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)
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

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

ability to rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses at the local, state, and regional level.

DATES: CDC must receive written comments on or before June 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0021 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffery M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*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–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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; and
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.
5. Assess information collection costs.

Proposed Project

Drug Overdose Surveillance and Epidemiology (DOSE)—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The rapid increase in opioid overdose deaths since 2013, numerous severe fentanyl and fentanyl analog outbreaks occurring since 2015 across the United States, and the declaration of the opioid overdose epidemic as a national public health emergency on October 26, 2017 have highlighted the urgent need to rapidly establish and enhance timely surveillance of suspected drug, opioid, heroin, and stimulant overdoses. These data are critical to inform timely local, state, and regional responses, especially to acute and/or widespread multi-state outbreaks.

This new data collection effort is an essential component toward reducing the opioid crisis, one of DHHS's top priorities. DOSE data is critical to our ability to rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses at the local, state, and regional level. This will be accomplished by standardizing and enhancing sharing of existing ED data locally collected by 52 health departments (all 50 state health departments, the health department of Puerto Rico, and the health department of the District of Columbia) with CDC. In addition, CDC leadership communicates with HHS on an ongoing basis, and this data is part of its request to better monitor, plan, and implement programs to prevent overdose and reduce subsequent harms.

DOSE proposes to fund 52 health departments (50 state health departments, the health department of Puerto Rico and the health department of the District of Columbia) to rapidly share existing ED data on counts of ED visits involving suspected drug, opioid, heroin, and stimulant overdoses using two standard data forms (*i.e.,* the Rapid ED overdose data form and the ED discharge overdose data form) and standard CDC case definitions.

The system will leverage ED syndromic data and hospital discharge data on ED visits already routinely collected by state and territorial health departments. No new data will be systematically collected from EDs, and health departments will be reimbursed by CDC for the burden related to sharing ED data with CDC. The 52 funded health departments will rapidly share existing ED data with CDC on a monthly basis using the Rapid ED overdose data form and standard CDC case definitions. Data may come from different local ED data systems, but is expected to cover at least 75% of ED visits in the jurisdiction (*e.g.,* state).

CDC will require all participating health departments to provide counts of ED visits involving suspected drug, opioid, heroin, and stimulant overdoses by county, age group, sex, and time (*i.e.,* month and year) in a standardized manner using the Rapid ED overdose data form, which is an Excel data template. This form also collects data quality indicators such as percent of ED visits missing data on key variables (*i.e.,* metadata). In order to assess and improve rapid ED data sharing, all 52 participating health departments will also be asked to share counts of ED visits involving suspected drug, opioid, heroin and stimulant overdoses by county, age group, sex, and time (*i.e.,* month and year) from more finalized hospital discharge files, the current surveillance standard. The data will be shared with CDC on a quarterly or yearly basis using a standardized Excel data form, the ED discharge overdose data form, and standard CDC case definitions. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	No. of respondents	Total no. of responses per respondent	Average burden per response (hours)	Total annual burden (hours)
State health departments, the DC health department and PR health department.	Rapid ED overdose data form	28	12	3	1,088
Jurisdictions sharing case-level ED data with CDC through the NSSP BioSense (OMB #0920–0824).	Rapid ED overdose data form	24	12	0.5	144
State health departments, the DC health department and PR health department.	ED discharge overdose data form ...	26	4	3	312
State health departments, the DC health department and PR health department.	ED discharge overdose data form ...	26	1	3	78
Total	.....	.....	.....	.....	1,542

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

[60Day–19–19ABV; Docket No. CDC–2019–0019]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on 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 Information Collection on Soil-transmitted Helminth Infections in Alabama and Mississippi. CDC requests OMB approval to collect information on prevalence and distribution of soil-transmitted helminth infections and potential risk factors.

DATES: CDC must receive written comments on or before June 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0019 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Lead, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*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–D74, Atlanta, Georgia 30329; phone: 404–639–7118. Email: *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 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; and
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.
5. Assess information collection costs.

Proposed Project

Investigation on soil-transmitted helminth infections in Alabama and Mississippi—New—Center for Global Health (CGH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Soil-transmitted helminths (STH) are intestinal worms transmitted through contaminated soil. They include roundworms (*Ascaris lumbricoides*), whipworms (*Trichuris trichiura*), hookworms (*Ancylostoma duodenale* and *Necator americanus*) and the worm *Strongyloides stercoralis*. These infections were widespread across the American South through the early 20th