Clinical **L**aboratory **I**mprovement **A**dvisory **C**ommittee

Summary Report

October 28-29, 2020

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
October 28-29, 2020 Summary Report

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CLIAC OCTOBER 28-29, 2020 MEETING AGENDA ***Addendum 1***

CLIAC MEETING TRANSCRIPT ***Addendum 2***

RECORD OF ATTENDANCE

Committee Members Present
Dr. Valerie Ng, Chair
Dr. Birthale Archie
Dr. Marc Couturier
Dr. Mary Edgerton
Dr. Susan Gross
Dr. Lee Hilborne
Dr. Steven Hinrichs
Dr. Jordan Laser
Dr. Thomas Lorey
Dr. Lavinia Middleton
Ms. Carole Moss
Dr. Nirali Patel
Dr. Michael Pentella
Dr. Katherine Perez
Ms. Jennifer Rhamy
Dr. Gregory Sossaman
Dr. R.W. (Chip) Watkins
Dr. Thomas Williams
Dr. Donna Wolk
Mr. Andy Quintenz, AdvaMed (Liaison Representative)

Ex Officio Members
Dr. Collette Fitzgerald, CDC
Ms. Regina Van Brakle, CMS
Dr. Timothy Stenzel, FDA

Designated Federal Official
Dr. Reynolds Salerno, CDC

Executive Secretary
Ms. Nancy Anderson, CDC

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. The meeting was a full virtual Zoom webcast and approximately 110 public citizens attended one or both days of the meeting.

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC) BACKGROUND

The Secretary of Health and Human Services (HHS) is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to ensure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health pertaining to improvement in clinical laboratory quality and laboratory medicine. In addition, the Committee provides advice and guidance on specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic submission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

The Committee consists of 20 members, including the Chair. Members are selected by the Secretary from authorities knowledgeable in the fields of microbiology, immunology, chemistry, hematology, pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; the Administrator, Centers for Medicare & Medicaid Services; and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC also includes a non-voting liaison representative who is a member of AdvaMed and such other non-voting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions.

As a result of the different perspectives among its members, CLIAC is at times divided in the guidance and advice it offers to the Secretary. Even when all CLIAC members agree on a specific recommendation, the Secretary may not follow the Committee's advice because of other overriding concerns. Thus, while some of the actions recommended by CLIAC may result in changes to the CLIA regulations or may lead to other actions taken by HHS, all of the Committee's recommendations may not be accepted and acted upon by the Secretary.

CALL TO ORDER AND COMMITTEE INTRODUCTIONS *Addendum 3*

Dr. Reynolds Salerno, Designated Federal Official (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Director of the Division of Laboratory Systems (DLS), Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Office of Public Health Scientific Services (OPHSS), CDC, welcomed the Committee and the members of the

public. Dr. Valerie Ng, CLIAC Chairperson, welcomed the Committee and reviewed the process for public comments, quorum requirements, and the process for official CLIAC recommendations. Dr. Salerno recognized CLIAC outgoing members, Dr. Keith Davis, Dr. Bradley Karon, Dr. Sharon Massingale, Ms. Bonnie Rubin, and Ms. Cynthia Wilkerson, for their contributions to the Committee. A special presentation was provided that highlighted the CLIAC accomplishments during Ms. Karen Dyer's term as CMS Ex Officio and Dr. Peter Tobin's Term as FDA Ex Officio. All members then made self-introductions and financial disclosure statements relevant to the meeting topics. Dr. Ng stated that the agenda topics would include updates from the CDC, CMS, and FDA. Dr. Ng introduced the theme of the meeting, Clinical Laboratory Medicine in the Age of COVID-19, with presentations and discussions on Preparedness and Response: The Partnership between Clinical Laboratories and Public Health, Laboratory Data Exchange during COVID-19, and The Clinical Laboratory's Role in Identifying Health Inequities during the COVID-19 Response.

AGENCY UPDATES AND COMMITTEE DISCUSSION

Centers for Disease Control and Prevention (CDC) Update ***Addendum 4***

Collette Fitzgerald, PhD
Deputy Director for Science
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Office of Public Health Scientific Services (OPHSS)
Centers for Disease Control and Prevention

Dr. Fitzgerald updated CLIAC on CDC's COVID-19 response and the work of the Division of Laboratory Systems (DLS) to support the CDC Laboratory and Testing Task Force. She explained how the task force is integrated into the COVID-19 incident management system and how CDC uses this infrastructure to deploy CDC employees as part of the response. Dr. Fitzgerald described the task force's mission and three priority areas, and how the DLS response team activities focus on the clinical laboratory needs. Under laboratory testing and reporting, she highlighted various products including guidelines for rapid antigen tests, guidance for SARS-CoV-2 point-of-care testing, and, to help support reporting, a LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping Guide for SARS-CoV-2. Dr Fitzgerald discussed the DLS response activities related to biosafety, partnerships, and communications. She reviewed the metrics for the CDC Biosafety FAQ webpage, the webpage of guidelines for handling and processing COVID-19 specimens, and the clinical laboratory calls and email inquiries DLS has fielded. After a brief update on policy activities related to the COVID-19 response, she presented a summary of CDC's related training, job aids, and virtual reality courses. Dr. Fitzgerald concluded by announcing CDC OneLab, a new project being initiated in collaboration with the CDC COVID-19 Laboratory and Testing Task Force.

Centers for Medicare & Medicaid Services (CMS) Update *Addendum 5*

Regina Van Brakle, MT (ASCP)
Acting Director
Division of Clinical Laboratory Improvement and Quality (DCLIQ)
Center for Medicaid and State Operations (CMSO)
Centers for Medicare & Medicaid Services (CMS)

Ms. Van Brakle began by describing the realignment within the Division of Clinical Laboratory Improvement and Quality (DCLIQ). She summarized CMS DCLIQ COVID-19 activities, including changes to the CMS website to assist new facilities applying for a CLIA license. She provided statistics and descriptions of facilities that obtained a CLIA certificate during the public health emergency. Ms. Van Brakle explained the flexibilities and enforcement discretion the agency has allowed during this time. Some of the changes involve testing locations, such as allowing for remote review of pathology slides, proficiency testing, and timing for when new laboratories can begin testing. She also explained how surveys were reprioritized, conditions in which a laboratory could be surveyed remotely, and the number of cease and desist letters sent. Ms. Van Brakle concluded her presentation by discussing new or modified CLIA regulations to address reporting requirements set by the CARES Act. She explained who is required to report, the information to be reported, the determination of compliance, and the penalties associated with non-compliance.

Food and Drug Administration (FDA) Update *Addendum 6*

Timothy Stenzel, MD, PhD
Director
Office of In Vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)
U. S. Food and Drug Administration (FDA)

Dr. Stenzel began his presentation with an explanation of the Emergency Use Authorization (EUA), under what conditions it may be used, and a list of past public health emergencies or potential public health emergencies when it was used. He detailed how an EUA is different from the usual FDA approval path and the number of tests that have been granted an EUA. Dr. Stenzel discussed the different ways FDA has communicated with the laboratory testing community to update FDA's guidance and recommendations, especially as the laboratory testing landscape changed over time. He summarized the different types of tests FDA had to review, tools to allow easier submission of data to the FDA, and how FDA provided transparency by making public the results of testing multiple molecular methods against the FDA's reference panel. He presented lessons learned and how the agency has tried to help reduce shortages of reagents and supplies. Dr. Stenzel finished by stating that FDA is supportive of more authorizations.

Committee Discussion

- A Committee member inquired about temporary CLIA testing locations and when they will no longer be allowed. Ms. Van Brakle responded that these locations are allowed during the public health emergency and will be evaluated at a later point to determine if the temporary sites will continue to be allowed.

- A member asked if data were being collected regarding the flexibilities temporarily in place under CLIA to potentially inform future CLIAC recommendations. Ms. Van Brakle and Dr. Fitzgerald agreed that data has not been collected and neither was aware of any specific data available.
- One member asked about CMS oversight of nontraditional laboratories that are now performing COVID-19 testing. Ms. Van Brakle responded that all testing sites would continue to be held to the current guidance and requirements for laboratory certification and surveying. Another member inquired about sites performing surveillance testing and their oversight. Ms. Van Brakle clarified that CLIA regulations do not apply to surveillance testing. Dr. Salerno added that surveillance testing has evolved during the COVID-19 pandemic, which has resulted in complications with respect to CLIA. He said that CDC has a definition for surveillance testing which is consistent with the FDA definition.
- Committee members asked how many states are reporting all data elements required by the federal government and about standardization of reporting requirements for COVID-19. Ms. Van Brakle indicated that CLIA only requires that results be reported and that a reporting process needs to be established, but CLIA is not prescriptive on how a laboratory reports data or what elements are required. Dr. Salerno added that HHS guidance indicates the data elements need to be reported with positive and negative COVID-19 test results. Reportable disease reporting has always been a function of state government health departments; the states have jurisdiction over reporting requirements.
- A Committee member asked about the availability of home-use tests and suggested that the government design a home-use test if no manufacturers were developing one. Dr. Stenzel agreed on the need for at home testing and indicated that the FDA has received an EUA submission for an at-home test.
- A committee member suggested that rapid antigen tests be validated similarly to molecular and antibody tests, using a reference panel. Dr. Stenzel replied that reference panels that contain inactivated virus may not work for validation of antigen tests and studies are being performed regarding analytical accuracy and sensitivity and development of a reference panel for antigen test validation.
- A member asked how the units in the FDA reference panel relate to the more traditional limit of detection (LOD) units. Dr. Stenzel commented on the attempt to provide information on relative analytical sensitivities across all the EUA tests.

PRESENTATIONS AND COMMITTEE DISCUSSION

Clinical Laboratory Medicine in the Age of COVID-19

Overview of Meeting Topics ***Addendum 7***

Valerie Ng, MD, PhD
Chair, Clinical Laboratory Improvement Advisory Committee
Chair
Department of Laboratory Medicine and Pathology
Alameda Health System/Highland Hospital

Dr. Ng introduced the topics and presenters for the sessions and reviewed questions for the committee to consider during their deliberations.

Preparedness and Response: The Partnership between Clinical Laboratories and Public Health

Lessons Learned from the COVID-19 Response ***Addendum 8***

James M. Crawford, MD, PhD
Senior Vice President for Laboratory Services
Northwell Health
Professor and Chair, Pathology/Laboratory Medicine
Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

Dr. Crawford illustrated the progression of the pandemic, using graphs comparing the number of infections and deaths within the Northwell Health System and the state of New York. He also discussed COVID-19 statistics from March through September 2020, and referred to a recent publication in *Clinical Infectious Diseases* that provided an overview of geolocation, demographics, positivity rates, and hospitalizations for persons tested by Northwell Health. Dr Crawford demonstrated how COVID-19 affected different areas and populations of people, including those with co-morbidities. Dr. Crawford discussed the experience during the H1N1 pandemic in 2009 and emphasized how reporting was performed. He then discussed the strategic and tactical lessons learned during the current pandemic, gaps that negatively affected testing, and areas that were particularly successful, including the workforce and the community. Dr. Crawford highlighted some of the regulations that changed during pandemic and advocated for careful consideration of making some relaxation of regulations permanent. He concluded his presentation with a brief summary what the laboratory community gained and lost, and steps that would help to maximize the laboratory's contribution in future public health emergencies.

SARS-COV-2 Testing: The University of Washington Experience ***Addendum 9***

Alex Greninger, MD, PhD, MS, MPhil
Department of Laboratory Medicine and Pathology
University of Washington Medical Center

Dr. Greninger began his presentation by giving examples of how clinical laboratories are also part of the public health system although they often are not thought of in that way. He described the challenges his laboratory had encountered in obtaining SARS-CoV-2 positive samples and control materials required to validate a laboratory-developed test (LDT) and navigating the process to attain emergency use authorization for their LDT. Dr. Greninger suggested solutions to increase the availability of positive control materials and emphasized that authorized LDTs can assist in reducing supply chain challenges. Dr. Greninger explained that the authorization to perform sample pooling protocols enabled the Washington State to maintain specimen testing volumes when positivity rates are below 10%. He finished his presentation by reiterating the need for clinical laboratories to be included as part of the public health system. As part of this, he emphasized the need for equal access to specimens and positive control materials, including BSL-2 compatible clinical positive material, and better methods to report and share data. He also recommended that there should be open access to standards, such as those developed by the Clinical and Laboratory Standards Institute.

Clinical Laboratory and Public Health Partnership ***Addendum 10***

Elizabeth Palavecino, MD, FACP
Professor of Pathology
Director of Clinical Microbiology
Wake Forest Baptist Medical Center

Dr. Palavecino began by illustrating the differences between the Wake Forest Baptist Medical Center clinical laboratory and the Forsyth County Health Department public health laboratory in North Carolina, especially as related to COVID testing. She discussed the individual challenges affecting each of the laboratory types as well as those common to the clinical and public health laboratories. She described the differences with reporting requirements, describing challenges in the public health laboratory with reporting both positive and negative results, indicating that the information systems support in a large clinical laboratory is not readily available in the public health laboratory setting. Dr. Palavecino detailed issues that negatively impacted testing in both laboratory types, including allocation of reagents, shortage of reagents and supplies, authorization of tests, validation and verification of EUA tests, the need for clarification of guidance provided to laboratories, and personnel burnout. She emphasized that test volumes in the microbiology laboratory had not decreased during the pandemic as in other areas of the laboratory, resulting in internal competition for supplies and instrumentation also needed to perform other tests. This challenge has forced her, as the laboratory director, to make daily decisions about which tests to perform in-house, send out, or discontinue. Dr. Palavecino finished her presentation with a list of suggestions to improve the process for future unexpected events.

Public Comments
Addendum PC1
Addendum PC2

Committee Discussion

- Multiple committee members commented that they had similar challenges as those described in the presentations.
- Committee members suggested a recommendation for a federal agency to engage in allocation of reagents and supplies during a public health emergency. Another member commented that in a market-driven economy, the government is not best positioned to allocate resources.
- A member suggested engaging high-complex laboratories early in the response to assist with development of LDTs.
- A committee member commented that more resources for public health at all levels (federal, state, local) are needed to better respond to emergencies.
- A committee member commented that all laboratory systems should be considered when help is needed, such as veterinary diagnostic and commercial laboratories.
- Multiple committee members commented on the need for better coordination, communication, and partnership between different laboratory types to reduce the negative impact of supply shortages, allocation of supplies, and different testing strategies. A member suggested worldwide surveillance stations should be maintained to coordinate and work with other parts of the world in a pandemic.
- A committee member suggested modifying the public health infrastructure to mirror the national grid system while another suggested deploying the Laboratory Response Network (LRN) to help during a pandemic.
- A committee member suggested that FDA partner with other institutions to help review applications when a surge occurs due to a pandemic and there are too few staff to keep pace with the work.
- A committee member suggested that public education and self-testing be available to help reduce the pressure on the laboratories.
- Dr. Salerno commented on the memorandum of understanding (MOU) among CDC, the Association of Public Health Laboratories, the Council for State and Territorial Epidemiologists, and the American Clinical Laboratory Association to improve CDC's relationship with the commercial laboratory sector to address surge laboratory testing requirements during a public health emergency. He suggested that perhaps the MOU could be expanded to be more far-reaching and invited CLIAC to provide recommendations on how to do that.
- Dr. Salerno also reminded CLIAC that when considering supply shortages and distribution, it is important to consider the role of the HHS Assistant Secretary for Preparedness and Response, who is responsible for decisions about test and resource allocations for laboratories.

The Committee deliberated, voted, and approved the following recommendations on the topic of Preparedness and Response:

Recommendation 1: CLIAC recommends that CDC identify academic and community-based/regional clinical laboratories in distinct geographic regions to diversify the Public Private Partnership Taskforce, including healthcare organizations as stakeholders, to meet changing regional and community healthcare needs.

Recommendation 2: CLIAC recommends that CDC initiate a study to explore resources needed to develop a comprehensive, extensive laboratory network (for example, enhancing the Laboratory Response Network) that balances moments and areas of excess testing capacity to meet clinical needs during a public health emergency.

Laboratory Data Exchange during COVID-19

Utilization of Electronic Test Orders and Results (ETOR) in Public Health Laboratories during the COVID-19 Response ***Addendum 11***

Anthony Tran, DrPH, MPH, D(ABMM)
Director, DC Public Health Laboratory
DC Department of Forensic Sciences

Dr. Tran described the data system and reporting challenges faced during the Zika epidemic in 2016 that occurred as a result of not utilizing the laboratory information management system (LIMS) for ordering tests or reporting results. He outlined the steps the Washington, DC public health laboratory took to update their system for more efficient use after that public health emergency. Dr. Tran acknowledged the partnerships and collaborations needed to implement electronic ordering and reporting (ETOR), and explained how the COVID-19 response added new challenges. He provided an overview of the DC Department of Forensic Sciences Public Health Laboratory web portal and described the future reporting needs, including interfacing with hospitals and the public health laboratory using HL7 messaging. Dr. Tran described the Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform, which is a public health focused data messaging service. Dr. Tran concluded his presentation with plans for use and expansion of the multiple ETOR systems.

COVID-19 Laboratory Reporting Challenges and Opportunities ***Addendum 12***

Rajesh C. Dash, MD
Pathologist, Medical Director Laboratory Information Systems
Duke University Health System

Dr. Dash introduced the topic by listing the important features of a standardized naming convention for COVID-19 testing, and illustrated the Duke University Health System COVID-19 order guidance that is used to assist doctors in categorizing their patients. He explained key elements of the algorithm that targets important results, such as infection status and additional actions needed based on the test result. Dr. Dash described the challenges they encountered when trying to increase testing while facing supply shortages. He highlighted other potential barriers to

testing, such as specimen transport and triage, multiple instrument platforms available, and communication of test results. Dr. Dash discussed the confusion caused when multiple organizations mandate different reportable data and when there are multiple modes of communication. He also detailed the challenges surrounding different data elements and requirements for reporting, device identifier confusion, and the use of LOINC and SNOMED codes. He concluded his presentation with approaches to optimize data reporting and data transfer, such as having a single, centralized source for data reporting. He also suggested the College of American Pathologists could serve as a resource to help improve reporting in the future.

Intermountain Healthcare Point-of-Care Perspective ***Addendum 13***
Stanley M. Huff, MD
Chief Medical Informatics Officer
Intermountain Healthcare

Dr. Huff began by listing mandated communication or reporting related to COVID-19 testing and explained how a lack of coordination has resulted in reporting delays, an increased need for resources including additional personnel, and incorrect reporting. He discussed how, as testing volumes have increased, attempts have been made to streamline the reporting process to the state. He also described how the lack of interoperability between systems and interfaces resulted in the need for modifications to data exchange services. He concluded by recommending that standards should be mandated for sharing public health data so that when the next pandemic or other emergency arrives, the system is in place and ready to utilize.

Public Comments
Addendum PC3

Committee Discussion

- Multiple members suggested several options to make reporting less burdensome, including the need for standardization, a centralized repository to enhance and facilitate the use of structured data with a controlled vocabulary, and engagement with the Office of the National Coordinator.
- A Committee member suggested that the government field test planned regulations to determine burden prior to implementation.
- A Committee member suggested that groups other than the laboratory take ownership or be accountable for some of the data collection, especially if they are responsible for those data elements.
- One member commented that in order to have standardized data that can be shared by public health throughout the country, leadership from chief medical officers, governors, and epidemiologists must acknowledge that interoperability is a priority for the country. The same member suggested the use of a unique national patient identification number to prevent redundancy during data aggregation.
- A member commented on using the APHL AIMS platform as a model for data exchange because it is a secure, cloud-based platform that accelerates the implementation of health messaging by providing shared services to aid in the visualization, interoperability, security, and hosting of electronic data.

- Dr. Salerno provided information on the Data Modernization Initiative – a comprehensive strategy to modernize data, technology, and workforce capabilities that supports public health surveillance, research and decision making – and suggested that it may help address clinical laboratory reporting issues.

The Committee deliberated, voted, and approved the following recommendations on the topic of Laboratory Data Exchange during COVID-19:

Recommendation 3: CLIAC recommends that the Assistant Secretary for Preparedness and Response (ASPR) coordinate a national process to obtain and allocate critical diagnostic clinical laboratory testing resources to manage a public health emergency. Key features of the process include transparency about resource allocation and clearly defined approaches for both public health and clinical laboratories. Public health officials and clinical laboratory representatives need to collaborate to provide information to guide resource decisions. Processes, decisions (with justifications), and data provided by the public health and clinical laboratories and by responsible authorities (for example, public health and elected officials) should be made public.

Recommendation 4: CLIAC recommends that CDC use funding (for example, the CARES Act, the $500 million for data surveillance and analytical infrastructure) to improve (replace or upgrade) existing laboratory information system infrastructures, such as the Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform, to centralize and standardize public health reporting (for example, data clearinghouse or health information exchange). Key attributes include:

- Interoperability,
- Review of state reporting systems,
- Standardization of reporting requirements of public health/clinical laboratories and/or other diagnostic services,
- Technical specifications, and
- Advantages and challenges of investing in a centralized reporting infrastructure.

The Clinical Laboratory's Role in Identifying Health Inequities during the COVID-19 Response

Mitigating Health Disparities: The Role of the Clinical Laboratory ***Addendum 14***
Marissa White, MD
John Hopkins University School of Medicine
Department of Pathology

Dr. White opened her presentation with a definition of social determinants of health (SDOH) and noted that increased awareness of how SDOH impact health disparities can help improve research concepts and design, and the patients enrolled in clinical trials, thus improving how pathologists provide care and train the next generation of pathologists. She provided a timeline of federal initiatives to identify, measure, and address U.S. health disparities, highlighting the National Healthcare Quality & Disparities reports. Dr. White described the impact of SDOH

during the COVID-19 pandemic, including disparities in pre-disease conditions that increase risk of COVID-19 transmission and poor outcomes for COVID-19. She also described similar post-disease disparities that affect long-term outcomes for COVID-19, citing Native American communities as an example. Dr. White then reviewed how laboratory professionals can provide opportunities to mitigate health disparities, such as offering flexible testing site hours and ensuring that laboratory information is equitable and mindful of cultural and linguistic competencies. She provided an overview of federal resources to help guide implementation of initiatives to mitigate health disparities, including the Healthy People 2030 goals and objectives aimed to improve the health and well-being of all people. Dr. White provided several examples that can inadvertently exacerbate health disparities and diversion of medical resources away from racial and ethnic minorities. She closed by emphasizing how work-force diversity directly contributes to improved health outcomes and reduction of health disparities by enhancing patient-provider concordance, delivery of culturally appropriate and patient-centered care, innovation, awareness and emphasis of health disparities, clinical trial diversity, and quality of care.

How the Laboratory Community Can Contribute to Addressing Health Disparities ***Addendum 15***

Nichole Lurie, MD, MSPH
Harvard Medical School
George Washington University School of Medicine

Dr. Lurie provided a brief overview of an action model to achieve the Healthy People 2030 goals. She described six areas of opportunity for the laboratory community to contribute to addressing health disparities, categorized as the 6 A's; access, algorithms and reference ranges, awareness, action, adult education, and advocacy. Dr. White defined and provided examples of each area as it related to the COVID-19 pandemic, highlighting how inequitable distribution of internet access can affect telemedicine and the ability to electronically receive laboratory test results; the need for checklists and other tools to identify patient resources needed to manage their care or their social situation; and the need for health care workers to serve as ambassadors or educators in their community for advocacy of testing and vaccinations. She ended her presentation by emphasizing the opportunities and important roles that laboratory professionals can play to address social vulnerabilities in their institutions and communities.

Committee Discussion

The Committee posed a number of follow-up questions to the speakers prior to the general discussion of the health inequity topic:

- A Committee member inquired about algorithms and how many are based on associative experiences versus data-driven studies. Dr. White agreed and stressed the need for more research and data. Dr. Lurie suggested laboratory representation on the National Kidney Foundation and American Society of Nephrology joint task force to address estimated glomerular filtration rate (eGFR) algorithms and reassess the inclusion of race in diagnosis kidney disease.
- The Chair asked the speakers for suggestions as to how clinical laboratories and laboratory medicine should work to improve health equities. Dr. White advocated for national guidelines or quality improvement projects to ensure that patients are treated in

an equitable way. Dr. Lurie responded that CDC should promote the use of the Social Vulnerability Index or the COVID Vulnerability Index in test reporting to alert clinicians. She also suggested that a patient survey to determine vulnerabilities would be valuable.

- A member asked about the need for expedited development of point-of-care tests that can be rapidly deployed to vulnerable communities. Dr. White responded that there is a need to develop tests with easy-to-follow user instructions.
- A member commented on assessing the vaginal microbiome for gender reassignment surgery and the need for a national effort to increase collections. The member also commented on a Project Santa Fe initiative, Clinical Laboratory 2.0, that is actively engaged in risk stratification for a variety of projects that would benefit from SDOH measures.
- A Committee member inquired if any systematic review of the pathology and laboratory medicine landscape had been performed to find opportunities to improve health care disparities. Dr. White responded that she is not aware of any systematic reviews of disparities in pathology and advocated for such a review. Dr. Lurie added that a review should focus on the system broadly, including the workforce.
- A member commented on whether social determinants or social vulnerability assessments should become an orderable test. Dr. Lurie added the need for interventions to be taken related to the assessment results. Another member noted the opportunity to link test results and informatics with information about SDOH. A second member suggested leveraging the data that public health systems have regarding education levels, poverty, and regional disease prevalence.
- A member suggested there is a need to develop educational products for consumers regarding the COVID tests that are available. Dr. Lurie noted, as a result of COVID, vaccination models are being developed using claim data along with the Social Vulnerability Index.
- The Chair commented on basic infrastructure barriers and inquired on suggestions for overcoming those barriers. Dr. Lurie responded that partnerships are needed with multiple groups such as broadband provides, cell phone companies, school districts and others.

After the speakers finished responding to questions and concluded their remarks, the Committee discussed the following topics related to The Clinical Laboratory's Role in Identifying Health Inequities during the COVID-19 Response:

- Suggestions that product inserts for potential COVID-19 home tests include links to targeted specific instructions or recommendations for marginalized communities.
- Potential for the government to make translational or interpreter services available to assist with laboratory test and result explanations in a variety of languages.
- The need for education and better communication of information in diverse and marginalized communities on topics such as sensitivity, specificity, positive and negative predictive value, and how these are related to laboratory test results.
- Issues such as supply demands for testing and implications of millions of false positive results depending on the prevalence of disease in the community being tested.
- Social and health inequities and the ability to rapidly identify vulnerable populations to ensure universal access to testing which may lead to a different level of care or a different level of surveillance.

- The need for rapid diagnostics for at-home or over-the-counter use, along with education for the public regarding the tests, to identify COVID-19 asymptomatic carriers.
- Suggestions to include the role of clinical laboratory medicine in the CDC COVID-19 Response Health Equity Strategy to accelerate progress towards reducing COVID-19 disparities and achieving health equity.

The Committee deliberated, voted, and approved the following recommendations on the topic of The Clinical Laboratory's Role in Identifying Health Inequities during the COVID-19 Response:

Recommendation 5: CLIAC recommends that CDC develop guidelines for America's laboratories in addressing health disparities, resulting in a national plan to champion laboratory engagement in closing gaps in care that broadly address social determinants of health. CDC should consider:

- Expansion of traditional laboratory activities (for example, insights from commonly ordered diagnostic tests).
- New non-traditional roles of diagnostic and public health laboratories.
- Process for how the laboratory community can best engage with clinical colleagues to close gaps in care.
- Establishment of key metrics to demonstrate that laboratories are contributing to addressing health disparities across the total testing process.
- Identification of potential roles for different laboratories in the United States: public health, independent, academic, and community hospital laboratories.
- Establishment of a public-private partnership among federal, state, and local governments, professional societies, and care providers (for example, federally qualified healthcare centers) to ensure development and dissemination of a national plan.
- A study to identify embedded inherent bias that involves current test processes and reporting.
- Opportunities for pathologists and other laboratory professionals to educate, engage, and collaborate with clinical colleagues and interprofessional organizations to reconsider and rigorously validate algorithms for test result reporting that disproportionately impacts diverse marginalized groups.
- Test result reporting in an educationally, culturally, and linguistically appropriate manner.

ACRONYMS *Addendum 16*

NOMINATION INFORMATION *Addendum 17*

ADJOURN

Drs. Ng and Salerno acknowledged the staff that assembled the meeting agenda and thanked the CLIAC members and partner agencies for their support and participation.

I certify this summary report of the October 28-29, 2020 CLIAC meeting is an accurate and correct representation of the meeting.

Dr. Valerie Ng, CLIAC Chair Dated: