PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

	Inclusion	Exclusion
Population	• Age 18 and above with symptomatic cervical degenerative disease (*e.g.,* pain, radiculopathy, myelopathy) for all KQs except for KQ1, which includes asymptomatic patients.	• Younger than 18 years. *• Effectiveness and harms of surgery based on patient characteristics, disease characteristics and radiographic characteristics (*e.g.,* age, gender, comorbidities [e.g., comorbid lumbar disease, autoimmune disease, neurological disease, mental illness, Down's syndrome], severity of cervical degenerative disease, Frailty Index, sagittal vertical aspect, degree of kyphosis, prior treatment [*e.g.,* bracing, traction, medications, massage, acupuncture, injections, chiropractic care, spinal manipulation], duration of pain, skill of surgeon). • Patients without cervical degenerative disease. • Nonhumans.
Intervention	• Cervical spine surgery (*e.g.,* discectomy, disc replacement, fusion, arthroplasty, laminectomy, laminoplasty, corpectomy, cervical hybrid surgery, foraminotomy). • Non-surgical treatments (*e.g.,* heat, exercise, acupuncture, drugs, radiofrequency ablation, steroid injections, Botox® for neck pain, psychological strategies [e.g., cognitive behavioral therapy], occupational therapy, multidisciplinary rehabilitation). • Intraoperative neuromonitoring • Imaging to identify symptomatic pseudarthrosis after cervical fusion surgery. • Preoperative MRI to predict neurologic recovery in myelopathy.	• Preoperative imaging using CT or plain films.
Comparators	• Any included intervention • Placebo, waitlist, active control	• Nonoperative intervention versus nonoperative intervention without surgical comparator.
Outcomes	• Pain, sensory function, motor function, gait, quality of life (*e.g.,* VAS, NRS, NDI, SF–36, SF–12, EQ–5Dm, mJOA score, Nurick score, MDI, PROMIS–29, dysphagia scales, return to work). • Fusion rate, reoperation rate • Harms (*e.g.,* withdrawals due to adverse events, serious adverse events, new symptomatic adjacent segment disease, postoperative infection, device failure, ossification of the posterior ligament, development of kyphotic deformity). • Sensitivity and specificity of imaging after cervical fusion surgery.	• Nonvalidated instruments.
Timing	• All time periods.	
Setting	• Inpatient, outpatient, ambulatory surgical centers..	
Study Design	• RCTs, prospective trials and retrospective observational studies with a control group (study N≥50), current systematic reviews for identification of additional studies.	• Pre-post single-arm studies, case series, case reports, systematic reviews published prior to 2007.

CT = computed tomography; EQ–5D = EuroQol–5 dimension instrument; KQ = key question; MDI = myelopathy disability index; MRI = magnetic resonance imaging; mJOA = modified Japanese orthopedic association scale; NDI = neck disability index; NRS = numerical pain rating scale; PROMIS–29 = patient reported outcome measurement information system; RCT = randomized controlled trial; QOL = quality of life; SF = short form health survey (12 or 36 items); VAS = visual analogue scale for pain.

Dated: August 9, 2022.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–21IO]

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 ''Evaluation Reporting Template for National and State Tobacco Control Program'' 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 October 13, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. 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

Evaluation Reporting Template for National and State Tobacco Control Program—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's Office on Smoking and Health (OSH) created the National and State Tobacco Control Program (NTCP) in 1999 to encourage coordinated, national efforts to reduce tobacco-related diseases and deaths. The NTCP provides funding and technical support to state and territorial health departments. NTCP funds 50 states, Washington DC, Puerto Rico, and Guam. NTCP-funded programs are working to eliminate exposure to secondhand smoke, promote quitting among adults and youth, prevent initiation among youth and young adults, and identify and eliminate tobacco-related disparities. To reach these goals, the programs implement state and community interventions, mass-reach health communication interventions, tobacco use and dependence treatment interventions, and conduct surveillance and evaluation.

This information collection project supports the NTCP tobacco program managers, administrators, and evaluators by specifying which information should be included in their annual evaluation reports. Furthermore, the information collected via this form will allow OSH to monitor and evaluate program performance, document facilitators and barriers, lessons learned and promising practices, establish processes to support continuous program improvement and development, and assess the effectiveness and outcomes of the NTCP.

Information will be collected electronically using an Excel spreadsheet tool titled ''Evaluation Reporting Template for National and State Tobacco Control Program'' (ERT). The collection of this information is part of a federal reporting requirement for funds received by NTCP recipients. The information collection form will consolidate information necessary for evaluation of the NTCP.

The data collected through the Evaluation Reporting Template for National and State Tobacco Control Program (ERT) was compared to all other potential evaluation data sources and designed not to duplicate any information collected in other tools. Although other NTCP data collection tools are currently in use to collect data for NTCP (Monitoring and Reporting System for the National Tobacco Control Program; OMB Control No. 0920–1097, Exp. 04/30/2023), these existing data collection tools are focused on financial and programmatic management, program implementation, and performance measurement. By contrast, the ERT will collect process and outcome evaluation findings resulting from individual evaluations designed by each NTCP recipient. Findings will include contextual factors, indicators, lessons learned, and information about health inequities and health disparities.

Recipients will use the ERT for National and State Tobacco Control Program to report information to CDC about their Tobacco Control Program evaluation findings. Each recipient will submit an Evaluation Report template annually. OMB approval is requested for three years. Intended respondents include 53 cooperative agreement recipients. The estimated burden per response is eight hours for each Annual Evaluation Report. The total estimated annualized burden is 424 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State and Territorial Health Department Tobacco Control Program Staff.	Evaluation Reporting Template for National and State Tobacco Control Program.	53	1	8

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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