

Childhood Blood Lead Surveillance (CBLs) and Adult Blood Lead Epidemiology and Surveillance (ABLES)

OMB Control No. 0920-NEW

New Information Collection Request

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Table of Contents

B.1.	Respondent Universe and Sampling Methods.....	3
B.2.	Procedures for the Collection of Information.....	4
B.3.	Methods to Maximize Response Rates and Deal with Nonresponse.....	9
B.4.	Test of Procedures or Methods to be Undertaken.....	9
B.5.	Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	9
	References.....	11
	List of Attachments.....	15

Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The goal of the National Center for Environmental Health (NCEH) Childhood Blood Lead Surveillance (CBLS) Program is to promote primary prevention of exposure to lead in children, and, as a secondary prevention strategy, to prevent adverse health effects when lead exposures occur in children, through improved program management and oversight in respondent jurisdictions for blood lead testing, surveillance, and targeted population-based interventions. The goal of the National Institute for Occupational Safety and Health (NIOSH) Adult Blood Lead Epidemiology and Surveillance (ABLES) Program is to build state capacity for adult blood lead surveillance programs to measure trends in adult blood lead levels and to prevent lead over-exposures. Thus, blood lead surveillance over the human lifespan is covered under this single information collection request (ICR), specifically for children through CBLS at NCEH, and for adults through ABLES at NIOSH.

Although the two collections do not involve statistical sampling methods to obtain blood lead surveillance data, NCEH and NIOSH will use Part B to describe the respondent methods used to collect blood lead data from the target populations in the jurisdictions from which they arise.

Respondents: The respondents will include partners in State or local public health agencies, or their bona fide fiscal agents, that will submit NCEH childhood (n=48) and NIOSH adult blood lead surveillance data (n=40).

- CBLS: NCEH respondents will be 48 CDC cooperative agreement awardees from State or local health departments, or their bona fide agents, who have received funds to develop and implement a childhood lead poisoning prevention program (CLPPP).
 - In most state and local lead poisoning prevention programs, blood lead testing and laboratory reporting of all blood lead levels are required by law (NCSL, 2010).¹
- ABLES: Over the next three years, principal investigators in up to 40 state ABLES Programs will submit BLL data from adults, directly to the ABLES Program on an annual

¹ As described in Section A.10, these target populations are not considered respondents with imposed burden under 5 CFR §1320.3(b)(2) and (b)(3), because the reporting, recordkeeping, or disclosure activities needed to comply within jurisdictions are usual and customary, or are required by state or local law even in the absence of the federal requirement.

basis. Currently, 28 programs are reporting ABLES data. NIOSH will work to establish data sharing agreements with up to 12 additional programs.

- o For states to be eligible to participate in the ABLES program, they must have mandatory state regulations requiring the reporting of adult BLLs by both public and private laboratories to the state health department or another state health agency or department designated by the state to direct and coordinate the state's adult lead poisoning surveillance program.

Target populations: The target populations for CBLS are children, less than 16 years, and for ABLES are adults, 16 years and older, who have blood lead testing performed by health care providers, laboratories, hospitals, or other facilities that analyze blood samples for lead, store those data on servers housed on their premises, and report the results to their state or local health departments, or their bona fide agents (i.e., the respondents).

- For CBLS, NCEH assumes that the following 2015 Terms of Clearance (**Attachment 3c**) will again apply to the new ICR. The data are not intended to be generalized:
 - o *"These data were collected for program management purposes. The data are not generalizable at the national, state, or local level. Furthermore, because inclusion criteria vary across grantees, comparisons of aggregate statistics across programs can be misleading (i.e., state policies and practices for blood lead testing vary and local priorities drive decisions regarding which homes receive assessments for other housing hazards). However, descriptive statistics can be used to compare changes overtime in a given area when the method by which housing units are chosen for inclusion remains the same. With a thoughtful understanding of the approach used to include housing units in a given location, HHLPPS can be used to make associations between the number of individuals in a given area and a specific housing hazard or health condition and geographic descriptors such as poverty, age of housing, tenancy, and health conditions."*
- ABLES: Data collected by the ABLES Program will be used to estimate national and state prevalence rates to track trends prevalence rates over time. Data will also be used to see what industries have more cases of adults with elevated blood lead levels. This information is very useful to prioritize allocation of resources.

B.2. Procedures for the Collection of Information

An overview of both CBLS and ABLES is found in Section A.10.

CBLS:

- Reporting within Jurisdictions – CLPPPs in funded State or local health departments receive data from health care providers, laboratories, hospitals, or other facilities that analyze blood samples for lead and store those data on servers housed on their premises.

- o State and Local Systems: NCEH provides technical support but does not provide funding for system development. To promote standardization, NCEH provides Healthy Homes and Lead Poisoning Prevention Surveillance System (HHPSS) software at no cost to State or local programs. HHPSS is primarily a program management tool for partners to manage their lead surveillance and other data such as for healthy homes programs. HHPSS or equivalent systems and the data therein are owned by partners. Their systems are customized for jurisdiction-specific program needs, and are subject to state or local legal codes and IT security requirements. Thus, data residing within these data systems and owned by the programs are more accurately referred to as “HHPSS Variables.”
- Required Quarterly Reporting to CBLS - The awardees are required to submit quarterly data to CDC by the final business day of the following quarter (e.g. data collected during the first quarter, is due on the final business day of the second quarter) (**Attachment 5a**). All data are transmitted to CDC via a secure FTP site.
 - o CDC System: Partners are required to deliver a subset of their program data to the NCEH system, CBLS. Specifically, the required quarterly reports include federally sponsored data on childhood blood lead screening. These data delivered to NCEH will be referred to as “CBLS Variables” for the Fiscal Year 2017 (FY17) program.

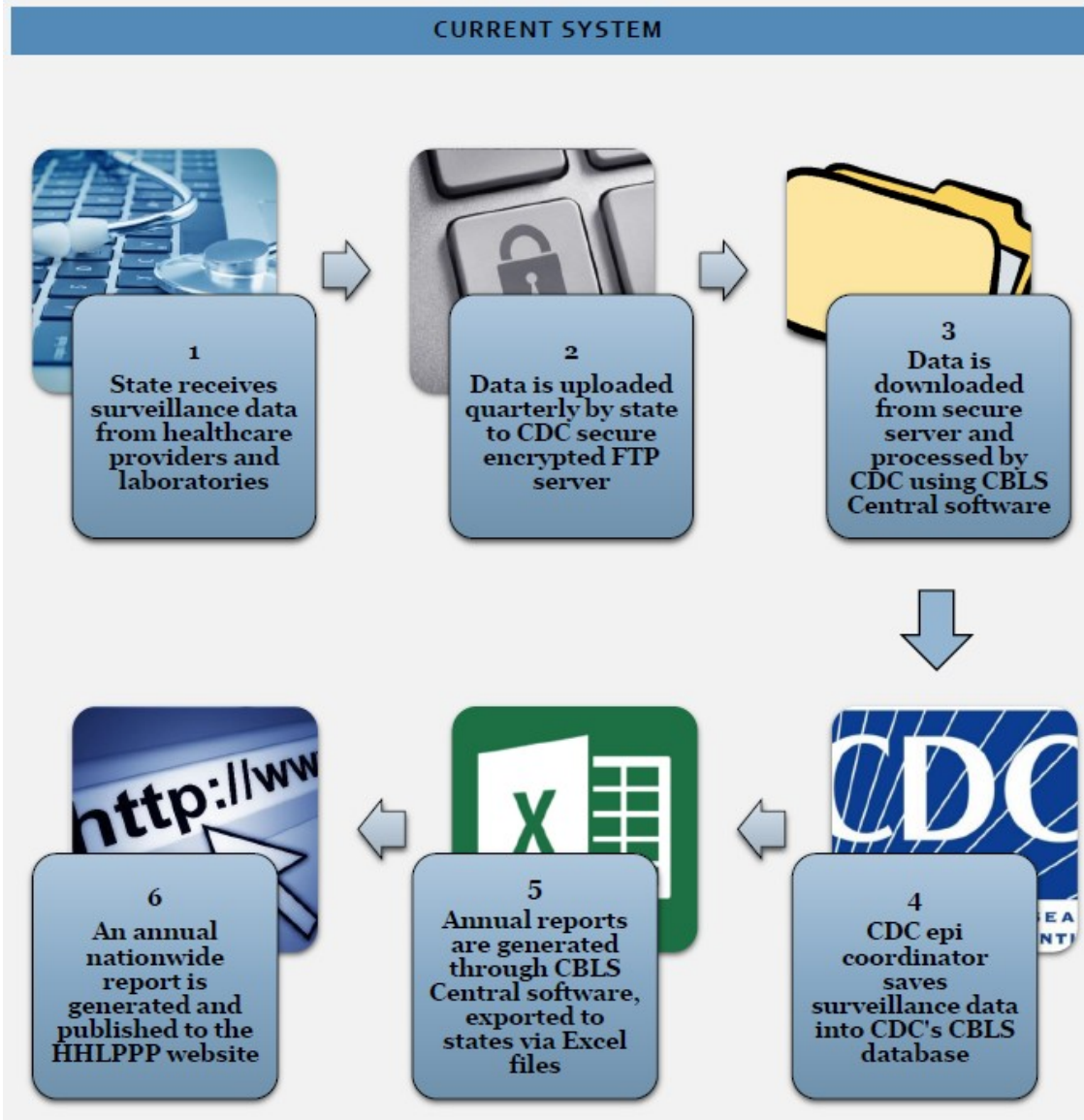


Figure 1. Overview of the Current Childhood Blood Lead Surveillance System

Figure 1 provides a graphical overview of the current CBLS data collection system.

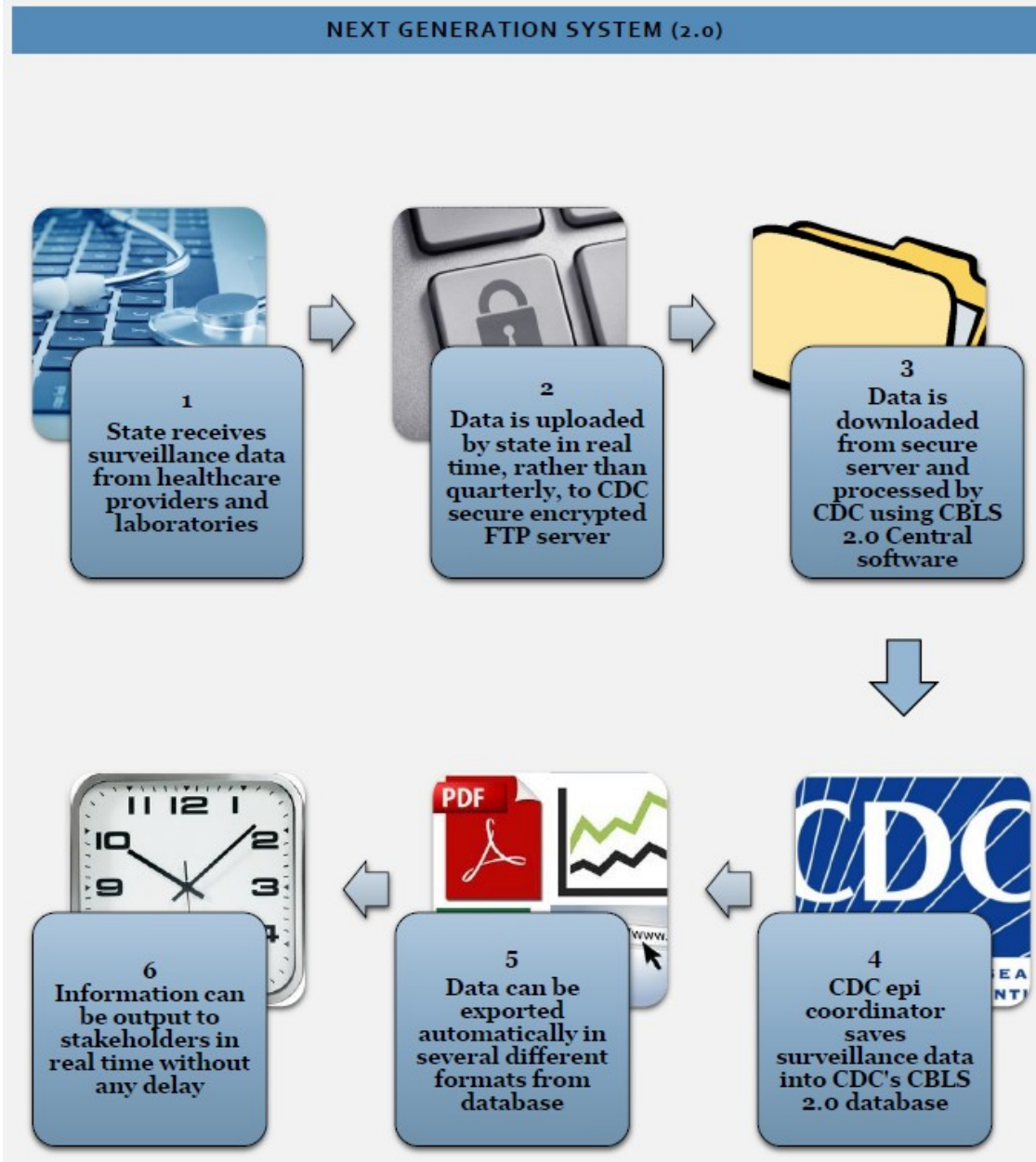


Figure 2. Overview of the Next Generation Childhood Blood Lead Surveillance System

The next generation CBLS will be a web-based system which is anticipated to go into production in Fall 2017 (**Figure 2**).

- CBLS Data Delivery and Processing Report Dissemination - Data submitted in text files to NCEH are processed and maintained in the CBLS database. NCEH uses its processing software, CBLS Central, to perform data checks on awardee text files for required formatting. Text files are parsed into separate linkable data tables (e.g., Address, Child, Lab Results, and Investigation) (**Attachment 5a**). Processing reports are generated and

sent to awardees, to indicate how many records were properly parsed and entered into the CBLS database and how many records were not loaded with an explanation of the rejection. Corrections from awardees are returned in the next quarterly report. Therefore, NCEH has a 1 to 2 quarter lag with on-time data delivery. CBLS Annual Reports are based on the calendar year and are sent to awardees at the end of the second quarter of the fiscal year.

NCEH estimates that one respondent will submit aggregate CBLS data (**Attachment 5b**).

ABLES:

Reporting from States: State ABLES Programs collect data on adult BLLs from laboratories and physicians through mandatory reporting and follow-up on adults with BLLs ≥ 5 , ≥ 10 , or ≥ 25 $\mu\text{g}/\text{dL}$ ² to ensure completeness of information (e.g., the industry in which the adult is employed and whether the exposure source is occupational, non-occupational, or both) (Alarcon, 2016). The main reason for tracking both BLLs ≥ 10 and ≥ 25 is because the case definition has changed from ≥ 25 to ≥ 10 and there is now a need to monitor the historic trend of occupational lead exposure based on BLLs ≥ 25 . Prior to 2009, States were only obligated to report cases with BLL ≥ 25 and cases with BLL ≥ 10 were not reported until 2009. This data is submitted to NIOSH/ABLES on an annual basis.

ABLES Data Delivery and Processing Report Dissemination – State ABLES Programs submit an electronic data file by the second quarter of the succeeding calendar year (i.e., 4/30/2017). States may submit data in two different data collection formats; 1) individual data records for each case, and 2) aggregated data in which only the final counts are provided. The formats for these electronic data files are attached (**Attachments 5c & 5d**). The data file includes: 1) The data in the prescribed format, and 2) a brief narrative report describing any notable lead surveillance activities during the year. NIOSH consolidates data from reporting state ABLES Programs, conducts data quality control, analyzes the data using SAS, and disseminates the findings among stakeholders.

² NIOSH continues to track the earlier case definitions of elevated BLLs ≥ 10 and ≥ 25 $\mu\text{g}/\text{dL}$ because there is now a need to monitor the historic trend of occupational lead exposure. Prior to 2009, States were only obligated to report cases with BLL ≥ 25 $\mu\text{g}/\text{dL}$. Cases with BLL ≥ 10 $\mu\text{g}/\text{dL}$ were not reported until 2009, and cases of BLL ≥ 5 $\mu\text{g}/\text{dL}$, in 2015.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

CBLS: Since data for CBLS are required to be submitted as part of the cooperative agreement, NCEH anticipates a 100 percent response rate. In the event that an awardee does not submit its quarterly progress report and CBLS data, the assigned project officer will contact the program to help them overcome any barriers to submitting the progress report.

Additionally, NCEH develops reports to provide feedback to each awardee about the quality of their data. NCEH project officers, epidemiologists, and IT specialists will use these reports to highlight weaknesses in the data and recommend ways to improve program activities and to ensure consistency with stated objectives.

ABLES: State ABLES Programs submit data to the ABLES Program on a voluntary basis. To encourage submission, NIOSH ABLES develops effective working relationships with State ABLES Programs by providing technical assistance and guidance in adult blood lead surveillance, prevention, and intervention. Additionally, NIOSH ABLES works closely with state partners to produce educational materials, MMWRs, and journal articles.

B.4. Test of Procedures or Methods to be Undertaken

No tests of procedures or methods were conducted for CBLS or for ABLES. The CBLS and the ABLES methods have been used and proven over many years at CDC. See summary of program activities in **Attachment 4**.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following are the people who:

- Designed the data collection;
- Will collect the data, and;
- Will analyze the data.

Table B.5.1. Personnel Responsible for CBLS Methods and Design	
Mary Jean Brown, ScD, RN (retired 2016)	Adrienne S. Ettinger, ScD, MPH, MS

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Qaiyim Harris, BS Business Analyst, Karna (CDC contractor) Email: gah3@cdc.gov Tel: 770-488-7115	Naveen Krishna Reddy, MCA Application Developer, Karna (CDC contractor) Email: ysn8@cdc.gov Tel: 770-488-7080

Table B.5.2. Personnel Responsible for Collection and Analysis of CBLS Data	
Adrienne S. Ettinger, ScD, MPH, MS Chief, HHLPPP, NCEH, CDC Email: abe7@cdc.gov Tel: (770) 488-7492	Perri Zeitz Ruckart, MPH Lead Epidemiologist, HHLPPP, NCEH, CDC Email: afp4@cdc.gov Tel: 770-488-3808
Stella O. Chuke, MBBS, MPH Epidemiologist, HHLPPP, NCEH, CDC Email: slc7@cdc.gov Tel: 770-488-3475	Kathryn B. Egan, PhD, MPH Epidemiologist, HHLPPP, NCEH, CDC Email: nky9@cdc.gov Tel: 404-718-5778

Table B.5.3. Personnel Responsible for ABLES Method and Design	
Rebecca Tsai Project Officer (current), NIOSH, CDC Email: yht5@cdc.gov Tel: 513-541-4398	Walter Alarcon Project Officer (former), NIOSH, CDC Email: wda7@cdc.gov Tel: 513-541-4451
Marie Sweeney Branch Chief, NIOSH/DSHEFS/SB, CDC Email: mhs2@cdc.gov Tel: 513-541-4102	

Table B.5.4. Personnel Responsible for Collection and Analysis of ABLES Data	
David Wall Information Technology Specialist, NIOSH, CDC Email: dkw0@cdc.gov Tel: 513-541-4331	Rebecca Tsai Project Officer (current), NIOSH, CDC Email: yht5@cdc.gov Tel: 513-541-4398
Scott Henn Industrial Hygienist, NIOSH, CDC Email: ajn4@cdc.gov Tel: 513-541-4173	Walter Alarcon Project Officer (former), NIOSH, CDC Email: wda7@cdc.gov Tel: 513-541-4451

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List of Attachments

Attachment 1. Authorizing Legislation

- 1a. NCEH Authority
- 1b. NIOSH Authority

Attachment 2. 60-day Federal Register Notice

Attachment 3. Funding Opportunity Announcements

- 3a. FY17 NCEH CBLS FOA
- 3b. FY14 NCEH HHLPPP FOA
- 3c. 2015 HHLPPS Terms of Clearance

Attachment 4. Summary Table CBLS-ABLES Program Activities

Attachment 5. Data Collection Forms

- 5a. CBLS Variables – Text Files
- 5b. CBLS Aggregate Records Form
- 5c. ABLES Case Records Form and Brief Narrative Report
 - 5c1. ABLES Case Records Format
- 5d. ABLES Aggregate Records Form and Brief Narrative Report

Attachment 6. Privacy Impact Assessment

- 6a. CBLS PIA
- 6b. ABLES PIA

Attachment 7. Research Determinations

- 7a. NCEH CBLS Research Determination
- 7b. NIOSH ABLES Research Determination