

grants programs and other agency information exchange mechanisms.

**Method of Collection**

Grantees are required to enter data related to the progress of their grant funded research quarterly through a secure online interface which requires a user id and password.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents. It will take grantees an estimated 10 minutes to enter the necessary data into the Grant Reporting System (GRS) and reporting will occur four times annually. The total

annualized burden hours are estimated to be 333 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents. The total estimated cost burden for respondents is \$11,159.

**EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Data entry into GRS .....	500	4 .....	10/60 .....	333
Total .....	500	na .....	na .....	333

**EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN**

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Data entry into GRS .....	500	333	\$33.51 .....	\$11,159
Total .....	500	333	na .....	11,159

\* Based upon the average wages for Healthcare Practitioner and Technical Occupations (29-0000), "National Compensation Survey: Occupational Wages in the United States, May 2009," U.S. Department of Labor, Bureau of Labor Statistics.

**Estimated Annual Costs to the Federal Government**

The annual cost to the government is \$100,000 for licensing, support and maintenance.

**Request for Comments**

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

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

Dated: August 16, 2010.  
**Carolyn M. Clancy**,  
*Director.*  
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**BILLING CODE 4160-90-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Avoiding Readmissions in Hospitals Serving Diverse Patients." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on June 21st, 2010 and allowed 60 days for public comment. One comment was received. The purpose of

this notice is to allow an additional 30 days for public comment.

**DATES:** Comments on this notice must be received by September 30, 2010.

**ADDRESSES:** Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by e-mail at [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) (attention: AHRQ's desk officer).

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

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

*Avoiding Readmissions in Hospitals Serving Diverse Patients*

An important part of AHRQ's mission is to disseminate information and tools that can support improvement in quality and safety in the U.S. health care community. The transition process from the hospital to the outpatient setting is nonstandardized and frequently inadequate in quality. One in five hospital discharges is complicated by an adverse event (AE) within 30 days, often leading to an emergency department visit and/or rehospitalization. Many

readmissions stem from errors that can be directly attributed to the discontinuity and fragmentation of care at discharge. High rates of low health literacy, lack of coordination in the "hand-off" from the hospital to community care, gaps in social supports, and other limitations also contribute to the risk of rehospitalization.

Boston University Medical Center (BUMC), through a grant from AHRQ, previously defined the discharge process and determined what improvements could be made to improve this care transition for patients. This new process was called the "re-engineered discharge" (RED). The RED consists of 11 elements, including educating the patient throughout the hospital stay, making follow-up appointments, and giving the patient a written discharge plan. The RED was tested in a randomized controlled trial in an academic safety net hospital at BUMC with English speaking, general medical patients being discharged to home or community settings. Results of this trial of 749 patients showed a reduction in rehospitalizations within 30 days and emergency department visits following hospital discharge. Participants also followed up with primary care providers more often and reported higher patient satisfaction with the discharge process. Project RED researchers created several tools to help hospitals replicate RED. After AHRQ and Project RED researchers fielded many inquiries about how to implement Project RED at hospitals nationwide, AHRQ realized that the Project RED Toolkit did not provide sufficient guidance to potential replicators. Various components of the RED were not documented, and issues regarding implementing the RED at hospitals serving linguistically and culturally diverse patient populations had not been addressed. AHRQ has therefore contracted with the RED researchers to create a revised RED Toolkit that will address these issues.

This proposed information collection supports AHRQ's mission by improving upon the RED Toolkit. This project has the following 2 goals:

(1) To pre-test the revised RED Toolkit in ten varied hospital settings, evaluating how the RED Toolkit is implemented in varied hospital settings by: (a) Documenting the implementation process; (b) assessing the fidelity of implementation; and (c) identifying the factors that affect redesign fidelity, including intensity of technical assistance (TA).

(2) To modify the revised RED Toolkit based on pre-testing and to disseminate it.

BUMC will provide TA at two varying levels. Four selected hospitals will receive "train-the-trainer" TA, which includes:

(1) Telephone assistance in conducting a baseline needs assessment;

(2) Master trainer training;

(3) Access to webinar trainings specifically designed for each user (nurse, IT professional, hospital leadership, and pharmacist);

(4) An electronic template to print an After Hospital Care Plan (AHCP) booklet; and

(5) E-mails regarding updates to the RED Web site and the opportunity to ask questions about the newly revised and enhanced RED tools and implementation via telephone and e-mail.

Six selected hospitals will receive intensive TA, which includes:

(1) Telephone baseline needs assessment;

(2) On-site training;

(3) Monthly semi-structured interviews via phone calls with the implementation team to discuss implementation efforts and barriers;

(4) Adaptation of the revised RED Toolkit to include specific details about the hospital (such as the hospital name on the cover of the AHCP booklet and hospital-specific services provided to patients included in the AHCP booklet);

(5) An assessment and evaluation site visit by the organizational change evaluator (a member of the implementation team), at baseline and 12 months after the start of implementation efforts to interview select participating hospital staff;

(6) IT support to install and support the RED Toolkit software to automatically generate the AHCP booklet; and

(7) E-mails regarding updates to the RED Web site and the opportunity to ask questions about the newly revised and enhanced RED tools and implementation via telephone and e-mail.

A diverse group of hospitals will be selected to receive each level of TA, based upon hospital size, location, readmission rate and patient population. Implementing the revised RED Toolkit in diverse settings will provide a better understanding of whether and how RED can be best implemented in different hospital settings.

The project will be framed within a model of organizational change and transformation called the Organizational Transformation Model (OTM), which is

based on the evaluation of Robert Wood Johnson Foundation's Pursuing Perfection initiative. OTM identifies key elements that drive dramatic system change and informs the implementation process and impact evaluation. Using a mixed-methods design, the evaluation tracks change over time and across the implementation period within each hospital. The evaluation therefore will encompass feedback on specific implementation processes and factors in microsystems where RED is adopted, in the larger organizational context, and interactions between the two.

This research study is being conducted by AHRQ through its contractor, BUMC, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and disseminate information 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. 299(b) and 299a(a)(1) and (2).

#### Method of Collection

To achieve the projects' goals, the following data collections and training will be implemented for the six hospitals that will receive intensive TA as well as the 4 hospitals receiving train-the-trainer TA, unless otherwise noted:

(1) Baseline needs assessment to help each hospital plan and prepare for implementation of the revised RED Toolkit and to evaluate it in varied settings (*see* Attachment C). This is not a data collection but will impose a time burden on the participating hospitals as they prepare to participate in this project. The purpose of the needs assessment is for the hospital to become familiar with their discharge process and what parts of the process are being done well and what parts of the process need improvement. In order to implement the new RED discharge process, it is important for a hospital to plan how they will do this. This information will be shared during the baseline key contact semi-structured interview.

(2) Baseline key contact semi-structured interviews will be administered by telephone, approximately two months prior to implementation, to the key contact at each of the ten study hospitals (*see* Attachment D). The purpose of the interview is to identify the implementation team, collect some basic information about the hospital, such as the number of beds and if electronic medical records are used, and

to establish the baseline readmission rate.

(3) Monthly semi-structured interviews with the key contact or other implementation team member will be conducted monthly for 12 months after implementation (see Attachment E). These interviews will be conducted by phone with each of the six hospitals receiving intensive technical assistance (TA) (the two levels of TA are described above). The purpose of these interviews are to allow hospitals to share their experiences with implementing the revised RED Toolkit, their use of specific tools, changes resulting from using the tools and problems encountered implementing the revised RED Toolkit and how they are being addressed.

(4) Baseline semi-structured interviews will be conducted prior to the implementation of the revised RED Toolkit with 15 hospital staff from each of the six study hospitals receiving intensive TA (see Attachment F). The purpose of this interview is to measure the staff's opinion of the current discharge process, their perceived need for a redesigned process, and the perceived barriers and facilitators to redesigning the discharge process.

(5) Post implementation semi-structured interviews will be conducted 12 months after the implementation of the revised RED Toolkit with 15 hospital staff from each of the six study hospitals receiving intensive TA (see Attachment G). The purpose of this interview is to measure the staff's opinion of the redesigned discharge process, which tools were used and their opinion of the tools, and the observed barriers and facilitators to redesigning the discharge process.

(6) Patient surveys will be administered by telephone to a random sample of patients 30 days after being discharged from one of the six intensive TA study hospitals (see Attachment H). The purpose of this survey is to measure patient outcomes, including satisfaction with the care they received, 30-day hospital and emergency department visits, and physician appointments, to help determine the success of the RED

Toolkit implementation in diverse patient populations. The survey will be administered by a hospital staff member to patients during the pre-implementation period and again during the post-implementation period to compare patient outcomes.

(7) Medical record review of patient outcomes at all ten study hospitals (see Attachment I). This data collection will be conducted both pre- and post-implementation of the revised RED Toolkit and will inform the success of the revised RED Toolkit implementation in diverse patient populations. Outcomes to be collected include process outcomes, such as primary care provider appointments scheduled prior to discharge, and patient outcomes, such as 30-day hospital and emergency department visits.

(8) Master trainer training will be conducted with 3 staff members from each of the 4 hospitals receiving train-the-trainer TA (see Attachment J). These people will be trained to administer the RED Toolkit and be able to use recorded webinar training sessions within their organization. They will be invited to travel to BUMC for a 2-day onsite orientation of the RED intervention. These people will meet with several members of the BUMC implementation team (physician leader, discharge advocate nurse) and will have the opportunity to shadow the nurse discharge advocates in conducting the RED intervention.

(9) Intensive training will be conducted with about 28 staff from each of the 6 hospitals receiving intensive TA (see Attachment K). The training will consist of a two-day on-site orientation and training at each hospital conducted by the BUMC implementation team. The BUMC implementation team will consist of a physician researcher, a discharge advocate nurse, an organizational change champion/evaluator and the information technology expert. The BUMC team will spend two days, 8 hours per day, to train the relevant hospital staff to perform the 11 components of the RED discharge. The training will include material for senior hospital

management, hospital physicians, nurses, IT staff, and pharmacists.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours associated with the respondent's time to participate in this research. The baseline needs assessment will be conducted by staff at each of the 10 participating hospitals and takes about 8 hours to complete. Baseline key contact semi-structured interviews will be conducted with the key contact at each hospital and requires 1 hour to complete. Monthly semi-structured interviews with the key contact or other implementation team member will be conducted monthly for 12 months after implementation. These interviews will be conducted by phone with each of the six hospitals receiving intensive TA and will require 1 hour to complete. Both the base-line and post-implementation semi-structured interviews will be conducted with 15 staff members from each of the 6 hospitals receiving intensive TA and will last about one hour. The patient survey will be administered twice, pre and post implementation, to 3,108 patients recently discharged from one of the 6 hospitals receiving intensive TA and requires 10 minutes to complete. The patient survey will be administered by the hospital staff and will require 10 minutes of their time to administer. Medical record review will be performed at all 10 participating hospitals both pre and post implementation and will take about 41.6 hours. Master trainer training will be conducted with 3 staff members from each of the 4 hospitals receiving train the trainer TA and will last 16 hours. Intensive training will be conducted with about 28 staff members from each of the 6 hospitals receiving intensive TA and will also last 16 hours. The total annualized burden is estimated to be 6,126 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this research. The total annualized cost burden is estimated to be \$194,163.

**EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Baseline needs assessment .....	10	1	8	80
Baseline key contact semi-structured interview .....	10	1	1	10
Monthly semi-structured interview .....	6	12	1	72
Baseline semi-structured interview .....	6	15	1	90
Post implementation semi-structured interview .....	6	15	1	90
Patient survey .....	3,108	2	10/60	1,036

## EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Administration of patient survey by hospital staff .....	6	1,036	10/60	1,036
Medical record review .....	10	2	41.6	832
Master trainer training .....	4	3	16	192
Intensive training .....	6	28	16	2,688
Total .....	3,172	na	na	6,126

## EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Baseline needs assessment .....	10	80	<sup>a</sup> \$41.94	\$3,355
Baseline key contact semi-structured interview .....	10	10	<sup>b</sup> \$51.91	519
Monthly semi-structured interviews .....	6	72	<sup>c</sup> \$40.91	2,946
Baseline semi-structured interview .....	6	90	<sup>d</sup> \$38.51	3,466
Post implementation semi-structured interview .....	6	90	<sup>e</sup> \$38.51	3,466
Patient survey .....	3,108	1,036	<sup>f</sup> \$20.32	21,052
Administration of patient survey by hospital staff .....	6	1,036	<sup>b</sup> \$31.31	32,437
Medical record review .....	10	832	<sup>g</sup> \$17.32	14,410
Master trainer training .....	4	192	<sup>h</sup> \$31.31	6,012
Intensive training .....	6	2,688	<sup>i</sup> \$40.91	109,966
Total .....	3,172	6,126	na	194,163

\* Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States May 2008, "U.S. Department of Labor, Bureau of Labor Statistics."

(a) 75% Nurses (29–1111, \$31.31/hr), 20% Physicians (29–1069, \$79.33/hr) and 5% General and Operations Managers (29–1069, \$51.91/hr).

<sup>b</sup> 100% General and Operations Managers (29–1069, \$51.91/hr).

<sup>c</sup> 80% Nurses and 20% Physicians.

<sup>d</sup> and <sup>e</sup> 85% Nurses and 15% Physicians.

<sup>f</sup> 100% General public (00–0000, \$20.32/hr).

<sup>g</sup> 100% Statistical assistants (439111, \$17.32/hr).

<sup>h</sup> 100% Nurses.

<sup>i</sup> 80% Nurses and 20% Physicians.

**Estimated Annual Costs to the Federal Government**

this clearance. The total cost is \$449,976.

Exhibit 3 shows the total and annualized cost over the 18 months of

## EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annual cost
Project RED Toolkit Development .....	\$97,413	\$64,942
Dissemination Planning and Support .....	98,080	65,387
Data Collection Activities .....	84,563	56,375
Data Processing and Analysis .....	52,215	34,810
Publication of Results .....	3,184	2,123
Project Management .....	28,892	19,261
Overhead .....	85,629	57,086
Total .....	449,976	299,984

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination

functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of

automated collection techniques or other forms of information technology.

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

Dated: August 20, 2010.  
**Carolyn M. Clancy,**  
*Director.*  
 [FR Doc. 2010-21503 Filed 8-30-10; 8:45 am]  
**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60 Day 10-10GP]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. Alternatively, to obtain a copy of the data collection plans and instrument, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarify of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the

use of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

*Clostridium difficile* Infection (CDI) Surveillance—New—National Center for Emerging and Zoonotic Infectious Diseases, (NCEZID), Centers for Disease Control and Prevention, (CDC).

*Background and Brief Description*

Steady increases in the rate and severity of *Clostridium difficile* infection (CDI) indicate a clear need to conduct longitudinal assessments of the impact of CDI in the United States. *C. difficile* is an anaerobic, spore-forming, gram positive bacillus that produces two pathogenic toxins: A and B. CDI ranges in severity from mild diarrhea to fulminant colitis and death. Transmission of *C. difficile* occurs primarily in healthcare facilities, where environmental contamination by *C. difficile* spores and exposure to antimicrobial drugs are common. No longer limited to healthcare environments, community-associated CDI is the focus of increasing attention. Recently, several cases of serious CDI have been reported in what have been considered low-risk populations, including healthy persons living in the community and peri-partum women.

The surveillance population will consist of persons residing in the catchment area of the participating Emerging Infections Program (EIP) sites. This surveillance poses no more than minimal risk to the study participants as there will be no interventions or modifications to the care study participants receive. EIP surveillance personnel will perform active case finding from laboratory reports of stool specimens testing positive for *C.*

*difficile* toxin and abstract data on cases using a standardized case report form. For a subset of cases (e.g., community-associated *C. difficile* cases) sites will administer a health interview. Remnant stool specimens from cases testing positive for *C. difficile* toxin will be submitted to reference laboratories for culturing, and isolates will be sent to CDC for confirmation and molecular typing. Outcomes of this surveillance project will include the population-based incidence of community- and healthcare-associated CDI, and a description of the molecular characteristics of *C. difficile* strains and the epidemiology of this infection among the population under surveillance.

For this proposed data collection, there is no cost to respondents other than their time. An estimated total of 8,750 CDI Surveillance Case Report Forms (CRFs) will be completed during a one-year study period. Approximately 4,370 cases will require a completed CRF taking one hour; the remaining 4,380 cases will only require a partially completed CRF taking 15 minutes. An estimated total of 500 CDI Surveillance Health Interviews (HI) will need to be completed for the same time period. The estimated time to complete the HI is 45 minutes. Therefore, the total estimated annualized burden for this data collection is 5,840 hours.

The proposed surveillance for CDI through the Emerging Infections Program will expand CDC capacity to monitor incidence of *C. difficile* in community and healthcare settings as well as to monitor and detect antimicrobial resistance. This activity supports the HHS Action Plan for elimination of healthcare-associated infections.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
CDI Surveillance Case Report Form—Complete .....	10	437	1	4,370
CDI Surveillance Case Report Form—Partial .....	10	438	15/60	1,095
CDI Surveillance Health Interview .....	10	50	45/60	375
<b>Total .....</b>				<b>5,840</b>