DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the General Atomics Facility in La Jolla, California, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the General Atomics facility in La Jolla, California, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: General Atomics.

Location: La Jolla, California.

Job Titles and/or Job Duties: All Atomic Weapons Employees who worked for General Atomics at its facility in La Jolla, California, during the period from January 1, 1960 through December 31, 1969, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

Period of Employment: January 1, 1960 through December 31, 1969.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

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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: ''Improving Hospital Informed Consent With an Informed Consent Toolkit.'' In accordance with the Paperwork Reduction Act, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by September 8, 2014.

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

SUPPLEMENTARY INFORMATION:

Proposed Project

Improving Hospital Informed Consent With an Informed Consent Toolkit

The ultimate aim of this project is to pilot test a toolkit to improve the informed consent process in U.S. hospitals. Clinical informed consent is the process by which a patient is told about the risks and benefits of proposed treatments or procedures, as well as alternatives, and makes a decision based on that information. Informed consent may be jeopardized by incorrect clinician assumptions about patient comprehension, the manner in which consent is sought, and poor readability of consent forms (Paasche-Orlow et al., 2013). All too frequently, patients do not understand the risks, benefits, and alternatives of their treatments even after signing a consent form (Braddock et al., 1999; Sudore et al., 2006). De-identified accreditation data analyzed as part of AHRQ's preliminary research for this data collection effort suggest that some hospitals are not following the basic ethical principles underlying informed consent. These data, as well as the guidance from the study's Expert and Stakeholder Panel, indicate that hospital administrators and clinicians could benefit from training on evidence-based practices to improve the informed consent process. These include improving communication, using interpreters to meet the communication needs of patients with limited English proficiency, using high-quality decision aids to support the informed consent discussion, and using teach-back to verify patient understanding (Temple University Health System, 2009). Hospital system changes that can facilitate these practices include improving hospitals' informed consent policies and enhancing the infrastructure that supports the informed consent process (e.g., interpreter services, high-quality decision aids, easy-to-understand forms).

Building upon a previously published guide, a review of the literature, and the aforementioned analysis of de-identified accreditation data, AHRQ has developed a new Informed Consent Toolkit. Toolkit content will be delivered via two training modules of approximately one hour each (one for hospital leaders, the other for frontline clinical staff), to be offered through a Learning Management System. Clinical staff taking the training will be eligible for continuing education (CE) credit.

AHRQ will pilot test the toolkit to assess:

- Facilitators of and barriers to implementing the toolkit
- Effectiveness of the toolkit in improving informed consent processes and relevant outputs and outcomes

Pilot test results will be used to improve the toolkit and provide information to hospitals considering using it to improve their informed consent processes. The pilot test will take place in four hospitals. Each participating hospital will be asked to:

- Train the leaders of their choosing using the training module Champion improvements in their informed consent policies and processes based on the information and tools in the leader training.
- Train frontline staff members in four units, including at least one surgical unit. Using the frontline training module.
- Implement improvement initiatives over a period of two to six months in participating units based on materials presented in the frontline training.
  - In at least one unit implementation will last at least three months and use

at least one of the techniques presented in the training (e.g., use teach-back to confirm patient understanding, use high quality decision aids, overcome communication barriers)

- Conduct and cooperate with assessment activities:
  - In at least one unit, use the Rapid Feedback Patient Survey.
  - In at least one surgical unit, collect surgical cancellation and delay rates.
  - Collect other metrics to assess the effectiveness of the informed consent toolkit.
  - Cooperate with project team in the data collection efforts described below.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

The following data collections efforts will be pursued in participating hospitals to achieve project goals:

1. The Hospital Informed Consent Baseline and Final Assessment will be completed by the four hospitals participating in the pilot testing at baseline and upon completion of the implementation period. The assessment, completed by the hospital's designated liaison to the project and the leaders of the participating units (unit leaders), will describe each hospital's informed consent policies and processes (e.g., procedures that require signed informed consent forms, clinical staff roles and responsibilities in informed consent, when interpreter services should be used), and document any changes that occurred as a result of toolkit implementation. Questions will include both open-ended questions (e.g., descriptions of process) and Likert scale questions (1 to 5) regarding the extent to which essential components are covered in informed consent discussions (e.g., benefits and risks of alternatives) and evidence-based practices to improve the informed consent process are used.

2. Pre-/Post-Training Quiz. A quiz is given both before and after the training to measure whether knowledge (related to the content in the Toolkit) increases after completing the training module(s) and to identify potential Toolkit improvements. The pre-test is given after the participant registers for the training but before they begin the course content. Immediately after the participant completes the course content, they will be given the post test. The post quiz will also include a separate section with questions regarding learner's reactions to and evaluation of the Toolkit training. A post quiz score of 80% will be used as the threshold to obtain CE credits. There will be a pre/post quiz for each training module.

3. The Monthly Check-In Call. A project team member will hold a monthly check-in call with hospital liaisons and unit leaders to assess the progress of implementation of training programs and improvement initiatives at each hospital and within each unit. Check-in calls will occur monthly for up to six months. Each call will be up to 30 minutes in duration.

4. Frontline Clinical Staff Survey. A brief survey will be administered electronically to all clinicians who take the frontline staff training, both prior to training and approximately two to three months after completing it. Hospital liaisons will provide email addresses for the staff who will be invited to complete the training from each participating unit. These email addresses will be used to send clinicians the pre and post-training surveys. The survey will collect information about clinicians' self-reported use of evidence-based practices described in the frontline staff training, a self-assessment rating of their informed consent effectiveness, attitudes regarding patients' rights in informed consent, and reported learning and implementation experiences. The survey will also collect information about the clinician and their background (e.g., years in practice, practitioner type) and department. The survey will consist largely of closed-ended questions (e.g., scale or Likert response options) with several open-ended questions.

5. Interview and Site Visit Guide. Site visits and interviews will be conducted at each of the four participating hospitals. Each site visit will occur over a two-day period at least three months after sites have trained the majority of their staff on the participating units. The project team will conduct up to 18 in-depth interviews at each pilot site with hospital leaders and frontline clinicians. Leaders will include hospital champions spearheading the pilot test in their hospital (such as chiefs of surgery, department chairs, chief anesthesiologist/head of anesthesiology, nurse managers, charge nurses, nurse educators, patient safety/quality officers, legal/risk management officers) and leaders of units where the toolkit was piloted. Frontline clinician interviewees will be selected by unit leaders or hospital liaisons from the units where the toolkit was piloted. Liaisons and unit leaders will be asked to nominate a range of clinicians from those who embraced changes to those who were less willing to implement changes. Site visits will also involve limited observation (e.g., to observe documentation of informed consent completion, view new signage to remind clinicians to verify patient understanding in an informed consent discussion). The project team will also obtain relevant organizational documents (e.g., informed consent policies, training completion rates, implementation tracking data) and data (e.g., surgical cancellation rates). Interviews will capture qualitative data regarding clinician learning, toolkit implementation, behavior, and results pertaining to patient engagement.

6. Rapid Feedback Patient Survey. Hospitals participating in the pilot test will be required to implement the Rapid Feedback Patient Survey provided in the Toolkit in a subset of patients in at least one participating unit to capture patient's understanding of the information conveyed during the informed consent process, and their satisfaction with the informed consent discussion and process. Time to complete the rapid feedback patient survey is estimated at five minutes. We expect hospitals to administer this survey to at least 50 patients before implementation and 50 patients after implementation in at least one unit and randomize selection of patients to minimize potential bias.

Other outcome and output data from administrative records or electronic medical records (Secondary Data). Hospitals will also be asked to report on their rates of surgical cancellations and delays in at least one participating surgical unit, since prior research suggests that these rates can be improved (i.e., reduction in cancellations and some delays) when strategies such as teach-back were used in the informed consent process (NQF, 2005). Hospitals may also select other outcome measures of interest based on administrative records or electronic medical records. They may also report on output data such as number of informed consent forms improved or number of staff present during a teach-back or quality improvement exercise. Since these data collections involve extractions from existing clinic records or use of administrative records, they pose only minimal data collection burden to the hospital, specifically the person who needs to collect the data (i.e., hospital liaison or unit leader).

The purpose of the proposed data collection effort is to obtain information needed to modify and enhance the Informed Consent Toolkit and to provide information to hospitals considering using the toolkit to improve their informed consent processes. Since this is only a pilot study in 4 sites, outcomes or impacts will not be generalizable.

The data collected will help the project team: (1) understand the facilitators and barriers of implementing the tools and recommended improvements to informed consent policies and processes, and (2) assess the effectiveness of the toolkit in improving informed consent processes and other outcomes in four pilot implementation sites. The data collection effort may also provide insights that could guide dissemination of the toolkit. For example, if it was found that specific units (e.g., surgical units) across the pilot test hospitals strongly benefited from implementing a specific strategy suggested in the toolkit, then AHRQ could tailor and target its dissemination of the toolkit to those individuals and organizations that represent them. Once revisions are made based on results of the pilot study, the toolkit will be published on AHRQ's Web site. A manuscript describing the pilot study and its results will also be produced for publication in a peer-reviewed journal.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on prior experiences with pilot testing materials in hospitals and what can reasonably be requested of participating hospitals. The number of respondents listed in column A, Exhibit 1 reflects a projected 80 percent response rate for data collection efforts 2a, 2b, 4, and 6 below.

1. The Hospital Informed Consent Baseline and Final Assessment will establish a baseline and final assessment of each hospital's informed consent policies and processes that is completed by the site liaisons (one per hospital) and unit leaders (four per hospital) and will take each person 30 minutes to complete each time.

2. Pre-/Post-Training Quiz will be administered after participants register for the training but before they begin the course (pre-test), and immediately after participants complete the course content (post-test). There will be a pre-post quiz for each module. Each quiz will take 20 minutes to complete:

a. Frontline Staff Pre-/Post-Training Quiz: We assumed 40 frontline staff per unit for a total of 160 staff per hospital and a total of 640 across all four hospitals. We assumed 512 frontline staff will complete the pre-/post-training quiz based on an estimated 80 percent response rate.

b. Hospital Leader Pre-/Post-Training Quiz: We assumed eight leaders per hospital for a total of 32 across all four hospitals. We assumed 26 will complete the pre-/post-training quiz based on an estimated 80 percent response rate.

3. The Monthly Cheek-In Calls will occur with hospital liaisons and four unit leaders for a total of five individuals per hospital to assess the progress of implementation of training programs at each site and within each unit. Check-in calls will occur monthly for six months and will each take 30 minutes.

4. Frontline Clinical Staff Survey. A brief survey will be emailed to all clinicians both prior to training and approximately two to three months after completing the training. We assumed 40 frontline staff per unit for a total of 160 staff per hospital and a total of 640 across all four hospitals. We assumed 512 frontline staff will complete the survey based on an 80 percent response rate. It is expected to take 15 minutes to complete.

5. Interview and Site Visit Guide. Each site visit will occur over a two-day period and include up to 18 one hour interviews in each pilot site, with:

a. Two hospital leaders (e.g., legal, risk management) and four unit leaders (six per hospital).

b. Three front-line clinicians in each of four units (12 per hospital).

6. Rapid Feedback Patient Survey. The Rapid Feedback Patient Survey will be given to 100 patients (50 patients before implementation and 50 patients after) immediately following an informed consent discussion. It should take five minutes to complete. We assumed 100 patients per hospital for a total of 400 across all four hospitals. We assumed 320 patients will complete the survey based on an 80 percent response rate.

7. Other outcome and output data from administrative records or electronic medical records (Secondary Data). These secondary data will be provided by the hospital liaison or unit leaders. We have assumed five hours for each hospital liaison and unit lead to collect and provide these data.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method or project activity	A. Number of respondents	B. Number of responses per respondent	C. Hours per response	D. Total burden hours
1. Hospital Informed Consent Baseline and Final Assessment	20	2	1	40
2a. Frontline Staff Pre-/Post-Training Quiz*	512	2	20/60	341
2b. Hospital Leader Pre-/Post-Training Quiz*	26	2	20/60	17
3. Monthly Check-in	20	6	30/60	60
4. Frontline Clinical Staff Survey*	512	1	15/60	128
5a. Interview—Clinical Staff	48	1	1	48
5b. Interview—Hospital Leaders	24	1	1	24
6. Rapid Feedback Patient Survey*	320	1	15/60	27
7. Secondary data	4	1	5	20
Total		na	na	705

*Number of respondents (Column A) reflects a sample size assuming an 80% response rate for these data collection efforts.

Exhibit 2, below, presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be about $25,270.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method or project activity	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
1. Hospital Informed Consent Baseline and Final Assessment	20	40	$42.78	$1,711
2a. Frontline Staff Pre-/Post-Training Quiz	512	341.33	33.62	11,476
2b. Hospital Leader Pre-/Post-Training Quiz	26	17.33	51.95	900
3. Monthly Check-in	20	60	42.78	2,567
4. Frontline Clinical Staff Survey	512	128	33.62	4,303
5a. Interview—Clinical Staff	48	48	33.62	1,614
5b. Interview—Hospital Leaders	24	24	51.95	1,247
6. Rapid Feedback Patient Survey	320	26.67	22.33	596
7. Secondary data	4	20	42.78	856
Total				25,270

The average hourly wage rate of $42.78 for the informed consent baseline, readiness assessment, and monthly check-in was calculated based on the 2013 average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions) of $33.62 and mean hourly wage rate for medical and health services managers, $51.95.

The average hourly rate of $33.62 of hospital staff pre- and post-training quiz and in-depth interviews was calculated based on the 2013 average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions), $33.62.

The average hourly rate of $51.95 for hospital leaders pre- and post-training quiz and in-depth interview was calculated based on the 2013 mean hourly wage rate for medical and health services managers, $51.95.

The average hourly wage rate for patients of $22.33 was calculated on the 2013 mean hourly wage rate for all occupations. Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on ''Occupational Employment and Wages, May 2013'' found at the following URL: *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, 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 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 25, 2014.

Richard Kronick,

AHRQ Director.

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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: ''Taking Efficiency Interventions in Health Services Delivery to Scale.'' In accordance with the Paperwork Reduction Act of 1995, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on April 8th, 2014, 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 August 8, 2014.

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

SUPPLEMENTARY INFORMATION:

Proposed Project

Taking Efficiency Interventions in Health Services Delivery to Scale

The primary care workforce is facing imminent clinician shortages and increased demand. With the implementation of the Affordable Care Act (ACA), Federally Qualified Health Centers (FQHCs) are expected to play a major role in addressing the large numbers of people who become eligible for health insurance as well as continue in their role as safety net providers. Thus, understanding new models of service delivery and improving efficiency within FQHCs is of national policy import. The proposed data collection supports the goal of developing a more efficient FQHC service delivery model through studying outcomes associated with a ''delegate model,'' which is designed to improve provider and team efficiency, and the spread of this model throughout a large FQHC.

Recent models of practice transformation have documented the use of an Organized Team Model that distributes responsibility for patient care among an interdisciplinary team, thereby allowing physicians to manage a larger panel size while practicing high quality care. The delegate model requires that all team members perform