

SUPPORTING STATEMENT: PART A

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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SUMMARY TABLE

- **Goal of the Study:** To perform a formative evaluation to inform CDC of best practices for implementation of opioid prescribing program in a hospital discharge setting at University of California, San Francisco (UCSF) to reduce risk of falls in older adults.
- **Intended use of the resulting data:** To provide information on ways to improve opioid prescribing to reduce risk of falls in older adults including provider practice changes, prescribing protocols, and decision support tools.
- **Methods to be used to collect:** A set of cross-sectional surveys of patients at 0,14,30,60 days after discharge, UCSF clinical staff, and outpatient primary care providers (PCP) involved in discharged patient care.
- **The subpopulation to be studied:** Patient surveys will be limited to UCSF Medical Center inpatient older adults (65 years and older) considered high risk for falls and high dose opioid use. The UCSF clinical staff will be limited to nurses, pharmacists, and physicians involved in older adult patient pain management and post-discharge planning. The PCP survey will be limited to outpatient PCPs associated with UCSF Medical Center who care for older adult study patients discharged from UCSF.
- **How the data will be analyzed:** Categorical questions will be analyzed using frequencies, cross-tabulations, and regression analysis. The open-ended questions will be analyzed to identify themes. Results will be presented by theme.

JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests Office of Management and Budget (OMB) approval for three years for this new data collection to perform a formative evaluation of the implementation and impact of an opioid prescribing program in a hospital discharge setting at University of California, San Francisco (UCSF) to reduce risk of falls in older adults. Components of the program will include opioid medication prescribing practices to reduce high dose opioid prescribing and reduce readmissions for falls in older adults after discharge.

CDC will use the information collected to help inform best practices and material development of opioid prescribing protocols and decision support tools at post-discharge setting to reduce opioid use and risk of falls in older adults by:

- (1) Evaluating the impact of a modified intervention on opioid prescribing patterns (e.g. use of non-opioid medications); opioid refills prescribed at discharge; readmissions for falls; and incidence of falls and/or medically treated falls.
- (2) Describing post-discharge use of opioids or alternative therapies for pain management and their impact on the above listed outcomes.
- (3) Describing post-discharge adherence and follow up by older adults with primary care doctors and/or specialist referrals (e.g. physical therapy, occupational therapy, exercise therapy, ophthalmology, and podiatry) for pain management and fall prevention efforts and their impact on the above listed outcomes.
- (4) Identifying fidelity of and improvement opportunities for the implemented fall prevention program.

The proposed new information collection will complement secondary data collection and analysis using the patients' electronic health records (EHR).

Authority for CDC's National Center for Injury Prevention and Control (NCIPC) to collect these data is granted by Section 301 of the Public Health Service Act (42 U.S.C. 241). This act gives federal health agencies, such as CDC, broad authority to collect data and participate in other public health activities, including this type of study (Attachment A).

Over 1 in 4 older adults report a fall and 1 in 10 report a fall injury each year (Bergen et al., 2016). Falls result in serious injuries. They are the leading cause of traumatic brain injuries in older adults (Tayler et al., 2017) and 95% of hip fractures in older adults are due to falls (Parkkari et al., 1999). Additionally, falls are the leading cause of injury related death in older adults (WISQARS, 2016). Older adult falls are due to multiple and varied risk factors including decreased muscle strength, impaired balance, changes in vision and hearing, foot problems, unsafe home environment, certain chronic diseases, and medication adverse effects (Ambrose, 2013). Evidence-based interventions targeting modifiable risk factors can lower the risk of falls in older adult (Gillespie, 2012).

Certain types of medications, known as psychoactive medications, have been associated with an increased fall risk in older adults (American Geriatric Society Beers Criteria, 2015). Psychoactive medications, including opioids and benzodiazepines, affect the central nervous system and can cause side effects such as dizziness, sedation, confusion, blurred vision, and orthostatic hypotension (Gerlach et al., 2017). When taken together, psychoactive medications can have a synergistic effect on cognition and physical function, potentially leading to a more pronounced injury or unintentional overdose (Wright et al., 2009; Pratt et al., 2014).

Opioid prescribing in emergency department settings, inpatient settings, and at hospital discharge setting is very common and may increase future chronic opioid use (Calcaterra et al., 2016; Barnett et al., 2017). Studies have shown that opioid treatments in older adults are associated with significantly increased risk of falls, injurious falls, and fractures (Karin et al., 2013 and Rolita et al., 2013). Additionally, chronic use of opioids at doses higher than 50 morphine milligram equivalents are associated with a twofold increased risk of fractures in older adults (Saunders et al., 2010). Between 2007 and 2012, the percent of Medicare Part D beneficiaries receiving a 90 day or more supply opioid prescription increased by approximately 60% in older adults (Kuo, 2015). Additionally, between 2010 and 2015, opioid-related hospital stays increased by 34% and opioid-related emergency department visits increased by 74% among older adults (Weiss, 2018). Older adults are more prone to medication adverse events due to physiological changes that occur with aging (Klotz, 1981; Albala et al., 1994; Boss et al., 1981; Rowe et al., 1976; and Tan et al., 2015). Therefore, targeting opioid prescribing in older adults at the inpatient or hospital discharge setting may reduce medication adverse events - specifically falls and unintentional injuries in older adults – post hospitalization.

A key intervention in the CDC's fall prevention program is medication management to reduce fall risk in older adults. Medication review and management, especially upon care transitions, can reduce inappropriate opioid use, the risk of falls and injury, and improve patient health (AGS/BGS, 2001). Certain intervention such as physical or occupational therapy, serve a dual role of preventing falls, as well as serving as a non-opioid treatment for pain.

For this current project, opioid prescribing protocols and decision support tools to reduce opioid prescribing were incorporated into the inpatient care process and workflow using the Electronic Health Record (EHR). Older adults on high opioid doses or those on a combination opioid benzodiazepine will be identified through the EHR as high risk for adverse events and falls. **Figure A.2** shows the intervention components specific to the opioid management and how these components will be implemented into the workflow. An oral morphine equivalent (OME) calculator was developed to determine if the older adult patient meets the threshold for opioid management. The OME calculator determines the total daily dose of all opioids and doses the patient takes over 24 hours. Higher OME doses are associated with higher risks of adverse drug events including

overdose and orthostatic hypotension that may further increase risk of falls and injuries. The new recommendations around morphine milligram equivalents is to avoid total daily doses equal to or greater than 90 MME/day and to monitor patients closely with tapering considerations for doses equal to or greater than 50MME/day. For our purposes, patients on doses equal to or higher than 50 were included in this study (intervention and data collection).

The intent of this data collection is to perform a formative evaluation to inform CDC of best practices for implementation of a fall prevention program into the hospital discharge process targeting opioid prescribing and management. The data collection from this questionnaire will inform whether provider practices change in response to education and availability of prescribing protocols and decision support tools to reduce opioid prescribing to older adults and reduce fall risk after discharge.

This information collection is unique as there are no other funded efforts to design, implement and evaluate CDC's fall prevention initiative in a hospital discharge setting with the goal of preventing post-discharge opioid adverse effects and readmission for falls.

A.2. Purpose and Use of Information Collection

The goal of the data collection is to do a formative evaluation to inform CDC of best practices for the implementation of adding a fall prevention program into the hospital discharge process targeting opioid prescribing and management.

The information collection will consist of four questionnaires: (1) *Pre-Discharge Patient Questionnaire*, (2) *Post-Discharge Patient Questionnaire*, (3) *UCSF Clinical Staff Evaluation Questionnaire*, and (4) *Primary Care Provider (PCP) Post-Discharge Questionnaire*.

The study population for the *Pre-Discharge and Post-Discharge Patient Questionnaires* will be older adults (age 65 years and over). Inclusion criteria includes being English speaking, not cognitively impaired, currently hospitalized at UCSF with plan to be discharged. Older adults will be excluded if they are on hospice, currently in ICU, reside in a prison or correctional facility, or are seen for same day admission or observation only. Older adults qualify for the intervention and data collection if they are considered high risk for falls due to high dose opioid use defined as patients admitted and started on new long-acting opioid, patients on high oral morphine equivalent regimens, or those on combination opioids and benzodiazepines.

The study population for the *UCSF Clinical Staff Evaluation Questionnaire* will include UCSF Medical Center clinical staff (i.e., nurses, pharmacists, physicians) involved in patient pain management and post-discharge planning who work in hospital units where the opioid management program has been implemented.

The study population for the *Primary Care Provider Post-Discharge Questionnaire* will be outpatient Primary Care Providers (PCPs) associated with the UCSF Medical Center who provide outpatient care for older-adult study patients discharged from UCSF each month.

The data collection from the patient questionnaires will inform whether patient education about pain management alternatives and controlled opioid prescribing during inpatient stay reduce risk of falls in older adults' post discharge. The provider questionnaires will inform whether provider practices change in response to education and availability of prescribing protocols and decision support tools to reduce opioid prescribing to older adults and provide non-opioid options for pain management to reduce fall risk. CDC will use the

information collected to help inform best practices to implement opioid prescribing protocols at post-discharge setting to reduce falls in older adults. Possible components of the opioid prescribing protocols and decision support tools will be adapted and modified to include in the CDC fall prevention initiative tools and resources.

Conceptual Framework for Analysis

For the patient questionnaires our impact analysis plan and patient-focused data collection tools recognize the complex relationships between pre-hospital (or baseline) patient factors, factors that take place in the hospital, and post-hospital clinical events and factors, as influences on patients’ clinical outcomes as measured at 14, 30, and 60 days post discharge. Post-hospital outcomes of interest in this study include falls, fall-related healthcare encounters, access to community support programs, and various measures related to pain and opioid use. We provide selected examples of references supporting this well-established conceptual model below.

A large and well-developed literature has firmly established the complex relationships between these factors (Pines et al., 2011; Covinski et al., 2003; Mamikonian-Zarpas et al., 2015). We will approach this by treating some issues (such as baseline functional status) as *adjusters* in logistic models, and others (that take place after the active exposure to our intervention) as mediators, thereby permitting us the ability to carry out mediation analyses (Orive et al., 2015; Goldman et al., 2018). These relationships and the connectedness of our longitudinal approach are well suited to the mediation analytic approach.

For example, a patients’ likelihood of falls, may be partially predicted by their pre-hospital activities of daily living (ADL) and instrumental activities of daily living (IADL) dependencies (Clough-Gorr et al.,2008; Tinetti et al., 1998). This is powerfully modified by whether they have a post-hospital complication (such as a urinary tract infection); a patient’s functional status, fall risk, or pain at 30 days is also influenced by these same factors as measured at 14 days. A patient’s pre-hospital level of depression (as measured by PHQ-9) may be associated with ongoing opioid use but influenced further by post-hospital changes in anxiety or difficulties with identifying social supports after discharge (Woo, 2010, Min et al., 2011).

An expanded description of our modeling approach: Adjusters + Key Predictor + Mediators = Outcomes

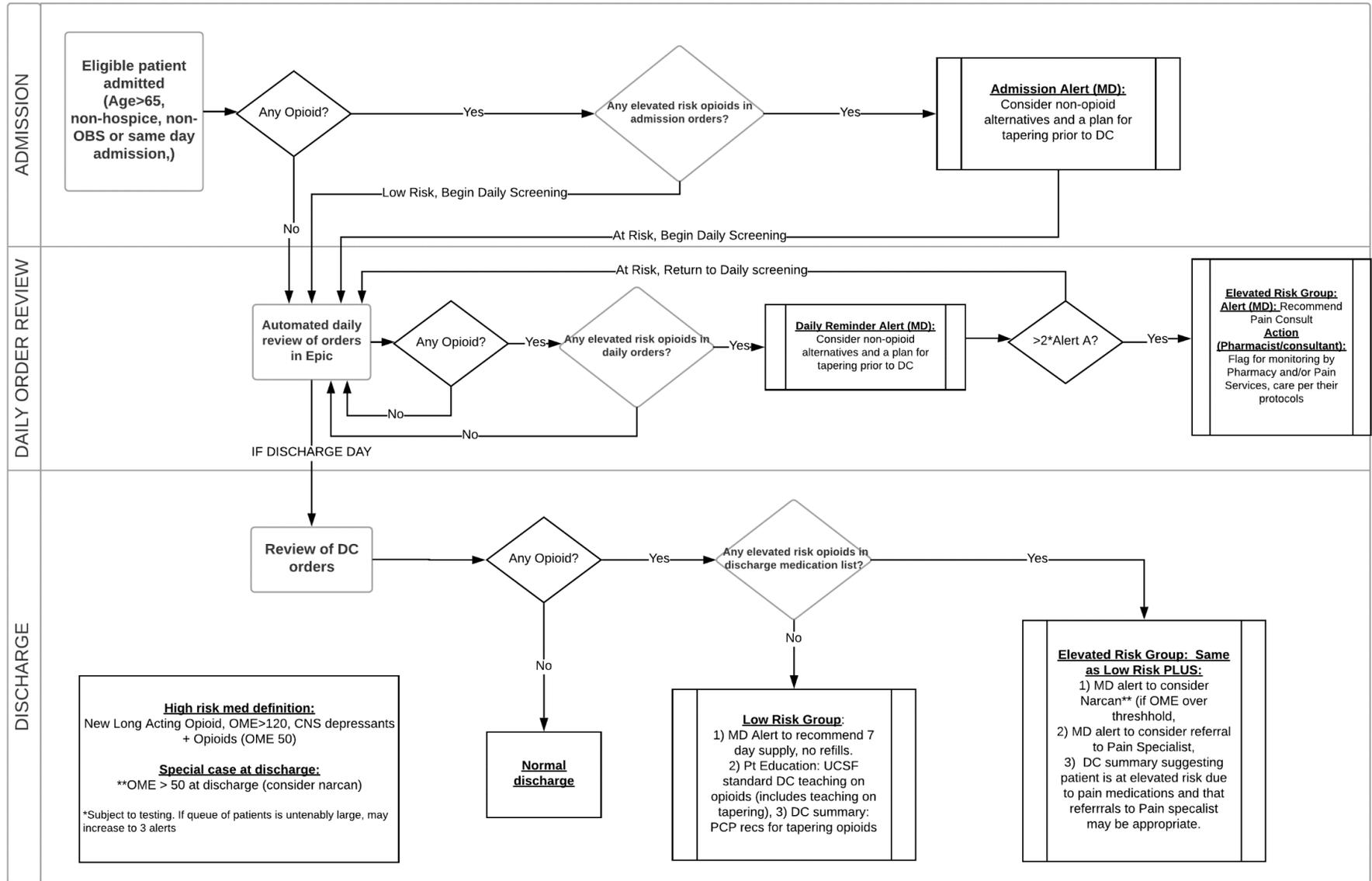
Using this general schema, we can further expand on both the types of adjusters, predictors, and mediators, as well as describe specific data to be tested in models.

We will approach other analyses (such as PCP and clinical staff surveys, as well as patient-collected questions regarding receipt of post-hospital education from providers) using a simpler model, as the influences of clinical outcomes general model components for patient perceptions of educational receipt in hospital or from post-acute provider (**Table A.1**)

Table A.1: General model components for study predictors and outcomes

<i>Study predictors</i>	<i>Outcome</i>
Time and location of care	Example patient reported educational outcomes
Patient cared for on unit with active intervention at time of stay	<ul style="list-style-type: none"> • Report they received teaching about community supports from PCP • Report that they were instructed to taper opioids

Figure A.2: Implementation of opioid management components of a fall prevention initiative into the inpatient workflow



Data Collection Description

The data collection will include four components: *Pre-Discharge Patient Questionnaire*, *Post-Discharge Patient Questionnaire*, *UCSF Clinical Staff Evaluation Questionnaire*, and *Primary Care Provider (PCP) Post-Discharge Questionnaire*. **Table A.2** shows a summary of data collection methods under this OMB request. **Table A.3** shows a crosswalk of each survey and the evaluation (implementation and impact) it will support. **Tables A.4.a-d** show a crosswalk of the survey questions and the specific indicators that they will support. Study data for the *Patient Questionnaires* will be collected from older adults identified as high risk for falls due to their opioid use (e.g. patients started on a new long-acting opioid during admission, patients on high OME regimens, and those on a combination of opioids and benzodiazepines). Patients will be included in the data collection if they received medication management for opioids during their discharge planning from the UCSF Medical Center, are English speaking, and are not cognitively impaired. The patient *questionnaires* will be conducted once prior to discharge (*Pre-Discharge Patient Questionnaire*) and 3 times after discharge (*14, 30, and 60 days Patient Post-Discharge Questionnaires*). The questionnaires can be self-administered online or facilitated by the clinical research coordinator (CRC) in person for the pre-discharge and via phone for the post-discharge.

The questionnaires (**Attachments E1& I1, E2 & I2**) include questions about the patient's health status, use of medication and non-medication therapies for pain, follow through with and adherence to recommendations on tapering efforts, and referral to specialists and readmissions for falls or other conditions. The questionnaires are expected to take an average of 10 minutes to fill out. The information collection will supplement information (e.g. discrete clinical data, medication administration) obtained from the electronic health records at the UCSF medical center which will be linked to the survey results.

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 the opioid prescribing protocol and decision support tools have been implemented into the hospital discharge process to reduce falls and risk of opioid adverse events. The questionnaire (**Attachment E3 & I3**) includes questions about the respondent's use and experience with opioid prescribing guidance and their opinion of the effectiveness of the program to reduce falls and opioid adverse events. The questionnaire is expected to take approximately 5 minutes to complete.

Study data for the *PCP Post-Discharge Questionnaire* will be collected from study patients' outpatient PCPs who are associated with the UCSF Medical Center as identified in the patient's electronic health record. An average of 25% of these older adults see a PCP affiliated with UCSF Medical Center. As a part of the implementation, all patient's PCP will receive (either electronically or from their patient at the first post-discharge visit) a discharge summary and post-acute care plan recommendation for each identified patient. The UCSF-associated PCPs (for about 25% of older adults) will receive a questionnaire (**Attachment E4 & I4**) that includes questions about the usefulness of the discharge summary (e.g. information about patient functional status and fall risk) and usefulness of the clinical recommendations (e.g. need for continued physical or occupational therapy, non-opioid suggestions for pain management, and opioid tapering guidance).

Table A.2: Summary of data collection methods

Data collection method	Data collected	Respondent type	Administration
Patient Questionnaires (Pre-Discharge And Post-Discharge)	Outcome data on patient health status, opioid use, follow through with recommended interventions	Older adults (65+) admitted as inpatient at UCSF Medical Center identified during discharge planning as high risk for falls due to high use of opioid or high risk of opioid misuse.	Self-administered online or facilitated in-person/ via phone by clinical research coordinator. Pre-discharge questionnaire administered once while still admitted/in hospital during discharge planning; and post-discharge administered at 14, 30, 60 days after discharge from the hospital. Each questionnaire is expected to take 10 minutes to complete
UCSF Clinical Staff Evaluation Questionnaire	Program implementation and process evaluation	UCSF Medical Center clinicians (nurses, pharmacists, and physicians) involved in older adult patient pain management and discharge planning who work in hospital units where the fall prevention program has been implemented.	Self-administered once. The survey is expected to take 5 minutes to complete.
PCP Post-Discharge Questionnaire	Process and outcome evaluation	Primary Care Providers (PCP) associated with the UCSF Medical Center who care for older adult study patients discharged from UCSF each month.	Self-administered once. The survey is expected to take 5 minutes to complete.

Table A.3: Crosswalk of each survey and its use in the program assessment

Data collection method	Respondents	Implementation Assessment	Impact Assessment
Data Collection requested			
Patient Questionnaires (Pre-Discharge and Post-Discharge)	Older adults (65+) inpatient at USCF Medical Center at pre/post-discharge		√

UCSF Clinical Staff Evaluation Questionnaire	Clinical staff (nurses, pharmacists, physicians at UCSF)	√	
PCP Post-Discharge Questionnaire	Primary care providers in the UCSF community identified in the patient's EHR record	√	√
Data from alternate data sources			
Billing data	Readmission encounters for fall recurrence		√
Electronic Health Records	Identification of patients in the target population of the study; discrete clinical data for each patient, including Medication Administration Records and PCP information.	√	√
Clinical workflow observations and notes, and team meeting minutes	Structured clinical observations on implementation of the falls prevention initiative with the opioid management component.	√	

Tables A.4.a-d: Summary of Survey Crosswalk – Question and indicators.

Table A.4.a: Pre-discharge Patient Questionnaire (Attachment E1)

Question(s)	Description	Validated Indicator / Source	Role in Analysis
1-12	Patient reported health status inpatient prior to discharge	SF-12 health assessment ¹	Adjuster
13 - 17	Patient reported activity limitations	Activities of daily living (ADL) ²	Adjuster
18-22	Patient reported activity limitations	Instrumental activities of daily living (IADL) ³	Adjuster
23	Patient social support system	Social support beyond a spouse/partner	Adjuster
24-25	Patient reported falls and risk for falls	Falls and risks for falls ⁵	Outcome, Adjuster
26-31	Patient knowledge, attitudes, beliefs about falls	Patient's beliefs ⁶	Adjuster
32-33	Patient use and misuse of alcohol	Alcohol use ⁷	Adjuster
34-50	Patient reported pain assessment	Pain and approaches to caring for pain ^{8,9}	Outcome, Adjuster
51	General patient status	Patient comment	

1. Adapted from the “12-Item Short-Form Health Survey” (Ware et al., 1996)
2. Adapted from the Barthel Index (Mahoney et al., 1965)
3. Adapted from the Lawton and Brody Index (Lawton et al., 1969)
4. Adapted from the Health and Retirement Survey
5. Adopted from fall related questions Behavioral Risk Factor Surveillance System (BRFSS).
6. Adopted from the New South Wales Falls Prevention Baseline Survey
7. Adapted from alcohol related questions Behavioral Risk Factor Surveillance System (BRFSS).
8. Adapted from the Prescription Opioid Misuse Index. (Kinsley et al., 2008)
9. Adapted from the Chronic Pain Screener Questions from National Pain Strategy.

Table A.4.b: Post-Discharge Patient Questionnaire (14, 30 and 60 days after discharge from hospital)
(Attachment E2)

Question(s)	Description	Validated Indicator / Source	Role in Analysis
1-4	Medical visits since discharge ¹	Medical visits ¹	Outcome, Mediator
5-10	Patient reported medical events	Self-report of post-discharge events ²	Mediator
11-16	Patient reported falls	Self-report ³	Outcome
17-28	Patient reported health status inpatient prior to discharge	SF-12 health assessment ⁴	Mediator
29-33	Patient reported activity limitations post-discharge	Activities of daily living ⁵	Mediator
34-38	Patient reported activity limitations post-discharge	Instrumental activities of daily living ⁶	Mediator
39	Social support	Social support beyond spouse/partner ⁷	Mediator
40-44	Patient reported fall risk communication and education	Self-report of post-discharge instruction ⁸	Outcome, Mediator
45-49	Patient reported pain assessment/interventions	Self-report of post-discharge management of pain ⁸	Outcome, Mediator
50-51	Patient use and misuse of alcohol	Alcohol use ⁹	Adjuster, Mediator
52-66	Patient reported pain assessment	Pain and approaches to caring for pain ^{10,11}	Outcome, Adjuster
67	General patient status	Patient comment	

1. Questions aim to measure seeking medical care by different healthcare settings after discharge
2. Adapted from Krumholz et al., 2013 for health conditions included commonly associated with post-hospital complications and contribute independently to loss of function, falls, and pain.
3. Questions adapted from BRFSS around self-reported falls with modifications to measure fall frequency and severity.
4. Adapted from “12-Item Short-Form Health Survey” (Ware et al., 1996) to measure overall health status and used to compare to baseline.
5. Adapted from the Barthel Index (Mahoney et al., 1965) to measure ability to carry out activities of daily living and compare to baseline.
6. Adapted from the Lawton and Brody Index (Lawton et al., 1969) to measure ability to carry out instrumental activities of daily living and compare to baseline.
7. Adapted from the Health and Retirement Survey to predict of loss of function and re-hospitalization in older adults
8. Questions developed by clinical team to measure post-discharge pain management, medication adherence and the primary outcome of falls.
9. Adapted from alcohol related questions Behavioral Risk Factor Surveillance System (BRFSS).
10. Adapted from the Prescription Opioid Misuse Index. (Kinsley et al., 2008)
11. Adapted from the Chronic Pain Screener Questions from National Pain Strategy.

Table A.4.c: UCSF Clinical Staff Evaluation Questionnaire (Attachment E3)

Questions	Question(s) Description	Indicator
Questions 1 through 7	Provider demographic: age, gender, years in practice, professional role, location of work	Verification of respondent eligibility, and perceived expertise & proficiency
Questions 8 through 13	Provider experiences in caring for patients with pain and/or opioid use	Practices around pain and opioid management
Questions 14 through 26	Provider confidence in ability to address issues related to pain and/or opioid use	Self-efficacy around pain and opioid management practices
Questions 27 through 30	Effectiveness of electronic health records prompts to make clinical decisions	Perceptions of the EHR as an aid to pain management
Question 31	Provider comments	Suggestions for improvement regarding the care of patients with pain and/or opioid use

Questions were developed by clinical staff at UCSF.

The data collection from this questionnaire will help inform CDC about practices for implementation of fall prevention program into the hospital discharge process targeting opioid prescribing and management.

The data collection from this questionnaire will inform whether provider practices are changing in response to education and decision support tools from the implemented program and training.

Table A.4.d: Primary Care Provider Post-Discharge Questionnaire (Attachment E4)

Questions	Question(s) Description	Indicator
Question 1	PCP recall of patient discharges	Time lapse estimate for patient seen after discharge
Questions 2 through 3 and 5 through 7	Usefulness of falls prevention protocol	PCP perceptions of fall prevention instructions
Questions 4 and 8 through 11	Usefulness of opioids and pain management protocol	PCP perceptions of instructions regarding opioids and pain management

Questions were

developed by clinical staff at UCSF.

The data collection from this questionnaire will help inform CDC with best practices for communication with outpatient primary care providers that care for discharged older adults at risk for falls due to opioid use important for care continuation and coordination.

A.3. Use of Improved Information Technology and Burden Reduction

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 Questionnaires*, 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 (Attachment H) and administer the initial questionnaire, in person in the hospital. Patient may specify they wish to continue with the study via contact with a CRC, and the CRC can then conduct follow up questionnaires by phone. The second is through electronic contact, where a patient receives an electronic invitation to consent (via patient-portal message or email – Attachment H) and join the study via a web interface while the patient is still in the hospital prior to discharge. Patient will then self-administer consent and carry out the survey using the same platform. If the consent form is not signed while the patient is still an inpatient during discharge planning, the patient will not be invited to participate in the questionnaire after they are discharged. Patients who sign the consent form are invited to take the *Pre-Discharge Patient Questionnaire* during their hospital stay and then take the follow up patient *Post-Discharge Patient Questionnaire* at days 14, 30, and 60. The questions have multiple-choice responses, are easy to read and patients can respond by a few clicks per question/answer. The system will auto-advance after each question is answered and allow respondents to skip questions that may not be applicable. The platform is user-friendly, the survey is presented in a comfortable font size for older adults and it is estimated that the survey will require an average of 10 minutes to complete. The system tracks survey completion by respondent and automatically sends a limited number of reminders, only to those who have yet to complete the post discharge survey.

The *UCSF Clinical Staff Evaluation Questionnaire* will use the same platform commonly used by clinical staff at UCSF. 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.

The *PCP Post-Discharge Questionnaire* will be administered by email or secure fax internal to UCSF Medical System on the preference of each PCP. This survey is limited to 11 multiple-choice questions and is expected to require five minutes to complete.

During the data collection process, a secure database, that will include the contact information for each respondent, will be used to track each individual respondent. Upon survey completion, the database will update the tracking system so that no additional unnecessary 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 during a time that is convenient to their schedules, to avoid interference with work routine.

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

The questionnaire was 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, with questions designed to measure those factors.

A.4. Efforts to Identify Duplication and Use of Similar Information

No effort to collect similar data is being conducted within the agency. The previous project, “Test Predictability of Falls Screening Tools” OMB#: 0920-1220, intends to measure available screening tools and effectiveness at capturing older adult fall risk. An earlier collection at UCSF, “Stopping Elderly Accidents, Deaths, and Injuries (STEADI) in a Hospital Discharge Setting” (OMB# 0920-1009 (18KW) approved through an OMB Generic mechanism) provided a basic measure of STEADI-based fall prevention interventions (excluding medication management and opioid prescribing) during discharge process to reduce the risk of post-discharge falls and readmissions for a fall.

Additionally, no efforts outside the agency have been made to collect these data. There are other government agencies that collect hospital falls data on older adults including:

1. National Hospital Discharge Survey (NHDS) (OMB#: 0990-0212). The NHDS provides detailed information on characteristics, diagnoses, and surgical and other procedures for patients discharged from short-stay non-federal hospitals in the United States. The information collected is available in written reports in unpublished form through standardized in-house tabulations or special tabulations, and on public use tapes. NHDS collects quantitative information about hospital admissions. It does not collect program evaluation data about implementation of falls prevention programs.
2. National Institutes on Aging (NIA):
 - a. Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE) - In partnership with the Patient-Centered Outcomes Research Initiative (PCORI), NIA funded this study with the goal of reducing serious fall-related injuries by implementing individually tailored interventions. This study is directed at outpatient practice and will not collect information on incorporating falls prevention into the hospital discharge process.
 - b. Fall Prevention in High- and Low-Fall Hospital Nursing Units – The purpose of this project is to examine interventions to reduce in-hospital falls, as opposed to prevention of post-discharge falls in our study.

The data collection proposed by this project is important because it represents the first federal effort to measure provider practices change in response to education and availability of prescribing protocols and decision support tools to reduce opioid prescribing to older adults and reduce fall risk after discharge. This data collection will help inform best practices for provider training and implementation of an opioid prescribing protocol and decision support tools at the post-discharge healthcare setting to control opioid prescribing to older adults and reduce fall risk.

CDC reached out to other federal agencies in September 2018 that have an interest in preventing older adult falls, including the National Council on Aging [NCOA], and Administration for Community Living [ACL]. These agencies do not currently have similar data collection efforts but will be interested in the findings from this project, and we plan to share results during our monthly partnership calls. CDC is unaware of other federal efforts from the Centers for Medicare and Medicaid Services [CMS] and National Institutes of Health [NIH] for similar data collection.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved or impacted in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

For the *Pre-discharge and post-discharge patient questionnaires*, the request is for a baseline questionnaire administered while each patient is hospitalized, and three follow up questionnaires at 14 days, 30 days, and 60 days post-discharge. The recurrent data collection is necessary to measure patient outcomes and adherence with interventions including referrals and opioid tapering in the short and long term after discharge. The data collection also allows for estimating number and outcome of self-reported falls up to 2 months post hospital discharge. If these data are not collected, CDC will not have necessary information about what strategies are most likely to be effective for opioid education, tapering, referral to specialists, and use of alternative therapies for pain in older adults' post-discharge.

For the *UCSF Clinical Staff Evaluation Questionnaire*, the request is for a one-time survey in which data will be collected from respondents on post-opioid prescribing guidance implementation. (No recurrent data collection is requested).

For the *PCP post-discharge questionnaire*, the request is to survey PCP physicians only one time for one of their patients discharged from UCSF. (No recurrent data collection is requested).

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A.8.a.) Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on February 7, 2019. Vol. 84. No. 26, pp. 2520 (Attachment B). CDC received two non-substantive and one substantive public comment (Attachment B1-3). CDC did not respond as contact information was not provided by any of the commenters. The substantive public comment expressed the need of starting patients' medications while in the hospital to monitor for possible reactions to medications. This study identifies patients already on an opioid medication or prescribed an opioid medication while inpatient, thus they have been receiving the medication under clinical staff supervision, before discharge planning. No changes were made to the data collection.

A.8.b.) Efforts to Consult Outside the Agency

CDC made the following efforts to consult outside of the agency:

1. CDC reviewed the list of projects funded by the National Institute on Aging and found two projects directed at falls prevention in clinical settings.
2. CDC is in regular contact with other federal agencies that have an interest in preventing older adult falls (e.g., Administration for Community Living [ACL], Centers for Medicare and Medicaid Services [CMS], National Institutes of Health [NIH]). These agencies will be interested in the findings from this project, as they are engaged in complementary but not redundant efforts (see above), and we plan to share results during our partnership calls. CDC meets monthly with NCOA and ACL and as needed with other federal partners.
3. CDC included a description of this proposed project in presentations at the American Geriatric Society Annual Meeting, the Living Well Academy, the Gerontological Society of America Annual Meeting, and a National Council on Aging webinar.

A.9. Explanation of Any Payment or Gift to Respondents

Respondents will not be provided with any payment or gift for participating in this data collection.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Office of the Chief Information Officer at the CDC has determined that the Privacy Act does apply. The applicable System of Records Notice (SORN) is 09-20-0136 Epidemiology Studies and Surveillance of Disease Problems. Published in the Federal Register on November 24, 1986. Volume 51, Number 226, Page 42484-42485. The Privacy Impact Assessment (PIA) is attached (**Attachment C**). All respondents will be informed that the information they provide will be treated in a secure manner and will be used only for the purpose of this evaluation, unless otherwise compelled by law.

Patient Pre- and Post-Discharge Questionnaires. To ensure privacy, personally identifiable information will not be collected during the survey. A participant ID will be assigned to each respondent. After the survey response, only the ID and other (non-Protected Health Information) categorical variables necessary for analysis will be available. Within 3 months of the end of the study period, UCSF will destroy the link between the ID code and the participant's personally identifiable information. No personally identifiable information (names, addresses, and telephone numbers) will be in the database delivered to CDC. All data containing identifying information about participants will be destroyed within three months of the end of the study period. CDC will not have access to personally identifiable information.

Unique identifiers will be assigned to each case in the data files as data are collected and participants removed from contact lists when their interview participation is complete. Survey data will be stored by the contractor in secure servers. All respondents will be told during the consent process that the data they provide will be treated in a secure manner to the extent allowed by law. They also will be informed that participation is voluntary, that they may refuse to answer any question, and can stop at any time without risk. In addition, names of participants in any component of the study will not be provided to the federal government. Instead, a unique ID will be assigned to each participant.

UCSF Clinical Staff Evaluation Questionnaire. To ensure privacy, personally identifiable information will not be collected during the survey. The system will keep track of who has responded and automatically contact only those who have not responded. Personally identifiable information such as an email will not be shared outside the database.

PCP post-discharge questionnaire. To ensure privacy, personally identifiable information will not be collected during the survey.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

CDC has received IRB approval for this evaluation activity involving human subjects where CDC is not engaged through UCSF. UCSF has its own IRB, which meets all the Federal requirements as specified in 45 CFR 46, registered with the Office for Human Research Protections and with Federal Wide Assurance (FWA00000068). This ensures that this project involving human subjects comply with Federal regulations. (**Attachment D**)

Sensitive Questions

For the *Pre-Discharge and Post-Discharge Patient Questionnaires*, most of our questions are not likely to be viewed as sensitive by patients, with the exception of questions around self-management of pain. These

questions may be viewed as more sensitive. However, none of the questions on our surveys are required, and patients may decline to answer any question they deem unreasonable or sensitive.

The *UCSF Clinical Staff Evaluation Questionnaire* asks questions about gender, which may be viewed as sensitive, and we allow respondents to decline to answer this question. None of the questions on the survey are required, and respondents may decline to answer any question they deem unreasonable or sensitive. The *PCP Post-Discharge Questionnaire* does not contain any sensitive questions but also allows for declining to answer.

A.12. Estimates of Annualized Burden Hours and Costs

The estimated respondent burden consists of the burdens of participants answering a series of questions (mostly multiple choice with a few free-text form questions). For the *Pre-Discharge Questionnaire*, older adult participants will be asked to participate during their hospital stay in preparation for discharge in person or electronically via patient-portal message or email (Attachment G1). The *Pre-Discharge Questionnaire* is expected to take 10 minutes to complete. Over three years, we expect 9,850 older-adult patients to meet our selection criteria for high-risk opioid use that will receive pain management and fall prevention interventions during their discharge planning. Of those, we expect around 30% to be non-English speaking, prison residence or from a correctional facility, cognitively impaired, or receiving ICU care based on previous UCSF norms. These groups will be excluded/ not invited to participate in the questionnaires. The remaining 6,895 will be invited to participate in the questionnaires over 3 years. Approximately 2,400 total respondents are expected to complete the surveys in the 3 years. We chose 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. For the *post-discharge questionnaire*, older adult participants that completed the initial pre-discharge questionnaire will be asked to participate at 14 days, 30 days, and 60 days post-discharge.

For the *UCSF Clinical Staff Evaluation Questionnaire*, UCSF Medical Center clinicians (nurses, pharmacists, and physicians) will be identified by using electronic records of order and documentation activity in units targeted by our study. An electronic correspondence letter (Attachment G2) will be sent to a randomly selected (using block randomization of digits to match provider ID numbers) sample of clinicians per month. Those completing the survey are expected to use approximately 5 minutes. We expect 300 individuals (nurses, pharmacists, and physicians) will be invited to participate over the course of 3 years from whom we anticipate a 50% response rate (150 total responses) over 3 years. The anticipated survey completion rate is based on historical norms within UCSF for similar clinician surveys. For the *PCP Post-Discharge Survey*, outpatient providers will be identified using electronic record data listing PCPs for older adult study patients discharged from UCSF. Approximately 25% of patients treated at UCSF Medical Center see an UCSF-affiliated PCP. We will use block randomization schema matched to patient medical record numbers to invite a sample of providers to be surveyed each month. Those completing the survey are expected to use approximately 5 minutes (Attachment G3). We anticipate inviting 300 PCPs over the course of 3 years and anticipate 50% response rate (150 total responses over 3 years).

Table A.5 Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondent	Number of Responses	Average Burden	Total Burden
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		s	per Respondent	per Response (in hours)	Hours (in hours)
Older adult Patients	Pre-discharge Patient Questionnaire (Attachment E1)	800	1	10/60	133
	Post-discharge Patient Questionnaire (Attachment E2)	800	3	10/60	400
UCSF clinical staff (Pharmacists, nurses, physicians)	Clinical Staff Evaluation Questionnaire (Attachment E3)	50	1	5/60	4
Primary care providers (PCP) associated with UCSF medical center	PCP post discharge survey (Attachment E4)	50	1	5/60	4
Total annual burden hours					541

A.12.2. Estimated Annualized Respondent Burden Costs

Participation in this study is voluntary, and there are no costs to patient respondents beyond the time spent completing the surveys. The cost to respondents was calculated using the Social Security Administration annual wage estimation.

There is no cost to UCSF clinical providers (nurses, pharmacists, physicians) or primary care providers beyond the time spent completing the surveys. The hourly wage for clinical staff and providers is based on the 2016 US Department of Labor, Bureau of Labor Statistics Labor Survey. **Table A.6** shows the estimated annualized burden costs on patients and providers.

Table A.6 Estimated Annualized Burden Cost

Type of Respondent	Form Name	No. of Respondents	Total Burden (in hours)	Hourly Wage Rate (in dollars)	Total Cost
Older adult Patients	Pre-discharge Patient Questionnaire (Attachment E1)	800	133	\$23.39	\$3,110.87
	Post-discharge Patient Questionnaire (Attachment E2)	800	400	\$23.39	\$9,356
UCSF clinical staff	Clinical Staff Evaluation Questionnaire	50	4	\$64.10	\$256.4

(Pharmacists, nurses, physicians)	(Attachment E3)				
Primary care providers (PCP) associated with UCSF medical center	PCP post-discharge questionnaire (Attachment E4)	50	4	\$64.10	\$256.4
Total					\$12,979.67

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

No capital or maintenance costs are expected. Additionally, there are no start-up, hardware, or software costs. No incentives will be given for participating in the survey.

A.14. Annualized Cost to the Government

It will take three years to conduct this data collection under contract 200-2017-95356. The total cost to the government will be \$198,939.99. The annualized cost to the government will be \$51,313.33 in contract costs to Intellix (Contractor) and UCSF and \$15,000 in other federal costs, including salary, fringe, travel, and supply expenses related to the involvement of two federal employee to devote 5% FTE to the project (**Table A.7**).

Table A.7 Annualized Cost to the Government

Type of Cost	Description of Services	Annual Cost
Contractor	Study design, data collection, data analysis	\$51,313.33
Two technical monitors at 5% FTE (CDC)	Study planning and contractor oversight	\$15,000
Total Annual Estimated Costs		\$66,313.33

A.15. Explanation for Program Changes or Adjustments

This is a new collection.

A.16. Plans for Tabulation and Publication, and Project Time Schedule

After the survey data are cleaned, the data file will be prepared for statistical analysis.

Data analysis will include frequencies, cross-tabs, and regression analysis. Proposed analysis tables are in Attachments F and F1.

Analyses determining effectiveness of our program in terms of outcomes will employ multivariable logistic models. Potential clustering of patients by physician, site, or surgical service will be handled using extensions of the logistic models with random effects to account for such clustering; specifically, we will use the normal logistic model implemented in Stata.

Selected study findings will be published in a peer-reviewed journal. Once published, there will be a link to the publication on the CDC’s Older Adult Falls webpage. The high-level time schedule for the project activities is summarized in **Table A.8** below.

Table A.8 Project Time Schedule

Activity	Schedule
Identify participants (older adult patients, UCSF clinical staff, and primary care providers).	Ongoing months 1-24 after OMB approval
Screen participants and conduct survey	Ongoing months 6 - 30
Data Collection, cleaning, analysis	Ongoing through month 36

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Paperwork Reduction Act.

REFERENCES

1. Albala C, Yáñez M, Salazar G, Vio F. Body composition in the elderly: Total body water and anthropometry. *Nutrition Research*. 1994;14: 1797-1809
2. Ambrose AF, Paul G, Hausdorff JM. Risk factors for falls among older adults: a review of the literature. *Maturitas* 2013;75:51–61. <http://dx.doi.org/10.1016/j.maturitas.2013.02.009>
3. American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *Journal of the American Geriatrics Society*. 2015;63: 2227-2246.
4. American and British Geriatric Society
5. Barnett ML, Olenski AR, Jena AB. Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use. 2017;376(7):663-673.
6. Behavioral Risk Factor Surveillance System (BRFSS). 2014. https://www.cdc.gov/brfss/data_documentation/index.htm
7. Bergen G, Stevens MR, Burns ER. Falls and Fall Injuries Among Adults Aged >=65 Years United States, 2014. *MMWR Morb Mortal Wkly Rep*. 2016;65(37):993-998
8. Boss GR, Seegmiller JE. Age-Related Physiological Changes and Their Clinical Significance. *Western Journal of Medicine*. 1981;135: 434-440.
9. Calcaterra SL, Yamashita TE, Min SJ, Keniston A, Frank JW, Binswanger IA. Opioid Prescribing at Hospital Discharge Contributes to Chronic Opioid Use. *Journal of general internal medicine*. 2016;31(5):478-485.
10. Centers for Disease Control and Prevention NCIPC. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. Accessed at www.cdc.gov/injury/wisqars Feb, 2019.
11. Centre for Health Advancement and Centre for Epidemiology and Research. New South Wales Falls Prevention Baseline Survey: 2009 Report. Sydney: NSW Department of Health, 2010.
12. Chronic Pain Screener Questions from National Pain Strategy: A Comprehensive Population Health-Level Strategy for Pain. Appendix D. Page 65. https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf
13. Clough-Gorr KM, Erpen T, Gillman G, et al. Preclinical Disability as a Risk Factor for Falls in Community-Dwelling Older Adults. *Journal of Gerontology*. 2008: 63A (3): 314-320

14. Covinsky KE, Palmer RM, Fortinsky RH, et al. Loss of independence in activities of daily living in older adults hospitalized with medical illnesses: increased vulnerability with age. *Journal of the American Geriatrics Society*. 2003;51(4):451-458.
15. Gerlach LB, Olfson M, Kales HC, Maust DT. Opioids and Other Central Nervous System–Active Polypharmacy in Older Adults in the United States. *Journal of the American Geriatrics Society*. 2017;65:2052-2056.
16. Gillespie LD, Robertson MC, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2012;(9):CD007146
17. Health and Retirement Survey. Accessed 7/2018 available from <https://hrs.isr.umich.edu/documentation/questionnaires>
18. Janet S. Knisely, Martha J. Wunsch, Karen L. Cropsey, Eleanor D. Campbell. Prescription Opioid Misuse Index: A brief questionnaire to assess misuse. *Journal of Substance Abuse Treatment*. 2008; 35.4:380-386. ISSN 0740-5472. <https://doi.org/10.1016/j.jsat.2008.02.001>. ational chronic pain screener prescription opioid misuse index
19. Johnston YA, Bergen G, Bauer M, Parker E, Wentworth L, McFadden M, Reome C, Garnett M. Implementation of the Stopping Elderly Accidents, Deaths, and Injuries Initiative in Primary Care: An Outcome Evaluation. *The Gerontologist*. 2018 Sep 20. DOI: 10.1093/geront/gny101
20. Klotz U. The elderly—a challenge for appropriate drug treatment. *European Journal of Clinical Pharmacology*. 2008;64: 225-226.
21. Krumholz HM. Post-hospital syndrome--an acquired, transient condition of generalized risk. *The New England journal of medicine*. 2013;368(2):100-102.
22. Kuo YF, et al. (2015) Trends in Opioid Prescriptions Among Part D Medicare Recipients From 2007 to 2012. *The American Journal of Medicine* (2016) 129, 221.e21-221.e30.
23. Lawton, M.P., & Brody, E.M. (1969). Assessment of older people: Self-maintaining and instrumental activities of daily living. *The Gerontologist*, 9(3), 179-186 to measure ability to carry out instrumental activities of daily living.
24. Mahoney FI, Barthel D. “Functional evaluation: The Barthel Index.” *Maryland State Medical Journal* 1965;14:56-61 to measure ability to carry out activities of daily living.
25. Mahoney J. Sager M. Durham NC. Johnson J. Risk of falls after hospital discharge. *J Am Geriatr Soc*. 1994 Mar;42(3):269-74.
26. Mamikonian-Zarpas A, Lagana L. The Relationship between Older Adults' Risk for a Future Fall and Difficulty Performing Activities of Daily Living. *Journal of aging and gerontology*. 2015;3(1):8-16.
27. Min, L. , Ubhayakar, N. , Saliba, D. , Kelley-Quon, L. , Morley, E. , Hiatt, J. , Cryer, H. and Tillou, A. (2011), The Vulnerable Elders Survey-13 Predicts Hospital Complications and Mortality in Older Adults with Traumatic Injury: A Pilot Study. *Journal of the American Geriatrics Society*, 59: 1471-1476. doi:10.1111/j.1532-5415.2011.03493.x
28. Orive M, Aguirre U, Garcia-Gutierrez S, et al. Changes in health-related quality of life and activities of daily living after hip fracture because of a fall in elderly patients: a prospective cohort study. *International journal of clinical practice*. 2015;69(4):491-500
29. Parkkari J, Kannus P, Palvanen M, et al. Majority of Hip Fractures Occur as a Result of a Fall and Impact on the Greater Trochanter of the Femur: A Prospective Controlled Hip Fracture Study with 206 Consecutive Patients. *Calcified Tissue International*. 1999;65(3):183-187.
30. Pines JM. Lotrecchiano GR. Zocchi MS. Lazar D. (2011) Development of a Conceptual Model for Management of Acute, Unscheduled Care in the United States. The George Washington University Office for Clinical Practice Innovation. Inform Best Practices.
31. Pratt NL, Ramsay EN, Kalisch Ellett LM, Nguyen TA, Barratt JD, Roughead EE. Association Between Use of Multiple Psychoactive Medicines and Hospitalization for Falls: Retrospective Analysis of a Large Healthcare Claim Database. *Drug Safety*. 2014;37: 529-535.
32. Rolita, L. , Spegman, A. , Tang, X. and Cronstein, B. N. (2013), Greater Number of Narcotic Analgesic Prescriptions for Osteoarthritis Is Associated with Falls and Fractures in Elderly Adults. *J Am Geriatr Soc*, 61: 335-340. doi:10.1111/jgs.12148
33. Rowe JW, Andres R, Tobin JD, et al. The effect of age on creatinine clearance in men: a cross-sectional and longitudinal study. *J Gerontol* 1976; 31:155.
34. Saunders, K.W., Dunn, K.M., Merrill, J.O. et al. Relationship of Opioid Use and Dosage Levels to Fractures in Older Chronic Pain Patients. *J GEN INTERN MED* (2010) 25: 310. <https://doi.org/10.1007/s11606-009-1218-z>

35. Söderberg, K.C., Laflamme, L. & Möller, J. Newly Initiated Opioid Treatment and the Risk of Fall-Related Injuries. *CNS Drugs* (2013) 27: 155. <https://doi.org/10.1007/s40263-013-0038-1>
36. Tan JL, Eastment JG, Poudel A, Hubbard RE. Age-Related Changes in Hepatic Function: An Update on Implications for Drug Therapy. *Drugs Aging* 2015; 32:999.
37. Taylor CA, Bell JM, Breidline MJ, Xu L. Traumatic Brain Injury–Related Emergency Department Visits, Hospitalizations, and Deaths — United States, 2007 and 2013. *MMWR Surveill Summ* 2017;66(SS-9):1-16.
38. Tinetti ME, Speechley M, Ginter SF. Risk Factors for Falls among Elderly Persons Living in the Community. 1988;319:1701-1707
39. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical care*. 1996;34(3):220-233 to measure overall health status.
40. Weiss AJ, et al. (2018). Opioid-Related Inpatient Stays and Emergency Department Visits Among Patients Aged 65 Years and Older, 2010 and 2015: Statistical Brief #244. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville (MD).
41. Woo AK. Depression and Anxiety in Pain. *Rev Pain*. 2010;4(1):8–12. doi:10.1177/204946371000400103
42. Wright RM, Roumani YF, Boudreau R, et al. Impact of Central Nervous System (CNS) Medication Use on Cognition Decline in Community Dwelling Older Adults: Findings from the Health, Aging and Body Composition Study. *Journal of the American Geriatrics Society*. 2009;57: 243-250.