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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	Average Burden per Response

			Respondent	(in hours)
Shigella 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

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