

## I. Background

Vaccination is one of the most important public health achievements of the 20th century. Vaccines save lives and improve the quality of life by reducing the transmission of infectious diseases. However, the benefits of vaccination are not realized equally across the U.S. population. Adult vaccination rates remain low in the United States and far below Healthy People 2020 targets. In an average year, 95 percent of the approximately 20,000 to 50,000 Americans who die as a result of vaccine-preventable disease are adults, depending on the severity of annual influenza outbreaks. Substantial racial and ethnic disparities also exist.

The National Vaccine Plan (NVP), released in 2010, provides a guiding vision for vaccination in the United States for the decade 2010–2020. While the NVP serves as a roadmap for protecting all U.S. residents from vaccine-preventable diseases, historically low vaccination rates in the adult population and unique attributes of the adult vaccination delivery system highlight the need for focused attention on adult vaccination.

The NAIP is a five year national plan with an emphasis on coordination and prioritization of what federal and non-federal partners can accomplish together. Given this time frame, the NAIP will be informed by emerging science and changing circumstances. The NAIP also aims to leverage the unique opportunity presented by the passage and ongoing implementation of the Affordable Care Act.

Through their analysis and discussion, NVPO identified four major goals:

- Goal 1: Strengthen the adult immunization infrastructure
- Goal 2: Improve access to adult vaccines
- Goal 3: Increase community demand for adult immunizations
- Goal 4: Foster innovation in adult vaccine development and vaccination related technologies

Within each goal, the NAIP details measurable objectives and sub-objectives.

## II. Request for Comment

NVPO requests input on the draft report and draft recommendations. In addition to general comments on the draft NAIP, NVPO is seeking input on efforts or barriers to adult immunizations not represented in the report where HHS efforts could advance adult immunization efforts. Please limit your comments to six (6) pages.

## III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests in adult immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

- general public;
- advocacy groups, non-profit organizations, and public interest organizations;
- academics, professional societies, and healthcare organizations;
- public health officials and immunization program managers;
- provider groups including all physician and non-physician providers that administer immunization services to adults, including pharmacists; and
- representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed six (6) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

Dated: January 27, 2015.

**Bruce Gellin,**

*Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day–15–0964]

### Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and

instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

### Proposed Project

Interventions to Reduce Shoulder MSDs in Overhead Assembly (OMB No. 0920–0964, expires 4/30/2015)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. Under Public Law 91–596, sections 20 and 22 (Section 20–22, Occupational Safety and Health Act of 1970), NIOSH has the responsibility to conduct research to advance the health and safety of workers. In this capacity, NIOSH proposes a three year extension

for a study to assess the effectiveness and cost-benefit of occupational safety and health interventions to prevent musculoskeletal disorders (MSDs) among workers in the Manufacturing (MNF) sector.

An extension is requested for this ICR because only one quarter of the necessary sample size was enrolled during the previous cycle. The eligible employee population will be expanded to include other Departments at the facility to achieve the necessary sample size. It is believed that the targeted number of interventions, which was not achieved in the previous year, can be achieved by expanding to additional Departments.

Musculoskeletal disorders (MSDs) represent a major proportion of injury/illness incidence and cost in the U.S. Manufacturing (MNF) sector. In 2008, 29% of non-fatal injuries and illnesses involving days away from work (DAW) in the MNF sector involved MSDs and the MNF sector had some of the highest rates of MSD DAW cases. The rate for the motor vehicle manufacturing sub-sector (NAICS 3361) was among the highest of MNF sub sectors, with MSD DAW rates that were higher than the general manufacturing MSD DAW rates from 2003–2007.

In automotive manufacturing, overhead conveyance of the vehicle chassis requires assembly line employees to use tools in working postures with the arms elevated. These postures are believed to be associated with symptoms of upper limb discomfort, fatigue, and impingement syndromes (Fischer et al., 2007). Overhead working posture, independent of the force or load exerted with the hands, may play a role in the development in these conditions.

Recent studies suggest a more significant role of localized shoulder muscle fatigue in contributing to these disorders. Fatigue of the shoulder muscles may result in changes in normal shoulder kinematics (motion) that affect risk for shoulder impingement disorders (Ebaugh et al., 2006; Chopp et al., 2010).

The U.S. Manufacturing sector has faced a number of challenges including an overall decline in jobs, an aging workforce, and changes in organizational management systems. Studies have indicated that the average age of industrial workers is increasing and that older workers may differ from younger workers in work capacity, injury risk, severity of injuries, and speed of recovery (Kenny et al., 2008; Gall et al., 2004; Restrepo et al., 2006). As the average age of the industrial population increases and newer systems of work organization (such as lean manufacturing) are changing the nature of labor-intensive work, prevention of MSDs will be more critical to protecting older workers and maintaining productivity.

This study will evaluate the efficacy of two intervention strategies for reducing musculoskeletal symptoms and pain in the shoulder attributable to overhead assembly work in automotive manufacturing. These interventions are, (1) an articulating spring-tensioned tool support device that unloads from the worker the weight of the tool that would otherwise be manually supported, and, (2) a targeted exercise program intended to increase individual employees' strength and endurance in the shoulder and upper arm stabilizing muscle group. As a primary prevention strategy, the tool support engineering control approach is preferred; however, a cost-efficient opportunity exists to concurrently evaluate the efficacy of a preventive exercise program intervention. Both of these intervention approaches have been used in the Manufacturing sector, and preliminary evidence suggests that both approaches may have merit. However, high quality evidence demonstrating their effectiveness, by way of controlled trials, is lacking.

This project will be conducted as a partnership between NIOSH and Toyota Motors Engineering & Manufacturing North America, Inc. (TEMA), with the intervention evaluation study taking place at the Toyota Motor Manufacturing Kentucky, Inc. (TMMK)

manufacturing facility in Georgetown, Kentucky.

The prospective intervention evaluation study will be conducted using a group-randomized controlled trial multi-time series design. Four groups of 25–30 employees will be established to test the two intervention treatment conditions (tool support, exercise program), a combined intervention treatment condition, and a control condition. The four groups will be comprised of employees working on two vehicle assembly lines in different parts of the facility, on two work shifts (first and second shift).

Individual randomization to treatment condition is not feasible, so a group-randomization (by work unit) will be used to assign the four groups to treatment and control conditions.

Observations will be made over the 10-month study period and questionnaires will include the Shoulder Rating Questionnaire (SRQ), Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, a Standardized Nordic Questionnaire for body part discomfort, and a Work Organization Questionnaire. In addition to the monthly questionnaires, a shoulder-specific functional capacity evaluation test battery will be administered pre- and post-intervention, to confirm the efficacy of the targeted exercise program in improving shoulder capacity.

In summary, this study will evaluate the effectiveness of two interventions to reduce musculoskeletal symptoms and pain in the shoulder associated with repetitive overhead work in the manufacturing industry. The evidence-based prevention practices that may result from this associated research project will be disseminated to the greatest audience possible.

NIOSH expects to complete data collection in 2015–2016 and there is no cost to employee respondents, as they will participate in this study during their normal working hours at their regular wage.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Employees .....	PAR-Q (Physical Activity Readiness) .....	125	1	2/60	4
	Shoulder Rating Questionnaire (SRQ) .....	125	10	4/60	83
	Disabilities of the Arm Shoulder and Hand (DASH) .....	125	10	6/60	125
	Standardized Nordic Questionnaire for Musculoskeletal Symptoms.	125	10	4/60	83
	Work Organization Questionnaire .....	125	3	26/60	163

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total .....	.....	.....	.....	.....	458

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-R-245]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by March 9, 2015.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395-5806 or *Email:* [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations; *Use:* The Outcome and Assessment Information Set (OASIS) data set is

currently mandated for use by Home Health Agencies (HHAs) as a condition of participation (CoP) in the Medicare program. Since 1999, the Medicare CoPs have mandated that HHAs use the OASIS data set when evaluating adult non-maternity patients receiving skilled services. The OASIS is a core standard assessment data set that agencies integrate into their own patient-specific, comprehensive assessment to identify each patient's need for home care that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs.

The Office of Management and Budget (OMB) approved the OASIS-C1 information collection request on February 6, 2014. We originally planned to use OASIS-C1 to coincide with the original implementation of ICD-10 on October 1, 2014. However, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) was enacted. This legislation prohibits CMS from adopting ICD-10 coding prior to October 1, 2015. Because OASIS-C1 is based on ICD-10 coding, it is not possible to implement OASIS-C1 prior to October 1, 2015, when ICD-10 is implemented. The passage of the PAMA Act left us with the dilemma of how to collect OASIS data in the interim, until ICD-10 is implemented.

The OASIS-C1/ICD-9 version is an interim version of the OASIS-C1 data item set that was created in response to the legislatively mandated ICD-10 delay. There are five items in OASIS-C1 that require ICD-10 codes. In the OASIS-C1/ICD-9 version, these items have been replaced with the corresponding items from OASIS-C that use ICD-9 coding. The OASIS-C1/ICD-9 version also incorporates updated clinical concepts, modified item wording and response categories and improved item clarity. In addition, the OASIS-C1/ICD-9 version includes a significant decrease in provider burden that was accomplished by the deletion of a number of non-essential data items from the OASIS-C data item set. *Form Number:* CMS-R-245 (OMB control number: 0938-0760); *Frequency:* Occasionally; *Affected Public:* Private sector—business or other for-profit and not-for-profit institutions; *Number of Respondents:* 12,014; *Total Annual*