

- Update respondent costs to reflect current wage data from 2017.

The 12-month approval will allow CDC to continue to monitor states' program planning and delivery of public health activities and the programs' collaboration with health care systems for the remainder of the fifth and final year of cooperative agreement EH14-1404 (program period: September 2014—August 2019), and the third and final year of cooperative agreement EH16-1606 (program period: September 2016—August 2019).

The goal of this data collection is to provide NCEH with routine information about the activities and performance of the state and territorial awardees funded under the NACP through an annual reporting system. NACP requires awardees to report activities related to partnerships, infrastructure, evaluation and interventions to monitor the state programs' performance in reducing the burden of asthma. AIRS also includes

two forms to collect aggregate ED and HD data from awardees.

AIRS was first approved by OMB in 2010 to collect data in a web-based system to monitor and guide participating state health departments. Since implementation in 2010, AIRS and the technical assistance provided by CDC staff have provided states with uniform data reporting methods and linkages to other states' asthma program information and resources. Thus, AIRS has saved state resources and staff time when asthma programs embark on asthma activities similar to those done elsewhere.

In the past three years, AIRS data were used to:

- Serve as a resource to NCEH when addressing congressional, departmental and institutional inquiries.
- Help the branch align its current interventions with CDC goals and allowed the monitoring of progress toward these goals.

- Allow the NACP and the state asthma programs to make more informed decisions about activities to achieve objectives.

- Facilitate communication about interventions across states, and enable inquiries regarding interventions by populations with a disproportionate burden, age groups, geographic areas and other variables of interest.

- Provide feedback to the grantees about their performance relative to others through the distribution of two written reports and several presentations (webinar and in-person) summarizing the results.

- Customize and provide technical assistance and support materials to address implementation challenges.

There will be no cost to respondents other than their time to complete the three AIRS spreadsheets annually. The estimated annualized burden hours are 89.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Asthma Program Awardees ..	AIRS Performance Measures Reporting Spreadsheets.	25	1	150/60
	AIRS Emergency Department Visits Reporting Form.	25	1	30/60
	AIRS Hospital Discharge Reporting Forms.	25	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-19LX]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Assessment of Clinical and Microbiologic Outcomes in Patients Infected with *Shigella* with Decreased Susceptibility to Ciprofloxacin and Azithromycin through a Prospective Case-Control Study in California to the Office of

Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 29, 2018 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) 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;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assessment of Clinical and Microbiologic Outcomes in Patients Infected with *Shigella* with Decreased Susceptibility to Ciprofloxacin and Azithromycin through a Prospective Case-Control Study in California—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

A broad 60-day notice for this project entitled “Applied Research to Address Emerging Public Health priorities” was published on May 29, 2018. This project is part of a series of CDC research projects funded under that Broad Agency Announcement.

Multidrug-resistant *Shigella* is a public health problem in the U.S, including California. Resistance to first line drugs (azithromycin and ciprofloxacin) limits treatment options and may be associated with worse patient outcomes. In 2017, the Centers for Disease Control and Prevention (CDC) reported an increase in *Shigella* isolates with ciprofloxacin minimum inhibitory concentration (MIC) range=0.12–1.0 µg/mL. In 2018, this was updated (<https://emergency.cdc.gov/han/han00411.asp>) and confirmed a continued increase in such isolates.

While current Clinical and Laboratory Standards Institute (CLSI) criteria categorize *Shigella* isolates that fall within this range as susceptible, these strains often harbor a quinolone resistance gene, which may be associated with decreased susceptibility to ciprofloxacin. Little is known about the clinical implications of infection with *Shigella* with ciprofloxacin MICs in the range of 0.12–1 µg/mL; including whether treatment with a fluoroquinolone is associated with a worse clinical outcome for the patient, or will result in prolonged shedding and further reduction in ciprofloxacin susceptibility. In addition, CLSI has not established clinical breakpoints for azithromycin, making treatment decisions challenging for clinicians when managing patients with multidrug-resistant *Shigella* infections. Systematically collected data regarding the clinical and microbiologic outcomes of patients infected with *Shigella* with ciprofloxacin MIC 0.12–1 µg/mL or that fall above the epidemiologic cutoffs for azithromycin (≥16 µg/mL for *S. flexneri*, ≥32 µg/mL for *S. sonnei*) are needed to inform clinical breakpoints.

The primary objectives of the study are to: (1) Estimate the proportion of California *Shigella* isolates with a ciprofloxacin MIC range of 0.12–1.0 µg/mL and the proportion of *Shigella*

isolates that fall above the epidemiologic cutoffs for azithromycin; (2) determine whether patients who were infected with *Shigella* with a ciprofloxacin MIC range of 0.12–1.0 µg/mL and treated with a fluoroquinolone (and thus have decreased susceptibility to ciprofloxacin, or DSC *Shigella*) have worse clinical and microbiologic outcomes than patients who were infected with *Shigella* with a ciprofloxacin MIC <0.12 µg/mL and were also treated with a fluoroquinolone; (3) systematically describe the clinical outcomes of patients infected with *Shigella* that fall above the epidemiologic cutoffs for azithromycin (referred to as decreased susceptibility to azithromycin, DSA *Shigella*); and (4) explore microbiologic features including antimicrobial susceptibility testing (AST) patterns and WGS of *Shigella* isolates with DSC and DSA. Results of this investigation will provide data that may inform CLSI breakpoints and shape public health recommendations on management and prevention of DSC and DSA *Shigella* infections.

CDC is seeking one year of OMB approval. There is no cost to respondents other than the time to participate. Total estimated annual burden is 878 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
<i>Shigella</i> cases and controls	Case Interview Form Initial	230	1	45/60
	Case Interview Form Second	230	1	45/60
	Symptom Log Form	230	1	30/60
	Stool collection and submission initial.	230	1	90/60
	Stool collection and submission second.	144	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-19-19ACB; Docket No. CDC-2019-0021]

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 and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled “Drug Overdose Surveillance and Epidemiology (DOSE).” This new data collection effort is an essential component toward reducing the opioid crisis, one of HHS Department’s top priorities. DOSE data is critical to our