SUPPORTING STATEMENT

Part A

Identifying and Testing Strategies for Management of Opioid Use and Misuse in Older Adults in Primary Care Practices

Version: *April 1, 2020*

Agency for Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that Make the Collection of Information Necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see https://www.ahrq.gov/policymakers/hrqa99a.html), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care; and

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

Project Overview and Alignment with AHRQ Mission

The project "*Identifying and Testing Strategies for Management of Opioid Use and Misuse in Older Adults in Primary Care Practices*" fully supports AHRQ's mission. The goals of this project are to assess and describe the current prevalence, awareness, and management of opioid use, misuse, and abuse in older adults, and identify gaps and areas of needed research. Additionally, this project will support primary care practices (PCP) in developing and testing innovative strategies, approaches, and/or tools for opioid management within the context of facilitated learning collaboratives, culminating in a Compendium of Strategies for opioid management in older adults in primary care settings.

On average, 130 Americans die every day from an opioid overdose.[1] In 2016, the National Survey on Drug Use and Health (NSDUH) reported over 2 million individuals had an opioid use disorder (OUD), and over 11 million individuals reported misusing prescription opioids – 2 million for the first time.[2] The Department of Health and Human Services (HHS) declared the opioid epidemic a public health emergency in 2017.[3] In response to this national crisis, policymakers passed the bipartisan SUPPORT Act[4] to mitigate the opioid crisis, which was signed into law on October 24, 2018. HHS devised a 5-point strategy to combat the opioid crisis, and the Agency for Healthcare Research and

Quality (AHRQ) has done its part synthesizing the evidence, leveraging data and supporting practices.[5]

While there have been extensive efforts to address the opioid epidemic in general, there has been relatively little attention on the risks and effects of opioid use, misuse and OUD in older adults. The rate of opioid misuse in older adults increased in recent years compared to a decrease over the same time in the non-older adult population.[6] Use of opioids among older adults is associated with increased risk of harm compared to a younger population due to changes in metabolism, physiology, drug-drug interactions, among other reasons.[7] For several decades, opioid medications have been included in the Beers Criteria, a list of inappropriate medications for older adults,[8] for whom the risk of harm is often greater than the benefit. A recent Healthcare Cost and Utilization Project (HCUP) report by AHRQ provides evidence of this risk of harm by documenting a significant increase in opioid-related inpatient admissions and emergency department visits among older adults between 2010 and 2015, paralleling the corresponding increase in use of opioids in Part D Medicare pharmacy data.[9] The majority of opioid prescriptions provided to older adults are written by primary care clinicians,[10] and older adults' chronic pain is commonly managed in primary care settings. Therefore, any strategy designed to address opioid use, misuse, and abuse in older adults must be a good fit for the typical PCP context (e.g., mapping onto workflows).

Strategies for managing opioid use are not one-size-fits-all; rather their effectiveness depends on how well they address the specific concerns and conditions of patients and how providers apply those strategies (to whom and when). Many conditions that cause chronic pain are more common in older adults than in younger adults[11], and opioids—and certain specific opioids— are more effective for treating some of these conditions than others. The risks of adverse medication consequences also differ for older adults, including falls, respiratory depression, negative cognitive effects, hazardous drug-drug interactions (e.g., concurrent prescriptions for opioids and benzodiazepines), and poorly coordinated care, among others.[12,13,14] How patients presenting with pain are treated also differs significantly from one prescriber to another. Provider practices differ according to patient characteristics including age, racial/ethnic status, geographic region of residence, gender, etc.[15,16,17,18] Understanding how pain in older adults is treated in practice, as well as the risks and benefits of prescribing opioids and other medications to older adults is therefore a necessary initial step in our project.

Project Goals and Data Sources

Through this project, AHRQ is addressing the gap in knowledge around opioid use in older adults in primary care settings. To accomplish this we are synthesizing what is known about the development and testing of innovative strategies, approaches, and/or tools for opioid management of older adults with pain on opioid medication, and/or opioid use disorder.

The goals of this project are to:

1. Assess and describe the current prevalence, awareness, and management of opioid use, misuse and abuse in older adults in PCPs in order to **identify gaps and areas of needed research**.

2. **Support PCPs in developing and testing innovative strategies, approaches, and/or tools** for opioid management within the context of facilitated learning collaboratives.

3. **Produce a Compendium** of new and existing strategies, tools, and approaches to support the management of opioid use, misuse and abuse in older adult in primary care settings.

To achieve the goals of this project the following data collections will be implemented:

1. We will conduct a **thorough environmental scan** to identify existing opioid management strategies, resources, and tools for primary care clinicians. It will consist of targeted searches of specific organizations' websites on geriatrics (e.g., Gerontological Society of America), pain (e.g., NIH Pain Consortium Centers of Excellence in Pain Education), opioid tools (e.g., CDC, AHRQ, National Academy of Medicine, AHRQ CDS Connect), and other known resource pages (e.g., Oregon Pain Guidance). We will also conduct a **search of the peer-reviewed and gray literature** to identify recent and relevant evidence, existing strategies, resources and tools.

2. We will conduct a **web-based survey of primary care clinicians (Attachment A)** who care for older adults. The purpose of the survey is to assess primary care clinician experiences caring for older adult patients with chronic pain on opioids. The survey will be sent to 5,000 randomly selected primary care clinicians and will address the following research questions:

   a. How have clinician experiences been providing care for patients with chronic pain on long-term opioid therapy? How confident are primary care providers in their ability to provide care for older adults using opioids? What approaches do primary care providers use in providing care for older adults using opioids?

   b. Which resources do primary care providers have to provide care for older adults with chronic pain on long-term opioid therapy? Which resources do they feel are lacking?

   c. How do clinician experiences and reported availability of resources vary by provider and practice characteristics?

3. We plan to conduct an **informal interview with nine exemplar practices** that have developed and/or are implementing innovative approaches to managing opioid medications for chronic pain, particularly relevant for **older adults**. The following questions will help guide the discussion:

   a. Would you please take a few minutes to describe your approach or strategy again?

   b. Why did you initiate this strategy? What concern were you hoping to address?

   c. How did you roll this strategy out, barriers (specific implementation strategies)? What challenges did you encounter and how did you overcome them?

      d.   What additional resources or staff training were required to implement?

      e.   What has been the patient response?

      f.   How has implementing this strategy impacted patient outcomes?

      g.   What metrics/data did you collect to either prepare for or monitor your innovation?

To identify the exemplar practices, we posted a 45-day notice in the Federal Registry.[19] The Request for Information stated that ARHQ is interested in all innovative approaches that address the opioid management concerns in older adults, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed. The strategies and approaches could come from a variety of health care settings including but not limited to home health care organizations, PCPs, skilled nursing care settings, emergency departments and inpatient care. Other sources of these strategies might include health care payers, accountable care organizations, and organizations that provide external quality improvement support.

From the responses to the Federal Registry notice, the team will select the nine most relevant, innovate strategies and conduct informal telephone interviews with practices that submitted entries.

4. Participating learning collaborative practices will be asked to implement strategies related to each of the key areas on the continuum: prevention, management and treatment of opioid use, misuse and OUD in older adults. **We will collect primary data via observations, interviews, and a survey, and secondary data including practice and learning collaborative documents.** The following data collection activities are the proposed:

    1. Primary Data

      a. **PCP Clinical Staff Survey (Attachment B).** A brief web-based survey will be emailed to all clinical staff participating in the learning collaborative at baseline before starting implementation and approximately 15- months later. We assumed 20 clinical staff per clinic site, and 24 clinics for a total of 480 staff.

      b. **Interviews**. In-depth interviews will occur with up to three staff at each health care organization participating in the learning collaborative, for a total of up to 72 individuals. The evaluation team will conduct these interviews with:

         i.   Quality Improvement (QI) champion for the initiative in the clinics at baseline, mid-point and post-implementation **(Attachment C)**

         ii. Two additional staff (e.g. clinician, information technology analyst, behavioral health specialist) per organization (mid-point and post-implementation). **(Attachment D)**

      c. **Self-Assessment.** The QI champion will complete a self-assessment tool at baseline. A similar tool is used in the Six Building Blocks program[20],

and Centers for Disease Control (CDC) Opioid QI Collaborative (**Attachment E)**. This tool is for clinics or health systems to assess the status their QI efforts to improve opioid prescribing, and the extent to which care is consistent with the CDC Opioid Prescribing Guidelines.

d. **Quality Improvement Measures**. Each clinic will report quarterly on the QI measures (see Attachment F). The QI measures include both process and outcome measures. Process measures are reflective of recommended clinical strategies or tools being implemented, and outcome measures examine intermediate outcomes. A data analyst at each organization will provide aggregate reports of the specified QI measures to the evaluation team on a quarterly basis over the course of a 15-month period. The QI measures are measures of opioid prescribing that are critical for understanding the potential improvements in opioid prescribing in implementing the strategies. The prioritized measures to monitor improvements in recommended prescribing practices could include the following:

    i.   Number and percentage of clinical staff that completed training on opioids and older adults

    ii.   Number and percent of patients who are on opioid medication

    iii. Number and percentage of patients who are on opioid medication for pain

    iv.   Number of patients on long-term opioid therapy (LTOT)

    v.   Number of patients tapered off LTOT/discontinued opioids

    vi.   Number of older adult patients on LTOT

    vii. Number and percentage of patients in which the was used PEG with older adults to assess pain and function

    viii. Percentage of older adult patients on LTOT who are on greater than 50 morphine milligram equivalents (MMEs)

    ix.   Percentage of older adult patients on LTOT who are co-prescribed a benzodiazepine

    x.   Percentage of older adult patients on LTOT who had the prescription drug monitoring program (PDMP) checked

    xi.   Percentage of older adult patients on LTOT who have had a urine drug screen

    xii. Number and percentage of providers assessed older adult patients for OUD

    xiii. Of the older adult patients with OUD, the percentage that are prescribed or referred to MAT

    xiv. Percentage of older adults patients on LTOT who are prescribed naloxone

      xv.   Number of BH providers engaged in pain management/opioid use

   2. Secondary Data

     a. **Practice documents.** Secondary data will be provided by the QI champion at each organization at the end of the implementation. Documents that are relevant to the project and compiled as part of routine business practice, will be provided to the evaluation team by the QI champion at each practice. Examples of practice documents include:

        i.   A copy of newly recommended policy and procedures for caring for older adults.

        ii.   Meeting notes from kickoff with clinicians for how they are going to improve care and how they are going to implement these strategies.

        iii.   Revised treatment agreements tailored to older adults (i.e., pain contract).

        iv.   New patient education materials for older adults and/or their caregivers.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

The purpose of the proposed data collection effort is to 1) assess and describe current perceptions of the challenges associated with managing opioid use, misuse and abuse in older adults; and 2) create a final, public-facing Compendium of Strategies for the management of opioid use, misuse and abuse in older adults in primary care settings.

The evaluation of the strategies implemented by learning collaborative PCPs is a hybrid type III implementation-effectiveness design.[21] The data collected will help the project team: 1) understand the feasibility and effectiveness of implementing the strategies on workflow and processes, 2) illustrate the effectiveness of the strategies on intermediate outcomes, 3) recommend changes or improvements to the strategies tailored to needs and workflow of specific practices, and 4) culminate in the development of a public-facing Compendium of Strategies. The data collection effort will provide feedback that will inform the final version of a Compendium of tools and resources for the prevention, management and treatment of opioid use, misuse and abuse in older adults. The Compendium content will be driven by the findings, along with the concepts outlined in the Six Building Blocks of Opioid Management as the framework. The Six Building Blocks study, funded by AHRQ, clearly demonstrated that changes in clinic systems can result in significant changes in opioid prescribing.[22] We will identify and adapt examples of how each building block can be applied uniquely to older adults' care in the following graphic.

Adaptations of the 6BBs Change Framework for Older Adults

Six Building Blocks	Adaptations or Strategies Tailored to Older Adults
1: Leadership & consensus	• No anticipated adaptations needed
2: Policies, patient agreements & workflows	• Tailor policies for older adults (e.g., additional monitoring) • Establish ***Medicare Annual Wellness Visit*** workflow to incorporate assessing for misuse and OUD, pulling prescription drug monitoring program (PDMP) data, etc. • Refer older adults on multiple medications for polypharmacy review by pharmacist • Education and training on non-opioid, effective pain management options for older adults
3: Tracking and monitoring patient care	• Screening tool for OUD tailored for older adults • Training for clinicians on the risks of high MMEs in older adults, despite being on dosage for years • Shared decision-making tool for older patients on pain management options • Educational tools for older adults and family members on safety of opioids • Registry of older adults on opioids long-term
4: Planned, patient-centered care visits	• Design the ***Medicare Annual Wellness Visit*** to include examining appropriateness of opioid prescriptions, discuss alternatives and potential tapering, screen for opioid misuse or OUD, also whether taking a benzodiazepine • Design EHR notes templates for pain visit with labs, screening, pain and functional assessment, PDMP check, and other strategies to employ • Potential workflows for screening tools, complete documentation for visits related to pain and older adults • Explore shared medical appointments for elderly patients on opioids long-term
5: Caring for complex patients	• Develop tools with an overview of 'unique' considerations of opioids and pain treatment options in older adults: constipation, drug interactions, pharmacodynamic effects, neurobehavioral changes, comorbidities, cognitive impairment and side effects of opioids[23] • Clinical decision aid for providers decided among MAT options and considerations for older adults, specifically (e.g., drug interactions, side effect profile, risks) • Older adult-tailored guidance for tapering protocols, approaches and education
6: Measuring success	• Examine metrics of recommended strategies (e.g., check PDMP, urine drug screen) for older adults and even cross-sections of older adult populations, maybe by pain conditions as well • Consider unique metrics keyed to older adults-e.g., measures of renal and liver function on a regular basis, specific education on side effects

Once revisions to the Compendium are made based on results of this evaluation, the Compendium will be published on AHRQ's website. A manuscript describing the study and its results will also be produced for publication in a peer-reviewed journal.

3. Use of Improved Information Technology

A broad range of the data collected during the project will use information technology.

a. **Web-conferencing:** To facilitate document review, the project kickoff was presented through web-conferencing with video capability as will all client and internal team meetings, technical expert panel (TEP) meetings, and monthly meetings with learning collaborative QI champions.

b. **Posting on AHRQ's The Academy Integrating Behavioral Health and Primary Care Library.[24]** The project includes a comprehensive environmental scan of peer-reviewed and gray literature to identify existing opioid management strategies, resources, and tools for primary care clinicians. The final results will be posted on AHRQ's academy website.

c. **Web-based provider survey:** The Abt Team will use a national database of health care providers maintained by IQVIA for the survey sample. The IQVIA database includes all clinicians in the U.S. billing to Medicare. It contains the names and contact information of roughly 5,000 providers in all 50 states who bill Medicare, work in outpatient settings, and have first, second, or third-tier specialty as "Geriatric Medicine" (among physicians) or "Gerontology" (among nurse practitioners). The database comprises a diverse set of providers with respect to their occupation (i.e., physicians, nurse practitioners, physician assistants), geographic region, and practice type (i.e., private small, private large, public, hospital affiliated, VA), as these characteristics have been associated with differences in opioid prescribing practices. The database includes mailing addresses for all these providers and email addresses for 76% of them. The brief survey will be sent to the 5,000 randomly selected primary care clinicians. The survey instrument (**Attachment A**) will include no more than 30 items. The survey specifically addresses the following domains relating to clinician experiences in caring for older adults with chronic pain on opioids: (1) Perceptions, attitudes, and awareness; (2) Clinician treatment patterns; (3) Practice or system processes; and (4) Clinician and practice characteristics. The survey is expected to take approximately 15 minutes to complete. Respondents can elect to take the survey electronically or by telephone. We will send survey invitations via email and by US mail, providing two approaches for contacting respondents.

d. **Web-based survey for learning collaborative clinical staff.** A brief, web-based survey will be sent to all clinical staff at the participating practices in the learning collaborative at baseline before starting implementation and approximately 15 months later.

e. **Website:** We plan to develop a private community website to include an overview of practices, the specifications for the QI measures, resources, and upcoming and past webinar schedule. The website can include a place for document sharing, threaded discussion, webinar recording, and other collaboration tools. The site will be password protected and built on the Drupal Content Management System (Centers for Medicare & Medicaid Services) which will make transition to AHRQ seamless and the security process for obtaining an

Authority to Operate (ATO) simpler **(see Attachment G).** A simple "forgot password" function will allow users to easily reset their password, reducing a common obstacle to utilization. The Abt Team has successfully built an online LC for HRSA's Infant Mortality Collaborative Improvement & Innovation Networks (CoIIN). This tool, also built in Drupal, has role-based authentication for each separate CoIIN team to share documents with each other, a shared calendar at the specific CoIIN level, and CoIIN-wide collaboration and learning. The tool is also the repository for the evaluation data collection where the grantees can enter or upload their data and see data visualizations of how their data has changed over time. Attachment G includes a detailed description of Abt's baseline security requirements, incident response, secure data storage, and compliance with HHS and Federal IT Policies.

f. **Electronic transfer of data.** All data collected by the learning collaboratives will be transferred to Abt using a secure document collaboration and client portal, Huddle. Huddle is made up of a network of online workspaces that are managed by Workspace Managers. Huddle serves as a file transfer site for projects involving sensitive information such as Personally Identifiable Information (PII) and Protected Health Information (PHI). This platform enables study team members to send and receive sensitive information securely with people inside and outside of Abt.

g. **Posting on AHRQ's website.** Several of the project deliverables will be posted on AHRQ's website. The infographic developed from findings from the environmental scan, the final Compendium of Strategies, final case studies, and the final report will be public-facing and posted on AHRQs website.

4. Efforts to Identify Duplication

The tools and resources that compile the Compendium are gathered through a review of secondary data sources, an environmental scan and literature review, and interviews with nine individuals from exemplar practices about innovative strategies that they have implemented. A duplication of effort is unlikely. While there have been extensive efforts to address the opioid epidemic, relatively little attention has been paid to the risks and effects of opioid use, misuse and OUD in older adults and the information available for best practices with older adults is de-centralized. AHRQ has sustained close contact with other organizations doing related work in an effort to identify similar existing information and has not identified any such sources.

5. Involvement of Small Entities

This project does not intend to intentionally involve nor exclude or impact any small entities. However, to the extent an identified and recruited health care organization meets the requirements for participation and is a small entity, we will involve them and expect no greater impact than on other participating health care organizations. The instruments and procedures used to collect data are designed to minimize the burden on all respondents.

6. Consequences if Information Collected Less Frequently

The frequency of data collection varies depending on type of data being collected. The data collected for the provider survey, interview with nine individuals from exemplar practices, learning collaborative self-assessments, and sharing of provider documents are all collected at one point in time. The purpose of these one-time data collection activities is to gather information to inform or build the Compendium of Strategies. The learning collaborative self-assessment will help practices assess the status their QI efforts to improve opioid prescribing and identify areas of QI on which to target with appropriate resources, strategies, and tools to help them achieve their QI goals. The provider documents will help AHRQ understand outputs as part of the learning collaborative such as new policies and procedures, staff and resident/family education and trainings, and workflows related to managing opioid use, misuse, and abuse in older adults.

Across the 15-month learning collaborative initiative, the learning collaborative staff surveys will be administered to clinicians at two time points (baseline and post-implementation). Staff interviews also will occur two times (mid-point and once post-implementation). The QI champion interviews will occur three times (baseline, mid-point and post-implementation). Conducting the surveys and QI champion interviews pre- and post-implementation will allow us to assess the impact of the program in terms of processes and outcomes. The staff and QI champion mid-point data will allow the evaluation team and AHRQ to modify the strategies and tools and continue implementation and testing during the second half of program implementation. It also allows the practices participating in the learning collaboratives to take advantage of interim modifications and improvements for the remainder of the program rather than continuing to implement a strategy that may not be effective as first implemented.

The post-implementation data collected via the clinical staff survey and the QI champion interview will not only allow the evaluation team and AHRQ to assess change over time and the impact of the intervention, but along with post-implementation staff interview data will inform the final compilation of the Compendium of Strategies and tools for the management of opioid use, misuse and abuse in older adults in PCPs. To ease burden on staff, we are only collecting interview data at mid-point and post- implementation.

By collecting data in different forms (i.e., survey, interview, documents) we are able to triangulate the data for a more accurate assessment of the efficacy of the program, and inform the final collection of tools and strategies for the Compendium. Less frequent interview data collection would inhibit the evaluation team and AHRQ from assessing the impact of the intervention. It would also prevent AHRQ from making modifications to the strategies prior to the end of the program.

Finally, each clinic will report quarterly data on QI measures. A data analyst at each organization will provide aggregate reports of the specified QI measures to the evaluation team on a quarterly basis over the course of a15-month period. The QI measures are measures of opioid prescribing that are critical for understanding the potential improvements in opioid prescribing in implementing the strategies. Collecting these data on a quarterly basis is in large part due to the fact that if practices are using these measures as intended - they should be collecting them at least quarterly. The quarterly measure also allows the evaluation team to look at trends in the data, and the learning

collaborative leaders to discuss observed trends from participating practices. Collecting the data less frequently, could lead to incorrect assumptions about the efficacy of the intervention. For example, threats to external validity such as historical events (e.g. COVID-19) could incorrectly indicate that the intervention was not effective. However, by examining these data at five points in time, a rise or fall during one quarter will be considered when a general trend is plotted.

Not collecting these data, places us at risk of not collecting adequate information for the identifying and testing strategies to manage opioid use, misuse and abuse in older adults. Should we shorten the data collection period, we would have to also shorten the implementation period. A shorter implementation period would not allow time to educate or train providers, patients and their caregivers, fold into their routine workflow, or demonstrate interim outcomes. A shorter implementation likely would not allow for sufficient observation to identify potential barriers, facilitators or outcomes. This would limit the extent to which the final Compendium of Strategies would meet the needs of PCPs related to the management of opioid use, misuse, and abuse among older adults in PCPs.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13) and Office of Management and Budget (OMB) regulations at 5 CFR Part 1320 (60 FR 44978, August 29, 1995), ACF published a notice in the Federal Register announcing the agency's intention to request an OMB review of this information collection activity. This notice was published on June 8, 2020, Volume 85, Number 110, page 35090, and provided a sixty-day period for public comment. A copy of this notice is attached as Attachment H. During the notice and comment period, the government received no requests for information or substantive comments.

8.b. Outside Consultations

There are no outside consultants on this project. Kaiser Permanente of Washington Research Institute (KPWRI) is a subcontractor. The following KPWHRI staff serve as technical experts and will contribute to all aspects of the project.

- Michael Parchman, MD, MPH, the MacColl Center for Health Care Innovation at the Kaiser Permanente of Washington Health Research Institute

- Clarissa W. Hsu, MD, the MacColl Center for Health Care Innovation at the Kaiser Permanente of Washington Health Research Institute

9. Payments/Gifts to Respondents

Incentives will be offered as compensation for providers' involvement in the learning collaboratives:

1. Access to a free, high-quality Compendium of Strategies for managing opioid use, misuse and abuse in older adults;

2. Opportunity to participate in an opioid prescribing in older adults quality improvement project;

3. Opportunity to participate in a project funded by AHRQ;

4. Potential to improve primary care practices' opioid prescribing practices for older adults.

In addition to the above-mentioned incentives, we propose to offer the following honoraria for participants as follows. The following honoraria are based on and similar data collection methods from a recently-approved OMB package (OMB Control #0935-0248 *Evaluating and Implementing the Six Building Blocks Team Approach to Improve Opioid Management in Primary Care*).

1. **Provider Survey:** Each provider who completes and submits the web-based survey will receive $25.00. The incentive is to facilitate target response rates and is meant to help motivate busy, clinical staff to take the time to complete the surveys. The incentive amount is comparable to those used in similar studies.

2. **Primary care practice participation in the Learning Collaborative:** An honorarium of $1,500 for each of the 24 primary care practices (PCPs) participating in the learning collaborative is critical to achieve project aims. Over 15 months, practices will be asked to implement and test strategies and tools designed to help manage opioid use, misuse and abuse among older adults. To implement the strategies, practice staff will be trained and involved in the effort, and the strategies will need to be incorporated into the practice workflow. To implement the strategies, practices may have to obtain IRB approval, submit a self-assessment, participate in interviews, facilitate contacting staff for interviews and surveys, provide documents and collect and report QI measures. With regards to the QI measures, research demonstrates that collecting measures can be cumbersome for clinics, and providing an honorarium appropriately incentivizes clinic participation. As was observed in AHRQ's EvidenceNOW initiative of nearly 1,500 primary care clinics, there are numerous challenges to pulling measures for quality improvement purposes. CDC-funded projects working with clinics and health systems to improve opioid management practices using QI measures have also reported extensive challenges and time required to produce such measures.

   Besides the effort for implementing the strategies, practices as part of the learning collaborative, leads from each practice must participate in an in-person kick-off and virtual capstone meeting, and participate in routine, monthly collaborative check-in calls. While the previously-approved project (OMB Control #0935-0248) involved comparable level of effort for implementing strategies to address opioid use, misuse and abuse in primary care practices and provided a $1,000 honorarium, the practices in this group are also asked to commit substantial time as participants in the learning collaborative. As such, $1,500 was deemed the appropriate level of honoraria, without undue inducement.

While future PCPs will need to use resources to implement the Compendium of Strategies, several requests of practices participating in the learning collaborative will not necessarily be borne by future clinics who wish to use the Compendium of Strategies. These requests are described below:

- The **secondary data** refers to PCP documents that report on practices' progress implementing the strategies and tools for the management of opioid use, misuse and abuse in older adults. This could include meeting notes, new policies or workflows, etc. This also includes, for example, tracking and reporting back on their approach to help the evaluation team understand the extent to which they implemented the strategies.

- Participation in the **learning collaborative** are meant only for the participating practices as part of the learning collaborative, leads from each practice must participate in an in-person kick-off and virtual capstone meeting, and participate in routine, monthly collaborative calls.

- The **monthly check-in calls** are meant to be monthly calls with the QI champion and lead clinician from each practice to assess the progress of implementation of the intervention and improvement initiatives at each PCP.

- **QI measures**. While future clinics should ideally use QI measures to monitor their improvements in opioid prescribing over time, the participating practices in this study are asked to build or produce several different QI measures in a short period of time in service of the outcome evaluation component. For future clinics, they would likely not prioritize this many measures at one time given the complexity of producing these with electronic health record (EHR) data.

Given these informational needs from participating clinics to support the evaluation, we believe that a $1,500 honorarium per practice is appropriate, while still requiring time that practices should bear given the benefits they might accrue from implementing the strategies for managing opioid use, misuse and abuse among older adults.

3. Honoraria for each interview ($50 each for n=24, 3 times; and $50 for n= 24, 2 times) and each survey ($20 each for n=480, 2 time points) ensure target response rates and appropriate incentive for busy, clinical staff to take the time to complete the interviews and surveys. The honoraria amounts are the same amounts approved for interviews and survey of the practice staff in the similar OMB-approved study (OMB Control #0935-0248). The survey and interviews are used to assess the implementation and effectiveness of the strategies implemented. While future clinics should ideally monitor their improvements in opioid prescribing over time, the participating practices in this study are asked to complete the survey and interviews in service of the evaluation.

The team's belief is that health care organizations and clinicians will be motivated to participate primarily because of their interest in improving their opioid prescribing practices or because of the opportunity to participate in a research project with AHRQ, not because of monetary incentives.

Still, participation in this project and associated data collection activities will place a burden on practices and individuals, and research demonstrates that incentives that compensate for the added burden and costs associated with participation are viewed favorably and are seen as affirming participants' value and the importance of their participation in research.[25,26]

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

11. Questions of a Sensitive Nature

The data collection protocols do not contain any questions concerning political affiliations and attitudes; respondents' mental or psychological problems; illegal, antisocial, self-incriminating or demeaning behavior; critical appraisals of other individuals with whom respondents have close relationships; legally privileged relationships; or records describing how an individual exercises First Amendment rights. Nor do they contain questions related to sexual behavior and attitudes, religious beliefs, income or proprietary business information. However, surveys may elicit sensitive information that reflects negatively on staff or health care organization performance related to opioid prescribing. Respondents to the surveys will be explicitly informed that their participation is voluntary, information they provide is confidential to the extent provided by law, and they may choose to withdraw from the study or not respond to specific items without penalty. We will also remove individual staff and health care organization names from written interview records and reports to maintain respondent confidentiality (see Attachment G, Abt's Security Requirements).

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on prior experiences and what can reasonably be requested of participating providers (survey) and PCPs. The number of respondents listed in column A, Exhibit 1 reflects a projected response rate for data collection efforts.

1. **Provider web-based survey (Attachment A).** A survey will be sent to 5,000 randomly selected primary care clinicians. The survey will include no more than 30 items and is expected to take approximately 15 minutes to complete. We anticipate a 30% response rate, resulting in 1,500 completed surveys.

2. **PCP Learning Collaboratives Primary Data Collection**

   a. **PCP Learning Collaborative Clinical Staff Survey (Attachment B).** A brief survey will be emailed to all clinicians at baseline before starting

implementation and approximately 15 months later. We assume 20 clinical staff per clinic site, and 24 clinics for a total of 480 staff. We assume 360 clinical staff will complete the survey based on a 75% response rate. It is expected to take up to 20 minutes to complete.

b. **Interviews**. In-depth interviews will occur with up to 3 staff at each health care organization, for a total of up to 72 individuals. The evaluation team will conduct these interviews, each lasting up to 30 minutes with:

    i. **QI champion** for the initiative in the clinics at baseline, mid-point and post-implementation (Attachment C).

    ii. **Two additional staff** (e.g., clinician, information technology analyst, behavioral health specialist) per PCP at mid-point and post-implementation. (Attachment D).

c. **Self-Assessment (Attachment E).** A self-assessment tool used in the Six Building Blocks program, and CDC Opioid QI Collaborative for clinics or health systems will be provided to practices to assess where they are in their QI efforts to improve opioid prescribing, and the extent to which care is consistent with the CDC Opioid Prescribing Guideline. The QI champion or lead for the effort in each of the 24 participating PCPs will respond to the self-assessment which will take approximately 15 minutes to complete.

d. **QI Measures (Attachment F)**. Aggregate reports of the specified quality measures will be provided on a quarterly basis over the course of a 15-month period by a data analyst at each PCP. This activity will involve 12 individuals at each learning collaborative for a total of 24. The QI measures are measures of opioid prescribing that are critical for understanding the potential improvements in opioid prescribing in implementing strategies and tools for management of opioid use, misuse, and abuse. Each health care organization is asked to report quarterly on the QI measures. Clinics may obtain these measures from electronic health record (EHR) data, or they may not have the sophistication or capacity to do that and may track these measures using Excel files or other methods. The method of pulling these measures will vary by clinic, and we will charge clinics will developing a system for collecting these measures that works best for them. We assume it will take each clinic up to a total of 40 hours over the course of the project.

    i. Twenty hours to develop a system for pulling these measures.

    ii. Five hours to pull and submit these reports each quarter.

3. **PCP Learning Collaboratives Secondary Data Collection**

a. **Practice Documents.** These secondary data will be provided by the QI champion at each organization at the end of program implementation, for a total of 24 individuals. Documents that are relevant to the project and compiled as part of routine business practice, will be provided to the evaluation team. They include, for example, the PCP's policies and

procedures for pain management, opioid use among older adults. **These
documents will not require additional data collection as they are
collected and recorded as part of the PCP's routine business practices.**
Therefore, it is not expected that sharing these document will be a burden
to the practices.

Exhibit 1. Estimated annualized burden hours

Data Collection Method or Project Activity	A. Number of respondents	B. Number of responses per respondent	C. Hours per response	D. Total burden hours
1. Web-Based Provider Survey (Attachment A)[1]	1500	1	15/60	375
2a. Learning Collaborative Clinical Staff Survey (Attachment B)[2]	360	2	20/60	240
2bi. Learning Collaborative QI Champion Interview (Attachment C)	24	3	30/60	36
2bii. Learning Collaborative Staff Interview (Attachment D)	48	2	30/60	48
2c. Learning Collaborative Self-Assessment (Attachment E)	24	1	15/60	6
2di. Learning Collaborative QI Measures – develop system (Attachment F)	24	1	20	480
2dii. Learning Collaborative QI Measures – pull and submit (Attachment F)	24	4	5	480
TOTAL	**2028**	**n/a**	**n/a**	**1665**

[1]Number of respondents reflects a 30% response rate. [2]Number of respondents reflects a
sample size assuming a 75% response rate.

Exhibit 2, below, presents the estimated annualized cost burden associated with the
respondents' time to participate in this research. The total cost burden is estimated to be
about $72,145.62.

Exhibit 2. Estimated annualized cost burden

Data Collection Method or Project Activity	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
1. Web-Based Provider Survey[1]	1500	375	$101.82	$38,182.50
2a. Learning Collaborative Clinical Staff Survey[2]	360	240	$39.42	$9,460.80
2bi. Learning Collaborative QI Champion Interview[3]	24	36	$54.68	$1,968.48
2bii. Learning Collaborative Staff Interview[4]	48	48	$39.42	$1,892.16
2c. Learning Collaborative Self-Assessment[5]	24	6	$54.68	$328.08
2di. Learning Collaborative QI Measures – develop system[6]	24	480	$21.16	$10,156.80
2dii. Learning Collaborative QI Measures – pull and submit[7]	24	480	$21.16	$10,156.80
Total	**2028**	**1917**	**n/a**	**$72,145.62**

Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on "Occupational Employment and Wages, May 2018" found at the following URL: http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm

[1]The average hourly rate of $101.82 for the **provider survey** was calculated based on the 2018 mean hourly wage rate for family and general practitioners, (occupation code 29-1062).

[2]The average hourly rate of $39.42 for the **learning collaborative clinical staff survey** was calculated based on the 2018 mean hourly wage rate for medical and health services managers (occupation code 29-0000)

[3]The average hourly rate of $54.68 for **QI champion interviews** was calculated based on the 2018 mean hourly wage rate for medical and health services managers (occupation code 11-9111).

[4]The average hourly rate of $39.42 for **staff interviews** was calculated based on the 2018 mean hourly wage rate for medical and health services managers (occupation code 29-0000).

[5]The average hourly rate of 54.68 for the Learning Collaborative QI champion to complete the **self-assessment** was calculated based on the 2018 mean hourly wage rate for medical and health services managers (occupation code 11-9111).

[6]The average hourly rate of $21.16 to develop the Learning Collaborative **QI measures** was calculated based on the 2018 mean hourly wage rate for medical records and health information technicians (occupation code 29-2071).

[7]The average hourly rate of $21.16 to pull and submit the Learning Collaborative **QI measures** was calculated based on the 2018 mean hourly wage rate for medical records and health information technicians (occupation code 29-2071).

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

Exhibit 3a. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Provider Survey	$675,860	$168,965
Compendium of Strategies	$536,353	$134,088
Learning Collaborative & Evaluation	$1,603,696	$400,924
Reporting & Publication of Results	$456,233	$114,058
Total	**$3,272,142**	**$818,035**

Exhibit 3b. Government Personnel Cost

Tasks/Personnel	Annual Salary	% of Time	Cost
Government Personnel Costs			
Social Science Analyst – GS14*, Step 9			
Data Collection Oversight	$148,445	10%	$14,844.50
Review of Results	$148,445	10%	$14,844.50
Grand Total			**$29,689.00**

*Based on January 2019 OPM Pay Schedule for Washington/DC area:
https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB.pdf

15. Changes in Hour Burden

This is a new information collection.

16. Time Schedule, Publication and Analysis Plans

Exhibit 5   Project Timeline

Description (in chronological order)	Due Date
Draft Provider Survey	January 31, 2020
Final Provider Survey	March 13, 2020
Project Summary	Annually beginning March 15, 2020
Draft OMB Package	April 1, 2020
Identify Exemplar Practices to Rank	April 1, 2020
Draft Evaluation Plan	April 15, 2020
Final OMB Package	May 1, 2020
Final Evaluation Plan	May 13, 2020
Draft Environment	May 15, 2020
Synthesis of Exemplar Practices Memo	June 1, 2020
Final Environment Scan	June 12, 2020
Draft Compendium Version 1	July 28, 2020
Final Compendium Version 1	August 25, 2020
Website Mockup	October 1, 2020
Draft Infographic	November 15, 2020
Final Infographic	October 13, 2020
Draft Case Studies	August 15, 2021
Final Case Studies	September 13, 2021
Draft Survey Results	October 8, 2021
Final Survey Results	November 28, 2021
Draft Compendium Version 2	April 14, 2023
Draft Final Report	May 20, 2023
Final Compendium Version 2	May 24, 2023
Final Report	June 17, 2023
Draft Peer Reviewed Manuscript	June 30, 2023
Submit Peer Reviewed Manuscript	July 29, 2023
Learning Collaborative Support Report	Quarterly
Learning Collaborative Practice Progress	Quarterly

Publication Plan:

Study results will be disseminated through a peer-reviewed publication. The final Compendium of Strategies will be posted on the appropriate section of the AHRQ web site and disseminated via AHRQ's Office of Communication and Knowledge Transfer (e.g., e-mails to relevant professional associations and postings on listservs).

Analysis Plan:

As described above, the goals of the proposed data collection effort are to 1) assess and describe current perceptions of the challenges associated with managing opioid use, misuse and abuse in older adults; 2) create a public-facing Compendium of Strategies for the management of opioid use, misuse and abuse in older adults in primary care settings; and 3) identify remaining evidence gaps and areas of needed research.

AHRQ has proposed to use multiple data sources to triangulate findings to meet of the project goals.

Goal 1:	Assess and describe current perceptions of the challenges associated with managing opioid use, misuse and abuse in older adults.
Data collection strategy:	Provider survey.
Data analysis strategy:	Developing non-response weights, descriptive analysis of survey responses (mean, standard deviation, and distribution for continuous variables; frequencies and percentages for categorical and binary variables) and regression modeling to identify correlates of outcomes.

We will code responses to open-ended survey questions thematically and describe common themes, along with demonstrative examples of responses under each theme. We will stratify measures of clinician experiences caring for older adult patients with chronic pain on opioids by geographic region, clinician specialty, practice type, and other clinician characteristics as relevant. Stratified analyses will be bivariate (survey responses stratified by a given clinician characteristic). We will explore the feasibility of conducting multivariate analyses, to adjust for multiple provider characteristics concurrently. Multivariate analyses can also improve statistical power in some cases. All stratified analyses will be adjusted using non-response weights.

Goal 2:	Create a public-facing Compendium of Strategies for the management of opioid use, misuse and abuse in older adults in primary care settings; and.
Data collection strategy:	Learning collaborative clinical staff survey, interviews with staff and QI Champions, self-assessment, QI measures, and secondary data.
Data analysis strategy:	Quantitative analyses complemented with qualitative data from staff interviews as described below.

Data will be primarily analyzed qualitatively, identifying themes of facilitators and barriers to implementing the strategies and tools and improvements to PCPs' processes of

care and opioid prescribing practices. Qualitative analysis software (NVivo) will be used to synthesize and analyze the data as well as to allow for qualitative comparisons and synthesis by each organization, staff type (e.g., QI lead, clinical staff), geographic location, and in aggregate. Qualitative comparisons of data from the first to the second round assessments of opioid prescribing processes will be similarly analyzed. The insights regarding facilitators and barriers to implementation will be used to inform the final version of the Compendium of Strategies.

Quantitative data will be collected through two rounds of the clinical staff survey, two or three rounds of interviews (i.e., two rounds for staff; three rounds for QI champions), QI measures, and secondary data sources (practice documents, for example policies and procedures for pain management, opioid use among older adults.) describing the efficacy of strategy implementation. We will analyze these data using descriptive statistics (i.e., frequencies, averages). Additional analysis will include comparisons of survey data, interviews, and QI measures to measure changes over time.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments

Attachment A: Provider Survey
Attachment B: Learning Collaborative Clinical Staff Survey
Attachment C: Learning Collaborative QI Champion Interview
Attachment D: Learning Collaborative Staff Interview
Attachment E: Learning Collaborative Self-Assessment
Attachment F: Learning Collaborative Quality Improvement Measures
Attachment G: Baseline Security Requirements
Attachment H: 60-Day Federal Register Notice

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