SUPPORTING STATEMENT

Part A

Building Diagnostic Safety Capacity – TeamSTEPPS® Course Evaluation Plan

Version: *September 11, 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 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.

Background for this information collection

Delayed, wrong, and missed diagnoses, or diagnostic errors, account for 40,000 to 80,000 patient deaths each year[1-2]. Diagnostic errors are the most harmful type of medical error[3] and are responsible for 33% of malpractice claims that result in permanent injury or death[4] of the patient. 33% [5]of diagnostic-related malpractice claims have one or more communication breakdowns contributing to the event. The TeamSTEPPS® Course – to improve diagnostic-related communication among providers – seeks to mitigate provider communication breakdowns which contribute to diagnostic errors.

The diagnostic process is a team-based activity and in their 2015 report, Improving Diagnosis in Health Care, the National Academies of Science, Engineering, and Medicine (NASEM) identified the need for more effective teamwork in the diagnostic process among health care providers, patients, and their family members. Patient-provider encounters, diagnostic referrals, and daily team huddles are opportunities where improving communication among providers related to diagnosis may mitigate error[6-7].

The TeamSTEPPS® Course combines National Academy of Medicine's (NAM) Diagnostic Process Framework with established TeamSTEPPS® communication strategies and provides caregivers opportunities to learn about the diagnostic process, improve intra-professional communication and communication during the referrals process, practice mutual support and

situation monitoring in the diagnostic process. The Course also includes an educational module for leaders on strategies to facilitate improved communication related to diagnosis among healthcare providers.

This information collection has the following goal:

1. To pilot test a TeamSTEPPS® Course to improve communication among providers related to diagnosis (the Course) in order to reduce diagnostic errors and qualitatively examine:
    a. Feasibility of the implementing the Course with limited to no technical assistance;
    b. Receptivity of providers to the Course;
    c. Solicit feedback on areas to improve the Course and delivery within each setting.

To achieve the goals of this project the following information collection instruments will be completed using individual interviews and/or focus groups:

1) **Setting-Level Demographics Survey** (Appendix A) **-** designed to qualitatively describe the characteristics of the practices engaged in pilot testing (e.g. patient characteristics, practice size, and staffing).

2) **Individual Respondent Characteristics (Providers)** (Appendix B) **-** designed to qualitatively describe the characteristics of individual providers engaged in interviews and focus groups.

3) **Individual Respondent Characteristics (Staff)** (Appendix C) – designed to qualitatively describe the characteristics of individual staff members engaged in interviews and focus groups.

4) **Individual Respondent Characteristics (Administrators)** (Appendix D) – designed to qualitatively describe the characteristics of individual administrators engaged in interviews and focus groups.

5) **Organizational Readiness for Change Survey** (Appendix E) **-** designed to qualitatively assess each practices' readiness for implementing new practice processes, improvements, etc.

6) **Pilot Test Interview Protocol for Providers with TeamSTEPPS® Experience** (Appendix F) **-** designed to qualitatively assess the barriers and facilitators of implementing the Course in practice, provider receptivity to and experience with using the Course, and recommendations for improvements to improve satisfaction of use from providers with prior experience using TeamSTEPPS® strategies.

7) **Pilot Test Interview Protocol for Providers with no TeamSTEPPS® Experience** (Appendix G) **-** designed to qualitatively assess the barriers and facilitators of

implementing the Course in practice, provider receptivity to and experience with using the Course, and recommendations for improvements to improve satisfaction of use from providers with NO prior experience using TeamSTEPPS® strategies.

8) **Pilot Test Evaluation Protocol for Staff with TeamSTEPPS® Experience** (Appendix H) – designed to qualitatively assess the barriers and facilitators of implementing the Course in practice, staff receptivity to and experience with using the Course, and recommendations for modifications to improve satisfaction of use from staff members with prior experience using TeamSTEPPS® strategies.

9) **Pilot Test Evaluation Protocol for Staff with No TeamSTEPPS® Experience** (Appendix I) – designed to qualitatively assess the barriers and facilitators of implementing the Course in practice, practice staff receptivity to and experience with using the Course, and recommendations for improvements to improve satisfaction of use from staff members with NO prior experience using TeamSTEPPS® strategies.

10) **Pilot Test Evaluation Protocol for Administrators with TeamSTEPPS® Experience** (Appendix J) - The information collection approach will be qualitative. Information collected will assess the barriers and facilitators of Course implementation. It will summarize and synthesize qualitative information and recommendations for improvement based on stakeholder feedback (administrators with prior TeamSTEPPS® experience), satisfaction, and receptivity to the Course.

11) **Pilot Test Evaluation Protocol for Administrators with No TeamSTEPPS® Experience** (Appendix K) - The information collection approach will be qualitative. Information collected will assess the barriers and facilitators of Course implementation. It will summarize and synthesize qualitative information and recommendations for improvement based on stakeholder feedback (administrators with NO prior TeamSTEPPS® experience), satisfaction, and receptivity to the Course.

12) **Training Observation Tool** (Appendix L) – Designed to collect qualitative data on the use of the Course through direct observation during site visits.

This information collection is being conducted by AHRQ through its contractor, MedStar Health Research Institute, 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

AHRQ will use the information collected through this Information Collection Request to assess the feasibility of adopting the TeamSTEPPS Course to improve communication among providers related to diagnosis. A qualitative approach to data collection (e.g., individual interviews and/or focus groups) and analysis will be used to provide useful insights on stakeholders' perceptions and opinions, identify barriers and facilitators to Course implementation, receptivity to the Course by stakeholders, including clinicians, practice staff and administrators, as well as to

explore stakeholder feedback to enhance the usability of the Course. This information collection has two target audiences: i) settings that have experience with AHRQ's TeamSTEPPS® program and have an interest in learning about diagnostic error, and ii) settings that are interested in improving diagnosis communication but do not have experience in TeamSTEPPS®. This will give us important information on how feasible the TeamSTEPPS® for diagnosis Course is to implement for both experienced and novice TeamSTEPPS® stakeholders.

In this context, we will examine the question "*How and in what contexts do the chosen interventions work or can they be amended to work*", rather than evaluating effectiveness or "*Do they work*?" This approach will not consist of statistical surveys that yield quantitative results that can be generalized to the population. Pilot testing will occur at up to 20 information collection sites and feasibility of implementation will be assessed at the stakeholder and practice levels. The information collected from stakeholders will be used to revise the Course in order to promote widespread adoption.

The specific purpose of each of the information collection instruments is described below:

1. **Setting-Level Demographics Survey** (Appendix A). The information collection instrument will qualitatively summarize and describe the characteristics of the practices engaged in the pilot test. The information will be used to summarize information on practice characteristics in a qualitative manner. It will also allow for the project team to identify competing priorities that may inhibit full practice participation with the proposed qualitative methods. This information collection will provide context for the pilot tests and generate information on the type of practices where the Course interventions were pilot tested. It will thus support the ability to define the types of practices where the Course is found to be generally acceptable.

2. **Individual Respondent Characteristics (Providers)** (Appendix B). The information collection instrument will qualitatively summarize the characteristics of individual providers engaged in interviews and focus groups. These data will be presented in aggregate and used to describe the characteristics of the group providing feedback. No information will allow for individual identification of participants.

3. **Individual Respondent Characteristics (Staff)** (Appendix C) – The information collection instrument will qualitatively summarize the characteristics of individual staff members engaged in interviews and focus groups. These data will be presented in aggregate and used to describe the characteristics of the group providing feedback. No information will allow for individual identification of participants.

4. **Individual Respondent Characteristics (Administrators)** (Appendix D) – The information collection instrument will qualitatively summarize the characteristics of individual administrators engaged in interviews and focus groups. These data will be presented in aggregate and used to describe the characteristics of the group providing feedback. No information will allow for individual identification of participants.

5. **Organizational Readiness for Implementation Change (ORIC)** (Appendix E). The information collection instrument will qualitatively assess individual practice's readiness to change. One individual from the practice will complete the instrument in collaboration with a project team member/interviewer.

6. **Pilot Test Interview Protocol for Providers with TeamSTEPPS® Experience** (Appendix F) - designed to qualitatively assess the barriers and facilitators of implementing the Course in practice, provider receptivity to and experience with using the Course, and recommendations for improvements to improve satisfaction of use to improve satisfaction of use from providers with prior experience using TeamSTEPPS® strategies.

7. **Pilot Test Interview Protocol for Providers with No TeamSTEPPS® Experience** (Appendix G) - designed to qualitatively assess the barriers and facilitators of implementing the Course in practice, provider receptivity to and experience with using the Course, and recommendations for improvements to improve satisfaction of use from providers with NO prior experience using TeamSTEPPS® strategies.

8. **Pilot Test Evaluation Protocol for Staff with TeamSTEPPS® Experience** (Appendix H) – designed to qualitatively assess the barriers and facilitators of implementing the Course in practice, staff receptivity to and experience with using the Course, and recommendations for improvements to improve satisfaction of use from staff members with prior experience using TeamSTEPPS® strategies.

9. **Pilot Test Evaluation Protocol for Staff with No TeamSTEPPS® Experience** (Appendix I) – designed to qualitatively assess the barriers and facilitators of implementing the Course in practice, staff receptivity to and experience with using the Course, and recommendations for improvements to improve satisfaction of use from staff members with NO prior experience using TeamSTEPPS® strategies.

10. **Pilot Test Evaluation Protocol for Administrators with TeamSTEPPS® Experience** (Appendix J) - The information collection approach will be qualitative. Information collected will assess the barriers and facilitators of Course implementation. It will summarize and synthesize qualitative information and recommendations for improvement based on stakeholder feedback (administrators with prior TeamSTEPPS® experience), satisfaction, and receptivity to the Course.

11. **Pilot Test Evaluation Protocol for Administrators with No TeamSTEPPS® Experience** (Appendix K) - The information collection approach will be qualitative. Information collected will assess the barriers and facilitators of Course implementation. It will summarize and synthesize qualitative information and recommendations for improvement based on stakeholder feedback (administrators with NO prior TeamSTEPPS® experience), satisfaction, and receptivity to the Course.

12. **Training Observation Tool** (Appendix L) – Designed to collect qualitative data on the use of the Course through direct observation during site visits.

These information collection instruments (Appendices A-L) are designed to capture qualitative data (Appendices E-L) with some quantitative data (Appendices A-D). No claim is made that the results from this evaluation will be generalizable in a statistical sense, nor is the intent to conduct statistical analyses. However, every attempt will be made to recruit practices that are representative of diverse geographic locations as well as diverse patient populations served including practices that serve AHRQ priority populations. The goals of the evaluation are aimed at soliciting stakeholder feedback through interviews and/or focus groups on the challenges of implementation, receptivity to the Course, and feedback on how to improve the Course to support adoption and implementation. The information collected will be used to revise the Course to enhance usability and receptivity.

3. Use of Improved Information Technology

The information collection described herein will rely on paper data collection instruments in the form of interview and focus group guides to be used by the interview and/focus group facilitators and moderators for each information collection activity. Interviews and focus groups will be audio recorded for the purpose of transcription and coding. There will otherwise be no automated, electronic, or other technological collection techniques or other forms of information technology used for the information collection.

4. Efforts to Identify Duplication

The first phase of the parent study involved an extensive environmental scan to review the literature, including published, unpublished, and internet sources to identify existing interventions and resources pertinent to Course development. The environmental scan revealed key gaps in provider communication related to diagnosis leading to missed, delayed, and wrong diagnosis which are addressed, in part, by the Course being evaluated under this information collection request. To our knowledge, this does not involve a duplication of any existing efforts as suggested by the gap analysis resulting from the environmental scan.

5. Involvement of Small Entities

The information being collected under this request will reflect the variety of settings in which the Course will actually be used. This includes medium (4-9 clinicians) and large (more than 9 clinicians) ambulatory care practices, urgent care centers, skilled nursing facilities, and hospitals. However, to our knowledge none of the practices volunteering to participate would be considered small businesses or small entities.

6. Consequences if Information Collected Less Frequently

This information collection is for a onetime data collection only. All of the information needed to solicit stakeholder feedback to inform Course revisions under this information collection request does not need to be collected more than once.

7. Special Circumstances

This request is consistent with the generic 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

This information collection is being submitted under AHRQ's generic clearance. A Federal Register notice is therefore not required.

8.b. Outside Consultations

Not applicable.

9. Payments/Gifts to Respondents

Our information collection efforts will not offer direct payments or gifts to individual respondents. The organizations engaging in the information collection efforts will be sub-contractors to the MedStar Health Research Institute and their partners.

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. Participant characteristics that will be collected for individuals volunteering to pilot test the Course can be found in Appendices B-D. These data will be presented in aggregate and used to describe the characteristics of the group providing feedback. No information will allow for individual identification of participants

Participants will also receive the following confidentiality statements printed on any respondent materials*:*

"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 collected will be maintained in a secure HIPAA-compliant data server. All information collection will be stored using the contractor, MedStar's REDCap™ research data capture database. REDCap™ is a mature, secure web application for building and managing online information collection instruments and data. While REDCap™ can be used to collect virtually any type of data, it is specifically geared to support data capture for research studies. The REDCap™ Consortium is composed of 1,711 active institutional partners in 96 countries who utilize and support REDCap™ in various ways. REDCap™ can be established to support data entry forms and to conduct web-enabled surveys. The Course will also use a REDCap™ project space to securely store any documents received from the practices during the project. The MedStar Health Research Institute is a REDCap™ project collaborator site with a robust history of using this method for data collection.

The information collected will be primarily qualitative in nature (Appendices E-K). Responses to interviews and/or focus groups will be recorded and notes for each session transcribed. Transcription files will be uploaded to the REDCap™ file repository for security. Paper files will be retained in a locked file cabinet within MedStar Health. A case record form will be created within REDCap™ to record output from the thematic reviews of the transcripts to facilitate reporting and feedback to participants and to the study team. This information collection request (ICR) does not contain surveys, censuses, or employ statistical methods.

This ICR does not request any personally identifiable information.

This ICR does not include a form that requires a Privacy Act Statement.

Does this ICR contain surveys, censuses, or employ statistical methods? Yes **No**

Does this ICR request any personally identifiable information (see OMB Circular No. A-130 for an explanation of this term)? Please consult with your agency's privacy program when making this determination Yes **No**

Does this ICR include a form that requires a Privacy Act Statement (see 5 U.S.C. §552a(e)(3))? Please consult with your agency's privacy program when making this determination. Yes **No**

11. Questions of a Sensitive Nature

The proposed information collection does not include any questions of a sensitive nature. Each respondent will undergo an informed consent process that will describe participant rights. We anticipate that the MedStar Health Research Institute's Intuitional Review Board will grant a waiver of documentation for written consent as the consent form will be the only documentation linking the participant's identity to the information collection. Each participant will receive a copy of the study information sheet for verbal consent and an information sheet on the project that outlines the participant's rights as is standard for MedStar's exempt studies where active recruitment is required. The consent process will highlight the participants right to answer or not answer any questions that they are asked and their right to withdraw from the interview and/or focus group at any time without penalty or repercussions.

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
Appendix A: Setting Demographics Survey	20	1	1.5	30
Appendix B: Individual Respondent Characteristics (Providers)	120	1	0.08	9.6
Appendix C: Individual Respondent Characteristics (Staff)	120	1	0.08	9.6

Appendix D: Individual Respondent Characteristics (Admin)	60	1	0.08	4.8
Appendix E: Organizational Readiness for Implementation Change (ORIC)	20	1	.25	5
Appendix F: Pilot Test Interview Protocol for Providers – TeamSTEPPS®	60	1	.75	45
Appendix G: Pilot Test Interview Protocol for Providers – No TeamSTEPPS®	60	1	.75	45
Appendix H: Pilot Test Evaluation Protocol for Staff – TeamSTEPPS®	60	1	1	60
Appendix I: Pilot Test Evaluation Protocol for Staff – No TeamSTEPPS®	60	1	1	60
Appendix J: Pilot Test Evaluation Protocol for Administrators – TeamSTEPPS®	30	1	1	30
Appendix K: Pilot Test Evaluation Protocol for Administrators – No TeamSTEPPS®	30	1	1	30
Appendix L: Training Observation Tool	1	40	1.5	60
Total	**NA**	**NA**	**NA**	**389**

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Appendix A: Setting Demographics Survey	20	30	$54.68[a]	$1,640.40
Appendix B: Individual Respondent Characteristics (Providers)	120	9.6	$93.61[b]	$898.66
Appendix C: Individual Respondent Characteristics (Staff)	120	9.6	$20.23[c]	$194.21
Appendix D: Individual Respondent Characteristics (Admin)	60	4.8	$54.68[a]	$262.46

Appendix E: Organizational Readiness for Implementation Change (ORIC)	20	5	$54.68[a]	$273.40
Appendix F: Pilot Test Interview Protocol for Providers – TeamSTEPPS®	60	45	$93.61[b]	$4,212.45
Appendix G: Pilot Test Interview Protocol for Providers – No TeamSTEPPS®	60	45	$93.61[b]	$4,212.45
Appendix H: Pilot Test Evaluation Protocol for Staff – TeamSTEPPS®	60	60	$20.23[c]	$1,213.80
Appendix I: Pilot Test Evaluation Protocol for Staff – No TeamSTEPPS®	60	60	$20.23[c]	$1,213.80
Appendix J: Pilot Test Evaluation Protocol for Administrators – TeamSTEPPS®	30	30	$54.68[a]	$1,640.40
Appendix K: Pilot Test Evaluation Protocol for Administrators – No TeamSTEPPS®	30	30	$54.68[a]	$1,640.40
Appendix L: Training Observation Tool	1	60	$20.23[c]	$1,213.80
Total	**NA**	**389**	**NA**	**$18,616.23**

* National Compensation Survey: Occupational wages in the United States May 2018 "U.S. Department of Labor, Bureau of Labor Statistics."

[a] Based on the mean wages for *Medical and Health Services Managers (Code 11-9111)*

[b] Based on the mean wages for *Family Medicine/General Practitioners (Code 29-1062)*

[c] Based on the mean wages for *HC Support Occupations (Code 31-000)*

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

The total contractor cost to the government is estimated to be $202,738.56. As shown in Exhibit 3a, this amount includes costs for project development ($18,812.50); data collection activities ($93,152.31); data processing and analysis ($24,178.47), project management ($18,812.50) and overhead ($47,782.78).

Exhibit 3a. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$18,812.50	$18,812.50

Data Collection Activities	$93,152.31	$93,152.31
Data Processing and Analysis	$24,178.47	$24,178.47
Publication of Results	$0	$0
Project Management	$18,812.50	$18,812.50
Overhead	$47,782.78	$47,782.78
Total	$202,738.56	$202,738.56

Exhibit 3b. Federal Government Personnel Cost

Activity	Federal Personnel	Hourly Rate	Estimated Hours	Cost
Project oversight to include data collection oversight and review of results	Project Officer GS14	$75.57	25	$1,889.25
Total				**$ 1,889.25**

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

15. Changes in Hour Burden

This is a new information collection, thus no changes in hour burden is expected or reported here.

16. Time Schedule, Publication and Analysis Plans

The information collection will begin upon OMB approval (estimated October 2020) and will include recruitment of practices and completion of all data collection activities by June 2021. Qualitative analysis will be completed by July 2021 and materials will be revised based on stakeholder feedback by September 2021. We anticipate a 6-month pilot test timeline. Publication of the materials by AHRQ on their website will be completed after 508 compliance review. There are no other publication efforts associated with this information collection effort.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Appendix A: Setting Demographics Survey

Appendix B: Individual Respondent Characteristics Survey (Providers)

Appendix C: Individual Respondent Characteristics Survey (Staff)

Appendix D: Individual Respondent Characteristics Survey (Administrators)

Appendix E: Organizational Readiness for Implementation Change (ORIC)

Appendix F: Pilot Test Interview Protocol for Providers – TeamSTEPPS®

Appendix G: Pilot Test Interview Protocol for Providers – No TeamSTEPPS®

Appendix H: Pilot Test Evaluation Protocol for Staff – TeamSTEPPS®

Appendix I: Pilot Test Evaluation Protocol for Staff – No TeamSTEPPS®

Appendix J: Pilot Test Evaluation Protocol for Administrators – TeamSTEPPS®

Appendix K: Pilot Test Evaluation Protocol for Administrators – No TeamSTEPPS®

Appendix L: Training Observation Tool

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