

with non-specific symptoms like fever, headache, and muscle pain, but when left untreated the bacteria can cause damage to blood vessels throughout the body leading to organ and tissue damage. Delay in recognition and treatment of RMSF can result in irreparable damage leading to amputation of extremities, neurological deficits (such as hearing loss, paralysis, and encephalopathy), and death.

Case series in the peer-reviewed literature document long term sequelae (LTS) from RMSF in anywhere from 3–55% of cases, yet characterization of the

long-term impacts is still not well understood, and only a handful of studies have examined them in detail. Results of neurologic damage caused during acute RMSF illness may include symptoms ranging from paresthesia, insomnia and behavioral concerns to loss of hearing, motor or language dysfunction, and chronic pain.

This study will gather information related to neurologic sequela following RMSF illness. Information for this study will come from three sources: Medical charts, patient interviews, and neurological exams with a cognitive/

developmental assessment for children. Resulting data will provide information to healthcare providers, patients, and policy makers about the long term consequences of severe RMSF, including time to recovery, self-reported impact to daily function, and will look to identify risk factors during acute illness which may be associated with long term impairment.

There is no cost to respondents other than the time to participate. Total estimated burden is 42 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public	Patient screening questionnaire	84	1	10/60
	Neurological exam form	42	1	40/60

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Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–0604]

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 School-Associated Violent Deaths Surveillance System (SAVD) 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 February 2, 2019 to obtain comments from the public and affected agencies. CDC received four comments 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

School-Associated Violent Deaths Surveillance System (SAVD) (OMB#: 0920–0604, expiration 05/31/2019)—Revision—National Center for Injury Prevention and Control (NCIPC),

Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Violence Prevention (DVP), National Center for Injury Prevention and Control (NCIPC) proposes to maintain a system for the surveillance of school-associated homicides and suicides. The system relies on existing public records and interviews with law enforcement officials and school officials. The purpose of the system is to (1) estimate the rate of school-associated violent death in the United States and (2) identify common features of school-associated violent deaths. The system will contribute to the understanding of fatal violence associated with schools, guide further research in the area, and help direct ongoing and future prevention programs.

Violence is the leading cause of death among young people, and increasingly recognized as an important public health and social issue. In 2016, over 3,600 school-aged children (five to 18 years old) in the United States died violent deaths due to suicide, homicide, and unintentional firearm injuries. The vast majority of these fatal injuries were not school associated. However, whenever a homicide or suicide occurs in or around school, it becomes a matter of particularly intense public interest and concern. NCIPC conducted the first scientific study of school-associated violent deaths (SAVD) during the 1992–99 academic years to establish the true extent of this highly visible problem. Despite the important role of schools as a setting for violence research and

prevention interventions, relatively little scientific or systematic work has been done to describe the nature and level of fatal violence associated with schools. Until NCIPC conducted the first nationwide investigation of violent deaths associated with schools, public health and education officials had to rely on limited local studies and estimated numbers to describe the extent of school-associated violent death.

SAVD is an ongoing surveillance system that draws cases from the entire United States in an attempt to capture all cases of school-associated violent deaths that have occurred. Investigators review public records and published press reports concerning each school-associated violent death. For each identified case, investigators also contact the corresponding law enforcement agency and speak with an official in order to confirm or reject the case as an SAVD, and to request a copy

of the official law enforcement report for confirmed SAVD cases.

In past years, investigators would interview an investigating law enforcement official (defined as a police officer, police chief, or district attorney), and a school official (defined as a school principal, school superintendent, school counselor, school teacher, or school support staff) who were knowledgeable about the case in question; however, moving forward, the interviews with these respondents will be eliminated, and instead CDC study personnel will abstract data from law enforcement reports to enter using a Data Abstraction Tool. Data to be abstracted from the law enforcement report include the following: Information on both the victim and alleged offender(s)—including demographic data, their criminal records, and their relationship to one another; the time and location of the incident precipitating the fatality; the circumstances, motive, and method of the fatal injury; and the security and

violence prevention activities in the school and community where the death occurred, before and after the fatal injury event. The revised data collection process eliminating the use of telephone interviews will reduce respondents' burden greatly.

All data are secured through the use of technical, physical, and administrative controls. Hard copies of data are kept under lock and key in secured offices, located in a secured facility that can be accessed only by presenting the appropriate credentials. Digital data are password protected and then stored (and backed up routinely) onto a secure Local Area Network that can only be accessed by individuals who have been appropriately authorized. Study data are reported in the aggregate, such that no individual case can be identified from the reports. There are no costs to the respondents other than their time. The total estimated annual burden hours are 17.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Law Enforcement Officer	Law Enforcement Case Confirmation Script .. Letter to Local Law Enforcement Officials	50 50	1 1	5/60 15/60

Jeffrey M. Zirger,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92-463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as

patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PS15-001SUPP, Positive Health Check Evaluation Trial.

Date: June 27, 2019.

Time: 10:00 a.m.–5:00 p.m., (EDT).

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact:

Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop E60, Atlanta, Georgia 30329, (404) 718-8833, gca5@cdc.gov.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1346]

Development of Antiviral Drugs for the Treatment of Adenoviral Infection in Immunocompromised Patients; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Development of Antiviral Drugs for the Treatment of Adenoviral Infection in