

SUPPORTING STATEMENT

Part B

**A PROTOTYPE CONSUMER REPORTING SYSTEM FOR
PATIENT SAFETY EVENTS**

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B. Collections of Information Employing Statistical Methods

1. Respondent universe and sampling methods

The CRSPS prototype system will be implemented in a small to medium-sized metropolitan area with one or two integrated delivery systems that are engaged in patient safety improvement efforts, and a relatively mature health information technology environment. It will be made accessible to a wide range of provider types (pharmacy, hospital, home health, etc.), thereby collecting data from patients across the continuum of care.

The respondent universe consists of all patients in the selected community experiencing an adverse medical event; however, no frame exists from which to draw a sample. For this reason the set of responses to the pilot CRSPS is a self-selected convenience sample, and it is unknown how many responses the CRSPS will receive. However, the selected community will have roughly 376,000 adults older than 18 years of age. The CDC estimates based on Schiller, Lucas, Ward and Peregoy, 2012 indicate that 7.9% of adults in the United States who stay overnight in a hospital in a given year and that 82.2% visit a physician or other health care professional. The rate of adverse events for hospitalizations based on interviews is 23% (Weissman et al., 2008) and for ambulatory care based on survey data, 25% (Gandhi, 2003). Neither of these estimates is based on spontaneous voluntary reporting; however, based on these figures, 6,832 people might have an adverse event in a hospital and 77,268 in ambulatory care per year in the selected community, or 126,150 during the pilot period.

In an adverse event reporting system for cancer patients, roughly 1% of adverse events were voluntarily reported (Lipczak, et al. 2011). Therefore, of the 126,150 adverse events, the CRSPS would receive approximately 1% or 1,261 reports over the 18-month period, or 840 annually.

In focus groups conducted as part of the intake form development, about 10% of respondents consented to having their reports shared with the medical facility. This yields an estimate of approximately 84 follow up calls to health care providers.

The intake form will be available on a voluntary basis at hospitals and doctor's offices. The specifics of what will be available are contingent upon the interest and willingness of the pilot community. However, the minimum would be a free-standing dedicated cardboard display with the flyers. The intake form could be linked to a patient portal. Another option would be a staffed multi-purpose information desk/ kiosk with computer with internet access available to fill out the intake form on site at the hospital or doctor office. The maximum would be all of the above, while the most likely is a combination of these approaches. The flyer that would be handed out by office or hospital staff, available in the free-standing cardboard display, or attached to a provider's existing patient experience survey would include the web address and a brief description of the

system (see Attachment G for a sample of such a flyer). The flyer will also be given at pharmacies with prescriptions and mailed to the patient's home with the Explanation of Benefits (EOB) by means of the project's collaboration with insurance companies.

An investigation in Massachusetts highlights the heterogeneity of initial consumer reports (Weissman, et al. 2008). Therefore reports will be screened using inclusion/exclusion criteria: (1) the respondent needs to be older than 18 years of age; and (2) the report must be a patient safety concern, not a grievance or a service complaint. For example, the CRSPS will exclude complaints about billing, parking or food issues unless they have a direct bearing on safety.

2. Information Collection Procedures

For patient reports, the CRSPS prototype entails 2 modes of administration: web and telephone. The website contains a safety event intake form, instructions to access the telephone-enabled version of the form, and a frequently asked questions list and information sheet (see Attachment A, the introductory pages of the website; Attachment B, the safety event intake form formatted for the web; and Attachment C, the FAQs information sheet). The web-based intake form can be accessed and used directly by consumers.

The CRSPS prototype also includes a telephone-enabled version of the form. (See Attachment D, the introduction and phone intake script; and Attachment E, the intake form formatted for telephone.) A respondent calls a toll-free number and answers the questions with the assistance of a specially trained intake assistant who administers the web-based questionnaire as a telephone survey. The hotline will be staffed by human operators available during extended business hours. The interview can be conducted in English or Spanish. For the subset of respondents who consent to being contacted again, CRSPS staff will call to ask for clarification of the information in the initial report (see Attachment F, Follow-up questions to a respondent about a submitted report).

For another subset, respondents who consent to having their information shared with health care providers, CRSPS staff will contact the health care provider to determine (based on the patient's name, event type, and date of the incident) if there is a matching event in the provider's Incident Reporting System. If so, staff will record supplemental information such as what factors contributed to the occurrence of the safety event, who reported the event or unsafe condition to the provider organization, whether a root cause analysis was completed, what contributing factors were identified, and any recorded lessons learned. The protocol used for these provider interviews is in Attachment H, Script for matching a consumer submission to provider incident report.

3. Methods to Maximize Response Rates

Because the project does not sample systematically, response rates cannot be known. However, to maximize the number of responses, the CRSPS prototype system will be promoted in a community-based marketing campaign. Kiosks will be located at hospitals

and doctors' offices. Flyers containing the CRSPS web site address and the toll-free telephone number will be handed to patients at hospital discharge, at the conclusion of office visits, and with medications dispensed at pharmacies. The flyer will be included in patient experience surveys such as HCAHPS and Clinician Group CAHPS, and with insurance companies' Explanation of Benefits (see Attachment G).

Because the characteristics of all patients in the selected community experiencing an adverse medical event are unknown, the project cannot address issues of non-response.

4. Tests of Procedures

The majority of the questions and procedures in the intake form have been cognitively tested as part of the design work for this project and have been revised based on the recommendations of the participating patients and caregivers.

5. Statistical Consultants

This is not a statistical survey, but a convenience sample for a demonstration project. No statistical consultants were used.

References

Schiller JS, Lucas JW, Ward BW, Peregoy JA. Summary health statistics for U.S. adults: National Health Interview Survey, 2010. National Center for Health Statistics. Vital Health Stat 10(252). 2012