PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s): Adults with the following chronic pain (defined as pain lasting 12 weeks or longer or pain persisting past the time for normal tissue healing) conditions specified in the Key Questions:

Key Question 1: Nonradicular chronic low back pain
Key Question 2: Chronic neck pain without radiculopathy or myelopathy
Key Question 3: Pain related to primary or secondary osteoarthritis
Key Question 4: Fibromyalgia
Key Question 5: Primary chronic tension headache (defined as 15 or more headache days per month for at least 3 months)
Key Question 6: Patients with any of the five chronic pain conditions

Interventions (All Key Questions)

I. Exercise
II. Psychological therapies
III. Physical modalities
IV. Manual therapies
V. Mindfulness practices
VI. Mind-body practices
VII. Acupuncture
VIII. Functional restoration training
IX. Multidisciplinary/interdisciplinary rehabilitation

Comparators

I. For all Key Questions, subquestion ''a''
  A. Sham treatment
  B. Waitlist
  C. Usual care
  D. Attention control
  E. No treatment
II. For all Key Questions, subquestion ''b''
  A. Non-opioid pharmacological therapy (nonsteroidal anti-inflammatory drugs, acetaminophen, antiseizure medications, antidepressants)
  B. Opioid analgesics
III. Key Questions 1–4, 6, subquestion ''c'': Exercise
IV. Key Question 5, 6, subquestion ''c'': Biofeedback

Outcomes

I. Primary efficacy outcomes (in priority order); we will focus on outcomes from validated measures
  A. Function/disability/pain interference
  B. Pain
II. Harms and adverse effects
III. Secondary outcomes
  A. Psychological distress (including depression and anxiety)
  B. Quality of life
  C. Opioid use
  D. Sleep quality, sleep disturbance
  E. Health care utilization

Timing

I. Duration of followup: Short term (up to 6 months), intermediate term (6–12 months) and long term (at least 1 year); we will focus on longer-term (>1 year) effects where possible
II. Studies with <1 month followup after treatment will be excluded

Settings

I. Any nonhospital setting or setting of self-directed care
II. Exclusions: Hospital care, hospice care, emergency department care

Sharon B. Arnold,

Deputy Director.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*TeamSTEPPS 2.0 Online Master Trainer Course.*''

DATES: Comments on this notice must be received by July 17, 2017.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@ahrq.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

TeamSTEPPS 2.0 Online Master Trainer Course

In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection. As part of its effort to fulfill its mission goals, AHRQ, in collaboration with the U.S. Department of Defense's TRICARE Management Activity, developed TeamSTEPPS® (Team Strategies and Tools for Enhancing Performance and Patient Safety) to provide an evidence-based suite of tools and strategies for training teamwork-based patient safety to health care professionals. TeamSTEPPS includes multiple toolkits, which are all tied to, or are variants of, the core curriculum. TeamSTEPPS resources have been developed for primary care, rapid response systems, long-term care, and patients with limited English proficiency.

The main objective of the TeamSTEPPS program is to improve patient safety by training health care staff in various teamwork, communication, and patient safety concepts, tools, and techniques and ultimately helping to build national capacity for supporting teamwork-based patient safety efforts in health care organizations.

Created in 2007, AHRQ's National Implementation Program trains Master Trainers who have stimulated the use and adoption of TeamSTEPPS in health care delivery systems. These individuals were trained during two-day, in-person classes using the TeamSTEPPS core curriculum at regional training centers across the U.S. AHRQ has also provided technical assistance and consultation on implementing TeamSTEPPS and has developed user networks, various educational venues, and other channel of learning for continued support and the improvement of teamwork in health care. Since the inception of the National Implementation Program, AHRQ has trained more than 6,000 participants to serve as TeamSTEPPS Master Trainers.

Due to the success of the National Implementation Program, which resulted in increased requests for in-person training, AHRQ had been unable to match the demand for TeamSTEPPS Master Training, and wait lists for training at times exceeded 500 individuals.

To address this prevailing need, AHRQ developed TeamSTEPPS 2.0 Online Master Trainer course, which mirrors the TeamSTEPPS 2.0 core curriculum and provides equivalent training to the in-person classes offered through the National Implementation Program.

As part of this initiative, AHRQ seeks to continue to conduct an evaluation of the TeamSTEPPS 2.0 Online Master

Trainer program. This evaluation seeks to understand the effectiveness of TeamSTEPPS 2.0 Online Master Training and what revisions might be required to improve the training program.

This research has the following goals:

(1) Conduct a formative assessment of the TeamSTEPPS 2.0 Online Master Trainer program to determine what improvements should be made to the training and how it is delivered, and

(2) Identify how trained participants use and implement the TeamSTEPPS tools and resources.

The TeamSTEPPS 2.0 Online Master Trainer program is led by Reingold, Inc. This study is being conducted by Reingold's subcontractor, IMPAQ International (IMPAQ). This study is being conducted pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness, and value of health care services and with respect to quality measurement and improvement, 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve this project's goals, AHRQ will train participants using the TeamSTEPPS 2.0 Online Master Trainer program and then survey these participants six months post-training. Each activity is briefly described below.

1. *TeamSTEPPS 2.0 Online Master Trainer Course.* This training program, which includes 13 accredited hours of training, is based on the TeamSTEPPS 2.0 instructional materials and will be delivered online to 3,000 participants. The training will cover the core TeamSTEPPS tools and strategies, coaching, organizational change, and implementation science.

2. *TeamSTEPPS 2.0 Online Post-Training Survey.* This online instrument will be administered to all participants who complete the TeamSTEPPS 2.0 Online Master Training. The survey will be administered six months after participants complete the training program.

This data collection is for the purpose of conducting an evaluation of the TeamSTEPPS 2.0 Online Master Trainer program which was last approved by OMB on November 14th 2014 (OMB Control Number is 0935–0224), and will expire November 30th, 2017. The evaluation is primarily formative in nature as AHRQ seeks information to improve the delivery of the training.

This is a new data collection for the purpose of conducting an evaluation of TeamSTEPPS 2.0 Online Master Trainer program. The evaluation will be primarily formative in nature as AHRQ seeks information to improve the delivery of the training.

The OMB Control Number for the MEPS–HC and MPC is 0935–0118, which was last approved by OMB on December 20th, 2012, and will expire on December 31st, 2015.

To conduct the evaluation, the *TeamSTEPPS 2.0 Online Post-Training Survey* will be administered to all individuals who completed the TeamSTEPPS 2.0 Online Master Trainer program, six months after completing training. The purpose of the survey is to assess the degree to which participants felt prepared by the training and what they did to implement TeamSTEPPS. Specifically, participants will be asked about their reasons for participating in the program; the degree to which they feel the training prepared them to train others in and use TeamSTEPPS; what tools they have implemented in their organizations; and resulting changes they have observed in the delivery of care.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the study. The *TeamSTEPPS 2.0 Online Post-Training Survey* will be completed by approximately 3,000 individuals. We estimate that each respondent will require 20 minutes to complete the survey. The total annualized burden is estimated to be 1,000 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in the study. The total cost burden is estimated to be $45,320.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Training participant questionnaire	3,000	1	20/60	1,000
Total	3,000	N/A	N/A	1,000

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Training participant questionnaire	3,000	1,000	$45.32	$45,320
Total	3,000	1,000	N/A	$45,320

* Based on the mean of the average wages for all health professionals (29–0000) and wages for medical and health services managers (11–9111) for the training participant questionnaire presented in the National Compensation Survey: Occupational Wages in the United States, May 2016, U.S. Department of Labor, Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of

automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Reporting on Health Care Quality and Patient Safety

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of availability—new common formats.

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development of sets of common definitions and reporting formats (Common Formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the release of the Common Formats for Event Reporting—Hospital Version 2.0.

DATES: Ongoing public input.

ADDRESSES: The Common Formats for Event Reporting—Hospital Version 2.0 and the remaining Common Formats can be accessed electronically at the following Web site: *https://www.psoppc.org/psoppc_web/.*

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Choo, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N100B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs—called ''patient safety work product''—allows for the aggregation of data that help to identify and address underlying causal factors of patient safety and quality issues.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care providers may assemble information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs is privileged and confidential. Patient safety work product is used to conduct patient safety activities, which may include identifying events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Act and Patient Safety Rule which can be accessed electronically at: *http://www.pso.ahrq.gov/legislation/.*

Definition of Common Formats

The term ''Common Formats'' refers to the standardized reporting formats—using common language and definitions—that AHRQ has developed for reporting safety concerns from a variety of health care settings and throughout the quality improvement cycle. The Common Formats allow health care providers to collect and submit standardized information and facilitate aggregation of comparable data at local, PSO, regional, and national levels. The formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system; rather, the Common Formats are intended to enhance the ability of health care providers to report information that is standardized both clinically and electronically.

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF), and the public, AHRQ has developed Common Formats for three settings of care—acute care hospitals, skilled nursing facilities, and community pharmacies—in order to facilitate standardized data collection and analysis. The scope of the formats applies to all patient safety concerns including: incidents—patient safety events that reached the patient, whether or not there was harm; near misses or close calls—patient safety events that did not reach the patient; and unsafe conditions—circumstances that increase the probability of a patient safety event.

AHRQ's Common Formats for patient safety event reporting include:

- Event descriptions (definitions of patient safety events, near misses, and unsafe conditions to be reported);
- Delineation of data elements and algorithms to be used for collection of adverse event data to populate the reports; and
- Technical specifications for electronic data collection and reporting.

The technical specifications promote standardization of collected patient safety concerns by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning. They also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PSOPPC) for non-identification and data transmission to the Network of Patient Safety Databases.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began its development by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provided an evidence base to inform construction of the Common Formats. The inventory included many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (*e.g.,* from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems were included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has convened the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS—CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, Indian Health