2020 Carbapenem Resistance Veterinary Diagnostic Laboratory Survey

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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- **Purpose:** The survey will assess current activities and technologies used to detect carbapenem resistance in Enterobacteriaceae, *Pseudomonas*, and *Acinetobacter* from dogs and cats and to determine how information regarding carbapenem-resistance is shared with laboratory clients, the veterinary and scientific community, human and animal health officials, public health, and other interested parties.
- **Use:** Data will be used to determine if and how veterinary diagnostic laboratories are currently surveilling for novel resistance genes/pathogens of human health concern. Data will also be used to determine the approximate number of isolates from dogs and cats that were resistant to a carbapenem in 2019. This information will fill critical gaps in knowledge of veterinary diagnostic capacity and help inform future guidelines around testing.
- **Methods:** One-time online data collection instrument.
- **Respondent Universe:** State laboratory officials from 51 accredited veterinary diagnostics laboratories in 32 states.
- **Analysis**: Data will be analyzed using REDCap and Excel, generating a report showing summary statistics and results for each question (i.e. frequency and counts for categorical responses). The report will be shared with accredited laboratories via the AAVLD network.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using OMB No. 0920-0879 "Information Collections to Advance State, Tribal, Local and Territorial Governmental Agency System Performance, Capacity, and Program Delivery" nicknamed the "CSTLTS Generic." The respondent universe for this information collection aligns with that of the CSTLTS Generic. Data will be collected from 51 accredited state or publicly funded university veterinary diagnostic laboratories across 32 states from laboratory officials acting in their official capacities (**see Attachment A: Veterinary Diagnostic Laboratory Name, Location, and Type List**). These laboratory officials assume the roles of either director, administrator, chief, supervisor, or supervisory microbiologist. Regardless of title, the individuals asked to participate in the assessment were chosen because of their managerial role in a veterinary diagnostic laboratory.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of

☒ 1. Assess and monitor population health status, factors that influence health, and community needs and assets
☐ 2. Investigate, diagnose, and address health problems and hazards affecting the population
☐ 3. Communicate effectively to inform and educate people about health, factors that influence it, and how to improve it

☐ 4. Strengthen, support, and mobilize communities and partnerships to improve health
☐ 5. Create, champion, and implement policies, plans, and laws that impact health
☐ 6. Utilize legal and regulatory actions designed to improve and protect the public's health
☐ 7. Assure an effective system that enables equitable access to the individual services and care needed to be healthy
☐ 8. Build and support a diverse and skilled public health workforce
☒ 9. Improve and innovate public health functions through ongoing evaluation, research, and continuous quality improvement
☐ 10. Build and maintain a strong organizational infrastructure for public health[1]

Carbapenems are critically useful antimicrobial drugs that are reserved for treatment of infections caused by multidrug-resistant, gram-negative bacteria.[2] The emergence and spread of carbapenem-resistant Enterobacteriaceae (CRE) in human healthcare settings is a major clinical and public health concern.[2] Reports of carbapenem-resistant Enterobacteriaceae (CRE) in animals and animal settings are rare but have been documented in livestock, wildlife, and companion animals (dogs and cats).[3] A novel type of carbapenem-resistant Enterobacteriaceae (NDM-5-producing *Escherichia coli*) was recently detected in companion animals.[4,5] The ability to detect these antibiotic resistant pathogens and conduct public health response may be limited in the event veterinary diagnostic laboratories cannot adequately test for or identify resistant bacteria. There is no national surveillance for CRE in companion animals and there remain knowledge gaps in recommendations around testing. Our assessment will help us determine if and how veterinary diagnostic laboratories are currently surveilling for novel resistance genes/pathogens of human health concern, such as CRE. This information will fill critical gaps in knowledge of veterinary diagnostic capacity and help inform future guidelines around testing.

The purpose of this assessment is to evaluate current activities and technologies used to detect carbapenem resistance in Enterobacteriaceae, *Pseudomonas*, and *Acinetobacter* from dogs and cats and to determine how information regarding carbapenem-resistance is shared with laboratory clients, the veterinary and scientific community, human and animal health officials, public health, and other interested parties. The respondent universe consists of veterinary diagnostic laboratory officials from 32 states. We will work with the American Association of Veterinary Laboratory Diagnosticians (AAVLD) as a non-funded partner to conduct the data collection.

Thorough assessment of veterinary diagnostic laboratory activities and technologies will help to better monitor novel resistance genes/pathogens of human health concern among dogs and cats. This information will fill critical gaps in knowledge of veterinary diagnostic capacity and help inform future guidelines around testing. Additionally, the information laboratory officials report about sharing information regarding carbapenem-resistance can be used to help identify opportunities for multisectoral collaboration among public health partners.

Overview of the Information Collection System

Data will be collected via a web-based assessment allowing respondents to complete and submit their responses electronically (**see Attachment B: CRE Instrument – Word Version, Attachment C: CRE Instrument – Web Version,** and **Attachment D: CRE Instrument Attachment Laboratory Guidelines**). The online information collection instrument will be used to gather information from veterinary diagnostic laboratory officials regarding the current activities and technologies used to detect carbapenem resistance in Enterobacteriaceae, *Pseudomonas*, and *Acinetobacter* from dogs and cats. Additionally, the instrument will ask how information regarding carbapenem-resistance is shared with laboratory clients, the veterinary and scientific community, human and animal health officials, public health, and other interested parties. These veterinary diagnostic laboratory officials assume the roles of either director, administrator, chief or supervisor. This method of data collection was chosen to reduce the overall burden on respondents, as they can complete the assessment at a time convenient to them.

The information collection instrument was pilot tested by two veterinary diagnostic laboratory professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The online assessment consists of 54 questions designed to determine current activities and technologies among veterinary diagnostic laboratories to conduct testing for novel resistance genes/pathogens of human health concern. The questions are of various types, including dichotomous (yes/no), multiple response, and interval. No open-ended questions are included to limit questions requiring narrative responses. Skip patterns were utilized in the assessment so that if a question was no longer relevant because of a previous response, the question is disabled.

The instrument will collect data on the following:

- Questions about laboratory testing scope (Question 1 & 2)
- Questions about bacterial identification and antimicrobial susceptibility testing of Enterobacteriaceae*, Pseudomonas*, and *Acinetobacter* (Questions 3-44)
- Questions about what is done when carbapenem resistance from dogs and cats is detected in any Gram-negative organism (Question 45 & 46)
- Questions about laboratory test results from dogs and cats (Questions 47-54)

2. Purpose and Use of the Information Collection

The purpose of this information collection instrument is to determine veterinary diagnostic laboratory capacity to conduct testing for novel resistance genes/pathogens of human health concern. Specifically, the survey will assess current activities and technologies used to detect carbapenem resistance in Enterobacteriaceae, *Pseudomonas*, and *Acinetobacter* from dogs and cats and to determine how information regarding carbapenem-resistance is shared with

laboratory clients, the veterinary and scientific community, human and animal health officials, public health, and other interested parties.

Data will be used to determine if and how veterinary diagnostic laboratories are currently surveilling for novel resistance genes/pathogens of human health concern. Data will also be used to determine the approximate number of isolates from dogs and cats that were resistant to a carbapenem in 2019. This information will fill critical gaps in knowledge of veterinary diagnostic capacity and help inform future guidelines around testing. Additionally, the information laboratory officials report about sharing information regarding carbapenem-resistance can be used to help identify opportunities for multisectoral collaboration among public health partners.

Data will be analyzed and disseminated in a report to AAVLD laboratories showing summary statistics and results for each question. The information gathered in this survey may also be published; data will be published in aggregate form without identifying any individual laboratory in order to protect the privacy of the laboratory and maintain confidentiality.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based instrument allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden to respondents. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e. no open-ended questions).

The instrument was created in REDCap, and data will be stored on internal CDC servers that are fully CDC compliant. Data will only be shared among the four survey project officers in the Outbreak Response and Prevention Branch in the Division of Foodborne, Waterborne, and Environmental Diseases and the Antimicrobial Resistance Team in the Division of Healthcare Quality Promotion. Data will be stored on a secure CDC network drive and only those project officers will have access to the folder. A report will be created using REDCap and Excel data analysis tools and shared with AAVLD laboratories.

4. Efforts to Identify Duplication and Use of Similar Information

Experts in the field of antimicrobial resistance from CDC, FDA, USDA, and AAVLD were questioned about their knowledge of any previous information collection instruments that have attempted to gather similar information. A survey of methods used for antimicrobial susceptibility testing in veterinary diagnostic laboratories in the United States was conducted in 2015.[6] Our survey specifically focuses on surveillance for novel resistance genes/pathogens of human health concern and will supplement information collected in the prior survey. Antimicrobial resistance experts were unaware of information on methods to detect carbapenem resistance among dogs and cats having ever been systematically collected from veterinary diagnostic laboratories. Additionally, no formal documentation or publications on

systematic data collection efforts on carbapenem resistance in dogs and cats were found through a literature search conducted by the Office of Library Science at CDC.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Assess the ability of veterinary diagnostic laboratories to detect novel resistance genes/pathogens of human health concern.
- Increase awareness of carbapenem resistance in dogs and cats among veterinary diagnostic laboratories, animal health, and public health officials.
- Strengthen relationships with multidisciplinary experts and partners across and within CDC, federal regulatory agencies, private industry partners, and state and local health departments.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This data collection is being conducted using the Generic Information Collection mechanism of the CSTLTS Generic Information Collection Service (CSTLTS Generic) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on April 27, 2017, Vol. 82, No. 80, pp 19371-19373. One non-substantive comment was received. CDC sent forward the standard CDC response.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply to this data collection. STLT governmental staff and / or delegates will be speaking from their official roles.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature. This data collection is not research involving human subjects.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the data collection instrument by two public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 20 minutes (range: 15–20). For the purposes of estimating burden hours, the upper limit of this range (i.e., 20 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for diagnostic related technologists and technicians http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of $31.92 is estimated for all 51 respondents. Table A-12 shows estimated burden and cost information.

There will be a total of 51 respondents and 51 responses.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Veterinary Diagnostic Laboratory Official	51	1	20 / 60	17	$31.92	$543
TOTALS	**51**	**1**		**17**		**$543**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff to develop the data collection instrument, collect data, and perform data analysis. The total estimated cost to the federal government is $8,418. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Epidemic Intelligence Service Officer GS-13, Step 1 [develop OMB package, plan and implement data collection, data analysis, develop summary reports/presentations]	100	$46.06/hour	$4606
Epi Coordinator GS-14, Step 5 [supervise the following activities: develop OMB package, plan and implement data collection, data analysis, develop summary reports/presentations]	5	$61.68/hour	$308
Health Scientist GS-12, Step 4 [plan and implement data collection, data analysis, develop summary reports/presentations]	75	$42.60/hour	$3195
Epidemiologist O-5 [supervise the following activities: plan data collection, develop summary report/presentations]	5	$61.68/hour	$308
Estimated Total Cost of Information Collection			**$8417**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The data will be collated and analyzed by the Epidemic Intelligence Service Officer. The data collection instrument was created in REDCap, and data will be stored on internal CDC servers that are fully CDC compliant. Data will only be shared among the four project officers in the Outbreak Response and Prevention Branch in the Division of Foodborne, Waterborne, and Environmental Diseases and the Antimicrobial Resistance Team in the Division of Healthcare

Quality Promotion. Data will be stored on a secure CDC network drive and only those project officers will have access to the folder. Data will be disseminated in a report to AAVLD laboratories showing summary statistics and results for each question. Data collected during the assessment will be shared only in aggregate form. The information gathered in this survey may also be published; data will also be published in aggregate form without identifying any individual laboratory in order to protect the privacy of the laboratory and maintain confidentiality.

Project Time Schedule

- ✓ Design instrument ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test instrument ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- ❑ OMB approval ..... (TBD)
- ❑ Conduct data collection ..... (Open 6 weeks)
- ❑ Code data, conduct quality control, and analyze data..... (1 month)
- ❑ Prepare summary report(s) ..... (1 month)
- ❑ Disseminate results/reports ..... (1 month)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

A. Attachment A – Veterinary Diagnostic Laboratory Name, Location, and Type List
B. Attachment B – CRE Instrument – Word Version
C. Attachment C – CRE Instrument – Web Version
D. Attachment D – CRE Instrument Attachment Laboratory Guidelines

REFERENCE LIST

1. Centers for Disease Control and Prevention (CDC). " Essential Public Health Services." Available at: https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html.

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4. Cole SD, Peak L, Tyson GH, Reimschuessel R, Ceric O, Rankin SC. New Delhi Metallo-β-Lactamase-5-Producing Escherichia coli in Companion Animals, United States. *Emerg Infect Dis*. 2020;26(2):381-383. doi:10.3201/eid2602.191221.
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6. Dargatz DA, Erdman MM, Harris B. A survey of methods used for antimicrobial susceptibility testing in veterinary diagnostic laboratories in the United States. *J Vet Diagn Invest*. 2017;29(5):669-675. doi:10.1177/1040638717714505.