

Incidents of Public Health Significance in the National Poison Data System

OSTLTS Generic Information Collection Request

OMB No. 0920-0879

SUPPORTING STATEMENT – Section A

Submitted: 10/31/2014

Program Official/Project Officer

Name: Royal Kai Yee Law (HUA1)

Title: Associate Service Fellow / Epidemiologist

CIO: National Center for Environmental Health

Division: Division of Environmental Hazards and Health Effects

Branch: Health Studies Branch

Address: 4770 Buford Hwy NE, MS F-60, Chamblee GA 30341

Phone: 770-488-3416

Fax: 770-488-3450

Email: HUA1@CDC.GOV

Section A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from state epidemiologists within state health departments. These state epidemiologists will come from the public list of state epidemiologist contacts on the Council of State and Territorial Epidemiologists website.¹ There will be 100 chemical, environmental, drug, foodborne, biological and radiological exposures and illnesses of potential public health significance notifications, unique to each incident, sent to these state epidemiologist within 35 state health departments, making a total of 100 unique respondents (See Supporting Statement B for specific details on the respondent universe breakdown).

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information applies to the essential public health service for evaluating effectiveness, accessibility, and quality of personal and population-based health services.²

The Centers for Disease Control and Prevention (CDC), NCEH/EHHE/Health Studies Branch (HSB) uses the National Poison Data System (NPDS), a national surveillance system using all calls to all poison centers (PCs) in the United States, to identify potential incidents of public health significance.

The primary objective of this activity is to provide CDC with a national surveillance capability to better detect and respond to chemical, environmental, drug, foodborne, biological and radiological exposures and illnesses of potential public health significance. On average, every 24 minutes, 55 regional PCs upload data collected from calls made to their organizations to NPDS, which is owned and operated by the American Association of Poison Control Centers (AAPCC). Since 2001, CDC and AAPCC have developed methods to use NPDS data for near, real-time surveillance of exposures to hazardous substances of potential public health significance. CDC uses NPDS to:

- Improve national surveillance for chemical, environmental, drug, foodborne, biological and radiological exposures and illness of potential public health significance,
- Identify early markers of chemical, environmental, drug, foodborne, biological and radiological events in order to provide an effective and rapid public health response, and
- Identify and track exposures and cases of illness during an emerging or known public health threat.³

Operational since 1985, NPDS is the only national human poisoning database in the United States. The database currently logs approximately 2.5 million calls about potential exposures (exposure calls) annually. NPDS receives approximately 1.5 million calls requesting information (information calls) on a particular substance annually. The cumulative NPDS database contains information about more than 45 million potential poison exposures in humans.⁴

The data fields for NPDS include case information (center, date), call information (exposure site, reason for exposure), caller information (location by zip code, county, state), patient information (age, sex, pregnancy), exposure information (acuity, duration, number of substances, route of exposure, substance, and amount), and information about case management (management site, therapy, treatment), medical outcomes, and clinical effects (e.g., signs, symptoms, laboratory abnormalities).⁴

There are many approaches that are currently used by HSB to detect exposures and illnesses of potential public health significance. These approaches use automated algorithms to detect anomalies in call volume patterns and clinical effect volume patterns to PCs. When call frequencies exceed a pre-established threshold calculated as three standard deviations above a historical baseline using 3 years of historical information, an anomaly is identified and an automated email is generated alerting a team of CDC and AAPCC toxicologists and epidemiologists. This team of CDC and AAPCC toxicologists and epidemiologists analyze surveillance data daily to determine if further follow up activity is needed or if the call is of potential public health significance. Some of the criteria used in this process, in combination with clinical judgment, include determining if a cluster of exposure calls is associated with a reportable exposure or any other instance that may indicate a broader public health impact.⁵

After reviewing the data, AAPCC and CDC scientists determine whether the appropriate PC should be contacted to request additional information on the call(s) of interest. If available information suggests that an event warrants further investigation, CDC will notify the state health department as well as other appropriate federal agencies through a National Notification Protocol vetted through the Council of State and Territorial Epidemiologists and AAPCC (**see Att. A Protocol Example Email**).

Information about identified incidents is sent to the state epidemiologist for situational awareness and prompt state or local public health response as necessary. HSB wants to follow up on these notifications to state epidemiologists to ascertain what actions, if any, were initiated following notification of an incident.

The purpose of this assessment is to improve the incident notification process and NPDS surveillance by ascertaining the usefulness of the notifications following an incident. This assessment is an essential step in conducting NPDS surveillance in closing the loop between identification of an incident and resulting public health response, as well as an assessment of public health impact of surveillance using NPDS. The information provided by the information collection activity can improve the incident notification process and NPDS surveillance.

Overview of the Data Collection System

The information collection activity consists of a web-based questionnaire (**see Att. B Information Collection Form – MS Word version; Att. C Information Collection Form – Web Version**) designed to assess from the recipients of the national notification protocol email about a potential incident of public health significance regarding what actions, if any, were initiated following notification of an incident. The information collection instrument will be administered as a web-

based instrument. The information collection instrument was pilot tested by five public health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The information collection instrument will include four questions inquiring the state epidemiologist regarding what public health actions were taken following a notification of a public health significant incident as described in the background above. The first two questions inquire whether public health action was taken in response to the incident, and what actions were taken. The last two questions inquire whether the official was aware of the incident prior to email notification, and what actions were taken following the email notification. One question is dichotomous, one multiple response, and two multiple response with an open ended option.

2. Purpose and Use of the Information Collection

The purpose of this assessment is to improve the incident notification process and NPDS surveillance by ascertaining the usefulness of the notifications following an incident. This assessment is an essential step in conducting NPDS surveillance in closing the loop between identification of an incident and resulting public health response, as well as an assessment of public health impact of surveillance using NPDS. The information provided by the information collection activity can improve the incident notification process and NPDS surveillance.

This information collection activity will be used to recognize duplicative efforts in identifying incidents through poison center data at the state and national level. Many states have their own processes for identifying incidents of public health significance using local poison center data. This information collection activity will assess the number of incidents that the state already knows about prior to the notification. Furthermore, the information collection activity will gauge how effectively the activities conducted in NPDS surveillance is translating to public health action. This will allow HSB team members to prioritize areas of the surveillance and notification process that need improvement and to identify successful aspects that need to be maintained. This will result in a more effective and robust surveillance system for the branch, center, and CDC.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based questionnaire allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to four questions). An effort was made to limit questions that require narrative responses and included narrative optional questions to elaborate on feedback. Open ended questions are limited to 1000 characters.

4. Efforts to Identify Duplication and Use of Similar Information

The activities conducted by HSB team members at the national level are unique and therefore not duplicative of other efforts. By extension, an assessment of these surveillance activities will not be duplicative of other efforts as well. This new information collection will fill a gap intended to gauge the effectiveness of current surveillance efforts.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Without this data there would be:

- No timely feedback regarding effectiveness of HSB's activities to state public health agencies.
- Less effective interventions to improve the identification and notification of incidents identified by NPDS.
- Limitations to effective and timely assessment of capacities of governmental agencies to fulfill their public health mission.

This request is for a one time information collection. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information.

This data collection is not research involving human subjects.

10.1 Privacy Impact Assessment Information

No individually identifiable information (IIF) will be collected.

11. Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the information collection instrument by five public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately seven minutes. Based on these results, the estimated time range for actual respondents to complete the instrument is five to ten minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., ten minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$57.11 is estimated for all 100 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Data Collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
National Notification Protocol Follow up Information Collection Form	State Epidemiologist	100	1	10/60	17	\$57.11	\$971
TOTALS		100	1		17		\$971

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks. The information collection forms will be reviewed by a team lead FTE. A CDC FTE health scientist will administer the form, transcribe the responses to a dataset, and analyze and report the data. The estimated cost to the federal government is \$2,555.00. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Team Lead (GS-14) – Lead on development and changes to the instrument, review and oversee OMB package preparation, data collection, data analysis, and report preparation	10/60 * 100 collections per year	\$48.90	\$815
Associate Service Fellow (GS-12) – Develops and changes the instrument, prepares OMB package, collects and analyzes data	30/60 * 100 collections per year	\$34.80	\$1,740
Estimated Total Cost of Information Collection			\$2,555

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the results of this information collection activity. The results will be used internally to support the maintenance and improvement of NPDS surveillance. Immediately following OMB approval, data collection will commence using the information collection form. A summary of this timeline is provided below (assuming a notification of an incident of potential public health significance is sent out on the day following OMB approval).

Business days following OMB approval	Activity
1 day	Notification email sent
5 days	Commence data collection; form sent via email
10 days	Reminder email sent
260 days	CDC annual report generated

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- A. Protocol Example Email**
- B. Instrument MS Word Version**
- C. Instrument Web Version**

REFERENCE LIST

1. Council of State and Territorial Epidemiologists (CSTE). "State Epidemiologists." Available at <http://www.cste.org/?page=StateEpi/>. Accessed at 10/27/2014.
2. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at <http://www.cdc.gov/nphpsp/essentialservices.html>. Accessed on 8/14/14.
3. Centers for Disease Control and Prevention (CDC). "Understanding Chemical Exposures." Available at <http://www.cdc.gov/nceh/hsb/chemicals/ncrs.htm>. Accessed on 10/27/2014.
4. American Association of Poison Control Centers (AAPCC). "Annual Reports." Available at <http://www.aapcc.org/annual-reports/>. Accessed on 10/27/2014.
5. Law RK, Sheikh S, Bronstein A, Thomas R, Spiller H, Schier J. Incidents of potential public health significance identified by national surveillance of poison center data (2008-2012). Accepted for publication in the Journal of Clinical Toxicology, August 2014.