SUPPORTING STATEMENT

Part A

Clinical Decision Support (CDS) for Chronic Pain Management

Version: April 1, 2020

Agency of 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 http://www.ahrq.gov/hrqa99.pdf), 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 healthcare quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of healthcare; 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 healthcare quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of healthcare in inner-city areas, and in rural areas (including frontier areas); and (B) healthcare 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 healthcare needs, including individuals with disabilities and individuals who need chronic care or end-of-life healthcare.

Chronic pain is a multidimensional health condition defined as pain persisting or recurring for more than three to six months.[1] While the true prevalence of Americans living with chronic pain is difficult to define, 2014 surveys estimate approximately 25.3 million adults experience pain daily while 126 million adults reported some type of pain within the previous three months of being surveyed.[2,3] Pharmacological management of pain – including opioid analgesics – is often a first line of defense for many providers.[4] Incident rates of long-term opioid use for non-cancer related pain are increasing in the United States.[5] Despite their demonstrated benefits and effectiveness in pain relief in the short term, opioid analgesics for chronic pain may be less effective and can lead to opioid misuse and/or addiction.[6] Successful systems approach strategies for treatment and management of opioids for both patients and providers are needed to inform decision-making when managing a patient's chronic pain.

In 2017, the Department of Health and Human Services declared a public health emergency and announced a 5-Point Strategy for Combating the Opioid Crisis which includes: 1.) better addiction prevention, treatment, and recovery services; 2.) better data; 3.) better pain management; 4.) better targeting of overdose reversing drugs, and 5.) better research. Recommendations to achieve better pain management includes improved

awareness of and adherence to evidence-based guidelines for opioid prescribing and considerations of non-opioid therapies for chronic pain management. The Pain Management Best Practices Inter-Agency Taskforce highlights key concepts the proposed work addresses including: more informed, evidence-based management of chronic pain, individualized, patient-centered care, multi-modal approaches, education/ training, and innovative solutions.[7]

Prescription opioid pain medication overuse, misuse, and abuse have been a significant contributing factor in the opioid epidemic. Increased scrutiny of opioid prescribing for patients with chronic pain, especially among non-pain management specialists, has led healthcare systems to work on optimizing pain therapy and consider opioid-dose reductions. This research has the following goals:

1) To help patients track and manage chronic pain and daily function to support reduced opioid use through the design, development, implementation, and evaluation of a clinical decision support (CDS) tool that facilitates continued patient provider engagement.
2) To help primary care physicians support patients at high risk of harm from opioids by optimizing opioid dose reduction through the design, development, implementation, and evaluation of CDS that optimizes presentation of patient data and evidence-based guidelines to support opioid tapering.

To achieve the goals of this project the following data collections will be implemented. Several data collections were completed during the scientific-discovery and pre-implementation phases of the study. These data collections included: 1) Interviews of patients with chronic pain, family members of patients with chronic pain, patient-facing CDS developers, Primary Care Physicians, Pain Specialists, and provider-facing CDS developers; 2) Design workshops for patients with chronic pain and Primary care Physicians; 3) Usability testing with Patients with chronic pain and Primary Care Physicians; and 4) Workflow observations of Primary Care Physicians. These methods will be used to drive the development and design of the CDS tools prior to implementation. Please see the supplemental document (*Scientific Discovery_CDS for Chronic Pain_Draft_2020Mar24*) for details. Additional data collection methods used to achieve the goals of the project are described below.

1) **Post-Use Survey with Primary Care Providers "Evaluation Provider Survey":** This includes the collection of qualitative data through a short survey with primary care providers who used the application (up to a maximum of 60). The research team will collect insights from providers on their experience of implementing and using the CDS tools. The survey will be accessible in multiple ways given a provider's preference to include online or paper-based.
2) **Post-Use Survey with Patients "Evaluation Patient Survey":** This includes the collection of qualitative data through a short survey with patients who used the application (up to a maximum of 150). The research team will collect insights from patients on their experience of implementing and using the CDS tools. The survey will be accessible in multiple ways given a patient's preference to include online or paper-based.

3) **Post-Use Interview with Primary Care Providers "Evaluation Provider Interview":** This includes the collection of qualitative data through an in-depth thirty-minute interview with primary care providers who used the application (up to a maximum of 10). The research team will collect insights from providers on their experience of implementing and using the CDS tools.

4) **Post-Use Interviews with Patients "Evaluation Patient Interview":** This includes the collection of qualitative data through an in-depth thirty-minute interview with patients who used the application (up to a maximum of 20). The research team will collect insights from patients on their experience of implementing and using the CDS tools.

5) **Post-Use Interviews with Site Champions "Evaluation Site Champion Interview":** This includes the collection of qualitative data through thirty-minute interviews with site leads (up to a maximum of 15) and site visits during which the research team will collect insights from providers and patients on their experience of implementing and using the CDS tools.

This study is being conducted by AHRQ through its contractor, MedStar Health, 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 proposed work represents a multi-disciplinary approach that will tackle both technological and design components of health information technology architecture while understanding end-user needs (e.g., patients and providers), workflow, and data integration. The research team will leverage human factors methodologies including stakeholder interviews, workflow analysis, application of user-centered design principles, and usability testing. These methods will help the research team better understand human strengths and limitations in the design of interactive systems. The approach focuses on how systems work in actual practice to better design healthcare information technology that optimizes design of the CDS tools. This research will advance knowledge for patients and providers through CDS tools that enhance the quality of clinical discussion and shared decision-making for optimizing pain management therapy.

3. Use of Improved Information Technology

The research team will implement human factors derived designs and develop a user-friendly experience using highly accessible technologies such as patient portals, mobile applications, text message systems, or other means that will advance clinical decision support at the point of care. The patient-facing CDS tool will collect necessary data from the patient, such as relevant patient reported outcomes measures using appropriate standards, and appropriate data will be accessible by both the patient and provider facing components. Patients will be authenticated using the SMART on FHIR extension of the OAuth2 protocol. The research team will leverage technologies to improve access and interoperability such as the OpenID Connect specification to ensure secure identification of the patient and enable patients to control their data privacy. The tools will maximize

the portability and future adoption of the CDS by requiring minimal implementation effort through standardized integration with electronic health record systems that support modern standards such as SMART on FHIR and OpenID connect. The development process will follow a rigorous user-centered design approach to ensure that the resulting functional prototype meets the needs of end-users. The research team will leverage their relationships with electronic health record vendors and MedStar Health technical experts to meet health information technology challenges and consult with them throughout implementation.

The provider-facing CDS tool leverages the CDC Guideline for Prescribing Opioids for Chronic Pain, released in 2016.[4] The CDS tool will use patient-specific data and CDC guidelines to support the careful assessment of individual benefits and risks for continued opioid use. The proposed research builds off the AHRQ Pain Management Summary [8] functionality to consolidate patient-specific information normally distributed across different tabs and screens into a single view but also incorporates PRO data, data visualization, and personalizes CDC guidelines to operationalize the CDC's recommendations.

4. Efforts to Identify Duplication

No similar data have been gathered by the research team or are available from other sources known to the research team.

5. Involvement of Small Entities

There are no plans that any sites participating in this pilot test will be classified as small businesses.

6. Consequences if Information Collected Less Frequently

Data collected through the patient interviews, family member interviews, health information technology and clinical decision support developer interviews, physician interviews, and pain specialist interviews will be collected one time from each participant. Data collected through usability testing with patients with chronic pain and primary care physicians will each be collected through two rounds of usability testing of nine unique participants in each round. Data will be collected from each of these participants one time only. The post-use interviews with patients, providers, and site champions will be collected twice: once shortly after deployment of the CDS tools and again after three to four months of use by patients and providers. The timing of this section data collection point is necessary to ensure that any changes in the perception of value or intention to use the tools are captured while the experience with the tools is still recent. If data were collected less frequently, this analysis would not be possible.

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

As required by 5 CFR 1320.8(d), notices were published in the Federal Register on July 14th, 2020, for 60 days (see Attachment 6) on page 42404, volume 85. No substantive comments were received.

8.b. Outside Consultations

In addition to the expert MedStar project team, a team of collaborators and consultants composed of patient advocates, providers, researchers, and developers from industry and academia will inform all aspects of the project to ensure robust stakeholder input. Team collaborators include experts in health technology architecture, development, and patient-centered interface strategy from Perk Health, experts in health behavior, decision-making, and patient-reported outcomes from Georgetown Lombardi Comprehensive Cancer Care and Georgetown University Medical Center, and experts in patient safety, quality improvement, and evaluation of risky behaviors from IMPAQ International.

Expert consultants represent expertise in patient and family engagement, electronic health record implementation strategy, clinical data integration, and a partnership with the Capital Area Primary Care Research Network (CAPRICORN), a network of primary care providers in the Washington DC metropolitan area. These consultants will provide advisement in interview guide development.

9. Payments/Gifts to Respondents

There is no compensation for participants in the post-use evaluation data collection efforts.

10. Assurance of Confidentiality

The confidentiality of your responses are protected by Sections 944(c) and 308(d) of the Public Health Service Act [42 U.S.C. 299c-3(c) and 42 U.S.C. 242m(d)]. Information that could identify you will not be disclosed unless you have consented to that disclosure.

Information that can directly identify the respondent, such as name and/or social security number will not be collected in either the survey or the interview. Information necessary to schedule interviews (such as name, phone number) will be collected and stored separately from survey and interview data. During both the surveys and interviews, respondents will be assured that their answers will be kept confidential, and nothing will be reported in a way that could personally identify them. (That is, findings will be reported in aggregate, so that it is not possible to link comments to individuals.) Any survey results (once retrieved from the survey data collection tool), audio recording files, and interview notes will be stored in a FISMA-compliant secure server only accessible by the research team.

11. Questions of a Sensitive Nature

Surveys and interview tools have been designed without the need to ask questions of a sensitive nature. However, each respondent will be permitted to decline to answer questions in both the survey and the interviews if he or she does not feel comfortable answering that question.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Post-Use Survey with Providers	60	1	0.25	15
Post-Use Survey with Patients	150	1	0.25	37.5
Post-Use Interview with Providers	10	1	0.5	5
Post-Use Interview with Patients	20	1	0.5	10
Post-Use Interview with Site Champions	15	1	0.5	7.5
Total	**255**	**5**	**2**	**75**

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Post-Use Survey with Providers	60	15	$102.73[b]	$1,540.95
Post-Use Survey with Patients	150	37.5	$25.72[a]	$964.50
Post-Use Interview with Providers	10	5	$102.73[b]	$513.65
Post-Use Interview with Patients	20	10	$25.72[a]	$257.20
Post-Use Interview with Site Champions	15	7.5	$102.73[b]	$770.48
Total	**255**	**75**	**$53.95**	**$4,046.78**

* National Compensation Survey: Occupational wages in the United States May 2019, "U.S. Department of Labor, Bureau of Labor Statistics", https://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm.

[a] Based on the mean wages for *all occupations (00-0000)*

[b] Based on the mean wages for *Family Medicine Physicians (29-1215)*

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Total and Annualized Cost to the Government

Exhibit 3a. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$1,641,964.99	$820,982.50
Data Collection Activities	$255,339.66	$127,669.83
Data Processing and Analysis	$386,732.46	$193,366.23
Publication of Results	$291,088.66	$145,544.33
Project Management	$266,987.56	$133,493.78
Overhead	$934,134.78	$467,067.39
Total	**$3,776,248.11**	**$1,888,124.06**

Exhibit 3b. Federal Government Personnel Cost

Activity	Federal Personnel	Hourly Rate	Estimated Hours	Cost
Data Collection Oversight	Grade 15 Step 5 Grade 14 Step 4	$77.49 $58.13	25 30	$1,937.25 $1,743.9
Review of Results	Grade 15 Step 5 Grade 14 Step 4	$77.49 $58.13	25 25	$1,937.25 $1,453.25
Total				**$7,071.65**

Annual salaries based on 2020 OPM Pay Schedule for Washington/DC area: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB.pdf

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

Once OMB approval is received, a three-phase launch is scheduled to begin in February 2021. A mixed methods approach will be used to evaluate testing of the clinical decision support tools, with a focus on implementation processes, general evaluation of app usage, and post testing feedback from different stakeholder groups (i.e., providers, patients, site champions). The timeline of scheduled tasks is provided below:

1. Implementation of the clinical decision support tools
    a. Phase 1 roll-out (5 primary care clinics): February 2021
    b. Phase 2 roll-out (5 primary care clinics): March 2021
    c. Phase 3 roll-out (5 primary care clinics): April 2021
2. Report evaluation findings for the clinical decision support tools
    a. Phase 1 evaluation and learnings: May 2021
    b. Phase 2 evaluation and learnings: June 2021
    c. Phase 3 evaluation and learnings: July 2021
3. Dissemination of findings
    a. Final report: September 2021

The evaluation metrics are focused on patient and provider outcomes in reach, effect, adoption, implementation, and maintenance (RE-AIM framework). Given a two-year timeframe for development and implementation, the evaluation will focus on feasibility and usability (while still tracking long-term outcomes after the funding period). This includes quantitative and qualitative metrics to identify barriers to successful implementation, evaluating acceptability of methods and instruments to participants, and providing estimates of missing data and dropout, and estimating resources required for future implementations.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment 1 -- Evaluation Provider Survey

Attachment 2 -- Evaluation Patient Survey

Attachment 3 -- Evaluation Provider Interview

Attachment 4 -- Evaluation Patient Interview

Attachment 5 -- Evaluation Site Champion Interview

Attachment 6 -- Federal Register Notice

References

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8. Agency for Healthcare Research and Quality. Factors to Consider in Managing Chronic Pain: A Pain Management Summary. CDS Connect Artifact. Available at: https://cds.ahrq.gov/cdsconnect/artifact/factors-consider-managing-chronic-pain-pain-management-summary