Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM (42 U.S.C. 285l–3(a)). NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitation of new, revised, and alternative test methods. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov).*

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Dated: January 5, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011–669 Filed 1–12–11; 8:45 am]

BILLING CODE 4140–01–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: "Connecting Primary Care Practices with Hard-to-Reach Adolescent Populations." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by March 14, 2011.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

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

Connecting Primary Care Practices With Hard-to-Reach Adolescent Populations

The overall goal of this exploratory project is to improve the quality of adolescent health care. The project will address suboptimal adolescent care with respect to health risk behaviors, which can have serious health consequences. In particular, failure to address health risk behaviors among adolescents (*e.g.,* smoking, substance abuse, poor diets, physical inactivity, and high-risk sexual behavior) contributes significantly to increased morbidity and mortality. Adolescents (11–17 years of age) constitute 17% of the population of the U.S., but they are responsible for only 7% of medical office visits. As a result, primary care providers have relatively less opportunity to evaluate and counsel adolescents in their offices than most other patients. Even when adolescents receive routine health care, open communication with their health care providers may be problematic. A national survey found that the majority of adolescent boys and girls in the U.S. report at least 1 of 8 potential health risks, but most (63%) had not spoken to their doctor about any of these (Klein & Wilson, 2002). Improved engagement and communication between adolescents and their primary care providers could increase the likelihood that effective preventive services and health care are provided. It could also improve the efficiency of health care services for adolescents, in terms of appointments kept and adherence to recommended screening or treatment recommendations.

Technological interventions to improve care may be particularly appropriate for adolescents, since they are typically the early adopters of new technology (Skinner, Biscope, Poland, & Goldberg, 2003). Use of in-office electronic screeners before appointments has proven useful (Olson, Gaffney, Lee, & Star 2008; Salerno, 2008; Yi, Martyn, Salerno, & Darling-Fisher, 2009). Outside of the office, youth have increasingly turned to the internet for health-related information, and have also rapidly adopted mobile technology (Lenhart, Ling, Campbell, & Purcell. 2010) and social media (Lenhart, Purcell, Smith, & Zickuhr, 2010). Health plans (e.g., Kaiser Permanente) and practices (Hawn, 2009) have conducted early work in applying patient-centered web and mobile technologies. These projects have included interventions to decrease patient no-show rates, increase the use of sunscreen, and engage adolescents in diabetes management. Much work remains to be done, however, in understanding how primary care practices can best embrace advances in communications and information technology to improve health outcomes for adolescent patients.

This project has the following goals:

(1) Explore the benefits of supplementing an electronic in-office pre-visit screener with a set of web technologies for adolescent outreach and engagement outside of office visits.

a. The Rapid Assessment for Adolescent Preventive Services © (RAAPS), as described below, will be used for in-office pre-visit screening

b. The web technologies will include (i) a web page for more static content such as information about practices and health-related commentary from practice clinicians and staff, (ii) a Facebook page for social interaction about health topics including topical content that will engage adolescents in conversations about general, not personal, health behaviors and encouraging youth to discuss these issues with their primary care practitioners at clinic visits, and (iii) a Twitter site that will allow youth to use mobile phones with text messaging to subscribe to Facebook posts.

(2) Increase adolescent visits to primary care and identification of health risks during visits

(3) Promote healthier behavior in four domains: (1) Diet, (2) physical activity, (3) substance abuse (smoking, alcohol, and use of other recreational drugs), and (4) sexual health

(4) Develop a manual of best practices for these components in primary care.

This study is being conducted by AHRQ through its contractor, State Network of Colorado Ambulatory Practices and Partners (SNOCAP–USA), a practice-based research network (PBRN) based at the University of Colorado Denver, 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 clinical practice, including primary care and practice-oriented research. 42 U.S.C. 299a(a)(l) and (4).

Method of Collection

This project will be conducted in four primary care practice sites that have a substantial number of adolescent patients. The following activities and data collections will be implemented:

(1) RAAPS questionnaire. Practices will use the 21-item RAAPS questionnaire for in-office pre-visit screening. RAAPS was developed by the University of Michigan Regional Alliance for Healthy Schools to elicit information about risky adolescent behaviors that should be addressed, but often are missed, in primary care. It is available in both paper and online forms; the latter will be used in this project. The primary purpose of the RAAPS questionnaire is to improve clinical recognition of risky behaviors so that personal counseling may be provided.

(2) Process measures for web technologies. For each of the web technologies used (the web page, Facebook page, and Twitter site), data on the number of unique visitors, the frequency of their visits, and their activities (*e.g.* whether they create a new post or "like" postings) will be obtained by the research team. These data will not include personally identifiable information (*e.g.* the user's username, birth date, IP address, *etc.*). OMB clearance is not required for this data collection.

(3) Extraction of medical record data. Staff members at each practice will use their clinical information systems to extract medical record data for use by the research team. Data to be extracted consist of (a) Contact information for patients seen in the 18 months prior to the start date for implementation of RAAPS and the web technologies. This is the sample frame for the adolescent behavior and communication survey. These data will be used by the project staff to prepare the recruitment mailings. (b) Clinic notes for adolescents seen in the 12 months prior to implementation start date and for adolescents seen in the 12 months following the implementation start date. Clinic notes will be made accessible either by pulling paper charts or printing notes from electronic medical records. The notes will be reviewed and abstracted by the research team to assess whether the intervention had the intended effect of increasing adolescent visits to primary care and the identification of potential health risks during visits.

(4) Consent-assent form. This is used to obtain consent from the parent or guardian and assent from the adolescent to participate in the adolescent behavior and communication survey.

(5) Adolescent behavior and communication survey. A questionnaire (by mail, with an online option) will be administered twice to adolescent patients for whom consent-assent has been obtained: Once at baseline and again six months after the intervention. The purpose of this survey is to measure the adolescent's level of comfort with discussing their health with their

clinician and their level of satisfaction with their medical care, and to see how this changes after the intervention.

(6) Post-visit satisfaction survey. Practices will provide adolescents with a brief, post-card sized anonymous questionnaire at every office visit during the study period. The purpose is to assess the perceived utility of the RAAPS questionnaire, and whether the visit was related to the project's web technologies.

(7) Adolescent focus groups. Eight adolescents (two from each practice) will provide feedback on the web page, Facebook, and Twitter pages. There will be one in-person group meeting preimplementation, followed by a series of 3 additional asynchronous group discussions conducted via the web at three-month intervals. These provide a process for user-centered design and refinement of the of web technologies.

(8) Adolescent "think-aloud" sessions. These sessions, which will be conducted near the end of the study period, will involve a set of eight adolescent patients (two from each practice) that did not participate in the focus groups. Subjects will come to the practice for individual sessions in which they will be asked to say aloud what they are thinking about the Web technologies as they navigate them as they typically would. The purpose is to assess the perceived utility of the components of the Web, Facebook, and Twitter pages.

(9) Clinician semi-structured interviews. At each site, individual interviews will be conducted with two clinicians (eight clinicians total). The purpose is to assess clinician perceptions of the effects of the RAAPS questionnaire and the Web technologies on the clinical encounter and the care they provide.

(10) Administrator-staff semi-structured interviews. At each site, semi-structured interviews will be conducted with the practice manager and a front-desk staff member. The purpose is to assess the effect of the interventions on the check in process and other business processes.

(11) Semi-structured interviews for the draft manual. The draft manual of best practices in primary care for adoption of Web and assessment technologies (such as the RAAPS questionnaire) developed by the research team will be sent to the practice manager and the practice director (lead clinician) of each site. Their feedback will be solicited by telephone roughly two weeks later. This "member checking" enhances the validity of the manual's conclusions and recommendations.

The results from this exploratory project will be used to inform development of a manual to assist primary care practices in adopting interventions to improve the effectiveness of their outreach to and interactions with adolescent patients. In addition, information collected in the RAAPS questionnaire may be used by clinicians to improve clinical care.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. Among the 776 adolescent patients across the 4 participating practices, 310 are expected to complete the RAAPS questionnaire, which takes about 15 minutes to complete, at each office visit (on average there will be an estimated 1.25 office visits per patient). Practice staff members will perform the extraction of medical record data pre-implementation, and again post-implementation, for 50 patients. This task is estimated to require 4 hours per practice (slightly less than 5 minutes per patient record).

The consent-assent form for participation in the adolescent behavior and communication survey will be sent to the homes of all adolescents in the practice's panels. The estimated average time for reading and responding to the form is 15 minutes. The adolescent behavior and communication survey will be completed twice, pre- and post-intervention, by 233 adolescent patients and requires 15 minutes to complete. The post-visit satisfaction survey will be completed by each of the 310 participating adolescent patients after each office visit and will take 5 minutes to complete.

A series of four focus groups will be held with 8 adolescent patients over the course of the study period with each session lasting about 1.5 hours. In addition to the focus groups one "think-aloud" session will be held with a group of 8 adolescent patients and will also take 1.5 hours.

Feedback from the practice staff and the clinicians will be obtained through 3 different semi-structured interviews. Two staff members from each of the 4 practices will participate in these interviews. The clinician and administrator-staff semi-structured interviews will each last 30 minutes. Semi-structured interviews for the draft manual will require about one hour total (30 minutes to review the manual and 30 minutes to participate in the interview). The total annualized burden is estimated to be 548 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annual cost burden is estimated to be $8,601.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Activity/data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
RAAPS questionnaire	310	1.25	15/60	97
Extraction of medical record data	4	2	4	32
Consent-assent form	776	1	15/60	194
Adolescent behavior and communication survey	233	2	15/60	117
Post-visit satisfaction survey	310	1.25	5/60	32
Adolescent focus groups	8	4	1.5	48
Adolescent "think-aloud" sessions	8	1	1.5	12
Clinician semi-structured interviews	4	2	30/60	4
Administrator-staff semi-structured interviews	4	2	30/60	4
Semi-structured interviews for the draft manual	4	2	1	8
Total	1,661	na	na	548

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Activity/data collection	Number of respondents	Total burden hours	Average hourly wage rate [1]	Total cost burden
RAAPS questionnaire	310	97	$9.01 [2]	$874
Extraction of medical record data	4	32	18.15 [3]	581
Consent-assent form	776	194	22.11 [4]	4,289
Adolescent behavior and communication survey	233	117	9.01 [2]	1,054
Post-visit satisfaction survey	310	32	9.01 [2]	288
Adolescent focus groups	8	48	9.01 [2]	432
Adolescent "think-aloud" sessions	8	12	9.01 [2]	108
Clinician semi-structured interviews	4	4	84.53 [5]	338
Administrator-staff semi-structured interviews	4	4	29.63 [6]	119
Semi-structured interviews for the draft manual	4	8	64.75 [7]	518
Total	1,661	548	na	8,601

[1] Mean hourly and wage costs for Colorado were derived from the Bureau of Labor and Statistics National Compensation Survey for May 2009 (*http://www.bls.gov/oes/current/oes_co.htm*).
[2] Hourly rate for an entry level worker (occupation code 3 5–0000) estimates the cost of time for adolescents, although many will not be employed.
[3] Hourly rate for medical records and health information technician (29–2071).
[4] Hourly rate for the mean for all occupations (00–0000) estimates the cost of time for the parent or guardian of the adolescent.
[5] Average of hourly rates for a family medicine practitioner (29–1062) and a general internist (29–1063).
[6] Average of (1) the hourly rate for a medical and health services manager (11–9111) and (2) the average of the hourly rates for a receptionist (43–4171) and a medical assistant (31–9092).
[7] Average of (1) the hourly rate for a medical and health services manager (11–9110) and (2) the average of the hourly rates for a family medicine practitioner (29–1062) and a general internist (29–1063).

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the Federal Government for conducting this research. These estimates include the costs associated with the project such as the preparation of survey administration procedures, labor costs, administrative expenses, costs associated with copying, postage, and telephone expenses, data management and analysis, and preparation of final reports. The annualized and total costs are identical since the data collection period will last for one year. The total cost is estimated to be $436,524.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$72,364	$72,364
Data Collection Activities	48,904	48,904
Data Processing and Analysis	73,937	73,937
Publication of Results	21,890	21,890
Project Management	75,733	75,733
Overhead	143,696	143,696
Total	436,524	436,524

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: January 4, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–408 Filed 1–12–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–11–0338]

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,