

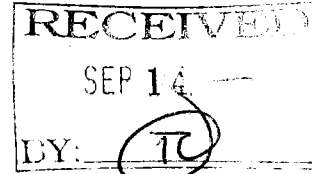


United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

1400 Independence
Avenue, SW
Washington, DC
20250

SEP - 8 2015



To Jennifer
Jr

Dr. Jeffrey P. Engel
Executive Director
Council of State and Territorial Epidemiologists
Suite 250, 2872 Woodcock Boulevard
Atlanta, Georgia 30341

Dear Dr. Engel:

Thank you for your letter of July 30, 2015, to Secretary Thomas J. Vilsack on behalf of the Council of State and Territorial Epidemiologists (CSTE), regarding CSTE's position statement, "Recommendations for Strengthening Antimicrobial Stewardship in Veterinary Medicine and Animal Agriculture."

We recognize the critical importance of the issue of antimicrobial resistance (AMR) and thank you for sharing the recommendations. We are pleased that significant steps are being taken to address this issue. President Obama's proposed fiscal year (FY) 2016 budget would nearly double Federal funding to support the National Strategy for Combating Antibiotic-Resistant Bacteria, to more than \$1.2 billion. The U.S. Department of Agriculture (USDA) will also solicit applications for competitive extramural funding to support FY 2016 research, education, and extension/outreach through the Antimicrobial Resistance Initiative program. This will add to the portfolio of the AMR program begun in FY 2012 and allow scientists to continue obtaining science-based data to inform policies, decisions, and activities related to antibiotic stewardship across the food chain.

USDA agrees that the success of antibiotic stewardship should ultimately be evaluated by demonstrable positive effects on public and animal health rather than on reductions in the aggregate sales of antimicrobials. We also agree that there is a need for the collection and analysis of additional data about antimicrobial use and other factors that contribute to AMR in animals, humans, and the environment. In March 2015, President Obama released The National Action Plan for Combating Antibiotic-Resistant Bacteria to address these knowledge gaps and guide future Federal efforts to address AMR. The National Action Plan describes how USDA and the U.S. Food and Drug Administration (FDA) plan to obtain and disseminate science-based, actionable information about antibiotic drug use and its potential role in the development of antibiotic resistance, as well as the relationship between drug use and resistance patterns and livestock



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Dr. Jeffrey P. Engel
Page 2

management practices. The AMR National Action Plan proposes that USDA conduct on-farm studies to assess the relationship between antibiotic use and development of resistance in bacteria. Such studies could help determine whether certain practices are associated with a lower risk of AMR occurrence.

The National Action Plan also identifies the on-farm data we believe necessary to accurately assess policy impacts. We have proposed adding this data collection to periodic surveys conducted by the National Agricultural Statistics Service and through the National Animal Health Monitoring System (NAHMS), typically conducted every 5-7 years. In addition, we propose that NAHMS conduct limited-scope AMR-focused studies on a more frequent basis.

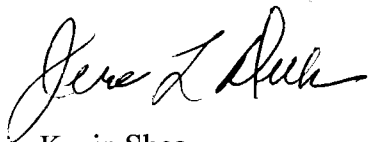
USDA is supporting efforts to ensure that current and future veterinarians are educated in judicious use and that antibiotic stewardship programs are included in the veterinary curriculum at colleges and universities. For example, USDA has created a training module, "Use of Antibiotics in Animals" as part of our National Veterinary Accreditation Program.

FDA, in collaboration with the USDA and the Centers for Disease Control and Prevention, is holding a public meeting on September 30, 2015, to obtain public input on possible approaches for collecting additional on-farm antimicrobial drug use and resistance data.

✓ We welcome CSTE input and look forward to your participation in those discussions. On August 20, 2015, the details of the public meeting were posted on the Federal Register at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-20557.pdf>.

Thank you again for writing. We look forward to further cooperation with CSTE on this important public and animal health issue.

Sincerely,

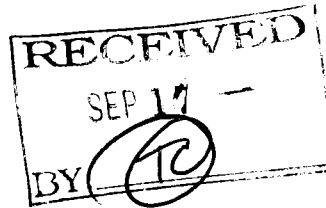

for Kevin Shea
Administrator



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329



September 14, 2015

To JL
JR

Jeffrey Engel, MD
Executive Director
Council of State and Territorial Epidemiologists
2872 Woodcock Boulevard, Suite 250
Atlanta, Georgia 30341

Dear Dr. Engel:

I am responding to your letter to Centers for Disease Control and Prevention (CDC) Director Dr. Thomas Frieden regarding the Council of State and Territorial Epidemiologists (CSTE) position statements that provide recommendations around surveillance and recommended changes in current case definitions of several conditions. Enclosed is CDC's response to the CSTE position statements listed below. Each of these statements was reviewed by one of the following centers: the National Center for Emerging and Zoonotic Infectious Diseases; the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention; and the National Center for Immunization and Respiratory Diseases.

Position statements

15-ID-01: "Standardized Case Definition for Acute Flaccid Myelitis"

15-ID-02: "Recommendations for Strengthening Antimicrobial Stewardship in Veterinary Medicine and Animal Agriculture"

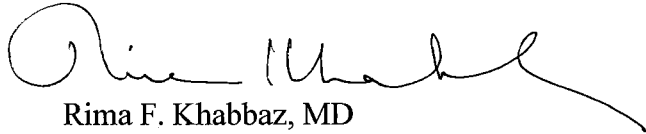
15-ID-03: "Revision of the Case Definition of Hepatitis C for National Notification"

15-ID-04: "Recommendations for Surveillance and Reporting of Healthcare Associated Infections in Long Term Care Facilities"

15-ID-05: "Standardized Definition for Carbapenem-resistant Enterobacteriaceae (CRE) and Recommendation for Sub-classification and Stratified Reporting"

I appreciate CSTE's ongoing commitment to these important public health issues as well as the opportunity for CDC's infectious disease programs to provide input to the position statements. We look forward to continued collaboration with CSTE regarding these and other public health issues of mutual concern.

Sincerely,

A handwritten signature in black ink, appearing to read 'Rima Khabbaz', with a long, sweeping horizontal line extending to the right.

Rima F. Khabbaz, MD
Deputy Director for Infectious Diseases
Director, Office of Infectious Diseases

Enclosure

cc:

Dr. Beth Bell, NCEZID

Dr. Jonathan Mermin, NCHHSTP

Dr. Anne Schuchat, NCIRD

**The Centers for Disease Control and Prevention's Comments
Regarding the
2015 Council of State and Territorial Epidemiologists' (CSTE)
Position Statements**

CSTE Position Statement 15-ID-01

Title: Standardized Case Definition for Acute Flaccid Myelitis

Statement of the desired action(s) to be taken

X 1. Utilize standard sources (e.g. reporting*) for case ascertainment for acute flaccid myelitis (AFM). Surveillance for AFM should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of Acute Flaccid Myelitis (AFM).

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	x	
Laboratory reporting		
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	x	
Death certificates	x	
Hospital discharge or outpatient records	x	
Extracts from electronic medical records	x	
Telephone survey		
School-based survey		
Other _____		

2015 Template

X 2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for acute flaccid myelitis (AFM) but do not add AFM to the *Nationally Notifiable Condition List*. If requested by CDC, jurisdictions (e.g. States and Territories) conducting surveillance according to these methods may submit case information to CDC.

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outline above.

Terminology:

* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health.

**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

CDC Comments: CDC appreciates the opportunity to collaborate with CSTE on this position statement and has no further comments. CDC concurs with the position statement.

CSTE Position Statement 15-ID-02

Title: Recommendations for Strengthening Antimicrobial Stewardship in Veterinary Medicine and Animal Agriculture

Statement of the desired action(s) to be taken

1. CSTE recommends that CDC (e.g., One Health Office) engage state healthcare associated infection (HAI) programs and public health veterinarians to collaborate with other agencies on state and national initiatives that build relationships, and facilitate sharing stewardship strategies between human and veterinary medicine, and animal agriculture. The degree to which health departments can pursue collaborative efforts with CDC, or within their state, will depend on resources available; collaboration between states may be an alternative option for states without access to resources such as training or subject matter expertise.
2. CSTE recommends that FDA and other stakeholders such as US Department of Agriculture (USDA), American Veterinary Medicine Association, and Centers for Disease Control and Prevention (CDC), develop appropriate metrics for tracking antimicrobial use in animal agriculture and companion animal practice.
3. CSTE recommends that CDC and other federal agencies increase funding for strengthening monitoring of antimicrobial resistance. Funding should support state AR surveillance activities as well as surveillance of resistant bacteria in food.
4. CSTE recommends that federal agencies, such as CDC, FDA, and USDA, coordinate a publicly accessible electronic library where stewardship models, projects and educational tools can be easily shared across jurisdictions.

See Appendix 1 for ideas and contact information.

CDC Comments:

The actions outlined in this position statement align with the principles informing the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB), the associated National Action Plan, and CDC's FY 2016 Antibiotic Resistance Solutions Initiative. Antimicrobial resistance is one of the most pressing health threats facing the world today. Strong stewardship of antimicrobials used in animal and human health is critical to preserving their effectiveness and slowing the emergence of resistance. CDC has worked collaboratively and will continue to do so with CSTE, public health veterinarians, healthcare associated infection programs, state and federal agencies, and One Health efforts around the nation to enhance coordination on antimicrobial stewardship initiatives. With future funding for this effort as a determining element for the specific activities undertaken, CDC will assist in the development of stewardship strategies and metrics with FDA, USDA, veterinarians, and animal agriculture industries. Antibiotics are a precious resource, and preserving their usefulness will require cooperation and

engagement by both animal and human health stakeholders to move antibiotic stewardship forward to ensure antibiotics are used appropriately and safely whenever they are used.

CSTE Position Statement 15-ID-03

Title: Revision of the Case Definition of Hepatitis C for National Notification

Statement of the desired action(s) to be taken

The current surveillance case definitions for hepatitis C (acute and past/present) should be revised and replaced for reporting of all incident cases or prevalent cases/incident diagnoses of probable or confirmed, acute and chronic hepatitis C for the purpose of national surveillance.



1. Utilize standard sources (e.g. reporting) for case ascertainment for hepatitis C (*per se*). Surveillance for hepatitis C (*per se*) should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of hepatitis C (*per se*).

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	X	
Death certificates	X	
Hospital discharge or outpatient records	X	
Extracts from electronic medical records	X	
Telephone survey		
School-based survey		
Other _____		
2015 Template		



2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for hepatitis C (*per se*) and add hepatitis C (*per se*) to the *Nationally Notifiable Condition List*.

☐ 2a. Immediately notifiable, extremely urgent (within 4 hours)

☐ 2b. Immediately notifiable, urgent (within 24 hours)

☒ 2c. Routinely notifiable

CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.



3. CDC should publish data on hepatitis C (*per se*) as appropriate in *MMWR* and other venues (see Section IX).

4. With adoption of the notifiability of hepatitis C (*per se*), separate notification of “Hepatitis C, acute” and “Hepatitis C, past or present” will be discontinued.

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined above.

Terminology:

* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health.

**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

CDC Comments: CDC appreciates the opportunity to review the position statement and offers the following comments.

Pages 4, 6, 7 (in the following sections):

VI. Criteria for case identification

- A. Narrative: A description of suggested criteria for case ascertainment of a specific condition
- B. Table of criteria to determine whether a case should be reported to public health authorities

VII. Case Definition for Case Classification

Note: Several different terms are used to describe/name the same laboratory tests; while all of the terms are accurate, CSTE may want to consider which terms to use (more) consistently:

- NAT for HCV RNA, HCV NAT, HCV RNA are the 3 terms used to describe Nucleic Acid Test for HCV RNA.
- Anti-HCV antibody test or Anti-HCV

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VI. Criteria for case identification

- C. Disease-specific data elements
Prevention recommendations for persons with HCV include vaccination against HAV and HBV. Adding vaccination history, as requested, allows

providers to determine if vaccination is needed and allows Public Health professionals to monitor adherence to recommendations.

Epidemiologic Risk Factors – please add

Vaccination History for hepatitis A

Vaccination History for hepatitis B

CSTE Position Statement 15-ID-04

Title: Recommendations for Surveillance and Reporting of Healthcare Associated Infections in Long Term Care Facilities

Statement of the desired action(s) to be taken

In order to implement HAI reporting from LTCFs, in a thoughtful and systematic manner possibly involving several tiers:

1. CSTE recommends use of National Healthcare Safety Network (NHSN) standards for healthcare-associated infection (HAI) surveillance in LTCFs, including surveillance definitions and infection event and denominator data requirements, and a standard interface for electronic HAI reporting to NHSN from long term care facilities in States or Territories that require or use a system other than NHSN for HAI surveillance in these settings.
2. CSTE recommends that CDC work with CMS to assure that infection prevention and control standards and resources (including staffing, information technology, and adequate support for competency-based training) in LTCFs are adequate to both conduct surveillance and to prevent and control infections in LTCF residents and staff.
3. CSTE recommends that CDC and CMS commit sufficient resources to NHSN for long term care facility enrollment, training, user support, and validation in anticipation of any future use of NHSN's long term care component in a federal quality measurement reporting program.
4. CSTE recommends CDC provide state and local health departments with sufficient resources for state and local health departments to adequately support LTCFs in their jurisdictions in the surveillance, prevention, and control of HAIs.
5. CSTE recommends that CDC work with state and local health departments to develop standardized methodology to conduct validation of the long term care module data reported to NHSN to support accurate reporting.
6. CSTE recommends that research, prevention, and other data collection projects (such as other infection prevention collaboratives) should align with NHSN surveillance definitions and use NHSN as the tool for these projects when possible.

7. CSTE encourages states to collaborate with other entities and stakeholders that have expertise in the long term care setting. State and local stakeholders in the long term care community should work together to ensure training, resources, and materials are provided to LTCFs.

8. CSTE recommends that CMS, CDC and CSTE leadership confer regularly on the progress and purpose of LTCF reporting with special emphasis on avoiding unintended consequences such as precipitous regulatory responses when alternative actions would address shortcomings that have been identified.

Additional detail on desired actions:

1. CSTE recommends that states review Appendix 1 for details on how the desired actions listed above can be implemented.
2. CSTE recommends that CDC and CMS partner with and offer technical assistance to state and local health departments on effective approaches to marshal and use resources (i.e., funding, technical assistance, direct assistance) to implement surveillance and prevention activities in LTCFs. This relates, in particular to desired actions numbers 2, 3, and 4.

CDC Comments:

Comments included with 15-ID-05

CSTE Position Statement 15-ID-05

Title: Standardized Definition for Carbapenem-resistant Enterobacteriaceae (CRE) and Recommendation for Sub-classification and Stratified Reporting

Statement of the desired action(s) to be taken

☒1. Utilize standard sources (e.g. reporting*) for case ascertainment for CRE. Surveillance for CRE should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of CRE

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	X
Laboratory reporting	X	X
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	X	X
Death certificates	X	X
Hospital discharge or outpatient records	X	X
Extracts from electronic medical records	X	X
Telephone survey		
School-based survey		
Other _____		

2015 Template

☒2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for CRE but do not add CRE to the *Nationally Notifiable Condition List*. If requested by CDC, jurisdictions (e.g. States and Territories) conducting surveillance according to these methods may submit case information to CDC.

3. Jurisdictions should stratify reports of cases of CRE using the methods outlined in Section VII.

4. CSTE requests that CDC adopt this revised, standardized reporting definition of CRE, including the revised laboratory criteria.

5. CSTE recommends that health departments and public health laboratories should work with clinical laboratories to collaborate around the identification and timely reporting of CRE to infection control and public health authorities to ensure timely communication. Interfacility communication should be strongly encouraged (also see CSTE position statement 13-ID-09: Communication of possible healthcare-associated infections across healthcare settings (8)).

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined above.

Terminology:

* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health.

**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

CDC Comments on Position Statements 15-ID-04 and 15-ID-05:

Thank you for the opportunity to respond to the recent CSTE position statements regarding HAI surveillance in long-term care settings and standardized definitions of CSTE reporting. CDC values CSTE as an important partner in protecting and improving public health and we are working diligently to make progress in the areas outlined in the

CSTE position statements. CDC agrees that NHSN standards should be used for HAI surveillance in LTCFs, just like NHSN serves as the HAI reporting standard for other healthcare settings. CDC recognizes that LTCF reporting in NHSN is still new and requires ongoing evaluation and validation. CDC looks forward to working with CSTE on surveillance standards that could form the basis for any state or territorial reporting expectations established for LTCFs. CDC will continue to work with state and local health departments to develop standardized methodology to conduct validation of the long term care module data reported to NHSN to ensure accurate reporting.

CDC also agrees that the state health departments and the federal government should target CRE case detection using clinician/hospital reports and laboratory-based reporting. CDC views clinician reporting, laboratory reporting, reporting by hospitals, hospital discharge and outpatient records, and extracts from electronic medical records as the best sources of data for CRE surveillance. CDC will continue to support public health departments in the identification and timely reporting of CRE to infection control authorities. CDC will continue to partner with CSTE to improve detection of CRE nationwide.

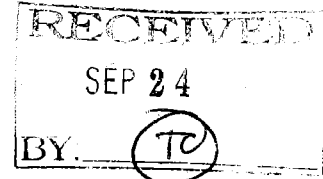


DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 17, 2015

Jeffrey P. Engel, M.D.
Executive Director
Council of State and Territorial Epidemiologists
2872 Woodcock Boulevard, Suite 250
Atlanta, GA 30341



Dear Dr. Engel:

Thank you for your letter sent on behalf of the members and the Executive Board of the Council of State and Territorial Epidemiologists (CSTE) regarding the CSTE position statement entitled "Recommendations for Strengthening Antimicrobial Stewardship in Veterinary Medicine and Animal Agriculture." You requested a response from the Food and Drug Administration (FDA) on this position statement, which you included in your letter.

The Agency has reviewed your position statement, and we certainly agree that antimicrobial resistance is an important human and animal health issue. We believe that a "One-Health" approach, such as that taken by the National Action Plan for Combating Antibiotic-Resistant Bacteria (National Action Plan), is important for effectively addressing this challenging problem. FDA finds CSTE's "statement of desired actions" to be generally consistent with the National Action Plan objectives relating to antibiotic stewardship and surveillance, where FDA, the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA) all have important roles to play.

FDA is committed to implementing, in collaboration with our federal and state partners and other key stakeholders, the important objectives outlined in the National Action Plan. As part of that effort, FDA is working in collaboration with USDA and CDC to jointly sponsor a public meeting to obtain public input on possible approaches for collecting additional on-farm antimicrobial drug use and resistance data. This directly relates to the second CSTE recommendation to "develop appropriate metrics for tracking antimicrobial use" in animals.

FDA believes that a data collection plan is needed to obtain additional information necessary to: (1) assess the rate of adoption of changes outlined in the FDA's Guidance for Industry #213; (2) help gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization; and (3) assess associations between antibiotic use practices and resistance. This meeting, scheduled for September 30, 2015, is the first opportunity for public input as part of

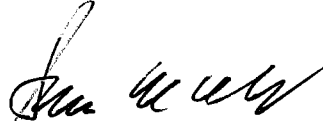
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Page 2 – Jeffrey P. Engel, M.D.

our ongoing effort to develop and implement plans for collecting additional on-farm antimicrobial drug use and resistance data.

Thank you for your interest in this important public health issue. FDA highly values the input from CSTE and we look forward to continued dialogue.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Ostroff".

Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Jeff:

THANKS FOR SHARING
THE POSITION STATEMENT.
PLEASE GIVE MY REGARDS
TO THE EXECUTIVE BOARD.

A handwritten signature in black ink, appearing to read "Jeff Engel".