November 12, 2020

Re: FDA-2020-N-1764

The Association of Public Health Laboratories (APHL) represents state, local and territorial governmental public health laboratories, many of whom have provided enteric isolates to the National Antimicrobial Resistance Monitoring System (NARMS) since its inception. The 2021-2025 NARMS strategic plan proposes expansion to include data from companion animals and the environment. If fully resourced, this is a vital step towards fully understanding the burden of antimicrobial resistance (AMR), its evolution and reservoirs. Our member laboratories have significant expertise in testing environmental matrices, and we look forward to opportunities to work with the Environmental Protection Agency (EPA) and the Centers for Disease Control (CDC) to potentially expand environmental microbial and AMR testing at state, local and territorial levels. We similarly look forward to any opportunities to work alongside our colleagues at veterinary and wildlife diagnostic laboratories whose data will be of vital importance in the collaborative fight against AMR.

The NARMS pivot to a One Health approach coupled with ambitious use of advanced technologies offers great opportunities for expanded laboratory data that can better inform decision making. However, achieving the plan's 4 intended goals will require collaboration with new federal and external partners and significant new investment. We have noted some specific considerations below.

GOAL 1: ENHANCE SAMPLING FOR FOODBORNE PATHOGENS WITHIN A ONE HEALTH FRAMEWORK

While surface waters are a good starting point for baseline testing in aquatic ecosystems, program expansion program to drinking water, wastewater and potentially other matrices such as biosolids should be considered. Further culture and sequencing of positive coliform tests in drinking water may be a useful pilot project. Public health laboratories (PHLs) currently sequencing environmental pathogens should be consulted to explore potential collaboration and utilization of current data. Some environmental laboratories may have advanced sequencing capabilities, but those that do not could still play a role by forwarding isolates. Funding laboratories to perform environmental AMR work through CDC Epidemiology and Laboratory and Capacity (ELC) or EPA grants would leverage capabilities already in place and help strengthen and enable our laboratories to bring quality environmental microbiology data into the NARMS program.

Increased NARMS collaboration with FDA Vet-LIRN and USDA NAHLN labs could significantly enhance the sampling and analysis of foodborne pathogens. Increasing funding for these laboratories through NAHLN, or new funding through CDC or FDA, could significantly increase their capacity for collecting isolates, Antimicrobial Sensitivity Test (AST) and especially Next Generation Sequencing (NGS) data.

Food borne disease outbreaks are increasingly being linked back to animal feed and pet food. Given funding, our members could likely expand their current testing of these products in an AMR program and we look forward to joining discussions of how this would be best accomplished.

GOAL 2: EMPLOY ADVANCED TECHNOLOGIES TO BETTER UNDERSTAND THE EVOLUTION AND SPREAD OF RESISTANCE AMONG FOODBORNE PATHOGENS

Funding to support NARMS activities at local and state levels is currently funded only through the ELC Cooperative Agreements. Increasing funding is needed for the continued implementation of next generation sequencing technologies and the supporting infrastructure required to increase capacity for Whole Genome Sequencing (WGS) of NARMS isolates and to perform isolate recovery on clinical specimens.

In order for PHLs to continue to move towards metagenomics, significant investments in instruments and training are needed at state and local levels. Funding to refine and test technology could initially be provided at Emerging Infection Program sites.

A significant rate limiting step for further advancing NGS including metagenomics at PHLs is data analysis. Similar to federal IT infrastructure, PHLs need huge investments in data storage, sharing and analysis capacity, and even access to high speed internet, if their NGS data is going to be of optimal use to national networks. A bioinformatics workforce to manage

and analyze this data is a vital component of any expansion and investments need to be made now to meet current and future needs. Bioinformaticians will continue to be lost to the private sector without long-term investments in these positions.

Reduced availability of isolates for surveillance purposes also presents a challenge as clinical laboratories transition to testing samples using culture-independent diagnostic methods. PHL's need resources to pull pathogens from CIDT positive specimens so they can be characterized by genomic methods. APHL and CDC are working on efficiencies to develop a systematic approach to the collection of specific samples that will allow this to be done at a lower cost.

GOAL 3: IMPROVE DATA SHARING, COMMUNICATION, AND COLLABORATION

PHL's need access to and training on the advanced genomic tools at NCBI for analysis of resistance data that can define outbreaks. Similarly, PHLs would appreciate further information and training on Resistome Tracker to be able to fully participate.

APHL is interested in being involved in any conversations the interagency NARMS group is opening, as mentioned in the CDC Data Sharing presentation, to share information faster for more timely response by all stakeholders. Technical gaps may be a significant obstacle for lower resourced jurisdictions as technology moves forward. As mentioned under Goal 2, investments in public health laboratory data systems and staff will be necessary to reach these goals.

GOAL 4: CONDUCT RESEARCH TO ASSESS THE SOURCES AND IMPACT OF RESISTANCE AND THE EFFECTIVENESS OF PREVENTION PRACTICES FOR FOODBORNE PATHOGENS

NARMS programs and resources should be aligned with related PH initiatives that address AMR research questions. ARLN objectives overlap with PulseNet and GenomeTrakr surveillance, for example. Further, the methods to accomplish these objectives are under the CDC Office of Advanced Molecular Detection umbrella. This work and the resources to accomplish it should be very closely coordinated.

Any research should ensure that traditionally underserved and potentially vulnerable populations are consulted and involved in decision making to ensure any data collected is appropriate for addressing the needs of these communities.

AMR is a threat that has likely only multiplied during the SARS CoV-2 Pandemic. APHL appreciates the opportunity to voice our support for the necessary expansion in technology and scope outlined in the NARMS strategic plan to work towards tackling the threat. Equally bold new funding will need be required to current and new recipients to ensure the mission of NARMS can be met.

Please contact Kuki Hansen, manager Regulatory and Public Policy (kuki.hansen@aphl.org), with any questions,

Sincerely,
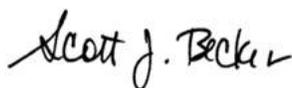
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APHL works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.