NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

14-06

STATEMENT OF POLICY

Enteric Disease Testing

Policy

Knowledge of the clinical and epidemiologic features of acute gastroenteritis (AGE) such as salmonellosis, campylobacteriosis, and Shiga-toxin-producing *Escherichia coli* (STEC) e.g., O157, has been developed through the study of culture-confirmed infections.[1] These infections are mainly foodborne and therefore preventable. Successful control of such illnesses may be at risk because AGE diagnostics are moving away from culture and are being replaced by culture-independent diagnostic tests (CIDT). The capacity for culture-based diagnostic testing or their equivalent must be retained in the medical care and public health sectors.

The National Association of County and City Health Officials (NACCHO) advocates that all positive results from non-culture assays used by clinical laboratories to detect bacterial foodborne disease pathogens of public health concern be confirmed through culture-based methods. In addition, whole genome sequencing (WGS) should be performed on all isolates in as close to real time as possible for outbreak detection and response.

Therefore, NACCHO strongly urges that the federal government sustain the capacity for culture-based or equivalent testing for AGE through financial support for laboratories to retain such capacity and through policies and rules-making that promote such testing.

Justification

Foodborne illnesses are a serious public health and economic issue in the United States. There are an estimated 48 million cases of illness each year; approximately 128,000 hospitalizations and 3,000 deaths.[2] The U.S. Department of Agriculture (USDA) estimates that foodborne illnesses cost the United States more than $15.6 billion each year.[3] Prevention and control measures depend upon coordination between public health regulations, investigations, and (currently) culture-based laboratory services. The proliferation of rapid CIDT is economically inviting (reducing healthcare and clinical costs) and clinically sound (results are available sooner and are actionable). An unfortunate consequence of the increasing use of nonculture diagnostic tests is that such diagnostics do not provide isolates critical for public health purposes. CIDTs skip the step of producing an isolate and as a result, DNA fingerprints or WGS cannot be produced.

The isolates from WGS are used for outbreak detection and for further antimicrobial susceptibility testing to identify resistant strains. This is essential for disease prevention and public health disease investigation. Without cluster detection, outbreaks may not even be

recognized, contaminated products may remain on shelves and in pantries, more people may become sick, and valuable opportunities for improving the safety of our food may be lost. Bacterial isolates are also necessary when investigating in antimicrobial resistance for determining an organism's strain or subtype, resistance pattern, or other characteristics.

CIDT may increase the ability to detect more cases of enteric and foodborne illness as stool culture is comparatively less sensitive than some CIDTs. For example, the percentage of *Campylobacter* diarrheal illnesses diagnosed only by CIDTs in FoodNet sites increased from 13% in 2012-2014 to 38% in 2018. Further evaluation is needed to assess the public health impact of CIDT on outbreak detection and investigation, and detection of emerging pathogens.[4,5] For example, public health surveillance for STEC has been based on culture-confirmed cases and WGS of *E. coli* O157.[6] Moving to CIDT will affect the numbers of cases being reported, and will compromise not only investigations, but also any analysis of trends over time and across the country, as well as an inability to distinguish specific strains of bacteria, such as STEC due to *E. coli* O157 from *E. coli* O26. [7,8] In addition, the sensitivity, specificity, and the associated positive and negative predictive values of CIDT will differ from those of culture and vary by type and brand. This can influence decisions about whether to include the results of such tests in the reportable disease roster and could lead to the underreporting or overreporting of cases. The public health laboratory system is a network of local, state, and national laboratories, working in partnership with epidemiologists, that play a key role in the prevention and control of communicable infectious diseases. The laboratory staff supporting this system do so by providing epidemiologists with population-based laboratory surveillance data to detect and investigate outbreaks of infectious diseases and to monitor significant trends in the development of antibiotic resistance and altered pathogenicity. Several national surveillance programs are built on this laboratory network, including PulseNet,[9] National Antimicrobial Resistance Monitoring System (NARMS),[7][10] and other non-food related pathogen-tracking systems. The PulseNet system exposes food safety risks to the public, thereby giving consumers, industry, and the government valuable information that can be used to reduce foodborne illness. In a 2016 study, the costs and benefits associated with the PulseNet program were assessed and showed the reduction in healthcare costs and other economic benefits. For example, accounting for underreporting and underdiagnosis, 266,522 illnesses from *Salmonella*, 9,489 illnesses from *Escherichia coli (E. coli*), and 56 illnesses due to *Listeria monocytogenes* are avoided annually. This reduces medical and productivity costs by $507 million. Additionally, direct effects from improved recalls reduce illnesses from *E. coli* by 2,819 and *Salmonella* by 16,994, leading to $37 million in costs averted. Annual costs to public health agencies are $7.3 million.[11]

These surveillance systems all require the continuous availability of microbial culture isolates for analysis. Without adequate numbers of such isolates as the starting material for the laboratory findings that populate relevant databases, the effectiveness of these national surveillance systems will be severely compromised. New policies are needed to address this risk to the public's health. Decisions about implementing new tests in clinical laboratories are usually based on cost, ease of use, sensitivity, and specificity. The test results' relevance to public health purposes are less likely to be emphasized when making decisions on which tests to use. All of these aspects need to be considered before new diagnostic tests and methods are implemented in clinical laboratories.[12,13] If laboratories are not submitting isolates to public health labs for a more complete set of characterizations, there is a risk that surveillance, prevention, and control of

foodborne diseases will become unreliable and unsuitable for eliminating such threats to the health of the community.

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Record of Action

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