

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-10-0816]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Youth Knowledge, Attitudes, and Feedback to Inform Choose Respect Implementation formerly known as Youth Advice and Feedback to Inform Choose Respect Implementation (OMB no. 0920-0816 exp. 6/30/2012)—Revision—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This is a revision for a currently approved collection, OMB# 0920-0816. This revision seeks approval to ask knowledge and attitude questions at several of the focus groups, and it seeks an adjustment in the ages of the youths (currently ages 11 through 14 to ages 11 through 18).

Over a three-year period, NCIPC seeks to understand youths' (ages 11 through 18) knowledge and attitudes regarding healthy and unhealthy relationships, and obtain their feedback regarding: Message development/placement, creative executions, appropriate partners, and other similar issues. This data collected will provide for ongoing implementation and evaluation of the Choose Respect campaign, which is an initiative intended to promote youth awareness of and participation in healthy dating relationships. Communication research indicates that campaign planning implementation must employ a consumer-oriented approach to ensure that program messages/materials, and their placement, can successfully gain the attention of and resonate with the intended audience. NCIPC proposes conducting further planning, implementation, and evaluation research that enlists the involvement and support of youths.

This proposed information collection will enlist geographically, culturally/

racially/ethnically, and socio-economically diverse groups of young people to complete: (1) Ten-minute online surveys, with 200 respondents, up to four times per year; and (2) up to 36 in-person focus groups, with up to eight participants each (or more smaller discussion groups with fewer people per group), twice per year (288 × 2). Online surveys will reduce the potential burden for young people as Web-based formats are convenient and consistent with the way they communicate and spend their leisure time.

Online surveys—Each Web-based survey will involve a different group of tweens/teens. The burden table shows time to screen parents and youth, as well as the actual time to complete the survey (rows 4-6).

In-person focus groups—First and second focus groups will involve different groups of young people. The focus groups will be segmented by age, gender, and race/ethnicity. Other variables for segmentation may include, but not be limited to, geography and language. Two youth contacts will be needed to successfully recruit one focus group participant, and two parent contacts will be needed to successfully recruit one online survey participant (*i.e.*, 400 participants screened to obtain 200 successful participants).

There are no costs to respondents other than their time. The total estimated burden hours are 1354.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Data collection type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Youths ages 11 to 18 and parents of boys and girls, ages 11 to 18.	Focus Group Screening Instrument for Youth and Script for Obtaining Verbal Consent from Parent.	576	2	5/60
Youths ages 11 to 18	Focus Group Survey	288	2	5/60
Youths ages 11 to 18	Focus Group Moderator's Guide (participation in focus group).	288	2	1.5
Parents of boys and girls, ages 11 to 18	Online Survey E-mail Invitation AND Online Survey Screening Instrument for Parents.	400	4	5/60
Youths ages 11 to 18	Online Survey Screening Instrument for Youth.	400	4	3/60
Youths ages 11 to 18	Online Survey	200	4	10/60

Dated: June 25, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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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: "Standardizing Antibiotic Use in Long-Term Care Settings (SAUL) Study." 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 May 3rd, 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 August 2, 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 (*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

Standardizing Antibiotic Use in Long-Term Care Settings (SAUL) Study
Inappropriate antibiotic prescribing practices by primary care clinicians caring for residents in long-term care (LTC) communities is becoming a major public health concern as it is a risk factor for morbidity and mortality among LTC residents. Antibiotics are among the most commonly prescribed pharmaceuticals in LTC settings, yet reports indicate that a high proportion of antibiotic prescriptions are inappropriate. The adverse consequences of inappropriate prescribing practices are serious and include drug reactions/interactions, secondary complications, and the emergence of multi-drug resistant organisms.

In an effort to reduce antibiotic overprescribing, Loeb and colleagues developed minimum criteria for the initiation of antibiotics in LTC setting (Loeb, M., et al. 2001). The criteria have been tested in several studies, but their implementation and tests of validity have been limited. In particular, though Loeb and colleagues developed distinct minimum criteria for several types of infection (skin and soft-tissue, respiratory, urinary tract, and unexplained fever), a rigorous evaluation has been conducted only for urinary tract infections.

Twelve nursing homes (NH) will participate in this project; six NHs will be recruited to serve as treatment sites

and six to serve as control sites. Once a nursing home community has been selected and randomly assigned to the treatment or control group, a facility recruitment letter will be sent to the facility Administrator. The letter will include a description of the study and inform the Administrator that the project manager will be calling in the near future to further discuss the project and answers any questions that he/she might have regarding the program.

The objectives of the study are to:

1. Implement a quality improvement (QI) intervention program to optimize antibiotic prescribing practices;
2. Evaluate the effect of the QI intervention on antibiotic prescribing practices including validation of the Loeb minimum criteria; and
3. Develop and execute a dissemination plan to ensure wide dissemination of the findings and recommendations for improving antibiotic prescribing behaviors in LTC settings.

To address the first study objective, the research team will conduct a six-month QI intervention program in the six treatment sites to improve antibiotic prescribing practices. The intervention incorporates investigative evidence including the Loeb algorithms. QI program procedures are documented in the draft intervention manual, including the Loeb algorithms. The protocol recognizes that not all factors will need attention in all instances, as (for example) some NHs may already be vigilant to advance directive completion. The QI program is intended for facilities to self-implement and monitor with guidance provided from the research team upon request.

In order to validate the Loeb Criteria and to test the efficacy of the QI intervention, recruited facilities will be matched in pairs with respect to bedsize, profit status and location (urban, suburban, rural) and within each pair, one facility will be randomized to each study arm (treatment and control).

This study is being conducted by AHRQ through its contractors, Abt Associates and the University of North Carolina, 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).

Method of Collection

The following data collection activities and trainings will be

implemented to achieve the first two objectives of this project:

(1) Pre-implementation semi-structured interviews will be conducted separately with physicians, facility administrators and with the director of nursing (DON) or nurse educators (*see Attachment D* for each type of pre-implementation interview) from the six treatment sites. The purpose of these interviews is to generate ideas on how best to implement the new procedures and what approaches work best across facilities. Related risk factors and remedial strategies also will be identified. These interviews will take place during the three month baseline period and feedback will be used to modify the intervention materials as appropriate.

(2) Administrator interviews will be conducted at the time of facility enrollment to collect facility-level data in order to describe the sample and to explore linkages to prescribing practices. General facility-level descriptors including size (number of beds), profit status, location (urban, suburban, rural), and staffing levels (number of full and part-time registered nurses, licensed practical nurses, and nurse aides) will be collected. Additionally, simple summary (facility-level) information regarding resident demographics will be collected (*e.g.* age, gender, race/ethnicity, proportion long-stay vs. post-acute/rehab). Facility data will be collected through interviews with the Administrator at all twelve facilities.

(3) Train-the-trainer training will be conducted during the baseline period (prior to the implementation of the intervention). Research staff will present information about the Antibiotic Use QI and Monitoring Program at one, two-hour in-person meeting held at each treatment site. The research team will work with physicians (the physician champion at each facility; a physician champion is an expert that provides education, champions a cause or product, or gives support to staff around the diffusion and implementation of clinical practice guidelines, protocols, or research evidence), administrators, directors of nursing and nurse educators using a train-the-trainer model to offer guidance on educating intervention site staff on how to implement the Antibiotic Use QI Program that is based on the Loeb criteria. Intervention and training materials include those products and strategies used in other successful projects (*e.g.*, written Loeb algorithms).

(4) Train-the-nurses training will be conducted by the nurse educator at each of the six treatment sites following the

train-the-trainer training. The nurse educator will introduce the facility nurses to the Antibiotic Use QI and Monitoring Program materials and train them on the use of the Loeb minimum criteria. This training will be offered two times at regularly scheduled in-service meetings; however each nurse will be required to attend only one session.

(5) Train-the-physicians training will be conducted by the physician champion at each of the six treatment sites following the train-the-trainer training. The project team will be present to address any questions regarding the study. The physician champion will introduce the facility physicians to the Antibiotic Use QI and Monitoring Program materials and discuss with them the use of the Loeb minimum criteria. An average of five physicians at each facility will be individually contacted by the physician champion to discuss the use of the Loeb criteria. Each physician will have received a letter with the study description and the Loeb criteria prior to contact by the physician champion.

(6) Medical record reviews (MMR) will be conducted by research staff to collect primary outcome data to determine antibiotic prescribing. Primary outcomes will be obtained by monthly chart review for a period of nine months: three months preceding the initiation of the QI intervention (for which the charts of all residents will be abstracted), and each month for six months following the inception of the program (for which the charts of all residents will be abstracted, regardless of whether or not they are discharged from the setting or die) at all 12 facilities (treatment and control) by trained research staff from current (not archival)

records. Since this data collection will not impose a burden on the facility staff OMB clearance is not required.

(7) Final semi-structured interviews with QI team members including physicians, facility administrators, and other key facility staff will be conducted at the completion of the intervention to determine their perceptions regarding facilitators and barriers to successful program implementation.

(8) Nurse survey will be administered to nurses in all twelve facilities in the month prior to program implementation, and again in the final month of implementation. The purpose of this survey is to collect secondary outcome data regarding the antibiotic prescribing decision-making process and to collect basic information about each nurse, such as their title, type of degree and years worked in a LTC facility.

(9) Physician survey will be administered in all twelve facilities in the month prior to program implementation, and again in the final month of implementation. Similar to the nurse survey, the purpose of this survey is to collect secondary outcome data regarding the antibiotic prescribing decision-making process and to collect basic information about each physician.

In response to the third study objective, AHRQ will draw upon its extensive experience of successfully disseminating information through varying strategies. To assist in designing a plan that has “real world” impact, AHRQ’s Dissemination Planning Tool will be utilized.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in this

research. Pre-implementation semi-structured interviews will be conducted with 3 staff members from each of the 6 intervention sites and will last about 1 hour. The administrator interviews will be completed with one administrator from each of the 12 participating NHs and will require 15 minutes. Train-the-trainer training will include 4 persons from each of the 6 intervention sites and will last 2 hours. Train-the-nurses training will be conducted with 24 nurses from each of the intervention sites; the number of responses per NH is 26 since the nurse trainer is an employee of the NH and will conduct the training twice, with about 12 nurses in each training. The nurse training will last about 1 hour. Train-the-physician training will be conducted with 5 physicians from each of the 6 intervention sites; the number of responses per NH is 6 since the physician trainer is affiliated with the NH. The physician training will last about 30 minutes.

Final semi-structured interviews will include 4 QI team members from each of the 6 intervention sites, at the completion of the intervention, and will last one hour. The nurse survey will be administered twice to 24 nurses from each of the 12 participating NHs and will take about 15 minutes to complete. The physician survey will be administered twice to 5 physicians from each of the 12 facilities and requires 15 minutes to complete. The total annualized burden hours are estimated to be 441 hours.

Exhibit 2 shows the estimated annual cost burden to the respondent, based on their time to participate in this research. The annual cost burden is estimated to be \$25,204.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of nursing homes	Number of responses per nursing home	Hours per response	Total burden hours
Pre-implementation semi-structured interviews	6	3	1	18
Administrator Interviews	12	1	15/60	3
Train-the-trainer training	6	4	2	48
Train-the-nurses training	6	26	1	156
Train-the-physicians training	6	6	30/60	18
Final Semi-Structured Interview	6	4	1	24
Nurse survey	12	48	15/60	144
Physician survey	12	10	15/60	30
Total	66	na	na	441

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of nursing homes	Total burden hours	Average hourly wage rate*	Total cost burden
Pre-implementation semi-structured interviews	6	18	**51.68	\$930
Administrator Interviews	12	3	***46.59	140
Train-the-trainer training	6	48	31.31	1,503
Train-the-nurses training	6	156	77.64	12,112
Train-the-physicians training	6	18	31.31	564
Final Semi-Structured Interview	6	24	77.64	1,863
Nurse survey	12	144	***46.59	6,709
Physician survey	12	30	46.10	1,383
Total	66	441	n/a	25,204

* Based upon the mean of the average wages, National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics, May 2008.

** Average wages for one registered nurse (\$31.31), one physician (\$77.64), and one Administrator (\$46.10).

*** Average wages for two registered nurse (\$31.31), one physician (\$77.64), and one Administrator (\$46.10).

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost for conducting this research. The total budget for this three year study is \$999,976. The administration task includes costs associated with the initial kick-off conference call with AHRQ and

monthly progress reports and ongoing conference calls. The research plan task includes costs to finalize the research plan; conduct the literature search; prepare and submit the IRB applications and OMB package; recruit facilities; collect baseline and monthly data from medical record reviews and conduct pre- and post-intervention provider interviews; implement the intervention;

and write the final report on the explanatory model. The dissemination costs include the writing of a dissemination plan and two manuscripts for publication as well as presentations at two national conferences. The final report costs include the writing of a draft and final report.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total	Annualized cost
Administration	\$24,474	\$8,158
Research Plan	591,788	197,263
Dissemination Plan	63,397	21,132
Final Report	46,501	15,500
Overhead	273,816	91,272
Total	999,976	333,325

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: June 22, 2010.
Carolyn M. Clancy,
Director.
 [FR Doc. 2010-15796 Filed 6-30-10; 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: "Assessing the Impact of the National Implementation of TeamSTEPPS Master Training Program." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to