

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQs 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: January 15, 2010.

Carolyn M. Clancy,
Director.

[FR Doc. 2010-1953 Filed 1-29-10; 8:45 am]

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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: "Evaluation of the GuideLines Into Decision Support (GLIDES)." In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on November 27th, 2009 and allowed 60 days for public comment. No comments were 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 March 3, 2010.

ADDRESSES: Written comments should be submitted to: AHRQs OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by e-mail at 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.

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluation of the GuideLines Into Decision Support (GLIDES)

With this project AHRQ proposes to evaluate how the translation of clinical knowledge into clinical decision support can be routinized in practice and taken to scale in ways that improve the quality of healthcare delivery for children in the U.S. Previously in the GLIDES project, AHRQ designed and implemented decision support tools based on guidelines for the prevention of pediatric overweight and obesity and the management of chronic asthma in the pediatric population (publication forthcoming). In this phase of the project, conducted for AHRQ through a contract with Yale University and Nemours, physicians will be surveyed about their experiences with the decision support tools developed in the previous phase. The participating study institutions (Yale University and Nemours) are geographically and organizationally diverse, and include a wide range of patients from a variety of social, economic and ethnic backgrounds. This project directly addresses AHRQ's mission of improving health systems practices, in particular for priority populations, including low-income groups, minority groups, women, children, and individuals with chronic diseases. See 42 USC 299(c)(1)(B).

The evaluation plan includes a physician survey component and an extraction of electronic medical record data. Participating physicians will be surveyed about their experiences with the decision support tools developed for this project. This will allow AHRQ to evaluate the fulfillment of knowledge transformation goals and the

effectiveness of the decision support tools in improving the quality of health care at the chosen sites. Without such an evaluation, it would be difficult to determine whether this project has met AHRQ's goals of enhancing the "quality, appropriateness and effectiveness of health services." See 42 USC 299(b); 42 USC 299a(a)(1). Consequently, it is necessary to collect this information to fulfill AHRQ's mission.

Method of Collection

Self-administered questionnaires will be used to elicit physicians' general opinions of guideline-based care and clinical decision support tools on a five point Likert-type scale. Results from low-utilizing physicians will be compared to high-utilizing physicians to determine whether general opinions of guidelines and technology correlate with actual practice. Results will also be analyzed by demographic characteristics included in the survey questionnaire to determine whether opinions vary by age, degree of computer experience and skill, level of training and professional degree. These analyses will be important to future studies and decision support designers because they will help us understand whether interventions need to be targeted differently to different audiences. For example, senior level specialists may have less desire or need for clinical decision support tools than novice generalists have. In-person qualitative interviews lasting approximately 30 minutes will be conducted with key personnel at each site (including physicians, nurse practitioners, and respiratory therapists). Participants will remain anonymous in the transcribed interviews. The interviews will be analyzed using standard qualitative techniques to explore barriers and facilitators to using the clinical decision support tool. The Human Investigation Committee (HIC) at Yale University has reviewed this protocol. The HIC found the survey study to be exempt from review under 45 CFR 46.101(b)(2). The HIC approved the interview study and required signed informed consent from participants.

Electronic medical record data will be extracted into an electronic spreadsheet for analysis. This extraction will occur at regular intervals to ensure continued maintenance and uptake of the tool. Utilization of the decision support tools at the provider and site level will be assessed based on the rate of electronic chart documentation. This is important to determine the rate of uptake of the intervention, as well as to determine whether there are any flaws in the design of the tool. Congruence of actual

practice with guideline recommendations will be assessed based on automatically generated disagreement flags in the electronic medical record as well as by manual chart review. This data collection, including the manual chart review, will be performed by project staff and will not impose a burden on the participating sites. In addition, project staff will directly observe a random sampling of clinicians using the tool in clinical settings to determine how the tool affects workflow. These observations will not require any effort, time or action on the part of the clinicians themselves and will not impose a burden on the participating sites.

Signed informed consent will be obtained prior to any observations. The Human Investigation Committee at Yale University has reviewed this protocol. It approved the medical record review, approved direct observation of clinicians and interviews of clinicians, required signed informed consent from clinicians, granted a waiver of informed consent from patients per 45 CFR 46.116(d), and granted a waiver of HIPAA authorization.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. The Asthma Management and Clinical Decision Support System Usability and User Satisfaction Survey (asthma questionnaire) will be

completed by 172 health care professionals across 3 sites and is expected to require about 6 minutes to complete. The Obesity Prevention and Clinical Decision Support System Usability and User Satisfaction Survey (obesity questionnaire) will be completed by 82 health care professionals across 2 sites and is expected to require about 6 minutes to complete. The in-person interviews will be conducted with a total of 50 clinicians at 3 sites and are expected to last 30 minutes each. The total burden is estimated to be 51 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be \$2,781.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of sites	Number of responses per site	Hours per response	Total burden hours
Asthma questionnaire—Yale	2	31	6/60	6
Asthma questionnaire—Nemours	1	110	6/60	11
Obesity questionnaire—Yale	1	57	6/60	6
Obesity questionnaire—Nemours	1	25	6/60	3
In-person interviews—Yale	2	15	30/60	15
In-person interviews—Nemours	1	20	30/60	10
Total	8			51

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of sites	Total burden hours	Average hourly wage rate*	Total cost burden
Asthma questionnaire—Yale	2	6	\$59.83	\$359
Asthma questionnaire—Nemours	1	11	59.83	658
Obesity questionnaire—Yale	1	6	47.25	284
Obesity questionnaire—Nemours	1	3	47.25	142
In-person Interviews—Yale	2	15	53.54	803
In-person Interviews—Nemours	1	10	53.54	535
Total	8	51		2,781

*Based upon the mean of the average wages for other physicians and surgeons, general pediatricians, and pediatric trainees (asthma questionnaire), and general pediatricians and pediatric trainees (obesity questionnaire), National Compensation Survey: Occupational wages in the United States 2008, "U.S. Department of Labor, Bureau of Labor Statistics," and Yale Pediatric Residency Program, 2008.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost for this research. Since

this project will not exceed one year the total and annualized costs are identical. The total cost is estimated to be \$5,703.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	\$1,406	\$1,406
Data Collection Activities	416	416
Data Processing and Analysis	780	780
Publication of Results	1,601	1,601
Project Management	200	200
Overhead	1,299	1,299

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Total	5,703	5,703

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 health care research, quality improvement and 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: January 25, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010-1894 Filed 1-29-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-10-0745]

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. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Maryam Daneshvar,

CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to 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 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 clarity 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 automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Colorectal Cancer Screening Program (OMB Number 0920-0745, exp. 7/31/2010)—Revision—Division of Cancer Prevention and Control (DCPC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer. Based on scientific evidence which indicates that regular screening is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for average-risk persons. Screening tests that are recommended by the United States Preventive Services Task Force, and that may be used alone or in combination, include fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), flexible sigmoidoscopy, colonoscopy, and/or double-contrast barium enema (DCBE).

In 2005, CDC established a three-year demonstration program, subsequently extended to four years, to screen low-income individuals 50 years of age and older who have no health insurance or inadequate health insurance for CRC. The five demonstration sites report information to CDC including de-identified, patient-level demographic, screening, diagnostic, treatment, outcome and cost reimbursement data (OMB No. 0920-0745, exp. 7/31/2010).

The information is being used to assess the feasibility and cost effectiveness of a publicly funded screening program and describe key outcomes, and has been critical in guiding the expansion of the program.

CDC will request OMB approval to continue the information collection for three years, with changes. First, the number of funded sites will increase from 5 to 26, and the term "Demonstration" will be deleted from the title of the program. Second, there will be a reduction in the burden per respondent associated with the collection of clinical information. Reporting forms for medical complications and medically ineligible clients will be discontinued, and reporting forms for colorectal cancer clinical data elements (CCDE) will be streamlined. Data elements that were underused in analysis of the demonstration program data, or difficult to standardize across programs, will be removed, and the level of detail collected from endoscopy and pathology reports will be reduced. As a result, the reporting burden per CCDE form will be similar regardless of primary test provided. Third, the collection of patient-level reimbursement cost data will be discontinued and will be replaced by the collection of program-level activity-based cost data. The revised information collection will utilize a Cost Assessment Tool (CAT) currently in use by another CDC-funded cancer program (OMB No. 0920-0812, exp. 6/30/2012). The information to be collected through the CAT will allow CDC to compare activity-based costs across multiple sites and programs, and will provide a more effective means of monitoring and improving the performance and cost-effectiveness of the CRC screening program.

The goals of the expanded CRC screening program are to increase population-based screening and to reduce health disparities in CRC screening, incidence and mortality. The program will continue to provide services to low-income individuals age 50 and older with inadequate or no health insurance. Each site will screen an estimated 375 patients per year (186 semiannually). The increase in the number of funded sites and the proposed changes will result in an