

## **OMB-SUPPORTING STATEMENT**

### **DoD PATIENT SAFETY CULTURE SURVEY**

#### **A. Justification**

##### 1. Need for Information

This data collection effort is being conducted in response to a task from the Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense (DoD), TRICARE Management Activity (TMA). Part of the DoD Patient Safety Program's mission is to identify and analyze reports on actual and potential problems within the medical systems and processes in each military treatment facility (MTF) within the Military Health System (MHS). The DoD Patient Survey Program must recommend effective actions to improve patient safety and health care quality throughout the MHS which is comprised of approximately 78 MTF hospitals and over 360 clinics. In support of its mission, the Program is planning to administer a web-based patient safety culture survey to a census of staff working in Army, Navy, and Air Force MHS facilities in the U.S. and internationally to assess the status of patient safety culture in MHS facilities.

The 2001 National Defense Authorization Act is applicable to this data collection effort. It contains specific sections addressing patient safety in military and veteran's health care systems. The legislation states that the Secretary of Defense shall establish a patient care error reporting and management system to study occurrences of errors in patient care and that one of the purposes of the system should be "To identify systemic factors that are associated with such occurrences" and "To provide for action to be taken to correct the identified systemic factors" (Sec. 754, items b2 and b3). In addition, the legislation states that the Secretary shall "Continue research and development investments to improve communication, coordination, and team work in the provision of health care" (Sec. 754, item d4).

In its ongoing response to this legislation, DoD plans to implement a web-based patient safety culture survey to obtain MHS staff opinions on patient safety issues such as teamwork, communication, medical error occurrence and response, error reporting, and overall perceptions of patient safety. The purpose of the survey is to assess the current status of patient safety in

MHS facilities as well as to provide baseline input for assessment of patient safety improvement over time.

The survey to be implemented is the pilot-tested Agency for Healthcare Research and Quality (AHRQ) Survey on Patient Safety Culture that was publicly released in November 2004 (see Attachment B1 for the survey and B2 for the safety culture dimensions assessed by the survey). The development and testing of this survey was funded by AHRQ and sponsored by the Department of Defense as an agency member of the Quality Interagency Coordination Task Force (QuIC)<sup>1</sup>, along with ten other Federal agencies. The pilot of the AHRQ Survey on Patient Safety Culture was previously approved by OMB (NO.: 0935-0115, EXP. DATE: 01/31/2004). This survey was chosen because it measures a number of different dimensions pertaining to patient safety culture, has demonstrated reliability and validity, and the specificity of the items will provide the DoD with actionable information about MHS patient safety.

2. How, by Whom, and for What Purpose Information Will be Used

The DoD patient safety culture survey will be critical to evaluate and better assess the needs of MHS facilities to promote patient safety culture. Survey results will be prepared at the facility and Service levels and MHS overall. Facilities will be provided feedback about their staff's responses to the survey which will provide insight on strengths and areas for improvement to support a safer environment for MHS patients and beneficiaries. Moreover, the survey will aid MHS facilities in meeting Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements. The survey will be useful not only to facilities, but at the Service and DoD levels as well. The survey will provide an overview of the status of MHS patient safety to higher leadership, who can then appropriately allocate the necessary resources and tools to decrease medical errors and increase safety.

3. Survey Techniques

Since a web survey is being implemented, responses will be obtained through the use of internet-based information technology. Using a web-based survey will facilitate survey administration, shorten the field period necessary for data collection since outgoing communications and incoming survey responses will be received almost immediately, and

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<sup>1</sup> The QuIC is comprised of representatives from 11 Federal agencies: Department of Health and Human Services, Labor, Defense, Veterans Affairs, Commerce, Office of Management and Budget, Office of Personnel Management, U.S. Coast Guard, Federal Bureau of Prisons, National Highway Transportation Safety Administration, Federal Trade Commission.

decrease the need for data cleaning since only valid responses can be entered and responses will be automatically stored in an electronic database.

4. Efforts to Avoid Duplication

There are no data already available that can be used for the purposes of obtaining staff views on patient safety culture, medical error, and error reporting from facilities MHS-wide. The proposed data collection will provide much-needed information to evaluate and better assess the needs of MHS facilities to support a safer environment for MHS patients and beneficiaries.

5. Small Business Impact

Only staff from MHS facilities will be surveyed. The 10-minute web survey can be completed at any time during or after work. There is no anticipated impact on small businesses in general.

6. Consequences of Not Collecting Information

If the proposed data collection is not approved, it will hinder the DoD Patient Safety Program from its mission to identify actual and potential problems within the MHS and make it difficult to evaluate and assess the needs of MHS facilities to support a safer environment for MHS patients and beneficiaries.

7. Special Circumstances

There are no special circumstances involved in this data collection effort.

8. Applicability to 5CFR 1320.8(d)

a. The draft notice to be published in the *Federal Register* in October 1, 2008 (73 FR 57062-57063).

b. No comments were received.

c. *Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any) and on the data elements to be recorded, disclosed, or reported.*

Extensive consultation was conducted during the development and pilot testing of the Survey on Patient Safety Culture which was previously approved by OMB (NO.: 0935-0115, EXP. DATE: 01/31/2004). As part of the instrument development process, drafts of the survey

underwent cognitive testing with hospital staff. In addition, university professors, hospital stakeholders, and patient safety experts reviewed and commented on the survey and survey results reporting format. Pilot data on the survey were gathered from over 1,200 staff from 21 hospitals. After data analysis, the survey was revised and the final survey (which will be used in this data collection within MHS facilities) has demonstrated reliability and validity. Additional DoD MHS staff (9 or fewer) are being consulted to determine whether any wording or instruction changes will be necessary to tailor the survey to the DoD.

9. Remuneration to Respondents

No payments or gifts will be provided to respondents.

10. Confidentiality

No individual identifiers will be used during data collection so all individual survey responses will be anonymous. Respondents will be asked on the web survey to indicate which MTF site they work in to allow feedback results to be grouped according to MTF. Smaller MTF clinics with 20 or fewer staff will be grouped together so respondents will only be asked to indicate if they work in one of the MTFs listed *within the group*. In this way, individual anonymity can still be maintained at sites with few staff. All survey responses will be collected through a secure survey web site hosted at Westat. Only aggregated group survey results will be delivered to MHS facilities.

11. Questions of a Sensitive Nature

Respondents will be asked to respond to questions about the work environments of their MHS facility and the specific department in which they work. There are no questions of particular sensitive nature. The survey is voluntary and there will be no negative consequences for staff who do not complete the survey.

12. Hour Burden Estimate

There are a total of approximately 125,663 MHS staff in the U.S. and internationally (estimate on 12/16/04). Of these staff, approximately 18,696 staff (about 15%) are contractors, local nationals, volunteers or other MHS staff who are not direct employees of the DoD. Because OMB approval is required only for the non-DoD staff component, we provide estimates of the respondent burden for only these non-DoD MHS staff. With a 75% response rate goal, we

anticipate responses from approximately 14, 022 non DoD MHS staff. The estimated annual burden is provided below.

**AFFECTED PUBLIC:** U.S. and International MHS staff who are not direct employees of the DoD (contractors, local nationals, volunteers, other non-DoD MHS staff).

**ANNUAL BURDEN HOURS:** 2,384

**NUMBER OF RESPONDENTS:** 14,022

**RESPONSES PER RESPONDENT:** 1

**AVERAGE BURDEN PER RESPONSE:** 10 minutes or 0.17 hours.

**FREQUENCY:** On occasion

Respondents will incur no monetary cost in completing the survey.

13. Capital, Start-up, and Maintenance Costs

Respondents will not be asked to maintain any records. No additional equipment purchases will be made to support data collection processes or record keeping.

14. Annualized Cost to Federal Government

The total cost to the government for conducting this one-time web survey data collection contract is approximately \$270,349 which includes the cost of web survey development, data collection, analysis, and feedback report preparation and delivery. The estimated cost of only the web data collection component is \$157,840, which includes labor costs, fringe expenses, administrative expenses, and costs associated with web survey development, testing, and implementation. Annual maintenance costs are estimated at \$70,177 based on a GS-12 Step 5 hour's rate of \$29.44.

15. Changes from OMB Form 83-I

This is a reinstatement of a previously approved collection.

16. Outside Publication

The data collected will be used for internal DoD use only and there are no plans for outside publication of results.

17. Expiration Date

The expiration date of the OMB approval will be displayed on the web survey.

18. Certification Statement

The proposed data collection does not involve any exceptions to the certification statement identified in line 19 of OMB Form 83-I. The following statement will be prominently displayed on the web survey:

“This study has been approved by the Office of Management and Budget. It is estimated that this survey takes 10 minutes to complete. If you have comments about this survey, its length, or any other aspects of this collection of information, send them to: TRICARE Management Activity Information Management Control Officer, HPA&E, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041.”

**B. Collection of Information Employing Statistical Methods**

1. Sampling and Response Rates

The proposed project will administer the patient safety culture survey as a web-based instrument to a census of all staff, both clinical and non-clinical, working in all U.S. and international MHS facilities. There are a total of approximately 125,663 MHS staff in the U.S. and internationally (estimate on 12/16/04). Of these staff, approximately 18,696 staff (about 15%) are contractors, local nationals, volunteers or other MHS staff who are not direct employees of the DoD. With the goal of an overall response rate of 75%, responses would be received from approximately 14,022 U.S. and International MHS staff who are not direct employees of the DoD (contractors, local nationals, volunteers, other non-DoD MHS staff). The survey takes about 10 minutes to complete. All survey responses are voluntary and will be individually anonymous; only group-level results will be tabulated to protect individual anonymity.

2. The Sample Frame and Methodology

The proposed project will administer the patient safety culture survey as a web-based instrument to a census of all staff, both clinical and non-clinical, working in all U.S. and international MHS facilities. Due to the large number of staff to be surveyed across the Services, data collection will be phased beginning with Army MHS facilities, followed by the Navy and then the Air Force.

3. Maximizing Response Rates

Our study design will implement standard techniques to maximize response rates. Potential respondents will receive a prenotification letter followed by an email survey notification containing an embedded hyperlink to the internet location where the survey can be completed. Two additional email survey notifications will be sent, a week apart, so that the data collection field period will be four weeks for each Service.

To maximize response rates, the following steps will be taken:

- 1) a prenotification letter will be sent to participants detailing the purpose of the survey;
- 2) a first survey email notification will be emailed including a hyperlink to the survey web site where they can complete the web survey,
- 3) a second survey email notification will be sent with hyperlink to the survey web site, and;
- 4) a third survey email notification will be sent with hyperlink to the survey web site.

To improve respondent trust of confidentiality and increase the likelihood of individual response, no individual identifiers will be used. Therefore, all follow-up survey notifications will be sent to everyone; those who have already completed the web survey will be thanked for their participation and asked to disregard additional follow-up notices.

#### 4. Tests of Procedures

The Survey on Patient Safety Culture to be used in this data collection was previously developed and piloted tested by Westat under an Agency for Healthcare Research and Quality (AHRQ) contract, approved by OMB (NO.: 0935-0115, EXP. DATE" 01/31/2004). Pilot data on the survey were gathered from over 1,200 staff from 21 hospitals. After data analysis, the survey was revised and the final survey (which will be used in this data collection within MHS facilities) has demonstrated reliability and validity.

#### 5. Name of Contractor Collecting and Analyzing Information for Agency

Westat, in Rockville, Maryland, has been contracted to conduct this web survey data collection and produce reports of the survey feedback results. The individuals assigned to the project include:

Veronica Nieva, Ph.D., Vice President, 301-251-8271

Joann Sorra, Ph.D., Senior Study Director, 301-294-3933

Theresa Famolaro, M.A., Research Analyst, 301-738-3547

No other persons have consulted on statistical aspects of this survey nor will any other persons either collect or analyze the data.