Division of Laboratory Systems

CLIAC Outgoing Member Recognition

Reynolds M. Salerno, PhD
Director
Division of Laboratory Systems
CLIAC Designated Federal Official

CLIAC 2022 OUTGOING MEMBERS

Susan J. Gross, MD, FRCSC, FACOG, FACMG

Lee H. Hilborne, MD

Lavinia P. Middleton, MD

Gregory N. Sossaman, MD

Donna M. Wolk, PhD, D(ABMM)

Valerie L. Ng, MD, PhD

Susan J. Gross, MD, FRCSC, FACOG, FACMG

Dr. Gross' experience as a Clinical Professor of Obstetrics and Gynecology, Pediatrics and Genetics, and Chief Medical Officer of Cradle Genomics provided a medical genetics perspective on a variety of Committee discussions. She was instrumental in drafting recommendations on many topics, including diagnostic errors, laboratory workforce shortages, laboratory data exchange during COVID-19, and clinical laboratory perspectives on laboratory-developed tests. We thank Dr. Gross for her service to the Committee.

Lee H. Hilborne, MD

Dr. Hilborne's role as a Senior Medical Director at Quest Diagnostics, a Professor of Pathology and Laboratory Medicine at the David Geffen School of Medicine at UCLA, and a previous CLIAC member allowed him to provide valuable comments on many issues considered by CLIAC. Dr. Hilborne served as Chair of the CLIA Personnel Regulations Workgroup, whose report resulted in 12 CLIAC recommendations. Dr. Hilborne led the development of recommendations for the laboratory workforce, the clinical laboratory's role in identifying health inequities, and laboratory data exchange and harmonization. He is currently serving on the CLIA Regulations Assessment Workgroup. We thank Dr. Hilborne for his contributions to CLIAC.

Lavinia P. Middleton, MD

Dr. Middleton's role as a Deputy Chief Medical Officer in Medical Affairs, Deputy Division Head of Quality in the Division of Pathology/Laboratory Medicine at MD Anderson Cancer Center allowed her to provide extensive knowledge of surgical pathology and quality and process improvement to the CLIAC discussions. Dr. Middleton provided contributions to the discussions and recommendations on the laboratory workforce, the role of the laboratory in improving diagnoses, integrating laboratory informatics systems with electronic health records, and advancing laboratory data exchange and harmonization. We thank Dr. Middleton for her valuable contributions to CLIAC.

Gregory N. Sossaman, MD

Dr. Sossaman's role as the System Chairman of the Ochsner Health System, Department of Pathology and Laboratory Medicine, as well as the Medical Director of three Ochsner laboratories, provided a diverse perspective to many CLIAC discussions. His clinical pathology, cytopathology, and informatics expertise led to CLIAC recommendations on many topics, including the role of the laboratory in improving diagnoses and laboratory data exchange and harmonization. He is currently serving as the co-Chair of the CLIA Regulations Assessment Workgroup. We thank Dr. Sossaman for his commitment to CLIAC.

Donna M. Wolk, PhD, D(ABMM)

Dr. Wolk's role as the System Director, Clinical and Molecular Microbiology, in the Geisinger Health System provided a microbiologist's perspective to a variety of CLIAC discussions. Dr. Wolk was instrumental in drafting recommendations on many topics including antibiotic resistance, next generation sequencing, laboratory personnel, laboratory developed tests, and the curation of standard codes for laboratory test orders and results. Dr. Wolk was also appointed as the CLIAC liaison to the CDC's Office of Infectious Diseases Board of Scientific Counselors. We thank Dr. Wolk for her service to the Committee.

Thank you, Dr. Ng!

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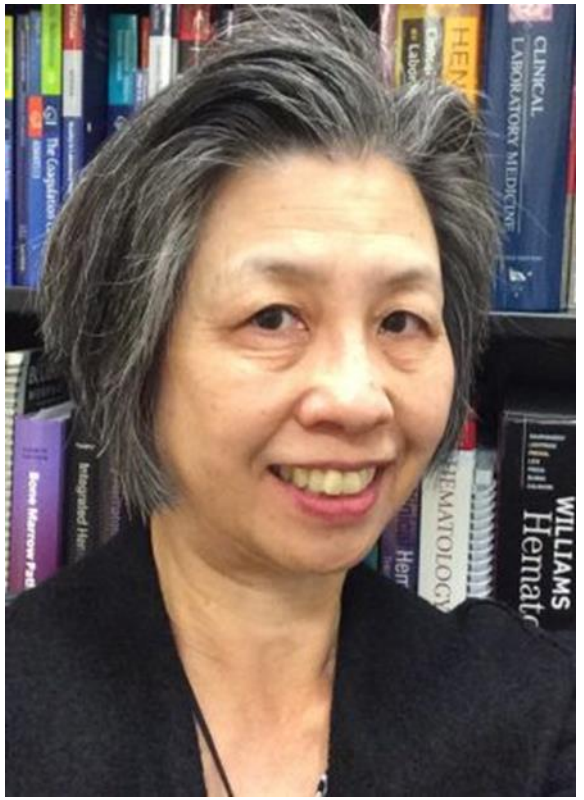
Recognition of Exemplary Leadership

- Previous CLIAC member from 2000-2007, current member since 2017
- 14 formal recommendations and one letter to HHS provided by CLIAC
- Chair of the CLIAC Nontraditional Testing Workflow Model Workgroup
- Transition to 100% virtual meetings in 2020



Recommendation Topics

- Remote Selection, Interpretation, and Reporting of Patient Results
- Laboratory Workforce
  - CDC should explore how virtual reality and simulation-based training can be used to achieve competency-based outcomes.
  - CDC should create an online library of clinical laboratory educational resources.
  - Agency partners should collaborate with relevant organizations to increase awareness of freely available CDC laboratory training resources.
  - CDC/HHS should create a strategy to communicate broadly to the clinical laboratory community the resources available through the Health Resources & Services Administration Health Careers and Opportunity Program.
- CDC should 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.

Recommendation Topics

- Laboratory Data Exchange
  - CDC should improve (replace or upgrade) existing laboratory information system infrastructures, such as the Association of Public Health Laboratories Informatics Messaging Services platform, to centralize and standardize public health reporting.
  - Assistant Secretary for Preparedness and Response should coordinate a national process to obtain and allocate critical diagnostic clinical laboratory testing resources to manage a public health emergency.
  - HHS agencies should leverage current standards and fund a phased approach by which specimens, actionable test results, and methods are coded for interoperability.
- Partnership between Clinical Laboratories and Public Health
  - CDC should initiate a study to explore resources needed to develop a comprehensive, extensive laboratory network that balances moments and areas of excess testing capacity to meet clinical needs during a public health emergency.
  - CDC should identify academic and community-based/regional clinical laboratories in distinct geographic regions to diversify the Public-Private Partnership Taskforce.
- CDC should develop training and educational materials for SARS-CoV-2 self-testing, point-of-care testing, and follow-up care.

Selection of Outcomes Achieved

- Three CLIAC workgroups formed:
  - CLIAC Regulations Assessment Workgroup
  - CLIA Certificate of Waiver and Certificate for Provider-performed Microscopy Procedures Workgroup
  - Next Generation Sequencing (NGS) Workgroup
- CDC posted over 80 COVID-19 relevant education and training materials in a variety of formats to the Lab Training | CDC Training Job Aids webpage. Additional job aids and infographics were posted on the Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing | CDC and Self-Testing | CDC webpages.
- As part of the OneLab™ Initiative, CDC has added over 80 new clinical laboratory education and training resources posted on the CDC Laboratory Training website.
- CDC conducted a survey, completed in September 2021, to gather information on clinical laboratory participation in response efforts.
- Developed and published over 85 customizable, ready-to-implement guidance documents, standard operating procedures, forms, and tools that can serve as a foundational or integrate into existing QMS through the Next Generation Sequencing Quality Initiative.
- Creation of the NGS Best Practices Forum for open discussion to assess current activities of each organization and determine where federal agencies can assist or lead in addressing gaps and challenges with guideline development and implementation in clinical laboratories.
- Improved engagement of CDC, CMS, FDA, and laboratory professionals with various SARS-CoV-2 initiatives.

Thank you!