Oral Health Basic Screening Survey for Children

Existing Collection in Use Without an OMB Control No.

Supporting Statement A

**Program Official/Contact**

Mei Lin, MD, MPH, MSc.

Epidemiologist

Division of Oral Health

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

P: 770 488 5109

F: 770 488 6080

hru3@cdc.gov

October 15, 2020

TABLE OF CONTENTS

[\_Toc40450106](#_Toc40450106)

[A. JUSTIFICATION 3](#_Toc40450107)

[*A1. Circumstances Making the Collection of Information Necessary* 3](#_Toc40450108)

[*A2. Purpose and Use of the Information Collection* 5](#_Toc40450109)

[*A3. Use of Improved Information Technology and Burden Reduction* 8](#_Toc40450110)

[*A4. Efforts to Identify Duplication and Use of Similar Information* 8](#_Toc40450111)

[*A5. Impact on Small Businesses or Other Small Entities* 9](#_Toc40450112)

[*A6. Consequences of Collecting the Information Less Frequently* 9](#_Toc40450113)

[*A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5* 9](#_Toc40450114)

[*A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency* 9](#_Toc40450115)

[*A9. Explanation of Any Payment or Gift to Respondents* 11](#_Toc40450116)

[*A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent* 12](#_Toc40450117)

[*A11. Institutional Review Board (IRB) and Justification for Sensitive Questions* 14](#_Toc40450118)

[*A12. Estimates of Annualized Burden Hours and Costs* 14](#_Toc40450119)

[*A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers* 16](#_Toc40450120)

[*A14. Annualized Cost to the Federal Government* 17](#_Toc40450121)

[*A15. Explanation for Program Changes or Adjustments* 18](#_Toc40450122)

[*A16. Plans for Tabulation and Publication and Project Time Schedule* 18](#_Toc40450123)

[*A17. Reason(s) Display of OMB Expiration Date is Inappropriate* 20](#_Toc40450124)

[*A18. Exceptions to Certification for Paperwork Reduction Act Submission* 20](#_Toc40450125)

REFERENCES

**[ATTACHMENTS](#_REFERENCES_(Tool_Tip:" \o "Tool Tip: You may copy and paste your list of Attachments from SSA or fill in below))**

1. Public Health Service Act [42 U.S.C. 241]; Oral health promotion and disease prevention [Section 247b-14]

2a. Instruction manual

2b. Supplemental guidance on sampling design

2c. Supplemental guidance on data analysis

2d. Invitation to schools to participate

2e. Consent forms

2f. Screening fields form

2g. Notice of screening results

2h. Request and reminder email to state respondents for data

2i. Data form requested from state respondents

3a. 60 day Federal Register Notice

3b. 60 day Federal Register Notice public comments and agency response

4. Institutional Review Board non-research determination

5. ASTDD sample screening budget

**JUSTIFICATION SUMMARY**

**Goal of the project:** To assist states in monitoring the oral health status of children and evaluating public health programs and policies.

**Intended use of the resulting data:** State surveillance data on the prevalence of dental caries and sealants among children published on CDC’s public-facing website is intended to 1) facilitate state oral health surveillance capacity to monitor oral health status, trends, and disparities, and to compare with other states; 2) inform planning, implementation and evaluation of oral health programs and policies; 3) measure state progress toward the Healthy People oral health objectives; and 4) educate the public and policy makers regarding cross-cutting public health programs.CDC also uses the data to evaluate performance of CDC oral health funding recipients.

**Methods to be used to collect:** Non-invasive oral health screenings of children conducted every 5 years from a probability sample representative of a state’s public schoolchildren or children enrolled in the Head Start program. Child-level information on presence of dental caries and sealants is collected and entered on paper or electronic forms by states; state-aggregated prevalence data are emailed to CDC’s partner for verification.

**The subpopulation to be studied:** A representative sample of a state’s public schoolchildren, particularly third gradestudents. Some states also survey Head Start program enrollees or children in grades K–2.

**How data will be analyzed:** Statesperformsampling surveyanalyses to generate prevalence estimates, and may also conduct chi-square tests and regression analyses to assess disparities and trends. CDC performs simple analyses based on the state prevalence data to describe state data distribution and changes over time.

1. **JUSTIFICATION**

## *A1. Circumstances Making the Collection of Information Necessary*

The Centers for Disease Control and Prevention requests a three-year OMB approval for an existing collection in use without an OMB control number to collect prevalence rates for dental caries and sealants among children in public schools and Head Start programs using a non-invasive screening conducted by state departments of public health. CDC is authorized to collect the information under the Public Health Service Act, Title 42, Section 247b–14, Oral Health Promotion and Disease Prevention, and Section 301 (Attachment 1).

Dental caries (also called tooth decay) is one of the most common chronic diseases among children in the United States and can lead to pain, infection, and diminished quality of life throughout the lifespan. Tooth decay disproportionately affects low socioeconomic status and racial or ethnic minority populations. Dental sealants are a cost-effective, evidence-based measure for preventing caries but remain underutilized, particularly among children at higher risk for caries.

Dental caries and sealants are best assessed through clinical examination. The National Health and Nutrition Examination Survey (NHANES) is the only nationally representative collection of oral health surveillance data based on clinical examination and monitors national progress toward the Healthy People objectives. However, it is not designed to provide state-level data. Moreover, the NHANES oral health examination requires highly skilled dental professionals, detailed measures of each tooth or each tooth surface, and complex analysis.

State public health policies and programs vary in both scope and priorities, and therefore state surveillance data inform the planning and evaluation of oral health programs and policies. In the 20th century, few state governments dedicated resources to oral health surveillance, and the only model for surveillance was the detailed NHANES oral health examination method. State-level oral health surveillance data were rare until the Basic Screening Survey (BSS) methodology was developed in the 1990s.

To address states’ critical need for oral health surveillance data for program planning and evaluation, the Association of State and Territorial Dental Directors (ASTDD) spearheaded an effort to develop a simple, standardized survey protocol referred to as the Basic Screening Survey (BSS) in 1997 in collaboration with the Ohio Department of Health and with technical assistance from the CDC’s Division of Oral Health.[1](#_ENREF_1) A CDC cooperative agreement supported the development of BSS. ASTDD published the first BSS manual in 1999 (Attachment 2a).[1](#_ENREF_1) ASTDD also provides supplemental guidelines on its website (www.astdd.org/basic-screening-survey-tool) (Attachments 2b and 2c).

The BSS protocol is designed to align with NHANES prevalence measures while also being simple and easy to implement. BSS is the only data source that provides state-representative data on oral health status based on clinical examination as well as the only source that state public health programs use to monitor progress toward key oral health Healthy People objectives.

CDC and ASTDD recommend that states administer the BSS at least once every five years at minimum for third graders.[2](#_ENREF_2) Third grade is a crucial developmental period when permanent dentition is emerging and preventive sealant placement is most beneficial.

The BSS provides key indicators in the National Oral Health Surveillance System (NOHSS), which was established by ASTDD, CDC, and the Council of State and Territorial Epidemiologists (CSTE) in 1999.[3](#_ENREF_3) NOHSS indicators are based on data available to most states and are aligned with Healthy People measures to facilitate use of standardized state-level indicators and enable cross-state comparisons.

Since that time CDC has expanded the scope of funding to ASTDD to include the collection, verification and compilation of state-aggregated BSS for Children data, which ASTDD submits to CDC for publication on the public-facing Oral Health Data (OHD) portal (www.cdc.gov/oralhealthdata/). Current CDC support to ASTDD for BSS is through a 5-year cooperative agreement, *Partner Actions to Improve Oral Health Outcomes*, CDC-RFA-DP18-1811, which began in September 2018. In addition to ensuring quality data and collecting it from states, ASTDD provides technical assistance to states, either funded by CDC through the cooperative agreement or paid by the state, to build and maintain an effective oral health surveillance system that includes the Third Grade BSS as a key component.

Wyoming, New Jersey, Tennessee, and Washington, DC have not conducted a BSS for Children, nor has any US territory. Some native American tribes have conducted BSS for Children under the purview of the Indian Health Service. CDC has also been supporting state oral health surveillance efforts through cooperative agreements since 2001. *State Actions to Improve Oral Health Outcomes*, CDC-RFA-DP18-1810, took effect in September 2018 and supports 20 states for five years. Recipients must administer a Third Grade BSS and submit state-aggregated data at least once during the project period.

## *A2. Purpose and Use of the Information Collection*

The purpose of the BSS for Children is to provide key state-level oral health surveillance data and to facilitate state capacity to 1) monitor children’s oral health status, trends, and disparities, and compare with other states; 2) inform planning, implementation and evaluation of effective oral health programs and policies; 3) measure state progress toward Healthy People objectives; and 4) educate the public and policy makers regarding cross-cutting public health programs.[1](#_ENREF_1)

CDC recommends that states maintain an oral health surveillance system per CSTE’s guidelines with BSS as a key component.[2](#_ENREF_2)

CDC publishes state-aggregated data on its public-facing OHD website to enable states to use the data to inform programs and policies and to educate the public and policy makers. CDC itself uses the data to evaluate performance of the funded states.

BSS is a state-tailored survey. Its frequency and target grade(s) are determined by individual states and vary from state to state. Among the 50 states and Washington DC, 47 have ever conducted a Third Grade BSS; some also surveyed children in other grades (K–2) or the Head Start program. Based on consultation with states and analysis of BSS frequency, CDC estimates that approximately 34 states (67%), including 20 CDC-funded states, will conduct at least one BSS for third graders during the three years for which this approval is being sought.

ASTDD hosts the survey protocol in an instruction manual (Attachment 2a) and publishes guidelines for survey sampling design and analysis on its public-facing website (Attachments 2b and 2c). ASTDD provides customized technical assistance to states, either funded by CDC through the cooperative agreement or paid by the state. The BSS requires minimal instruction for the examiners, is quick to administer yet consistent, and requires no sophisticated equipment or instruments. The protocol enables dental and non-dental health professionals such as hygienists or school nurses to administer the screening, effectively countering challenges posed by limited funding or lack of dentists.

The survey protocol instructs state health departments to obtain state data from a probability sample representative of the grade they plan to survey (or of children enrolled in the Head Start program). The health department contracts out or administers the survey by determining probability samples, arranging logistics with selected schools or Head Start sites, gaining consent, obtaining demographic data, training screeners, conducting the non-invasive oral observation, verifying and analyzing the data, and submitting the de-identified state-aggregated data to ASTDD.

States invite selected schools to participate and provide them a point of contact for logistics (Attachment 2d) and parent or guardian consent (Attachment 2e). BSS administrators train screeners at least once before each survey cycle through a combination of didactic and clinical training, which includes verifying each screener’s assessment of 20 children from the target grade level (Attachment 2a). Trainers also are required to review the ASTDD training materials.

States determine whether to employ passive or positive consent in conjunction with schools, districts or state Department of Education (DOE). Participation response rates have been depressed where positive consent is required. BSS recommends using either passive consent or positive consent with verbal consent supplemented. Some states include an optional parent questionnaire with the consent document. The questionnaire surveys family access to and use of dental care and aligns with questions on national surveys such as NHANES.

Screeners generally spend one day per school and1-2 minutes per student, surveying four data points in the non-invasive oral observation: 1) presence of treated caries, 2) presence of untreated tooth decay, 3) urgency of need for treatment, and 4) presence of dental sealants on at least one permanent molar tooth (Attachment 2f).

Screeners record their findings either electronically or on a paper form (see Attachments 2a and 2f). All parents or caretakers receive the screening results and, when appropriate, guidance about seeking dental care (Attachment 2g). If screeners find an urgent need for dental care, they inform the school contact for follow-up. Screeners transmit the data to the state program in a secure electronic format or through the USPS or other delivery service that protects privacy.

The minimal demographic data collected are grade and the school-level percentages of children eligible for the National School Lunch Program (NSLP). The school-level NSLP is a proxy measure of socioeconomic status; the data typically are publicly available on the state DOE website. BSS recommends that states collaborate with the DOE at state, district, or school level to collect certain child-level demographic information as well, including sex, date of birth (DOB) or age, race, ethnicity, and NSLP eligibility. This child-level demographic data are matched against the oral health data by a randomly generated state student identification number (SSID) assigned by the state DOE. For states that are not able to obtain the child-level demographics from government sources, the BSS manual provides a sample parent questionnaire to collect the data (Attachment 2a).

State programs analyze the data, de-identify it, and respond to ASTDD’s annual email request for state-aggregated BSS data (Attachments 2h and 2i). To accommodate states and ensure that published data are timely, ASTDD accepts data throughout the year. As BSS data are received, and at least quarterly, ASTDD verifies the data to ensure that survey design and data meet criteria for inclusion in NOHSS (Attachment 2a) and submits the data set to CDC for publication on the OHD website.

CDC launched a public-facing web portal in 2001 to display state-level data of select NOHSS indicators, including BSS data for children (<https://www.cdc.gov/oralhealthdata>). Since 2015 the website has evolved into CDC’s Oral Health Data portal, which incorporates data visualization and customization tools to facilitate data comparison across states and trend monitoring. CDC currently displays some BSS for Children data, including state prevalence estimates of caries experience with treated or untreated caries, untreated tooth decay, dental sealants, response rates, NSLP data, and a brief description of state BSS method. OHD includes surveys from 47 states dating back to the 1993–1994 school year, before which no state had BSS.[1](#_ENREF_1), [4](#_ENREF_4)

## *A3. Use of Improved Information Technology and Burden Reduction*

The BSS protocol recommends that state programs collect screening information electronically so that screeners use the same format and are limited in their response options, and so that data do not have to be entered later for verification. ASTDD has developed example electronic data entry templates for Epi Info and MS Access. States have used various customized electronic forms or created their own applications over the years, and there is no plan at this time to introduce a single standard web-based screening form.

Only about 20% of participating states collect child-level data electronically by using data entry tools such as Epi Info or MS Access. The remaining states report to ASTDD that electronic collection is burdensome and that screeners express varying levels of discomfort with electronics. ASTDD plans to educate states on the importance of electronic collection for data quality and to facilitate computer application literacy among screeners.

To encourage states to submit state-aggregated data in a standardized and electronic format, ASTDD emails them a simple fillable table that can be filled out and emailed back to ASTDD (attachments 2h and 2i).

The OHD portal is part of the CDC’s public-facing website. It brings together data for select NOHSS indicators from BSS and other state-level data sources and integrates various automated functions and visualization tools. Users can view data by indicator, state, year, or data source as well as view data in maps, graphs, or tables to facilitate data comparison and trend monitoring. Users can sort the data, customize the data view, and export maps, graphs, tables, and full or filtered datasets. The OHD portal is accessible by any web browser, and no special hardware or software is required.

## *A4. Efforts to Identify Duplication and Use of Similar Information*

To enable states to monitor their progress toward national objectives, BSS developers strove to align the BSS measures with Healthy People objectives, which are based on NHANES oral health measures. Though NHANES collects national data based on clinical examination, it is not designed to provide state-level representative data. Similarly, though the National Survey of Children’s Health (NSCH) provides national- and state-level data, and the National Health Interview Survey (NHIS) provides national-level data of some oral health measures, both are based on parent or caretaker-reported data and neither involves clinical examination. Dental caries and sealants are best assessed through clinical examination.

The federal government collects some program-specific sealant data: CDC collects data from CDC-funded school-based sealant programs, and Centers for Medicare & Medicaid Services collects sealant data of enrolled children based on Medicaid claims data. In both cases the collected data are specific to programs, and no data are representative of state-wide populations.

## *A5. Impact on Small Businesses or Other Small Entities*

The proposed collection does not include any small entities, only state governments.

## *A6. Consequences of Collecting the Information Less Frequently*

Conducting the BSS less frequently than every five years will inhibit both the quality of trend data and the likelihood that the resulting data will be analyzed and published. Less frequent BSS also will reduce the timeliness of data used to inform program and funding decisions. If data are requested less frequently, their timeliness and usefulness will be further diminished.

## *A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5*

This request fully complies with the regulation 5 CFR 1320.5.

## *A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency*

Part A: Public Notice

A 60-day Federal Register Notice was published in the *Federal Register* on July 2, 2020, Volume 85, Number 128, pages 39911–39913 (Attachment 3a). Three public comments were received and CDC provided a courtesy reply (Attachment 3b).

Part B: CONSULTATION

CDC consulted with seven state oral health programs in January 2019 to learn about the challenges and benefits of BSS and to determine the time and financial burden. The two primary challenges reported were difficulty obtaining demographic data and low response rates from families when positive consent is used.

To address those and other state-reported problems, ASTDD and CDC reviewed and updated the BSS manual in July 2019 to provide greater clarity, increased standardization, and more specific instructions. The manual improves the following areas:

* Provides guidance on how to work with departments of education that prefer positive consent, modifies the positive consent form to include verbal consent verification (Attachments 2a and 2e), and decouples the optional questionnaire from the positive consent form to further clarify that the protocol does not require parents to fill out the questionnaire in order for their child to participate.
* Strategizes and optimizes the methods for collecting demographic information: clarifies that school-level NSLP data publicly available from the state DOE is the minimally required demographic information, instructs programs to collect child-level demographic data from official data sources as primary data sources and to use DOE designated ID numbers to assure a child’s privacy, and removes the methodology for collecting sex, race, and ethnicity data by the screener’s observation.
* Standardizes and formalizes the process that ASTDD uses to request data and remind states to participate.
* Removes language implying that the BSS is research or human subjects research rather than public health practice.
* Modifies the race and ethnicity categories to reflect HHS and OMB guidance.
* Provides instruction to remove names and to transport or transmit data securely, and encourages electronic collection to reduce contact with paper containing personal information.
* Specifies the screener training protocol.

As part of the ongoing technical assistance it provides to states, ASTDD also collects feedback regarding how to improve and streamline the BSS process and to enhance consistency and utility of data. ASTDD then incorporates that feedback into its periodic revisions of the manual (Attachment 2a).

**Table 1.** Respondent Consultations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Title** | **Affiliation** | **Phone** | **Email** | **State Health Department** |
| Katya Mauritson, DMD | Dental Director | Oral Health Unit Manager, Health Access Branch | *(303) 692-2569* | [Katya.mauritson@state.co.us](mailto:Katya.mauritson@state.co.us) | Colorado Dept of Public Health and Environment |
| Jenny Wahby, MPH | School-Based Sealant Program Coordinator | Public Health Dental Program, Community Health Promotion | *(850) 617-1434* | [Jennifer.Wahby@flhealth.gov](mailto:Jennifer.Wahby@flhealth.gov) | Florida Department of Health |
| Sara Schlievert, BS, CPH | Executive Officer 2 | Bureau of Oral and Health Delivery Systems | *(515) 720-3488* | [Saralyn.schlievert@idph.iowa. gov](mailto:Saralyn.schlievert@idph.iowa.%20gov) | Iowa Department of Public Health |
| MeChaune Butler, MPA | Oral Health Promotion Manager | Well-Ahead Louisiana Office of Public Health | *(225) 342-7804* | [Mechaune.Butler@la.gov](mailto:Mechaune.Butler@la.gov) | Louisiana Department of Health |
| Genelle Lamont, PhD, MPH | Oral Health Surveillance Coordinator | Health Promotion and Chronic Disease Division, Oral Health Program | *(651) 201-5974* | [Genelle.lamont@state.mn.us](mailto:Genelle.lamont@state.mn.us) | Minnesota Department of Health |
| Raymond Lala, DDS | Dental Director | Division of Oral Health | *(803) 898-0830* | [lalarf@dhec.sc. gov](mailto:lalarf@dhec.sc.%20gov) | SC Dept of Health and Environmental Control |
| Debora Teixeira, DDS, MEd | Oral Health Program Administrator | Division of Health Promotion & Disease Prevention | *(802) 652-4115* | Debora.Teixeira@vermont.gov | Vermont Department of Health |

**Table 2.** Other Consultations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Title** | **Affiliation** | **Phone** | **Email** | **Role** |
| Alison Amoroso, M.Ed. | Consultant to the Associate Director for Science | Deloitte Consulting | *(470) 495-2521* | Uxl8@cdc.gov | Survey methodology advisor |
| Mei Lin, MD, MPH | Epidemiologist | Division of Oral Health, NCCDPHP, CDC | *(770) 488-5109* | Hru3@cdc.gov | Surveillance advisor |
| Kathy Phipps, DrPH | Data & Oral Health Surveillance Coordinator | Association‌ of‌ State‌ &‌ Territorial‌ Dental‌ Directors | *(805) 771-9788* | kphipps@astdd.org | Basic Screening Survey adviser |

## *A9. Explanation of Any Payment or Gift to Respondents*

Respondents do not receive an incentive.

## *A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent*

NCCDPHP’s Information Systems Security Officer has reviewed this submission and has determined that the Privacy Act does not apply. States collect child-level screening data that may include certain PII (e.g., child’s DOB, SSID) using the screening form (Attachment 2f) in paper or data entry tools such as Epi Info or MS Access. Data collection is not through an IT or web-based data collection system.

Two-levels of BSS data collection require privacy protection: child-level data and state-level aggregated data.

*States collect child-level data.* A child’s name is necessary at several points in the BSS process:

* To compile a roster of students to screen to verify the unique, randomly generated school or state DOE SSID.
* To verity consent and ensure that screening is provided to the correct child for whom consent was given.
* To provide screening results to parents or caretakers.
* To provide information to the school for follow-up if urgent dental care needs are found.

The child’s name is not entered onto the screening form (Attachment 2f).

Once the screening is completed, the results of the clinical observation (Attachment 2g) are placed in a sealed security envelope with the child’s name on it taken onsite from the class roster or the consent form and given to the teacher for distribution to the child to take home to the parent/caretaker. Only if the child is in need of urgent care, the screener informs the school contact to ensure follow-up with the child (Attachments 2a and 2g).

Some states collect the child’s DOB to calculate age, but only their age is retained in the analysis file. States might retain DOB in the original collection form in order to verify the age calculation.

States that obtain child-level demographics from DOE are instructed to inform the school to include SSID on the class roster. On the screening day at the school, the screener enters the SSID onto the screening form. The SSID is then used at DOE through its secured data system to link the oral health screening data with DOE maintained demographic data. Per BSS protocol, before sending the linked dataset to the state oral health program, DOE removes SSID from the dataset once the data linkage is complete.

Screeners are instructed to mail the paper consent forms, any paper instruments, and any other documentation from the screening via USPS or other state agency designated secure delivery service to the state health department designated contact, and to return or destroy the class roster.

The protocol specifies that along with training in clinical observation, screeners also be trained in privacy protection and their roles in protecting children’s privacy and using the data entry system.

BSS protocol instructs states to use a password-protected platform and encrypted files when handling PII. Per protocol, the system should be monitored by the agency or state security office and accessible only by authorized program personnel and IT administrators trained in data privacy protection and security. State programs are also instructed to store all paper forms in locked cabinets accessible only by program personnel. The consent form contains information on privacy protections (see Attachment 2e) and specifies that participation in the survey is voluntary.

After data entry, cleaning and generation, BSS recommends that only de-identified data are maintained in the state secured electronic data system, and that no data are stored on any partner systems. BSS instructs states to develop a data management plan (DMP) that includes information on methods to assure privacy and data security. CDC-funded states (20) are required to submit their DMP to CDC for approval.

*CDC collects state-aggregated data from states through ASTDD.* ASTDD includes an electronic data form (Attachment 2i) with an email inviting states to submit BSS data (Attachments 2h). The email specifies that states should provide only de-identified state-aggregated data.

States email the completed electronic data form (Attachment 2i) to ASTDD, where ASTDD’s Data and Surveillance Coordinator first verifies the data, then stores it on ASTDD’s secure server in Access/Excel format. Neither the name nor email address of the person submitting the data is included in the database. ASTDD’s secure server and the BSS database are password protected, and only the Executive Director, Grants Manager and Data Consultants have access. The database will be stored on ASTDD’s server for 10 years.

ASTDD emails the data to CDC as Excel file. CDC does not maintain or disseminate information in identifiable form; the data it receives do not include any identifiable information from children or state personnel. CDC posts the data set on its public OHD website, which adheres to all federal, HHS, and/or CDC IT security policies and procedures. CDC retains the data as long as the data are being used for surveillance and program needs. ASTDD is required to complete transmission of data records to CDC before the funding award terminates.

## *A11. Institutional Review Board (IRB) and Justification for Sensitive Questions*

It has been determined that this project is not human subjects research and does not require IRB review (Attachment 4). Information about tooth decay and sealants is vital for protection of public health. Demographic information allows state programs, federal agencies, and other public health entities to assess and monitor disparities, allocate resources, and implement effective programs to address specific populations at higher risk of tooth decay.

BSS is a voluntary surveillance tool. The BSS protocol provides letters states can use to enable parents or caretakers to opt out or deny consent (Attachment 2e).

## *A12. Estimates of Annualized Burden Hours and Costs*

Based on an analysis of current BSS data submitted to CDC[4](#_ENREF_4) and consultations with the states, CDC projects that approximately 34 states, including 20 states currently funded by CDC, will conduct one Third-Grade BSS during the three years for which this approval is being sought; among those 34 states, an estimated 10 states will also survey children enrolled in Head Start, and 11 will survey an additional grade.

The annualized estimated burden over the three years of this request is based on consultations with the states and applied to a total estimated participating sample size of 150,370 children across the 34 states, 2,890 schools or Head Start programs, and 301 screeners. On average, one screener per 500 children is estimated.

As summarized below in Tables A12-1 and A12-2, the estimated total annualized burden hours are 40,207 for the 34 states, with an average of 1,183 per state; the estimated total hours over the three years are 120,621. The corresponding total annualized cost to respondents is $887,462, with an average of $26,101 per state; the total 3-year cost is $2,662,386.

However, actual burden may range widely as a result of program decisions and local variables: number of grades surveyed, sample size, type of consent, ease of collaborating with schools or DOEs, and sample complexity if certain regions or populations are oversampled.

The annualized cost is based on consultation with state oral health programs, with an average ranging from $13,512 to $35,894 per state, and burden hours from 431 to 2,570 hours.

In addition to typical survey activities, the following are included in the estimation of time burden: students’ travel to and from class, school-level logistical planning and obtaining consent, state health department collaboration with DOE, and screening site setup.

Average hourly wages are calculated using data from the US Department of Labor, [Bureau of Labor Statistics](https://www.bls.gov/oes/current/oes_nat.htm) and align with the wages that states reported during consultation. See the summaries in Tables A12-2 below. The wage for the screeners is calculated using an average of dentist and hygienist wages because states generally report using either one or both.

**Table A12-1:** Estimated Annualized Burden Hours

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **No. of Respon-dents** | **No. of Responses per Resp-ondent** | **Avg Burden Hours per Response** | **Total Burden Hours** |
| Child | Screening form | 150,370 | 1 | 5/60 | 12,531 |
| Parent or caretaker | Consent | 150,370 | 1 | 1/60 | 2,506 |
| Screener | Screening form | 301 | 1 | 666/60 | 3,341 |
| School | Participation form | 2,890 | 1 | 68/60 | 3,275 |
| State Official | Data Submission form | 34 | 1 | 32,742/60 | 18,554 |
| Total |  |  |  |  | 40,207 |

**Table A12-2:** Estimated Annualized Burden Costs

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **No. of Respon-dents** | **Total Burden Hours** | **Avg. Hourly Wage** | **Total Cost** |
| Child | Screening form | 150,370 | 12,531 | NA | NA |
| Parent/ caretaker | Consent | 150,370 | 2,506 | $18.58 | $46,561 |
| Screener | Screening form | 301 | 3,341 | $55.5 | $185,576 |
| School/site | Participation form | 2,890 | 3,275 | $27.88 | $91,307 |
| State Official | Data Submission form | 34 | 18,554 | $30.40 | $564,018 |
| Total |  |  | 40,207 |  | $887,462 |

## *A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers*

The total burden for other costs is $81,138 annualized (3-year total $243,412) for the estimated 34 states. The BSS is free for schools and families. No special hardware or software is required to generate, maintain, or store the information collected. Data entry is basic, and Epi Info, if used, is free. Statistical software is routinely used by state health departments and therefore is not an added burden.

The BSS requires oral health screening supplies and travel to and from schools by the screeners. Supply and travel costs are calculated using a combination of state input and a model budget based on ASTDD’s technical assistance experience (see Attachment 5).

**Table A13.** Estimated Other Annualized Cost to the Respondents

| **Item** | **Cost per unit** | **Number of units** | **Total** |
| --- | --- | --- | --- |
| Disposable screening supplies | $0.28 per child | 150,370 children | $42,104 |
| Other screening supplies | $33.67 per screener | 301 screeners | $10,134 |
| Travel to schools/sites | $10 per school/site | 2,890 schools/sites | $28,900 |
| **Total Other Costs** |  |  | $81,138 |

## *A14. Annualized Cost to the Federal Government*

The average annual cost to the federal government for this data collection is $42,233 per year for a three-year total of $126,699. Costs include personnel costs of federal employees and contractors as well as the cost of funding of CDC’s cooperative agreement with ASTDD.

The personnel costs of CDC staff and contractors are to 1) review, format, upload, and maintain OHD web publishing for BSS data; 2) use the data to evaluate performance of CDC oral health funding recipients; and 3) provide technical consultations to facilitate periodic revisions of the BSS protocol and related materials. The average annualized costs are $8,869 to federal staff and $2,364 to contractors, for three-year totals of $26,607 and $7,092.

The average annualized cost to ASTDD for this data collection is $31,000, for a three-year total of $93,000. ASTDD’s costs are to 1) provide technical guidelines and assistance to states related to BSS planning, sampling, implementation, data analyses, and reporting; 2) conduct periodic review of and update to the BSS protocol and related materials; 3) request and verify state-aggregated BSS data and compile and submit the data to CDC.

There are no other operational or capital expenses. See table A14 for a summary.

**Table A14.** Estimated Annualized Cost to the Federal Government

|  |  |
| --- | --- |
| **Type of Government Cost** | **Annualized Cost** |
| Federal Staff |  |
| GS-13 health scientist at 2.5% FTE | $2,643 |
| GS-13 epidemiologist at 2.5% FTE | $2,643 |
| GS-14 health scientist at 2.5% FTE | $3,583 |
| Data Contractor (North Grumman, Atlanta, Georgia) | $2,364 |
| ASTDD through cooperative agreement funding | $31,000 |
| Total | $42,233 |

Federal pay table for Atlanta effective January 2019.

## *A15. Explanation for Program Changes or Adjustments*

This is the first request for OMB review of an existing collection without approval.

## *A16. Plans for Tabulation and Publication and Project Time Schedule*

States perform data entry, clean the data, determine sampling design parameters, generate sampling weights, and conduct analysis. ASTDD provides guidance on how to select a sample and how to weight and analyze the BSS data (see Attachments 2b and 2c, also available at https://www.astdd.org/basic-screening-survey-tool/#children).

Analysis plans vary by state and depend on which variables a state decides to monitor and its capacity to analyze the data collected. Basic analyses include calculation of prevalence estimates and 95% confidence intervals for NOHSS indicators on dental caries and sealants. Additionally, states may use chi-square tests and regression analyses to assess disparities and trends over time.

ASTDD collects state-aggregated data and reviews it for compliance with criteria for NOHSS before submitting it to CDC for publication on the OHD website. The criteria require that data come from a statewide representative probability sample and be weighted for the sampling scheme and non-response and that variance estimates and confidence intervals be calculated to account for stratification and cluster sampling effects.

CDC publishes state-aggregated BSS data for all participating states on its public-facing OHD portal (<https://www.cdc.gov/oralhealthdata>) within one month of receiving the data from ASTDD. The portal is interactive and currently provides state prevalence estimates of the three clinical indicators (caries experience with treated or untreated caries, untreated tooth decay, dental sealants), NSLP data, response rates, and a brief description of each state’s BSS method. To facilitate data comparison and customized data reporting, the data can be viewed by indicator, state, year, or grade; displayed in visual maps, graphs, and tables; and exported. CDC anticipates posting additional BSS data, including prevalence estimates of urgent dental care need and prevalence estimates of clinical indicators by school-level percentage of children eligible for NSLP.

CDC uses state-submitted BSS data to monitor state oral health surveillance, to evaluate the performance of funded states, and for presentation at conferences and meetings.

Within a year of data collection, states publish BSS data in publicly accessible formats and share data with policy makers, stakeholders, and oral health advocates. The ASTDD website provides links to state oral health programs, and BSS reports (https://www.astdd.org/state-programs/).

BSS implementation can span 1–2 years, which encompass planning, sample calculations, training, data collection, validation, and analysis. Implementation may take even longer in states that require active consent, have difficulty getting demographic data, or administer BSS to more than one grade. ASTDD and CDC recommend that states conduct a BSS at minimum for third graders at least every 5 years. The BSS does not follow a formal calendar or recur with consistent frequency; however, the 20 CDC funded states, as a condition of their award, implement at least one Third Grade BSS, submit prevalence data to ASTDD, and disseminate verified data through publicly available media during the five-year project period. Funded states also must use timely BSS data both as a primary data source for their program planning and evaluation and as evidence of surveillance capacity.

Although ASTDD and CDC encourage states to submit data to ASTDD as soon as analysis is complete, ASTDD formally collects the data annually. ASTDD validates and prepares data within one month of receipt and, as a condition of its funding, submits verified data to CDC quarterly if new data are available.

**Table A.16**. Estimated Time Schedule for Aggregate State Data Collection

|  |  |
| --- | --- |
| **Activity** | **Timeline** |
| States plan and implement BSS | 1–2 years (screening is during the school year) |
| States clean and analyze data | Within 3 months after data collection |
| ASTDD request to state programs emailed | Every September |
| ASTDD sends reminders | Every October |
| States submit aggregated data to ASTDD | Throughout the year when new data is available, and analysis is completed |
| ASTDD verifies data for NOHSS criteria | Within 1 month after receipt of state’s data |
| ASTDD prepares data for interoperability | Within 1 month after receipt |
| ASTDD sends data set to CDC | Within 1 month after receipt |
| CDC publishes data on oral health data portal | Within 1 month after receipt of data from ASTDD |
| States publish and disseminate oral health document (funded states) | Within one year of collection |
| ASTDD posts state reports | Within one year of collection |
|  |  |

## *A17. Reason(s) Display of OMB Expiration Date is Inappropriate*

The display of the OMB expiration date is appropriate.

## *A18. Exceptions to Certification for Paperwork Reduction Act Submission*

There are no exceptions to the certification***.***

REFERENCES

1. Malvitz DM, Barker LK, Phipps KR. Development and status of the National Oral Health Surveillance System. *Prev Chronic Dis*. 2009;6(2):A66.

2. Council of State and Territorial Epidemiologists. State-based oral health surveillance systems: conceptual framework and operational definition. 2013. Available: <https://www.cste.org/page/CSTEPublications>. Accessed: August 23, 2019.

3. Council of State and Territorial Epidemiologists. Position Statement 15-CD-01: Revision to the National Oral Health Surveillance System (NOHSS) Indicators 2015. Available: <http://www.cste.org/?page=PositionStatements>. Accessed: August 23, 2019.

4. Centers for Disease Control and Prevention. Oral Health Data. Available: <http://www.cdc.gov/oralhealthdata/>. Accessed: August 23, 2019.