

SUPPORTING STATEMENT: PART B

OMB#

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**Evaluating the implementation and impact of an opioid medication management program,
in a hospital discharge setting, to reduce falls in older adults.**

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CONTENTS

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1.	Respondent Universe and Sampling Methods	3
B.2.	Procedures for the Collection of Information	5
B.3.	Methods to Maximize Response Rates and Deal with Nonresponse ...	6
B.4.	Tests of Procedures or Methods to be Undertaken.....	7
B.5.	Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	7

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The respondent universe for this data collection will consist of three groups (Table 1):

- (1) Hospitalized older adult patients considered high risk for falls due to opioid use (Pre-Discharge Patient Questionnaire and Post-Discharge Patient Questionnaire)
- (2) UCSF clinical staff (pharmacists, nurses, physicians) (UCSF Clinical Staff Evaluation Questionnaires)
- (3) Primary care providers (PCPs) that care for older adults discharged from UCSF (Primary care providers Post-Discharge Questionnaire).

Study data for the *patient surveys* will be collected from older adults identified as high risk for falls due to opioid use. These include older adult patients admitted to inpatient units and started on a new long-acting opioid, patients on high oral morphine equivalent regimens, and those on combination opioids and benzodiazepines, who received medication management for opioids as part of their discharge planning from the University of California San Francisco (UCSF) Medical Center. Older adults who are receiving hospice care, those with observation only, or same day admission are not included. Additionally, patients who are cognitively impaired or do not speak English will be excluded. All eligible older adults will be invited to take the surveys (estimated 6,897 over 3 years). The expected response rate is 35%. The questionnaires (**Attachment E1 and E2**) include questions about the patient's health status, use of medication and non-medication therapies for pain control, follow through with recommendations on opioid tapering efforts, referral to specialists and readmissions for falls or other conditions. The questionnaire is expected to take an average of 10 minutes to complete.

Study data from the *UCSF Clinical Staff Evaluation Questionnaire* will be collected by a monthly cross-sectional survey of clinical staff (nurses, pharmacists, and physicians) at the UCSF Medical Center, where opioid prescribing protocols and decision support tools have been implemented into the hospital discharge process to reduce risk of opioid adverse events and falls. Using electronic records of ordering and documentation activity in units targeted by our study, we will identify all nurses, pharmacists, and physicians who have had clinical contact with older adult study patients. We will then send an electronic survey with the correspondence letter to a randomly selected (using block randomization of digits we will then match to provider ID numbers) sample of recipients per month for a total of 300 over 3 years. We expect a 50% response rate. The questionnaire includes questions about the respondent's use and experience with opioid prescribing guidance and their opinion of the effectiveness of the project to reduce falls and opioid adverse events (**Attachment E3**). The questionnaire is expected to take approximately 5 minutes to fill out.

Study data for the *Primary Care Providers Post Discharge Questionnaire* will be collected from PCPs associated with the UCSF Medical Center. The providers will be identified using electronic record data listing PCPs for older adult study patients discharged from UCSF. Using block randomization schema matched to patient medical record numbers, we will invite a sample of 300 providers to be surveyed over the 3 years. We expect a 50% response rate. The questionnaire

includes questions about the usefulness of opioid management enhancements to the discharge summary and PCP’s ability to taper opioids for their patients (**Attachment E4**)

Table 1 Summary of data collection activities

Data collection method	Respondent Universe	Targeted respondents	Method for selection
Patient Questionnaires (pre-discharge and post-discharge)	Older adult patients (65+ years old) treated at the UCSF Medical Center and identified at time of discharge, considered to be high risk for falls due to opioid use.	UCSF Medical Center inpatient older adults (not hospice, observation only, or same day admission), who speak English, are not cognitively impaired and considered high risk for falls related due to opioid use. These include patients that have an opioid prescription at time of admission, or are admitted and started on a new long-acting opioid, patients receiving high oral morphine equivalent regimens, and those on combination opioids and benzodiazepines.	All identified individuals that meet inclusion criteria are invited to participate while still hospitalized during discharge planning. They will be invited in person or via electronic communication during their hospital stay. We expect 6,897 individuals will be invited, of which approximately 2,400 will respond to consent forms and questionnaires.
Clinical Staff Evaluation Questionnaire	Clinical Staff at UCSF Medical Center	Clinical staff (doctors, nurses, and pharmacists) who work in the units where the opioids management and fall prevention study initiatives are being incorporated into the hospital discharge setting.	Using electronic records of ordering and documentation activity in units targeted by our study we will identify eligible clinicians. We will invite 300 clinical staff to take the survey using block randomization of eligible providers. We expect a 50% response rate or 150 responses.
Primary Care Provider Post Discharge Questionnaire	Primary care providers (post – acute) directly related to UCSF	Primary care providers who care for older adult study patients who have received opioid management and fall prevention interventions during their hospital stay/	Providers will be identified using electronic record data listing PCPs for older adult study patients discharged from UCSF. We will invite 300 PCPs using block

		discharge planning.	randomization schema matched to patient medical record numbers each month. We expect a 50% response rate or 150 total responses.
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B.2. Procedures for the Collection of Information

A secure and Health Insurance Portability and Accountability Act/Protected Health Information (HIPAA/PHI) compliant platform will be used to manage both the *Pre-discharge and Post Discharge Patient Questionnaires* process to reduce burden on administering and responding to the survey. For the Pre-discharge Patient Questionnaire, the process may be initiated in one of two ways. The first is direct patient contact, where a Clinical Research Coordinator (CRC) approaches the patient directly to obtain informed consent and administer initial surveys, in person in hospital. The second is through electronic contact, where a patient is sent an electronic invitation (via patient-portal message or email) to join our study via a web interface. Patient will then self-administer consent and carry out the survey using the same platform. An introductory letter and consent form (**Attachment G1 and Attachment H**) will be presented to patients within 48 hours of admission for their initial assessment. If the patient does not sign the consent form while still admitted (during discharge planning), the invitation to take the *Pre-Discharge Patient Questionnaire* will be deactivated (in electronic communication). Patients that sign the consent form and complete the pre-discharge survey will be followed up with at 14, 30, and 60 days after discharge to assess for clinical outcomes and events. The questions in the pre and post-discharge questionnaires are multiple-choice responses, easy to read and can be answered by a few clicks per question/answer. The questions will automatically advance after each answer and allows respondents to skip questions that may not be applicable. The platform is user-friendly. The survey is presented in a comfortable font size. It is estimated that the survey will require an average of 10 minutes to complete. The system tracks survey completion for each respondent and automatically sends a limited number of reminders only to those who have yet to complete the survey.

The *UCSF Clinical Staff Evaluation Questionnaire* Process will use a survey platform commonly used at UCSF by their clinical staff. This technology will reduce the burden on respondents because responses will be given by “clicking” a few computer keys rather than by completing paper survey forms. This survey is limited to 31 multiple choice questions and is expected to require five minutes to complete. An introductory letter (**Attachment G2**) will be sent to a randomly selected pool of participants one week in advance of data collection informing them of the planned assessment, the purpose, and dates of assessment, and contacts for further information. The online data collection instrument will remain open for a period of 3 weeks to allow ample time for completion by respondents.

The *PCP Post-Discharge Questionnaire* process will be administered by email/fax based on each PCP’s preference. This survey is limited to 11 multiple choice questions, and is expected to require five minutes to complete. An introductory letter (**Attachment G3**) will be sent to a random sample of PCP participants one week in advance of data collection informing them of

the planned assessment, the purpose, and dates of assessment, and contacts for further information. The online data collection instrument will remain open for a period of 3 weeks to allow ample time for completion by respondents.

During the data collection process, a secure database will be used to track each individual respondent that will include the contact information for each respondent. Upon survey completion, the database will update the tracking system so that no additional contact occurs. The system will reduce respondent burden by ensuring respondents are contacted at appropriate intervals, and not contacted more than needed. Implementing the survey online will allow respondents to address the questions when convenient, so it does not affect their work routine.

All data will be stored in secure environments. Access to study data will be restricted to study administrators only and will be password-protected. The survey questions are validated tools that have been used in multiple research settings and are voluntary in nature. None of the surveys or individual questions to the surveys are required; respondents are able to opt-out of any questions that are confusing or may provoke an emotional response.

The questionnaires were designed to collect the minimum amount of information necessary to achieve the goals of the project. The most important factors to measure with respect to the project goals were carefully considered and questions designed to measure those factors.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

For the *Patient Pre-Discharge Questionnaire*, the expected response rate is 35%. We estimate this anticipated survey completion rate based on previous work screening and enrolling patients at UCSF, where an approximately 35% enrollment rate has been the norm. Collecting data by online survey was determined to be the best method for the UCSF older adult patient population. Using our direct patient enrollment approach (in person or electronically) during hospitalization, we will be able to follow up in person with patients and promote the scientific and health benefits of participating in our study. We will also follow-up with patients that complete the pre-discharge questionnaire via phone or email to ensure completion of the post-discharge questionnaires.

For other survey participants (UCSF clinical staff and outpatient PCPs), we anticipate an approximate 50% response rate. We aimed to keep our survey brief and focused on clinically relevant questions. We will send up to three reminder e-mails to those who have not yet completed the online data collection halfway through the collection period. From previous experience, clinicians prefer brief online surveys that require less than 10 minutes to complete, in comparison to paper format. The study is backed by strong executive sponsorship throughout the UCSF clinical community. We will continue promotion of the study amongst healthcare providers during clinical team meetings, executive forums, and peer conferences.

B.4 Tests of Procedures or Methods to be Undertaken

Multiple phases of survey design, review, and revision were conducted to finalize the instruments. The specific items included on the survey instruments will be used for formative

evaluation of the post-discharge effects of an opioid prescribing protocol and decision support tools to reduce opioid adverse events, specifically falls, and improve patient adherence to fall prevention interventions prescribed at discharge. It will also inform us about required improvements in the safety and effectiveness of tools developed.

All data collection procedures to be used in this study will be tested by the contractor who assisted with design of the study protocol and questionnaire (Intellix/UCSF). The survey has been designed to be brief and ensure the highest possible response rates by clinical participants.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CDC collaborated with Intellix and UCSF's Health and Analytics staff to design the study protocol and questionnaires. Andrew Auerbach MD MPH and Martin Koenig, RN designed the implementation plan, evaluation plan and questionnaires. Intellix and UCSF will be responsible for conducting the data collection and analysis.

Gwen Bergen, PhD, MPH, MS, Jaswinder Legha, MD, MPH and Terri Head MBA, National Center for Injury Prevention and Control (NCIPC), Division of Unintentional Injury Prevention, CDC are the technical contacts for this project, responsible for providing scientific guidance to the Intellix and UCSF team. Dr. Bergen, Dr. Legha, and Ms. Head will approve and receive all contract deliverables