations with agriculture departments in states, particularly in the current H5N1 response. Dr. Jernigan acknowledged the need for enhanced collaborations across agencies and with communities. Some of this will be discussed in tomorrow's session on a new potential BSC workgroup.
- A Board member encouraged CDC to clearly characterize the benefits to public health and to the public of the innovations described and to make this information on the impact of these advances and investments available to partners.
- A Board member raised the need for rapid diagnostics for malaria, especially tests available across the US. Dr. Jernigan described several specific needs in this arena, including around greater accessibility of rapid testing and greater availability in more places.
- The Board is encouraged to provide input on next-generation sequencing and metagenomic approaches to improve pathogen detection and public health responses.

BSC ID Workgroups Overview

Sarah Wiley provided an overview of the Board of Scientific Counselors (BSC) to help new members understand its structure and operations. The BSC is a chartered Federal Advisory Committee, governed by specific laws, regulations, and policies. Its primary role is to advise on strategies, goals, and priorities for CDC's infectious disease programs and research. Additionally, the BSC monitors the overall direction of these programs and provides guidance to the Department of Health and Human Services (HHS) Secretary, CDC Director, and the Directors of key national centers, including the National Centers for Emerging and Zoonotic Infectious Diseases, HIV, Viral Hepatitis, STD, and TB Prevention, Immunization and Respiratory Diseases, and the Global Health Center. BSC meetings are open to the public, allowing for public input.

The BSC is composed of up to 17 Special Government Employees (SGEs), appointed by the HHS Secretary based on their expertise. There are also ex officio members, who are non-voting officials from other parts of HHS, as well as liaison representatives from other organizations relevant to infectious diseases.

Much of the Board's work is carried out through specialized work groups. These work groups are formed to analyze specific issues, and their findings inform the BSC's advice to the CDC. Workgroups are established by a vote of the Board and are given a specific set of questions to address. They are required to have at least two BSC members, and additional members are chosen for their expertise in the field. Unlike BSC meetings, workgroup sessions are typically closed to the public to allow for in-depth, often confidential discussions.

Currently, there are four active work groups under the BSC ID:

- 1. Acute Flaccid Myelitis (AFM) Task Force
- 2. Food Safety Modernization Act (FSMA) Surveillance Working Group
- 3. Infectious Disease Laboratory Workgroup (IDLWG)
- 4. Wastewater Surveillance Workgroup

These workgroups help guide BSC's recommendations and provide critical input to CDC's efforts in addressing various infectious disease challenges.

National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP) Updates and Priorities

Jonathan Mermin, Director of NCHHSTP provided an update on the Center's priorities, challenges, and strategies to address key public health concerns. NCHHSTP's work overlaps with the broader goals of the Board of Scientific Counselors (BSC) and has four primary objectives:

- 1. Reduce the incidence of HIV, viral hepatitis, STIs, and TB
- 2. Reduce morbidity and mortality associated with infections
- 3. Reduce disparities
- 4. Achieve organizational excellence

HIV Prevention

Dr. Mermin shared the current HIV incidence in the U.S., that has been declining, with a 12% decrease in the past four years. However, the absolute number of people living with HIV has increased to approximately 1.2 million, a 50% rise since 1996. HIV remains a significant health disparity. African American and Hispanic populations also face disproportionately high HIV rates.

To combat these disparities, NCHHSTP focuses resources on high-risk populations and utilizes strategies such as antiretroviral therapy (ART), pre-exposure prophylaxis (PrEP), and data-to-care programs to reconnect individuals who have fallen out of care. These efforts help prevent both new infections and disease progression.

Sexually Transmitted Infections (STIs)

Dr. Mermin also shared the rise in sexually transmitted infections (STIs), with approximately 2.5 million cases reported annually. While chlamydia rates have remained stable, gonorrhea decreased by 9% in the past year, while syphilis cases continue to rise, reaching the highest levels in history, including a concerning increase in congenital syphilis.

A promising approach in STI prevention is the use of doxycycline post-exposure prophylaxis (doxy PEP), which has shown effectiveness in reducing rates of chlamydia, gonorrhea, and syphilis. The cost of doxy PEP is low, and implementation in clinics, such as those in San Francisco, has shown significant reductions in STIs. However, antimicrobial resistance is a concern, and monitoring systems are in place to track the impact of doxy PEP.

Viral Hepatitis

Dr. Mermin discussed how viral hepatitis remains a serious public health threat, leading to liver cancer, cirrhosis, and thousands of deaths annually. Hepatitis B affects about 660,000 people in the U.S., and hepatitis C affects over 2.4 million. The opioid epidemic has contributed to the spread of hepatitis C, especially among people who inject drugs. NCHHSTP focuses on increasing vaccinations, improving diagnostics, and expanding treatment access for hepatitis C, which is curable with a short course of oral therapy.

Despite advancements, barriers to treatment remain, including insurance limitations and bureaucratic hurdles. The <u>Hepatitis C Elimination Initiative</u>, included in the President's budget, has not yet been funded but is considered cost-saving and crucial for addressing this health crisis.

Tuberculosis (TB)

Dr. Mermin shared the U.S. has seen a continued downward trend in tuberculosis (TB) incidence, now among the lowest in the world. However, about 13 million people in the U.S. are living with latent TB, and the majority are unaware of their condition. Reactivation of latent TB accounts for 80% of TB cases in the U.S. Screening for latent TB and providing treatment is a priority. NCHHSTP also supports electronic directly observed therapy to make treatment more accessible and cost-effective.

Syndemic Approach

Dr. Mermin provided an overview of a syndemic approach in addressing these overlapping diseases. NCHHSTP employs a syndemic approach that recognizes the interconnectedness of conditions like HIV, STIs, and hepatitis in high-risk populations. By focusing on social determinants of health, such as access to care and socio-economic factors, NCHHSTP aims to provide more holistic and impactful services.

Strategic Focus

NCHHSTP aims to focus resources on the geographic areas and populations most affected by these epidemics. NCHHSTP recognizes that attempting to tackle all issues simultaneously yields limited impact. Instead, it concentrates on interventions that are most likely to have a significant impact. This includes evaluating existing programs, revising policies, and adapting services to evolving needs.

BSC Comments and Discussion

- A suggestion was made for CDC to implement demonstration projects in communities with varying levels of wraparound services to assess the impact of comprehensive social support on health outcomes, particularly for vulnerable populations such as those with drugresistant TB.
- It was emphasized that larger-scale policies, such as Medicaid expansion, have proven to improve health outcomes and should be viewed as part of the solution to infectious disease prevention.
- In Las Vegas, the implementation of "street medicine" and contract tracing to provide services such as testing for HIV, syphilis, and hepatitis C to hard-to-reach populations,

particularly those who are homeless or lack access to clinics, has shown promising results, including the identification of a 30% hepatitis C prevalence in this population.

The discussion highlighted the importance of considering social determinants of health in public health interventions, recognizing that addressing the root causes of disparities is crucial to reducing the burden of infectious diseases.

Global Health Center (GHC) Updates and Priorities

Dr. Kayla Laserson, Director of the CDC's Global Health Center (GHC), gave an update on the center's current direction and activities. GHC plays a vital role in protecting people both in the U.S. and around the world by preventing, detecting, and responding to global disease threats. It focuses on the objective that a health threat anywhere is a threat everywhere, as dangerous pathogens can quickly cross borders. GHC's work is organized around three divisions addressing the global HIV and TB epidemics, global immunizations, and global health protection.

Key Areas of Focus:

- 1. Addressing the Global HIV and TB Epidemics: The Division of Global HIV and TB focuses on global efforts to end HIV as a public health threat by 2030. Through the President's Emergency Plan for AIDS Relief (PEPFAR), CDC provided lifesaving antiretroviral treatment to 12.6 million people in 2023 alone, or more than 60% of men, women, and children receiving treatment from PEPFAR overall. Since 2017, CDC has also initiated TB preventive treatment for 9.9 million people living with HIV worldwide.
- 2. Global Immunizations: The Global Immunization Division works to increase the reach of immunization, interrupt poliovirus transmission globally, and stop outbreaks of vaccine-preventable diseases (VPDs), including measles. Vaccination efforts have significantly reduced outbreaks, including a notable decrease in variant polio cases. However, outbreaks of other VPDs, including measles, continue to pose significant risks.
- 3. Global Health Protection: The Division of Global Health Protection strengthens health systems and helps countries prepare for public health emergencies to advance global health security. This includes building capacity in laboratories, epidemiology, and emergency management. The division runs the Global Laboratory Leadership Programme to enhance national laboratory systems and the Field Epidemiology Training Program, which has trained over 22,000 epidemiologists globally.

7-1-7 Approach

GHC has adopted the 7-1-7 approach as a global standard for understanding where there are bottlenecks in managing outbreaks. The goal is for countries to detect an outbreak within 7 days, report it within 1 day, and respond to the threat within 7 days. This approach ensures swift and effective responses to outbreaks and allows for ongoing evaluation and improvement of response efforts. Key to this is having strong public health systems in countries across the globe, including the ability to perform high-quality diagnostics and have trained personnel in place.

Strengthening Global Partnerships and Responses

GHC has over 60 country and regional offices, with a workforce of approximately 2,000 people overseas. The center works closely with ministries of health and global partners to prevent and respond to health emergencies and has established trusted relationships that enable rapid deployment during crises. Lessons learned from international work and responses, such as on HIV, immunization efforts, and Ebola, are applied domestically to improve U.S. national health security. In 2024 alone, GHC's efforts, expertise, and partnerships have been instrumental for global responses to major health threats including mpox, Marburg virus, dengue, Oropouche virus, polio, and bird flu.

HIV and TB Efforts

HIV remains a major global health issue, with 38 million people living with the virus. TB is the leading infectious disease cause of death and the leading cause of death for people living with HIV, reaching upwards of 10 million cases per year. GHC's efforts, through PEPFAR and other initiatives, aim to reduce these numbers and meet the Joint United Nations Programme on HIV/AIDS (UNAIDS) 95-95-95 targets for HIV testing, treatment, and viral suppression. Additionally, innovative programs like Operation Triple Zero help adolescents living with HIV achieve optimal health outcomes.

Immunization and Disease Prevention

GHC is focused on eradicating polio, with significant progress made in reducing cases globally. However, challenges remain in regions like Pakistan and Afghanistan, where wild poliovirus persists. GHC is focused on immunization recovery and reaching zero-dose communities through the "big catch-up," which seeks to bring global immunization back to pre-pandemic levels. Efforts to address measles outbreaks are also ongoing. GHC is also partnering on new innovations, such as a microneedle patch for measles-rubella vaccination that offers promise in reaching remote populations.

Global Health Strategic Framework

To unify CDC's global health efforts, GHC has developed the Global Health Strategic Framework, which includes four goals:

- 1. Stop health threats at their source before they spread globally.
- 2. Contain disruptive global disease outbreaks.
- 3. Use global data for disease prevention and mitigation.
- 4. Save lives and improve health globally.

This framework supports rapid response to outbreaks, as seen in the Mpox response in Kenya and avian influenza outbreaks in Cambodia. The integration of global data, surveillance systems, laboratories, and trained personnel has enhanced the world's ability to respond quickly and effectively.

Collaboration with Other Agencies

CDC's leadership and collaboration with other U.S. agencies, such as USAID and the State Department, is key to the success of global health initiatives. For example, the Playbook for Biological Incident Response, approved by the National Security Council in 2023, outlines roles and responsibilities for interagency coordination during global health emergencies. This playbook was used during the Mpox outbreak in the Democratic Republic of the Congo and is now being applied to other global responses.

Long-term Opportunities and Challenges

GHC aims to achieve country-owned and sustainable public health systems worldwide, strengthen collaborations with federal agencies and other partners, and scale up initiatives to eliminate the leading infectious disease killers like HIV, TB, and vaccine-preventable diseases like measles. The Center is also committed to advancing science and developing new public health tools to combat both existing and emerging health threats.

BSC Comments and Discussion

- GHC seeks input from the BSC on improving the messaging around the Global Health Strategic Framework, particularly in conveying its importance to U.S. national security.
- It also welcomes suggestions on how to better articulate the return on investment of global health efforts, particularly in terms of the number of outbreaks prevented, and how to model these impacts effectively.

Overall, GHC's approach is centered around global collaboration, quick response capabilities, and the strategic unification and strengthening of global health systems to combat infectious diseases, improve public health outcomes, and protect health in the U.S. and worldwide.

Discussion with CDC Leadership

Dr. Cohen, who assumed leadership of the CDC in July 2023, inherited significant ongoing efforts that focused on leveraging lessons learned from the unprecedented COVID-19 pandemic. A key focus of these efforts was determining how CDC needed to adapt and improve in the post-pandemic era to better respond to both known and potential unknown health threats.

Data-Driven Decision Making:

- One of the critical lessons from COVID-19 was the need for rapid, actionable data. The
 pandemic highlighted that data must be simple, easy to understand, and visualizable, so
 it can be communicated effectively to the public and help guide community actions.
- It is also essential for the data to be layered with public health information, which provides clear, common-sense solutions that allow people to protect themselves and their families.
- CDC made the decision to align all its data platforms across the agency (1CDCP) to
 ensure that all available data—whether from chronic disease efforts, infectious diseases,
 or other public health issues—could be used to protect community health. This

- alignment extends to collaboration with external partners, allowing CDC to integrate data from various sectors of the public health infrastructure.
- This integrated approach is being actively utilized in responses to ongoing public health challenges, such as mpox, avian influenza, and Lassa fever.

Laboratory Capacity and Partnerships:

- Alongside data, CDC recognized the importance of having robust laboratory capacity, both within the agency and at public health labs across the country and globally. This includes forming partnerships with commercial laboratories, which can scale laboratory efforts far beyond the capacity of traditional public health infrastructure.
- These partnerships are crucial for rapid diagnostic and test development, and they allow CDC to rapidly scale up efforts when needed, such as with the avian influenza response.
 Commercial labs have been instrumental in making diagnostic tests accessible quickly, even to healthcare providers like doctors and nurse practitioners.

Workforce Development and Scientific Innovation:

CDC's ability to respond to public health challenges relies on its talented workforce, which is continually developed through fellowship programs such as the Epidemic Intelligence Service (EIS) Fellowship, laboratory training, and global epidemiology training programs. These programs ensure that CDC invests in the people who carry out the critical work of scientific research and response.

Mental Health and Prevention:

- CDC is also addressing the growing concern of mental health, particularly the rising rates
 of suicide and overdose, especially among individuals under 50. CDC is using its data,
 expertise, and investments to tackle the increasing numbers of deaths caused by these
 issues.
- On the prevention front, CDC is working to be proactive in addressing a range of health threats, from infectious diseases to chronic conditions like diabetes and heart disease.
 CDC is focusing on improving vaccination rates and building core capacity for readiness and response across various health areas. The agency is working to ensure that it has the necessary infrastructure in place to respond to these challenges with evidencebased actions that positively impact communities.

CDC is focusing on identifying the most pressing scientific questions that need to be addressed, not only for immediate action but also for the long-term future. The agency is working to ensure that data, science, and evidence can be quickly turned into actionable solutions that benefit communities.

BSC Comments and Discussion:

- Communicating Risk Effectively: How can CDC help local decision makers interpret and
 use public health data? CDC is considering this, including how to build trust and ensure
 that we communicate risks to the community in a way that is clear, actionable, realistic,
 and considers varying risk tolerances. CDC also revised cdc.gov to prioritize what to
 communicate and be more timely and clear.
- Data Modernization and Harmonization: How does CDC plan to develop data definitions to better characterize populations at risk and then better harmonize prevention efforts? The agency is working to align around collaborative standards and to find ways to present data rapidly, with more granularity and depth, to provide a better understanding of the issues at hand and establish connections between data points. We need to harmonize data not just within public health, but also with the health delivery system.
- Emergency Funding for Outbreak Response: Does CDC have sufficient funding for responding to future emergencies? Some of CDC's COVID investments built infrastructure and capabilities at CDC and in states and localities. Current budget discussions are still underway in Congress. We are working to educate policy makers on the lessons we learned from the pandemic and also the importance of ongoing response readiness. CDC does have access to an infectious disease rapid reserve fund that could be used, for example, to mobilize early in a problem to better understand an emerging situation and try to prevent a bigger emergency.
- Translating Scientific Information into Action: CDC requests guidance on how to translate
 complex scientific information into impactful, visualized actions that are both accurate and
 timely. The goal is to ensure that scientific data is understandable and leads to effective
 public health responses.
- Making Complex Information Accessible: Another priority for CDC is finding ways to communicate complex scientific information, particularly related to risk, in an easily understandable format for the public and stakeholders.
- Identifying Key Scientific Questions: CDC seeks assistance from the BSC in identifying the
 most important scientific questions that need to be addressed, not just for the present
 day, but with a long-term outlook for the next five years. This includes input on any work
 that should be stopping. This will help guide CDC's research priorities and resource
 allocation.
- Understanding Resources: CDC requests the BSC to become familiar with CDC's mission and what CDC needs to fulfill that mission.

Report Back from the Food Safety Modernization Act Surveillance Workgroup (FSMA SWG)

The Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, mandated the formation of a working group to advise the Secretary of Health and Human Services (HHS) on improving foodborne illness surveillance. The FSMA Surveillance Working Group (SWG) provides annual reports to the HHS Secretary, which include recommendations that have been reviewed and approved by the BSC IC, for enhancing foodborne illness surveillance, based on a series of key areas outlined in the FSMA legislation. These include improving access to surveillance data,

addressing barriers to effective surveillance, and coordinating federal, state, and local efforts to prevent foodborne illnesses. Virginia Caine, Chair of the FSMA SWG provided a report on the work group's activities.

Key Areas for Guidance

The FSMA SWG is tasked with offering guidance regarding improvement of foodborne disease surveillance in the following key areas:

- 1. Priority Needs of key partners for information and analysis on foodborne illness and its causes.
- 2. Opportunities to improve the effectiveness of initiatives at federal, state, and local levels, particularly regarding coordination and integration of activities.
- 3. Improvement in the timeliness and depth of access to aggregated, de-identified foodborne illness surveillance data, benefiting regulatory and health agencies, the food industry, researchers, and consumers.
- 4. Key barriers to improving foodborne illness surveillance and its utility for preventing foodborne illness.
- 5. Capabilities needed for establishing automatic electronic searches of surveillance data.
- 6. Recommending actions to overcome barriers, implement improvements, and set measurable objectives and timelines, with necessary resources and staffing identified.

FSMA SWG Structure

The FSMA SWG is chaired by a Board of Scientific Counselors (BSC) member and consists of 15-20 experts including at least one additional BSC member and members from federal, state, and local food safety regulatory and health agencies, the food industry, consumer organizations, and academia, as called for in FSMA. These members serve three-year terms, with the possibility of one term extension. Current members include

- BSC Members: Virginia A. Caine, MD; Allison Aiello, PhD, MS; and Trish Perl, MD, M.Sc.
- Representatives from academia at the University of Georgia and University of Washington
- Members from various associations including AFDO, APHL, ASTHO, CSTE, NACCHO, NASDA, NEHA, industry
- A representative from the FDA/DHHS and one from FSIS/USDA.

Additional FSMA SWG members are being actively recruited.

Meeting Format and Topics Reviewed

Pre-pandemic, the FSMA SWG met twice a year. Since the pandemic, meetings have shifted to virtual or hybrid formats. The most recent meeting was held in December 2022, a hybrid meeting. Historically, some of the topics reviewed by the group include:

- Integrated Food Safety Analytics Collaborations (IFSAC)
- Culture Independent Diagnostic Tests (CIDTs)
- Integrated Food Safety Centers of Excellence (CoEs)

- Whole Genome Sequencing (WGS) and its effects on foodborne illness surveillance
- Antimicrobial Resistance planning
- Coordination and collaboration among government agencies

FY2023 Findings and Considerations

In fiscal year 2023, the SWG held robust discussions and reviewed a range of topics related to enhancing foodborne disease surveillance and data access. Given there are many new BSC members, the SWG Chair provided some of the findings and advice from the most recent workgroup report that were approved by the BSC at its November 2023 meeting. These included:

- BEAM Dashboard: Recommendations to integrate other data sources and data from
 existing dashboards into one, expand content and continue to evaluate the Dashboard's
 feasibility and utility.
- PulseNet Modernization: Addressing IT barriers and capabilities across different laboratories.
- Cryptosporidium Surveillance: Expanding pilot programs due to limited current reporting.
- Ingredient Collinearity in Outbreak Investigations: Emphasizing local investigations, training, and developing predictive models with partners.
- Salmonella and Raw Frozen Stuffed Chicken Products: Advocating for increased research, data collection, and industry engagement in investigations.
- Cronobacter surveillance update: At the time of the SWG meeting, Cronobacter was only
 reportable in two states. Overall, the SWG supported invasive Cronobacter infections in
 infants becoming nationally notifiable and since the SWG met, CSTE recommended it be
 nationally notifiable.

Future Topics for Review

The FSMA SWG has identified several future topics to review, which include:

- Cooperation with international partners and harmonization of methodologies for WGS/PulseNet International.
- Continued efforts to modernize data systems like BEAM and PulseNet.
- Impact of culture-independent diagnostic tests (CIDT) and progress with metagenomic approaches on surveillance.
- Exploring climate-related impacts on foodborne illnesses, including the effects on shellfish and produce.
- Issues related to surveillance and response in shellfish-related outbreaks.
- Updates on *Cronobacter* surveillance.

Plans for 2025

The FSMA SWG is scheduled to meet virtually in January 2025. Additionally, there will be an inperson meeting in the spring of 2025, coinciding with the BSC ID meeting. The topics for these

meetings will be informed by the previous findings of the SWG and CDC's program needs. The SWG will present its findings from the virtual meeting at the BSC ID meeting, and the FY25 annual report will be presented to BSC in FY26. Once approved by the BSC, the FSMA SWG report will be submitted to the HHS Secretary and published on the CDC website for public access.

Report Back from the Infectious Disease Laboratory Workgroup (IDLW)

Co-chairs Christine Hahn and Bisola Ojikutu provided a report on the Infectious Disease Laboratory Workgroup (IDLWG). This workgroup was initially established in 2013 and reestablished in 2024 with updated terms of reference. Its primary mission is to provide recommendations to the BSC ID on enhancing CDC's use of genomic, metagenomic tools, information technologies, and other diagnostic innovations to improve public health. IDLWG includes experts from state public health departments, clinical and public health laboratories, academic institutions, healthcare, technology, and industry, covering areas such as laboratory science, bioinformatics, IT, and public health.

Key Issues Addressed

- 1. Review Leadership Needs for Public Health Action:
 - Ensuring the application of advanced molecular detection (AMD) technologies to produce meaningful information for effective public health action.
- 2. Expansion of AMD in CDC Programs:
 - Prioritizing innovative research, capacity building at local and state levels, and workforce modernization for AMD.
- 3. Modernizing Infectious Disease Surveillance:
 - Ensuring the reduction in conventional culture methods in diagnostic labs does not hinder outbreak detection and monitoring.
- 4. Quality Control and Regulatory Compliance:
 - Integrating AMD with quality control systems and adhering to regulatory standards in collaboration with public health and private sector partners.
- 5. Bioinformatic Shared Services:
 - Leveraging shared bioinformatic services to rapidly detect and characterize pathogens.
- 6. Enhancing Laboratory Collaboration:
 - Strengthening linkages between public health, clinical, and reference labs to improve molecular diagnostic data integration into surveillance.

Focus Areas for 2024-2025

IDLWG is focusing on advancing the AMD Program and assessing the current and future state of diagnostic testing. The AMD program, launched in 2014, supports laboratory and bioinformatic innovations for pathogen genomics at CDC and throughout the U.S. public health system. The group will review AMD progress and provide guidance on strategic priorities.

Key discussion topics for AMD include:

- Assessing Current Diagnostic Capabilities: Reviewing existing diagnostic technologies and recommending improvements, including the rapid development and validation of AMDbased assays.
- Workforce and Regulatory Engagement: Ensuring workforce training and adherence to regulatory requirements in collaboration with public health partners.

Report from October 2024 IDLWG Meeting:

Presentations

• Dr. Ren Salerno's Presentation:

 Dr. Salerno, Director of the new Office of Laboratory Systems and Response, shared the transformation of CDC's laboratory systems. This office aims to enhance internal lab safety and quality, while fostering external partnerships for better preparedness and response during outbreaks. The office is divided into two main divisions: one focused internally and one on external collaborations.

• Dr. Duncan MacCannell's Presentation:

Dr. MacCannell, Director of the Office of Advanced Molecular Detection, highlighted advancements in bioinformatics and pathogen genomics. The AMD Program, originally focusing on foodborne pathogens like Listeria, is now evolving rapidly, with more states increasing sequencing capabilities.

Key Issues Raised for Future Discussion:

- Infectious Disease Test Review Board (IDTRB): Clarification of the IDTRB's composition and submission process for regulatory approvals.
- Balancing Resources and New Testing Technologies: How to allocate limited resources while adopting new diagnostic technologies.
- **Genomic Surveillance Capacity Building**: Strategies for local capacity building in genomic surveillance and increasing sequencing in clinical diagnostics.
- **Regulatory Compliance:** Addressing challenges in complying with evolving regulatory requirements for diagnostic tests.
- Lab Reimbursement and Public Health Infrastructure: Exploring CDC support for laboratory reimbursement and strengthening public health infrastructure.

Preliminary Questions for IDLWG Discussions at Upcoming Meetings:

- Are the CDC's AMD objectives forward-looking and comprehensive?
- Are the strategic and programmatic priorities for AMD clearly defined, and are there gaps that need more focus?
- How should CDC balance intramural versus extramural AMD activities?
- What partnerships external to CDC (state/local, other federal partners, private sector, academic) should be fostered to advance AMD?

BSC Comments and Discussion:

1. Regulatory Landscape:

 The final rule published by the FDA is a priority discussion topic, especially its impact on infectious disease diagnostics in public health labs and the private sector, particularly with respect to lab developed tests. This rule is expected to affect patient management and surveillance.

2. Local Lab Capacity and Molecular Testing:

 Emphasizing the need for local laboratories to have molecular testing capacity, as state labs may not always have the necessary resources to do core testing.

3. Metagenomic Sequencing Challenges:

 Metagenomic sequencing poses challenges in terms of FDA approval and laboratorydeveloped tests (LDTs), particularly in clinical labs.

4. Workgroup Composition/Expertise:

The workgroup should seek input from county or city-level lab professionals, as well as
front-line clinical laboratories. There is a need for input from those who work directly
with clinical labs and face day-to-day challenges.

5. Data Modernization and AI:

 Experts in data modernization, AI, and analytics should be included in discussions to improve lab efficiency and sequencing accuracy.

6. Financial Sustainability of New Technologies:

 Future discussions should consider how new technologies can be financially supported, especially since they may not be directly used for patient care but for public health research and investigations.

7. FDA and Other Regulatory Bodies:

- Consideration for inviting representatives from the FDA's Centers for Devices and Radiological Health (CDRH), Biologics Evaluation and Research (CBER), and Drug Evaluation and Research (CDER) to join the discussions, to offer insights into the regulatory challenges faced by diagnostic tests. Yodit Belew, FDA Ex Officio Representative, offered to facilitate this connection for future IDLWG discussions.
- Implementation of the rule is an area the group may want to discuss with FDA, including the possibility of specific waivers, exemptions, or alternative paths to meet the requirements for orphan pathogens, where there may be treatment or public health considerations in the case of very rare events.

8. Impact of Regulatory Changes on Tuberculosis Testing:

- Discussions should also recognize that that regulatory changes will likely have impact beyond rare diseases and orphan pathogens, such as on tuberculosis diagnostics.
- 9. Improving Laboratory Data Sharing and Collaboration:

- Enhancing data sharing between public health, hospital, commercial, and reference laboratories is critical. The group discussed utilizing cloud platforms and artificial intelligence to improve the efficiency of molecular diagnostic data sharing.
- Data modernization, artificial intelligence, and the intersection of lab data and public health is an area that IDLWG and BSC ID should discuss further.

Report Back from the Wastewater Surveillance Workgroup (WSW)

The Wastewater Surveillance Workgroup (WSW) was convened to provide observations and findings related to CDC's efforts in implementing wastewater surveillance nationally, with the aim of informing the BSC ID's advice to CDC on public health actions. The group is co-chaired by Drs. Anil T. Mangla and Thomas Wittum, with Jonathan Yoder serving as the designated federal officer.

Description of Activities:

The group will address issues in the following priority areas:

1. Wastewater Testing Target Selection:

o How to select relevant and feasible testing targets that provide public health value.

2. Ethical Considerations:

 Ensuring ethical practices in wastewater surveillance, such as confidentiality, data integrity, data sharing, and avoiding stigmatization.

3. Surveillance Coverage Goals:

 Determining appropriate coverage at local, county, or state levels, and understanding the implications for public health actions.

4. Sustainability:

 Addressing the sustainability of wastewater surveillance efforts, including how to maintain programs long-term.

5. Facility-Level Testing vs. Community-Level Testing:

• The need to evaluate the cost-effectiveness and public health value of testing at different levels (community vs. facility).

Report on October 2024 WSW Meeting:

In the WSWG's first meeting, Dr. Peggy Honein presented an overview of CDC's Wastewater Surveillance Program, which set the stage for further discussions. The presentation highlighted key aspects of CDC's role and the ongoing wastewater surveillance efforts, which sparked active discussions among workgroup members.

Several issues emerged during the discussions:

1. Selection of Surveillance Targets:

- Participants emphasized the importance of targeting high-traffic areas (e.g., tourist destinations) and the need for actionable community-level data.
- Ethical considerations were highlighted, particularly regarding bacteria testing and the challenge of identifying unique targets and their prevalence in the environment.
- There was debate over whether pathogens identified in wastewater should be reported to local, state, and CDC authorities.

2. Community-Based vs. Facility-Based Testing:

- o A mix of community-based and facility-based testing was seen as valuable.
- Ethical considerations varied between routine surveillance and outbreak monitoring.
- Facility-based testing, although expensive, could provide valuable insights into pathogen detection.
- o Wastewater data could complement existing health surveillance efforts.

3. Ethical and Resource Limitations:

- Ethical concerns, including the stigma associated with certain areas or populations, were discussed.
- Stakeholder engagement was emphasized, particularly the need to gain buy-in from utilities for wastewater surveillance.
- Decoupling wastewater surveillance from COVID-19 was highlighted as important to expand its application for other health threats.
- The group discussed the need for sustainable funding and called for the creation of educational materials, including success stories, to help overcome barriers to implementation.

Several next steps for sustaining wastewater surveillance were discussed, including:

• Right-sizing Coverage:

 The group discussed how to determine the appropriate level of coverage, whether national, regional, or local, and how to select effective metrics for geographic and temporal sampling.

• Ethical Framework and Public Perception:

- There was concern about how wastewater surveillance could be perceived as punitive, especially in sensitive settings like prisons or hospitals.
- The group emphasized the need to avoid stigmatizing certain geographic areas or populations.

Sustainability and Cost-effectiveness:

 The challenge of ensuring long-term sustainability, particularly in the context of resource constraints and the costs associated with setting up sentinel surveillance systems, was highlighted.

The workgroup identified several topics for future meetings:

1. Target Criteria and Use Cases:

 Further refinement of criteria for selecting surveillance targets, including prioritizing specific pathogens.

2. Evaluation Strategy:

o Outlining methods to evaluate wastewater data and develop thresholds.

3. **Decision-Making:**

Establishing clear protocols for interpreting results.

4. Ethical and Resource Constraints:

 Additional discussions on overcoming ethical and resource-related challenges to broader implementation of wastewater surveillance.

BSC Comments and Discussion:

- Wastewater surveillance can be a powerful tool for preventing outbreaks and monitoring
 public health. However, the ethical framework should include discussion of unintended
 consequences and how to prevent wastewater surveillance from becoming a punitive tool,
 including in facilities such as prisons.
- Community education is essential to overcome concerns about privacy and the potential for stigmatization. Emphasizing that wastewater surveillance tracks community-level trends rather than individual data may alleviate privacy concerns.
- Decisions to conduct wastewater surveillance need to also reflect a clear understanding of how the data will be used and that the use will allow for meaningful public health response.
- Skepticism surrounding the use of wastewater surveillance can be addressed by highlighting its utility in detecting community-wide increases in viruses and identifying unusual public health events.
- The group discussed sensitivities around testing for substances of abuse.
- The group also discussed the importance of local community engagement to ensure that the public understands the value of wastewater surveillance and is supportive of its use.

During the discussion, Drs. Christine Hahn and Bisola Ojikutu expressed interest in participating in future WSW discussions.

Report Back from Acute Flaccid Myelitis (AFM) Task Force

Overview

• The Acute Flaccid Myelitis (AFM) Task Force was originally established in 2018 to provide findings, observations, and outcomes to the BSC in two key areas: (1) AFM etiologies and pathogenesis, and (2) the clinical treatment or management of AFM.

AFM Background

- **First Identified**: AFM first gained national attention in 2014, with clusters of unexplained limb weakness and paralysis in children in California and Colorado.
- **Clinical Presentation**: AFM mimics polio, but with more frequent upper extremity involvement and no link to poliovirus.
- Etiology: AFM is associated with viral infections, including non-polio enteroviruses (e.g., EV-D68), West Nile, Japanese encephalitis, and herpes viruses. However, there is no proven treatment for AFM, with current management focusing on intravenous immunoglobulin (IVIG), steroids, and plasma exchange.

Surveillance and Research Findings

- CDC Surveillance: Since 2014, CDC has tracked AFM cases, observing peaks in 2014, 2016, and 2018, typically in late summer/early fall. EV-D68 was suspected as a causative agent, supported by temporal associations with respiratory outbreaks.
- Pathogen Detection: Despite evidence linking EV-D68 with AFM, detecting pathogens in AFM patient specimens has been challenging, with only a small percentage of cerebrospinal fluid (CSF) samples testing positive for enterovirus.
- EV-D68 and AFM: Over the years, evidence supporting EV-D68 as a key cause of AFM has
 grown, including case-control studies, animal models, and postmortem findings of EV-D68
 infection in anterior horn motor neurons in the spinal cord.
- Surveillance since 2020: The pandemic in 2020 seems to have interrupted the every-other-year pattern of increases in AFM. EV-D68 circulation did not significantly increase above baseline, most likely due to non-pharmaceutical interventions implemented during the pandemic. In 2022 EV-D68 respiratory disease returned and EV-D68 was circulating at high levels. However, there was no increase in AFM cases associated with the increase in EV-D^8 circulation, and it is unclear why.

Current AFM Case Trends (2024)

- Confirmed Cases: To date in 2024, there have been 15 confirmed AFM cases, lower than previous years (47 cases in 2022, 18 in 2023). These cases are geographically dispersed, with no clustering observed.
- **EV-D68**: No EV-D68 detections have been made in this year's confirmed AFM cases. However, respiratory infection surveillance in 2024 (through NVSN and wastewater monitoring) shows increases in EV-D68 circulation similar to previous peak years but without a corresponding increase in AFM cases.

Task Force Activities

- The Task Force was formed to provide findings on AFM etiology, pathogenesis, and clinical management. Key areas discussed included:
 - Evidence of EV-D68 as a cause of AFM
 - The role of host genetics and immune responses
 - o Long-term outcomes and rehabilitation for AFM patients
 - Surveillance strategies and the CDC's AFM case definitions
- **Proposed Sunset**: Dr. Kidd proposed sunsetting the AFM Task Force due to the current stable baseline of AFM cases and increased understanding of AFM, its management, and how to distinguish it from other neurologic conditions.

Ongoing CDC Activities

- Core Activities: CDC continues to prioritize AFM surveillance and research, including:
 - Case-based surveillance
 - EV-D68 and parechovirus testing
 - Preparedness for future outbreaks
 - Public engagement with AFM patient groups and academic partners
 - Various ongoing research studies, including NIH's AFM natural history study (completed in 2024) and the evaluation of EV-D68 monoclonal antibodies.

Dr. Kidd shared several resources available for clinicians:

- CDC's AFM Landing Page and Case Counts (updated monthly)
- NVSN Public Dashboard tracking EV-D68 trends
- WastewaterSCAN Dashboard for EV-D68 surveillance
- Siegel Rare Neuroimmune Association Physician Consult Portal for AFM clinical consultations

BSC Comments and Discussion

- Adult AFM and EV-D68 Surveillance: Expanded respiratory virus testing in adults was suggested to capture more comprehensive epidemiological data.
- **Neonatal Enterovirus Sepsis:** There is continued interest in the development of antiviral therapies for neonates affected by severe enterovirus-related diseases.
- **Diagnostic Distinctions:** It was noted that the available tests in the clinical setting provide a positive/negative results for enteroviruses and rhinoviruses, and currently cannot distinguish between enteroviruses and rhinoviruses.

Vote on Sunsetting the Task Force

• Motion: Do you agree with sunsetting the BSC AFM Task Force at this time?

Outcome: The BSC ID voted unanimously in favor of sunsetting the AFM Task Force.

The **AFM Task Force** will be sunsetted due to the stability in AFM cases and the broad understanding of the condition. However, CDC's core activities related to AFM, including surveillance and research, will continue.

National Center for Immunization and Respiratory Diseases (NCIRD) Updates and Priorities

Dr. Demetre Daskalakis, Director of the National Center for Immunization and Respiratory Diseases (NCIRD), presented an overview of the center's mission, priorities, and activities. NCIRD aims to prevent disease, disability, and death through immunization and the control of respiratory diseases, addressing both domestic and global health challenges. The center focuses on ensuring vaccine access for populations across all ages, from children to older adults.

Key Activities of NCIRD:

- 1. **Leadership and Expertise:** NCIRD provides leadership in laboratory and epidemiological sciences and immunization program delivery.
- 2. **Research and Data:** The center conducts applied research on disease prevention, translates findings into public health policies, and provides diagnostic services.
- Disease Surveillance: NCIRD monitors disease distribution both nationally and internationally, responding to outbreaks and ensuring decisions are based on high-quality scientific data.
- Public Health Communication and Education: NCIRD develops strategies to enhance awareness and understanding of immunization programs, both domestically and internationally.
- 5. **Collaboration and Partnerships:** NCIRD works with various domestic and international partners to improve immunization programs, policy development, and public health impact.

NCIRD's Focus Areas and Priorities:

- 1. **Workforce and Organizational Modernization:** Strengthening the workforce and modernizing organizational systems.
- 2. **Improved Response to Respiratory Viruses:** Enhancing infrastructure, partnerships, and preparedness for seasonal and pandemic respiratory outbreaks.
- 3. **Vaccine Accessibility:** Expanding outreach with trusted messengers to improve vaccine accessibility for all populations.
- 4. **Vaccine Use in Pregnancy:** Supporting the evaluation of vaccines during pregnancy to improve health outcomes.
- 5. **Partnerships for Diagnostic Test Development:** Expanding collaborations for rapid diagnostic test development.

6. **Modernizing Data Systems:** Updating information systems to better track immunization needs and respiratory disease trends.

Respiratory Virus Preparedness:

Dr. Daskalakis highlighted the importance of NCIRD's work to prepare for fall and winter virus outbreaks, particularly the co-circulation of RSV, influenza, and COVID-19. Data channels like the Respiratory Illness Data Channel allow the sharing of respiratory illness data, offering national insights and community snapshots. This season, RSV is expected to follow a more predictable pattern compared to post-pandemic years. Forecasting models indicate the potential for peak hospitalizations to be similar to last season, although uncertainties exist regarding new variants or flu strains.

Key Collaborations and Forecasting:

NCIRD works with the Center for Forecast and Outbreaks Analytics (CFA) to model respiratory season predictions. Despite ongoing declines in COVID-19 cases, the healthcare system remains at risk due to the co-circulation of viruses. Forecasting relies on the previous year's vaccination rates and ongoing public health education to reduce risks.

Disease Control and Vaccination Updates:

- RSV, Influenza, and COVID-19 Vaccinations: Updated guidance emphasizes immunizations
 for all individuals, with specific recommendations for pregnant women, older adults, and
 those with underlying conditions. RSV vaccines are particularly important for newborns
 and older adults.
- Pertussis Trends: Post-pandemic, pertussis cases are on the rise. NCIRD is working on a controlled human infection model to accelerate the development of longer-lasting vaccines.
- 3. **Measles Outbreaks:** Measles cases have significantly increased, with notable outbreaks in several U.S. cities, prompting a level four response.

Division Highlights:

- 1. **Division of Bacterial Diseases (DBD):** Focused on mycoplasma pneumonia infections and pertussis. The division also works on strategies to combat Legionnaires' disease and supports recommendations for pneumococcal conjugate vaccines.
- 2. **Division of Viral Diseases (DVD):** Addressing measles outbreaks and supporting polio eradication through global lab networks. The division is also involved in the development of HPV recommendations and planning for future availability of a vaccine for CMV.
- 3. **Influenza Division:** Focused on both seasonal flu preparedness and global surveillance efforts. The division is working to increase vaccine uptake, particularly in underserved populations, and has launched educational campaigns like "Wild to Mild."
- 4. **Coronavirus and Other Respiratory Virus Division (CORVD):** Established to address epidemic respiratory threats, CORVD contributes to vaccine recommendations for COVID-19 and RSV, using genomic surveillance to track the virus's evolution.

5. **Immunization Services Division:** ISD tracks vaccination rates, reporting a slight decline in kindergarten vaccine coverage post-COVID. NCIRD is working with partners to increase vaccination rates and address vaccine hesitancy, particularly through the "Let's Rise Initiative" and other outreach efforts.

Vaccines for Children and Adults:

The Vaccines for Children program is celebrating its 30th anniversary, having prevented millions of illnesses and deaths. NCIRD is advocating for the creation of a Vaccines for Adults program to increase access to vaccines for uninsured adults.

BSC Comments and Discussion:

- NCIRD seeks future discussion with BSC on balancing support for pathogen nonspecific systems and along with pathogen-specific expertise.
- Board members raised questions about efforts to enhance messaging around vaccinations, reduce misinformation, and increase vaccine uptake nationally and in communities. Dr.
 Daskalakis discussed NCIRD's work to simplify its messages around vaccination and engage with specific communities to increase motivation to be vaccinated. They are looking more deeply into survey data to identify specific barriers or concerns individuals may have about certain vaccines, so CDC can develop tools such as discussion guides and targeted messages for clinical providers to use with patients.
- A Board member asked about a vaccines for adults program, and Dr. Daskalakis explained that this is included in the President's budget to support vaccination by allocating funds to states for vaccines and for vaccine administration. This would move us towards a fully realized immunization program across the lifespan.

This meeting underscores NCIRD's critical role in respiratory virus preparedness, vaccine distribution, and disease prevention efforts, with a focus on public health collaboration.

Presentation and Discussion on Proposed Workgroup on Emerging Threats

Dr. Dan Jernigan provided a second presentation on the proposed creation of the Emerging Threats Workgroup of BSC. This proposal comes from all the infectious disease centers at the CDC, as well as the Office of Readiness and Response (ORR), overseen by Henry Walke. The goal is to improve the CDC's ability to engage with external partners, gain input, and make rapid decisions in response to emerging infectious disease threats.

Context of the Proposal:

- The CDC faces significant challenges in receiving timely input from external sources, particularly when it comes to community engagement, vulnerable populations, and nontraditional public health partners (e.g., community-based organizations, healthcare sector, private sector).
- James Macrae, an expert consultant, highlighted several issues in his CDC Moving Forward Report:

- "We do not yet know what the next threat will be" given the recent public health threats (e.g., COVID-19, mpox, polio).
- The public health landscape has changed post-COVID-19, and CDC needs to broaden its scope of partners.
- Greater collaboration is needed with industry, academia, state/local governments, and non-traditional public health partners.

Public Health as a Team Sport:

- Drs. Cohen, Houry, and Wong emphasized the importance of engaging diverse stakeholders and external experts early in the process of developing public health guidance.
- The CDC is focused on engaging non-traditional partners and incorporating external feedback earlier in the process to ensure public health guidance is widely accepted and effective.

Challenges:

- During outbreaks, rapid decision-making is necessary, but there is no structured way to access external input.
- While CDC traditionally relies on a few established partners, there is a need for broader community engagement beyond that to inform investigations and interventions.

Proposal for the Emerging Threats Workgroup:

Purpose:

 The workgroup would provide observations and findings to BSC ID on strategies and best practices for detection, control, and prevention of infectious diseases.

Initial Questions for the Workgroup:

- o How can CDC rapidly engage with external partners during outbreak investigations?
- What additional partners should be involved?
- What areas of expertise should be readily available during outbreak responses?
- How can the workgroup stay informed of emerging threats and engage effectively when needed?
- o Might this workgroup facilitate this further engagement?

Workgroup Responsibilities:

During a response:

- Assess strategies for detection, control, and prevention.
- Assemble rapidly to gather expert input on emerging threats.
- Provide input to BSC on critical infectious disease control strategies.

 Address operational challenges, countermeasures (treatments, vaccines, diagnostics), interventions for vulnerable populations, and conservation strategies.

During non-response times:

- The workgroup will periodically receive information on emerging issues and provide input to BSC on improving CDC's engagement with external partners and communities.
- Evaluate current CDC outbreak response strategies.

Annual Responsibilities:

 Provide an annual high-level review of CDC's responses and identify areas where attention should be increased, forecasting potential future threats.

BSC Comments and Discussion:

- Board members raised multiple questions and points around structure of the workgroup:
 - The group should not supplant existing lanes of expertise at CDC or among its standing advisory bodies, such as HICPAC.
 - The structure should mirror that of the Emergency Operations Center (EOC), with additional subject matter experts (SMEs) from areas such as communication and logistics.
 - Health system partners, including payer systems, should be considered as part of the workgroup.
 - A Board member suggested to consider a "bank" of special government employees (SGEs) with expertise in key areas that could be established to assist in rapid advisory roles when necessary.
 - The workgroup could function in two phases: an initial phase would involve a landscape review or discovery to understand the external capabilities needed, what is available, and what is lacking, with a second phase that would focus on designing the structure of the workgroup, ensuring it is adaptable to future threats.
- Dr. Jernigan reiterated that a key role of the group will be to provide input on what
 partners and types of expertise are needed to consult on particular topics. CDC wants to
 broaden the range of perspectives it considers in developing guidance and response
 strategies.

Vote

A unanimous vote was cast by the BSC ID to approve the creation of the Emerging Threats Workgroup.

Public Comments

Phone lines were opened for public comments at 3:34 PM. No comments were made.

Wrap-Up/Recap

Acknowledgements

The Board of Scientific Counselors (BSC) members expressed their appreciation to Dr. Lauren Meyers for her excellent facilitation of the meeting, keeping the group focused and on schedule. They also praised the meeting format, which allowed for a diverse range of presenters.

Dr. Meyers thanked the BSC members for their active participation and the engaging discussions. She also expressed gratitude to the CDC staff for their hard work in planning and organizing the event. Ms. Wiley joined Dr. Meyers in thanking the BSC for their engagement and contributions.

Future Meetings

The plan is to hold two in-person meetings in 2025: one around the April-May timeframe and another in November or December. Ms. Wiley will reach out to BSC members to check their availability for these meetings. Virtual attendance options will also be available for those unable to travel to Atlanta.

The meeting was adjourned at 3:40 PM.

APPENDIX: Meeting Participants

BSC Members

Lauren MeyersTri DoTrish PerlAllison AielloAnthony FloresSusan PhilipJosh BarocasChristine HahnThomas Wittum

Virginia Caine Anil Mangla Angela Caliendo Bisola Ojikutu

Liaison Representatives

Christine Markham, representing CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

Erica Shenoy, representing Healthcare Infection Control Practices Advisory Committee Lynn Sosa-Bergeron, representing Advisory Council for the Elimination of Tuberculosis Helen Keipp Talbot, representing Advisory Committee on Immunization Practices

Ex Officio Members

Yodit Belew, Food and Drug Administration Emily Erbelding, National Institutes of Health

CDC Staff

Tricia Aden Jennifer Brannon Jessica Fairbanks Rita Allen Cecily Campbell Susan Hariri John Barnes Serena Carroll Victoria Harp Nathelia Barnes **Shirley Castillo Heather Hastings** Dhwani Batra Roxana Cintron Vincent Hill Hanen Belgasmi-Allen Eleanor Click Peggy Honein Elise Beltrami Elizabeth Coke Marsha Houston Sara Benist Amanda Crouse **Ansley Hynes** Bina Jayapaul-Philip Oscar Bermudez Demetre Daskalakis Colin Bernatzky Laurie Dieterich Daniel Jernigan Angela Blackwell Pamela Dougherty **Heather Jones** Sophie Jones Allison Brady Shay Drummond

Gloria Kang Amy McMillen Jacqueline Rosenthal Samantha Katz Michael Melgar Sandra Roush Shannon Keckler Jonathan Mermin Hanna Schurman Matthew Keller Bryce Miller Alison St John LeiAnn Keuth Olga Stuchlik **Ruth Moro** Sarah Kidd Caryn Murillo Bill Switzer Josilene Nascimento Seth Kroop Xiaojuan Tan Seixas Matthew Kuehnert **Solomon Torres** Megin Nichols Wendi Kuhnert Kristi Tucker Kristen Nordlund Kayla Laserson Amra Uzicanin Shannon Novosad Brian Wakeman Jennifer Legardy-Williams Angela Oliver Brandi Limbago Xin Wang **Dometa Ouisley** Adriana Lopez Rory Welsh ketan Patel Cherry Luo Sarah Wiley Manisha Patel Mandy Lyons **Emmalee Williams**

Robin Pendley Louis

MN Woolfork

Xianfu Wu

Brian Yoo

Laura Yorke

Michael Mahar
Mandy Lyons
Victoria Ramirez
Grace Marx
Likhita Raparti
Melissa McDonald
Sherri McGarry
Nicole Pitts
Victoria Ramirez
Likhita Raparti
Missy Rasmussen
Jessica Ricaldi

Duncan MacCannell

Twenty members of the public joined the virtual meeting and registered their attendance. Additional individuals may have joined remotely but were not recorded.

I hereby certify that to the best of my knowledge, the formeeting of the Board of Scientific Counselors, Infection and complete.	
Lauren Meyers, Ph.D. Chair, BSC ID	Date