



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-25-0015; Docket No. CDC-2025-0011]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Global Action in Healthcare Network Antimicrobial Resistance Module (GAIHN-AR). This project supports planning and management of antimicrobial resistance prevention, detection, and response activities associated with the GAIHN-AR network.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0011 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal

(www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Global Action in Healthcare Network Antimicrobial Resistance Module (GAIHN-AR) – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This is a request for a three-year OMB approval of a New Information Collection Request (ICR). Antimicrobial resistance (AR) is a growing global public health threat that does not respect borders and was estimated to kill at least 1.27 million people in 2019 – more than HIV/AIDS or malaria. If no actions are taken, these numbers will grow up to an estimated two million deaths attributable to AR and eight million deaths associated with AR by 2050. The U.S. Centers for Disease Control and Prevention (CDC) works globally to detect and control emerging AR threats at the source before they cross borders and spread to other countries, including the United States.

The United States National Action Plan for Combating Antibiotic Resistant Bacteria Sub-Objective 2.5.3 describes the creation of a global network for “detection and containing new and critical antibiotic-resistant threats,” to “identify innovative and effective strategies for stopping the spread of antibiotic resistant pathogens in low- and middle-income countries,” and to “improve standardization of laboratory methodologies and data collection to improve the quality, reliability, and utility of data to facilitate global comparisons of antibiotic resistance.”

CDC has established this network, and it is called the Global Action in Healthcare Network – Antimicrobial Resistance Module (GAIHN-AR). GAIHN-AR aims to help prevent

and reduce the spread of AR threats before they reach the United States through coordinated laboratory detection, communication, and infection prevention and control (IPC) actions in healthcare. The initial focus is carbapenemase-producing carbapenem-resistant Enterobacterales (CP-CRE), an AR threat recognized as requiring urgent action by both CDC and the World Health Organization (<https://www.cdc.gov/antimicrobial-resistance/media/pdfs/2019-ar-threats-report-508.pdf> and <https://iris.who.int/bitstream/handle/10665/376776/9789240093461-eng.pdf?sequence=1>). Partners may also optionally include other epidemiologically important carbapenemase-producing organisms such as *Acinetobacter* spp. and *Pseudomonas aeruginosa*.

This network is implemented by the Department of Health and Human Services, CDC in response to the Executive Order 13676 of September 18, 2014, the National Strategy of September 2014, and to implement Subobjective 2.5.3 of the United States National Action Plan for Combating Antibiotic Resistant Bacteria of October 2020. Data collected throughout this network is also authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

GAIHN-AR is currently composed of healthcare facilities and laboratories in Argentina, Chile, Ethiopia, Greece, India and the United States, and additional healthcare facilities and laboratories in Costa Rica, Ecuador, Ukraine, and Cambodia are in the planning stages of implementation. These sites are supported by CDC, CDC's funded partners, and in some countries, Ministries of Health. The current participants are supported through CDC's CK21-2104, CK18-1801, GH21-2174, GH23-0048, GH0056, GH00-2375 and GH20-2110 Cooperative Agreements. Laboratories in the participating healthcare facilities and their supporting reference laboratories identify and characterize CP-CRE with known and novel mechanisms of resistance from clinical cultures and colonization screening specimens. Laboratories communicate detection events immediately to healthcare personnel at the participating healthcare facilities and relevant public health authorities for immediate action. IPC personnel within the participating healthcare facilities: 1) work with units that are at high risk for spreading CP-CRE to proactively strengthen IPC with a focus on hand washing, use of personal protective equipment, patient

placement strategies, and cleaning of the healthcare environment even before CP-CRE is detected; and 2) rapidly respond to detection of patients with CP-CRE to identify, prevent and contain further spread. Participating healthcare facilities and laboratories use a shared framework with harmonized methods and standardized data collection to improve and innovate prevention, detection, and rapid response strategies. Lessons learned are then shared with key partners such as Ministries of Health who can voluntarily translate the findings into national initiatives.

Funded CDC partners or Ministries of Health supporting the network healthcare facilities and laboratories will report the following information to the Program Office at CDC – Division of Healthcare Quality Promotion (DHQP):

1. Site demographics and qualitative challenges and successes encountered during implementation are reported yearly
2. Quantitative impact measures (e.g., number of carbapenem-resistant and carbapenemase-producing organisms detected, IPC practice auditing and compliance rates, rates of carbapenemase-producing organism transmission) are reported on a monthly basis
3. Key implementation milestones (e.g., performance of IPC practice assessments, creation of action plans), changes in laboratory methods, trainings, and containment responses are reported on an event-based frequency.

All data are based on data routinely collected in the healthcare facilities and laboratories as part of their normal operations and based on best practices for laboratory and IPC. The data described above may be shared with CDC in one of two ways: 1) funded CDC partners or Ministries of Health receive the data in secure intermediate databases that they host and own, and then the data is entered into CDC's secure online web portal or 2) participating healthcare facilities and laboratories enter the data directly into CDC's secure online web portal. CDC's web portal is based in the District Health Information System 2 (DHIS2) platform, which is an

open-source tool for collection, validation, analysis, and visualization of aggregate data that is used globally in more than 40 countries in Africa, Asia, and Latin America.

The data collected through GAIHN-AR is used to: (1) monitor progress toward core network activity implementation; (2) measure the impact, inform resource needs, and demonstrate return on investment for those activities over time; (3) provide data to the participating healthcare facilities, laboratories, and Ministries of Health to set priorities and support continuous improvement of prevention, detection, and response activities in the participating sites and at the national level within the country; and (4) facilitate collaboration with CDC on the improvement activities described in (3).

CDC requests OMB approval for a total estimated 1,491 annualized burden across GAIHN-AR is 1491 hours. There are no additional costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
CDC-funded Partner/Ministry of Health	Annual Country Successes and Challenges	9	1	45/60	7
Healthcare facility	Annual Facility Demographics	30	1	5/60	3
CDC-funded Partner/Ministry of Health	Annual Facility Demographics	9	4	5/60	3
Healthcare facility	Annual Unit Demographics	30	2	10/60	10
CDC-funded Partner/Ministry of Health	Annual Unit Demographics (Attachment 3c)	9	7	5/60	6
Laboratory	Annual Laboratory Demographics	43	1	15/60	11
CDC-funded Partner/Ministry of Health	Annual Laboratory Demographics	9	5	10/60	8

Healthcare facility	Monthly Unit Prevention Measures	30	24	20/60	240
CDC-funded Partner/Ministry of Health	Monthly Unit Prevention Measures	9	79	10/60	119
Laboratory	Monthly Laboratory Detection Measures	43	12	60/60	516
CDC-funded Partner/Ministry of Health	Monthly Laboratory Detection Measures	9	58	60/60	522
CDC-funded Partner/Ministry of Health	Event-based Trainings Form	9	15	5/60	12
Healthcare facility	Event-based Facility Response Measures	30	0.5	10/60	3
CDC-funded Partner/Ministry of Health	Event-based Facility Response Measures	9	2	20/60	6
CDC-funded Partner/Ministry of Health	Event-based Unit Prevention Measures	9	27	5/60	21
CDC-funded Partner/Ministry of Health	Event-based Laboratory Measures	9	5	5/60	4
Total					1491

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