SUPPORTING STATEMENT

Part A

Outcome Measure Harmonization and Data Infrastructure for Patient Centered Outcomes Research in Depression

Prepared for:
Agency for Healthcare Research and Quality
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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 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.

In support of this mission, AHRQ funded a prior project to harmonize the outcome measures collected across patient registries and routine clinical practice, with the goals of supporting the development of a robust data infrastructure that can consistently and efficiently collect high-quality data on outcome measures that are relevant to patients and clinicians and supporting patient-centered outcomes research and quality improvement. Harmonized outcome measures would also form the foundation for learning healthcare systems. Of note, AHRQ has supported the development of the Outcome Measures Framework (OMF). The OMF is a conceptual model for classifying outcomes that are relevant to patients and providers across most conditions. AHRQ, in collaboration with the U.S. Food and Drug Administration and the National Library of Medicine, recently supported an effort to use the OMF as a content model for developing harmonized outcome measures in specific disease areas, including depression.

Major depressive disorder (MDD) is a common mental disorder that affects an estimated 16.2 million adults and 3.1 million adolescents in the United States. Characterized by changes in mood, cognitive function, and/or physical function that persist for two or more weeks, MDD can reduce quality of life substantially, impair function at home, work, school, and in social settings, and result in increased mortality due to suicide. MDD also is a major cause of disability, with an economic burden of approximately $210.5 billion per year in the United States.

Despite the burden of MDD and the availability of treatment, the condition is often undiagnosed and untreated. In 2016, the U.S. Preventive Services Task Force recommended screening for depression in the general adult population, including pregnant and postpartum women, and in adolescents. While routine screening is intended to improve diagnosis and treatment of MDD, many questions remain, such as about the comparative effectiveness of different treatment approaches, the incidence of adverse events, when to add medications for patients who do not respond to an initial course of treatment, how and why depression recurs, and how to classify and treat treatment-resistant depression. Patient registries capture a wealth of data on depression treatment patterns and outcomes in the United States and could serve as the foundation for a national research infrastructure to address these and other research questions. Yet, a lack of harmonization in the outcome measures collected by each registry makes it challenging, if not impossible, to link and compare data across registries and related efforts. As documented in the prior project, existing registries use different outcome measures (e.g., remission as defined by the PHQ-9 vs. HAM-D) and capture data at different timepoints.

Depression registries offer an excellent opportunity to demonstrate the feasibility and value of implementing the harmonized outcome measures. Existing registries already capture some of the harmonized depression measures for quality reporting, although at different timepoints; capture of these measures and the additional measures at consistent intervals will enable the registries to generate more robust data suitable for research purposes.

AHRQ is now proposing to implement the harmonized depression outcome measures developed under the prior project in two patient registries (the PRIME Registry and PsychPRO) and a health system setting. The purpose of this project is to demonstrate that capturing the harmonized outcome measures in the clinical workflow and submitting these data to different registries can improve clinical care, reduce the burden of registry participation, and increase the utility of registry data for research purposes. The objectives of the project are to:

- Demonstrate that collection of the harmonized outcome measures is feasible, sustainable, and useful for clinicians participating in primary care and mental health patient registries (Registry Protocol – Attachment A).

- Demonstrate that collection of the harmonized outcome measures is feasible, sustainable, and useful for clinicians in a health system setting (Health System Protocol – Attachment B).

- Evaluate whether collection of the harmonized measures increases the utility of registry data for research purposes.

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

- Clinician Survey – the clinician survey is a brief, 20-question survey that clinicians in the health system setting will be asked to complete once at the conclusion of the project. The survey captures information the value of the harmonized outcome measures for informing patient care. (Attachment C)

The project is being conducted by AHRQ through its contractor, OM1, 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

Users of the information captured in this project will fall into two categories: clinicians providing care for patients with depression; and researchers using the de-identified data to answer a patient-centered outcomes research question. AHRQ will receive summary findings from the data analysis only; no patient-level data will be shared with AHRQ.

3. Use of Improved Information Technology

This project focuses on use of electronic methods of data collection whenever possible. The Clinician Survey (Attachment C) will be completed electronically.

4. Efforts to Identify Duplication

The purpose of this project is to implement the harmonized depression measures in two existing registries and a health system, with the goal of building data resources that can support patient-centered outcomes research. The registries and health system do not capture the harmonized measures currently, and so similar information is not already available.

5. Involvement of Small Entities

The collection of information does not impact small businesses or other small entities. Data will be collected from clinicians within a health system.

6. Consequences if Information Collected Less Frequently

The objectives of this project include improving clinical care by supporting regular measurement of the harmonized outcome measures across care settings and increasing the utility of registry data for research purposes. Failure to collect the Clinician Survey will make it difficult, if not impossible, to assess the value and burden of capturing the harmonized measures from the clinician perspective.

7. Special Circumstances

No special circumstances apply to the proposed data collection.

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published on Page 43810 of Federal Register, September 22, 2019 (Vol. 84, No. 163) for 60 days (see Attachment D). No public comments were received.

8.b. Outside Consultations

During Phase I of the project, AHRQ and OM1 consulted with a Stakeholder Panel to gather information about the availability of data on depression treatment and outcomes in registries and electronic medical records (EMRs), the proposed data collection strategies, and the frequency of data collection. The Stakeholder Panel includes representatives from patient advocacy groups, professional societies, organizations focused on quality improvement and measurement, payers, the pharmaceutical and medical device industry, the EMR industry, and other Federal agencies, as well as clinical experts in depression treatment and patient outcomes. The Panel provided guidance on the initial feasibility assessment and development of the project protocols (Attachments A and B) and will continue to provide guidance through quarterly meetings over the duration of the project.

9. Payments/Gifts to Respondents

Respondents will not receive any payment or gifts. Clinicians will complete the Clinician Survey voluntarily to provide feedback on the app; because the Clinician Survey can be completed in less than 5 minutes, no payment or gift will be provided.

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.

Information that can directly identify the respondent, such as name and/or social security number will not be collected. A statement of confidentiality will be included with the invitation to complete the Clinician Survey and will contain the following statement:

> 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.

An analysis of statistically de-identified data will be performed by AHRQ's contractor, OM1. All de-identified data and all Clinician Survey data will be stored on OM1's secure servers. AHRQ will receive summary findings from the project data analysis only.

11. Questions of a Sensitive Nature

While the project focuses on a mental health condition (depression) which could be considered sensitive, it is important to note that the Clinician Survey only captures information about the clinician's opinion of the value and burden of using the harmonized measures. The survey does not capture any patient data, and AHRQ will receive summary findings from the analysis only.

12. Estimates of Annualized Burden Hours and Costs

A key objective of this project is to demonstrate that the harmonized outcome measures can be captured as part of the routine clinical workflow, with little to no added burden for clinicians and patients. The harmonized measures will be calculated using routinely captured clinical data extracted from electronic medical records (EMRs) and ancillary systems used to capture patient-reported outcomes. Extraction of these data will not represent an additional burden for clinicians or patients, as only data that are recorded as part of routine clinical care will be used to calculate the harmonized measures. Clinicians participating in the health system component of the project will be asked to complete the Clinician Survey at the conclusion of the project. Burden is estimated below for completion of this survey by the clinician respondent.

Because the primary objective of this project is to determine the feasibility and value of extracting the relevant data and calculating the measures, a formal sample size has not been calculated. Five sites at the health system will participate in this project. We anticipate that three clinicians associated with each of the five health system sites will complete the Clinician Survey. Therefore, the total number of respondents for the Clinician Survey is estimated at 15. Respondents will be asked to complete the Clinician Survey once, at the conclusion of the project; the survey is designed to be completed in 5 minutes or less. If 15 clinicians complete the Clinician Survey once over the course of one year, the estimated annualized burden would be 1.25 hours. The total estimated annualized burden would be 43.75 hours.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
Clinician Survey	15	1	5 minutes	1.25 hours
Total	15	1	5	1.25 hours

Exhibit 2 shows the estimated cost burden associated with the respondent's time to complete the Clinician Survey as part of this project. The total cost burden to respondents is estimated at an average of $49.28 annually. The duration of this project is one year.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Clinician Survey	15	1.25	$39.42#	$49.28
Total	15	1.25	$39.42	$49.28

[#] Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29-0000. May 2018 National Occupational Employment and Wage Estimates. U.S. Department of Labor, Bureau of Labor Statistics. Available at: https://www.bls.gov/oes/current/oes_nat.htm#29-0000.

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

Costs to the Federal government are those costs associated with work by AHRQ's contractor, OM1, Inc., and OM1's subcontractors, American Board of Family Medicine, American Psychiatric Association, Baystate Health, and Elimu Informatics, to implement the harmonized outcome measures in the patient registry and health system settings and evaluate the value of the harmonized measures for informing patient care and supporting research. Over a two-year period, the total amount allocated for these tasks is $2,609,660. As such, the estimated annualized cost to the federal government is $1,304,830.

Per exhibit 3, the Federal Government Personnel Cost (at approximately 10%, or 208 hours, of an FTE Project Officer, GS 15, Step 5) is estimated at $15,622.80 on an annual basis.

Exhibit 3. Federal Government Personnel Cost

Activity	Federal Personnel*	Annual Rate	Estimated Hours	Annual Cost
Project Oversight	**Project Officer, GS 15, Step 5**	**$156,228**	**208**	**$15,622.80**
Total				**$15,622.80**

Annual salaries based on 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

No program changes or adjustments were made.

16. Time Schedule, Publication and Analysis Plans

The project findings will be published in three documents:

1. A final report will be submitted to AHRQ to describe the project approach, methods, any challenges encountered, key findings, and next steps.
2. A manuscript will describe findings from the pilot data analysis conducted with the harmonized outcome measure data from the patient registries. The specific nature of the analysis will be determined following selection of a research question by a Stakeholder Panel in early 2020. The pilot study will include, at minimum, descriptive analyses to gain an understanding of the study population (e.g., demographics, depression severity as indicated by PHQ-9 scores) and any subgroups of interest. A complete Statistical Analysis Plan will be developed following selection of a research question by the Stakeholder Panel. No complex analytical techniques are planned for this pilot data analysis.
3. A second manuscript will describe findings from implementation of the measures in the health system, including any workflow or health IT challenges encountered, and the results of the Clinician Survey. The survey data will be summarized for presentation in the manuscript, and no information that could be used to identify the individual Clinician participants will be included.

The final report will be submitted to AHRQ for publication on the AHRQ website. The manuscripts will be submitted to peer-reviewed scientific journals selected in collaboration with the Stakeholder Panel. The project activities will be conducted between May 15, 2019 and May 14, 2021. Data collection (pending PRA approval) is scheduled to begin by March 15, 2020 and conclude by March 15, 2021. Data analyses will be conducted in early 2021, with the report and manuscripts completed by May 15, 2021. (Note, manuscript publication dates will depend on the timelines for journal review, acceptance, and publication).

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Depression Capstone Project Registry Protocol

Attachment B: Depression Capstone Project Health System Protocol

Attachment C: Clinician Survey

Attachment D: Federal Register Notice