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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–23FJ]

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 ''Evaluating Deep Learning Algorithm Assessment of Digital Photographs for Dental Public Health Surveillance'' 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 June 5, 2023 to obtain comments from the public and affected agencies. CDC received two comments. 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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. 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

Evaluating Deep Learning Algorithm Assessment of Digital Photographs for Dental Public Health Surveillance—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

By age 19, 57% of U.S. adolescents have experienced tooth decay and 17% have at least one decayed tooth needing treatment. Prevalence of untreated tooth decay among non-Hispanic Black and Mexican American adolescents is about 30% higher than among non-Hispanic White adolescents, and among low-income, almost twice the prevalence of higher-income adolescents. Untreated tooth decay will not resolve and can cause pain, infection, and difficulties in learning. Poor oral health in youth is associated with both lower school attendance and grades. More than 34 million school hours are lost annually due to unplanned dental visits for acute care needs. Reducing the percentage of youths who have experienced tooth decay and the percentage with untreated tooth decay are national health goals (Healthy People 2030).

There are two highly effective interventions to prevent tooth decay. Dental sealants prevent about 80% of cavities over two years in the permanent molars where about 90% of tooth decay occurs. Fluoride can prevent decay in permanent teeth by 15% to 43% per year depending on mode of delivery. Although the American Dental Association recommends dentists provide topical fluoride and dental sealants to youth at risk for caries, uptake of these services is low with about 20% of low-income youth receiving them during an annual dental visit. Access to these preventive services as measured by dental sealant prevalence and receipt of preventive dental services among low-income children are national health goals.

The Centers for Disease Control and Prevention (CDC) has collected national data on caries, sealant, and fluorosis prevalence in the National Health and Nutrition Examination Survey (NHANES) for over 30 years and has supported State oral health programs to collect data on caries and sealant prevalence through cooperative agreements since 2001. Twenty States are currently funded from September 2018 to August 2023 by Actions to Improve Oral Health Outcomes, CDC–RFA–DP18–1810. Collecting these data can be resource intensive as they are obtained through visual/tactile examinations conducted by dental professionals. These data, however, have enabled Federal and State agencies to: (1) prioritize groups at elevated risk for enhanced prevention efforts; (2) monitor trends in children's oral health status and disparities; (3) inform planning, implementation and evaluation of effective oral health interventions, programs, and policies; (4) measure progress toward Healthy People objectives; and (5) educate the public and policy makers regarding cross-cutting public health programs. Having local estimates of these measures would enable decision-makers to better prioritize communities for programs that increase access to preventive dental services.

CDC is examining the feasibility and validity of using digital photos taken by non-dental professionals, which in turn would be analyzed by deep learning algorithms to assess youth's oral health status in lieu of human examination. This deep learning assessment tool ultimately could be used by public health officials for dental public health surveillance at the local, State, and national level. It is anticipated that obtaining information on dental conditions via deep learning assessment of digital images as opposed to human assessment will: (1) be more cost effective as it would not require dental personnel; and (2) improve the accuracy of assessment due to minimal bias and less confounding factors associated with the examiner (*e.g.,* subjective index and thresholding). This tool also would offer mobility, simplicity, and affordability for rapid and scalable adaptation in community-based settings.

In order to train and test the deep learning algorithms to identify caries, sealants, and fluorosis, data on these conditions as assessed by standardized examiners and corresponding photos are required. The CDC requests a one-year OMB approval for the one-time

collection of oral health data from 1,000 middle- and high-school students in Colorado communities with naturally occurring fluoride in the tap water at or exceeding one part per million. CDC is funding the Colorado State Health Department to implement the collection by recruiting eligible schools and dental examiners, gaining consent, arranging logistics, and collecting de-identified examination data and photos taken by the dental examiners. CDC is funding a national expert in dental public health data collection to train the examiners. Finally, CDC is funding researchers at Purdue University to develop photo-taking protocols and deep learning algorithms to identify dental conditions. Data collected for each student will include: (1) human assessment of fluorosis severity in the six upper anterior teeth, and caries/sealant assessment of the occlusal surfaces of the eight permanent molars; and (2) nine smartphone digital photos of the upper anterior teeth and 24 intraoral camera digital photos of the occlusal surfaces of the eight permanent molars. Digital photos of the teeth and the completed paper screening form will be uploaded to a HIPAA compliant cloud storage box that can only be accessed by examiners and designated CDC researchers with administrative rights. CDC is authorized to collect this information under the Public Health Service Act, title 42, section 247b–14, Oral health promotion and disease prevention; and the Public Health Service Act, title 42, section 301.

CDC proposes using data collected from 750 students to train the deep learning algorithms to assess caries, sealants, and fluorosis and data from 250 students to evaluate the accuracy of the algorithms in terms of agreement with standardized examiner assessment. Manuscripts on: (1) the methodologies used to ensure sufficient photo quality when taken under field conditions; and (2) the performance of the deep learning algorithms will be submitted to peer-reviewed journals. The deep learning tool, if sufficiently accurate, will be piloted in one data collection cycle of NHANES that is administered by the National Centers for Health Statistics (NCHS). Ultimately, the tool would be shared with the State and local oral health programs and other pertinent partners.

CDC requests OMB clearance for data collection for one year. The total estimated annualized burden hours are 827. There are no costs to student respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Child	Screening/photo/form	1,000	1	16/60
Parent or caretaker	Consent	1,000	1	1/60
Screener	Screening/photo form includes training, travel, screening and photos, and ongoing technical assistance.	6	1	90/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health; Notice of Charter Renewal

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the renewal of the charter of the Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH).

FOR FURTHER INFORMATION CONTACT: Maria Strickland, M.P.H., Designated Federal Officer, Board of Scientific Counselors, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, 400 7th Street SW, Suite 5W, Constitution Center, Washington, District of Columbia 20024. Telephone: (202) 245–0649; Email: *MStrickland2@cdc.gov.*

SUPPLEMENTARY INFORMATION: CDC is providing notice under 5 U.S.C. 1001–1014. This charter has been renewed for a two-year period through February 3, 2025.

The Director, Office of Strategic Business Initiatives, Office of 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.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the 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–2016–D–0643]

Labeling for Biosimilar and Interchangeable Biosimilar Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Labeling for Biosimilar and Interchangeable Biosimilar Products.'' This draft guidance is intended to help applicants develop draft labeling for proposed