

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Deputy, Information Collection Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Public Reporting of Cost Measures in Health

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public on public reporting of cost measures in health. Scientific information is being solicited to inform our technical brief on *Public Reporting of Cost Measures in Health*, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on public reporting of cost measures in health will improve the quality of this technical brief. AHRQ is conducting this technical brief pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before March 10, 2014.

ADDRESSES:

Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/>. Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: SIPS@epc-src.org.
Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Research Librarian, Telephone: 503-220-8262 ext. 58652 or Email: SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a technical brief of the evidence for Public Reporting of Cost Measures in Health.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its technical briefs. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on public reporting of cost measures in health, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <http://effectivehealthcare.AHRQ.gov/ehc/products/562/1838/public-reporting-cost-measures-protocol-140113.pdf>

This notice is to notify the public that the EHC program would find the following information on public reporting of cost measures in health helpful:

- A list of completed studies your organization has sponsored for this indication. In the list, *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the

trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The technical brief will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: <http://effectivehealthcare.AHRQ.gov/ehc/products/562/1838/public-reporting-cost-measures-protocol-140113.pdf>

1. What measures of costs about healthcare providers and facilities have been publicly reported?
 - a. Who produces these reports and where are they available?
 - b. For what facilities are costs reported?
 - c. At what level are these data aggregated (e.g. provider, facility, etc.)?
 - d. How are the cost data reported (e.g., dollar amounts, symbols, graphs etc.)?
 - e. How are the costs of providers/facilities compared (e.g., how many facilities, regional verses national comparisons etc.)?
2. Are the measures of costs that are being reported consumer centered?
 - a. How are consumers instructed to use the data?
 - b. What techniques are used to guide consumers to interpret the data appropriately?

- c. Is there evidence that the data is used by consumers?
- d. Is the data relevant to consumers making healthcare decisions?
- e. Is the data easily accessible and presented in a consumer friendly way?
- 3. What are the intended and unintended consequences of consumers' use of public-reported cost data?
 - a. Do consumers find the public reporting of cost measures relevant and are consumers satisfied with the experience?
 - b. Does the public reporting of cost measures impact (or have the potential to impact) consumers' decisions or behaviors?
 - c. What are the potential unintended consequences of public reporting of cost measures?
 - d. Are there key research gaps and needs for future research?

Dated: January 24, 2014.

Richard Kronick,
AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-13AGH]

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 (404) 639-7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Examining Traumatic Brain Injury in Youth—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Traumatic brain injury (TBI) is one of the highest priorities in public health because of its magnitude, economic and human impact, and preventability. The Centers for Disease Control and Prevention (CDC) estimates that approximately 1.7 million TBIs are sustained in the United States annually, either alone or in conjunction with another injury or condition. These figures may be an underestimation as they do not include people who are treated in physicians' offices or outpatient facilities, those who did not seek medical care, military personnel, or Americans living abroad. Moreover, the number of sports and recreation-related TBIs treated in U.S. emergency departments is increasing and has increased steadily since the early 2000s. Children ages 0 to 4 years and adolescents ages 15-19 are at the greatest risk of sustaining a TBI.

A TBI is caused by a bump, blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain. The severity of a TBI may range from "mild" (a brief change in mental status or consciousness) to "severe" (an extended period of unconsciousness or amnesia after the injury).

In 1996, Congress passed Public Law 104-166, the Traumatic Brain Injury Act, which charged CDC with implementing projects to reduce the incidence of traumatic brain injury. The CDC definition of TBI uses selected codes of the International Classification of Diseases, 9th Clinical Modification (ICD-9 CM) to identify cases of TBI from hospital and non-hospital databases containing billing records for services rendered to patients. It is thought, however, that the ICD-9 CM codes

currently used in CDC's surveillance system to capture cases of TBI are not sufficiently sensitive to capture diagnosed TBI.

CDC requests OMB approval for one year to collect de-identified medical information of a representative sample of pediatric patients, from two clinical settings, who received a confirmed diagnosis of mild to severe TBI and link these patients to their administrative medical claims forms. Collectively, the data will allow CDC to estimate the sensitivity of currently utilized ICD-9 CM codes to capture cases of diagnosed TBI, as well as ICD-9 CM codes not currently being utilized that may improve the sensitivity to capture cases of TBI. We propose to conduct a retrospective cross-sectional study of a random sample of patients with a suspected TBI within two clinical settings (Emergency Departments and Concussion Clinics).

A review of the medical coding data for additional ICD-9 CM codes that are not part of the CDC TBI definition will also take place to determine whether the addition of any of these codes improves the sensitivity of the CDC TBI definition to detect TBI.

The Emergency Department medical records of 150 patients will be abstracted in order to review ICD-9 codes and TBI diagnoses. Each record will take 60 minutes to abstract. Also, 50 patient medical records from the Concussion Clinic, located within the hospital, will be abstracted in order to review the selection criteria to confirm eligibility, which includes age of the patient, and the valid encounter with physician or nurse related to an injury consistent with a TBI. Each record will take 60 minutes to abstract. The same Research Assistant will be abstracting the data within the Emergency Department and the Concussion Clinic.

There are no costs to respondents other than their time. The total estimated annual burden hours are 200.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Emergency Department Research Assistant ..	TBI Records Data Tool	1	150	1
Concussion Clinic Research Assistant	TBI Records Data Tool	1	50	1