

SUPPORTING STATEMENT: PART A

OMB#

**Evaluation of CDC's STEADI Older Adult Fall Prevention Initiative in a Primary
Care Setting**

October 7, 2019

Point of Contact:

Gwen Bergen

Behavioral Scientist

Contact Information:

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control

4770 Buford Highway NE MS F-64

Atlanta, GA 30341-3724

phone: 770.488.1394

fax: 770.488.1317

email: gjb8@cdc.gov

Table of Contents

Justification.....	4
A.1. Circumstances that make the collection of information necessary.....	4
A.2. Purpose and Use of the Information Collection.....	9
A.3. Use of Improved Information Technology and Burden Reduction.....	13
A.4. Efforts to Identify Duplication and Use of Similar Information.....	14
A.5. Impact on Small Business or Other Small Entities.....	15
A.6. Consequences of Collecting Information Less Frequently.....	15
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	15
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	15
A.9. Explanation of Any Payment or Gift to Respondents.....	16
A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	16
A.11 Institutional Review Board (IRB) and Justification for Sensitive Questions.....	17
A.12. Estimates of Annualized Burden Hours and Costs.....	17
A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....	20
A.14. Annualized Cost to the Federal Government.....	20
A.15. Explanation for Program Changes or Adjustments.....	20
A.16. Plans for Tabulation and Publication and Project Time Schedule.....	20
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	21
A.18. Exceptions to Certification for Paperwork Reduction Act.....	21

Attachments

- A. Authorizing Legislation: Public Health Service Act
- B. Patient Survey
 - B1. Baseline Survey
 - B2. Follow-Up Survey
 - B3. Screenshot Baseline Patient Survey
 - B4. Screenshot Follow-up Patient Survey
- C. Consent Forms
- D. Stay Independent Fall Risk Screener
- E. Process Evaluation Interview Guide
 - E1. Provider Interview Guide
 - E2. Clinic Operations Manager Interview Guide
- F. Published 60-Day Federal Register Notice
 - F.1 Comment in response to Federal Register Notice
- G. Privacy Impact Assessment (PIA)
- H. Institutional Review Board (IRB) letter
- I. Illustrative Table Shells
- J. Falls Tracking Log

Summary Table Goal of the Study:

The goal of this study is to evaluate CDC's Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative in a primary care setting. This formative evaluation will determine the impact of both the comprehensive and selected components of STEADI on falls and fall injuries.

Intended use of the resulting data:

The data collected from this study will be used to: (1) demonstrate the impact of STEADI and different components of STEADI on falls and fall injuries in a primary care setting and (2) improve the implementation of STEADI in a primary care setting.

Methods to be used to collect:

Two data collection methods will be used: 1. First, the CDC's *Stay Independent Fall Risk Screener* will be administered to older adult patients at selected primary care clinics to determine which older adults are at high risk for a fall. Those who screen at high risk will be assigned, based on clinic attended and week of attendance, to one of three study arms. *Patient surveys* will be used to determine whether or not these patients experience a fall during the study period, are treated for a fall, and/or use any fall prevention strategies throughout the study period. Four surveys will be administered to each patient during a 12-month period: one baseline survey and three follow-up surveys. Older adults will also be asked to keep track of their falls in a falls tracking log, so they can accurately recall and report the information during the 12-month period for the patient surveys. 2. Second, *process evaluation interviews* will be used to understand the attitudes of clinical staff towards the implementation process, barriers and facilitators to implementation, and the implementation fidelity to core components of the STEADI initiative.

The subpopulation to be studied:

The study population for the *patient surveys* will be adults 65 and older who have an outpatient visit during the study period and screen as high risk for falls at the selected primary care clinics implementing the STEADI fall prevention initiative who consent to participate in the study. The study population for *the process evaluation* will include the clinical implementation staff at the selected clinics where the intervention will take place (physicians, physician assistants/nurse practitioners, and practice or operations manager).

How data will be analyzed:

Descriptive statistics and cross tabulations will be used to describe quantitative data from the *patient survey* and *process evaluation* data. Risk ratios of the effect of the intervention on post-intervention falls will be calculated comparing intervention and control groups while controlling for demographic, health, attitude, and behavior variables. Qualitative data from the process evaluation will be reviewed and coded to identify themes and contextualize the quantitative data.

Justification

A.1. Circumstances that make 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 evaluate CDC's Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative in a primary care setting. The goal of this evaluation is to determine the impact of both the comprehensive and selected components of STEADI on falls and fall injuries.

CDC will use this information collection to:

1. Evaluate the impact of the STEADI initiative on older adults by measuring incidence of falls, fall injuries, and falls requiring medical treatment (primary care visits, emergency department visits, hospitalizations) in each intervention patient group compared to the control patient group for the comprehensive STEADI initiative, the medication management component only, and the physical therapy only.
2. Monitor the process of implementing and maintaining STEADI in a primary care system.

Falls are the leading cause of both fatal and non-fatal injuries among older adults, defined as age 65 and older (WISQARS 2019). From 2007 to 2016, fall death age-adjusted rates increased by 31% (Burns et al., 2018). In 2017, over 30,000 older adults died as the result of a fall (WISQARS 2019). The economic consequences of falls are significant and growing as the population ages, with medical costs of older adult falls estimated at \$50 billion annually (Florence et al., 2018). Many older adult falls are preventable and represent a major source of modifiable morbidity, mortality, and health expenditures. Based on the American Geriatrics Society and British Geriatric Society fall prevention guidelines, CDC created the STEADI initiative to guide health care providers' fall prevention activities in the primary care setting.

The STEADI initiative includes the following core components to help providers address fall risk in their older patients:

1. **Screen** to identify patients at increased risk of falling using the STEADI screening questions
2. **Assess** to identify what modifiable fall risk factors are present (e.g. gait, strength, and balance test)
3. **Intervene** based on the modifiable risk factors discovered, by prescribing evidence-based strategies to reduce fall risk (e.g. Tai chi or physical therapy to address gait and balance issues) For more information about the tools and resources included in the STEADI initiative, visit <https://www.cdc.gov/steady>

One preliminary, prospective study of STEADI examined electronic health record (EHR) data and showed a reduction in fall-related hospitalizations in one primary care setting in New York State (Johnston 2018). There have, however, been no large scale studies with patients randomized to intervention and control groups to evaluate the health benefits of STEADI-based fall prevention. CDC needs additional research to inform the technical assistance that they provide on older adult fall prevention to health systems and national, state, tribal, and local partners. Additional research would also support wider dissemination of STEADI-based older adult fall prevention. Not only is there a need for

evidence whether STEADI reduces older adult falls, there is also a need to understand which components or the combination thereof (e.g. medication management, referral to physical therapy) are the most high impact, given limitations in time and money in an often overburdened healthcare system.

The proposed new data collection will complement secondary data collection and analysis using electronic health records (EHR). This study augments EHR data with patient survey data and process evaluation interviews. Once patients are screened to determine if they have an increased risk of falling, they will be randomized to one of three intervention groups or to the control group, depending on the clinic and week they visit. **Table A.1.1** shows the STEADI assessments and interventions to be conducted in each group.

This information collection is unique and will be the first study of STEADI-based fall prevention with randomization of patients to intervention and control groups. There are no other efforts that the CDC knows of to:

1. Implement STEADI in a primary care system or
2. Determine if less resource-intensive modifications of STEADI effectively prevent falls and fall-related injuries. In resource limited settings, it will be useful to know which aspects of STEADI have the highest potential to prevent falls.

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**).

Table A.1.1 STEADI Intervention Arms

STEADI Component	Setting and Staff Roles	STEADI A: Comprehensive Intervention	STEADI B: Physical Therapy	STEADI C: Medication Management	Control Group
Screening	<p>Eligibility and Risk Screening</p> <p>Research assistant checks for eligibility, distributes and assists with Stay Independent Fall Risk screener in the clinic waiting room, and calculates the risk score. If patient is high-risk then research assistant obtains consent from the patient for study participation. Patient is assigned to either one of three arms based on clinic and week of visit or to the control group</p>	X	X	X	X
Assessment	<p>Gait & Balance Test</p> <p>The research nurse performs the Timed Up and Go (TUG), 30 second chair test, and four stage balance test in a STEADI dedicated exam room. Records results in EHR.</p>	X	X	SoC	SoC
	<p>Postural Hypotension</p> <p>The research nurse assesses the patient's orthostatic blood pressure in the exam room. Records results in EHR. Pends recommendations for review if needed in EHR record.</p>	X	SoC	SoC	SoC
	<p>Medication Review</p> <p>The research nurse reviews the patient's medications to identify medications associated with falls, pends recommendations for review if needed to EHR record.</p>	X	SoC	X	SoC

	<p>Visual Acuity</p> <p>The research nurse ascertains visual acuity in STEADI exam room using a Runge card. Records results in EHR. Pends recommendation for eye care referral to EHR record.</p>	X	SoC	SoC	SoC
	<p>Comorbidities</p> <p>The research nurse will review patients diagnoses and flag any conditions that put patient at increased risk of falling</p>	X	SoC	X	SoC
	<p>Feet/footwear Assessment</p> <p>The research nurse checks shoes, asks about existing foot pain or loss of sensation. Records note in EHR for provider recommendation</p>	X	SoC	SoC	SoC
	<p>Falls History</p> <p>The research nurse ascertains the patient's fall history</p>	X	SoC	SoC	SoC
Intervention	<p>Patient education</p> <p>The research nurse provides the <i>What You Can Do To Prevent Falls</i> brochure.</p>	X	X	X	SoC
	<p>Physical Therapy</p> <p>Research nurse determines whether to recommend patient for referral to Physical Therapy based off of the gait and balance assessments. The provider reviews recommendation and accepts or rejects referral of the patient for Physical Therapy.</p>	X	X	SoC	SoC
	<p>Medication Modification</p> <p>Research nurse recommends medication adjustments. The provider reviews recommendations and, if indicated, adjusts</p>	X	SoC	X	SoC

	medications that are associated with increased risk of falling.				
	<p>Eye Specialist Referral</p> <p>The research nurse determines whether to recommend the patient for referral to an eye specialist and the provider reviews recommendations and accepts or rejects referral of patients with impaired vision to an eye-care provider.</p>	X	SoC	SoC	SoC
	<p>Home Hazard Modification</p> <p>The research nurse reviews the <i>Check for Safety</i> brochure with the patient</p>	X	SoC	SoC	SoC
	<p>Podiatry Referral</p> <p>If needed, the research nurse recommends referral to a podiatrist. The provider may accept or reject this recommendation</p>	X	SoC	SoC	SoC
	<p>Referral Exercise Program</p> <p>If needed, the research nurse recommends referral to a community-based exercise program (e.g. Tai Chi). The provider may accept or reject this recommendation</p>	X	SoC	SoC	SoC

SoC=Pre-STEADI implementation standard of care in the health system

A.2. Purpose and Use of the Information Collection

This data collection effort is a formative evaluation strategy to assess the impact of STEADI in a primary care system. The purpose of this information collection is to:

1. Evaluate the impact of STEADI on falls and health outcomes (*Patient Surveys*)
2. Evaluate whether less resource intense versions of STEADI result in similar fall prevention benefits compared to the entire module (*Patient Surveys*)
3. Evaluate the fidelity of the STEADI implementation to inform and interpret the impact results. (*Process evaluation interviews*)

To reach these goals, the data collection will consist of one pre-screener to determine eligibility, *STEADI Stay Independent Fall Risk Screener*, and two data collections: *Patient surveys and process evaluation interviews* (**Table A.2.1**)

The information collection will consist of two components: 1) *patient surveys* and 2) *process evaluation interviews*. The study population for the *patient surveys* will consist of patients 65 years and older who attend one of two selected primary care clinics in a large health system, screen as high risk for a fall, consent to participate, and are randomized, using block randomization, to either intervention or control groups. Clinics were selected based on their willingness to participate, their high volume of patients ages 65 and older, and their role as primary care facilities. This is a convenience sample, although randomization within clinics eliminate bias in the selection of patients to receive STEADI, results will not be interpreted outside of the study population. The population for the *process evaluation interviews* will include clinical intervention staff at the selected clinics who will implement and maintain STEADI.

Study data for *patient surveys* (**Attachment B.1**) will be collected from older adults identified as high risk for falls using the *STEADI Stay Independent Fall Risk Screener* (**Attachment D**), who consent to participate in the study (**Attachment C**). Surveys will be administered by the patient's choice of internet, mail, or telephone. All participants in the intervention and control groups will be given the Patient Baseline Survey (**Attachment B.1 & B.3**) at the start of the study. The Patient Follow-up Survey (**Attachment B.2 & B.4**) will be conducted at months 4, 8 and 12 post-baseline survey, for all of the intervention and control participants. The follow-up surveys will be conducted to capture falls that did not require medical attention, falls where medical attention was sought outside of the healthcare system so are not recorded in the EHR, and any fall prevention interventions the patient uses (**Table A.2.2**). Additionally, patients will be given the *Patient Falls Tracking Log* (**Attachment J**) to help patients track all falls and ensure an accurate count of falls reported on the patient surveys, these logs will not be collected by researchers. This log is provided to help patients keep track of any falls so they can accurately complete the surveys, but it is not required. Each survey is estimated to take an average 10 minutes to complete. The questions on the patient survey were compiled from previous older adult falls surveys, the Behavioral Risk Factor Surveillance System (BRFSS), and the CDC Test Predictability of Falls Screening Tool (OMB control No. 0920-1220).

With regard to testing feasibility of implementation, study data for the *process evaluation interviews* will be gathered in person or over the phone with the clinic staff (physicians, physician assistants/nurse practitioners, and clinic operations managers) who participated in the STEADI implementation in two large urban primary care clinics serving a demographically mixed population of older adults. The purpose of these interviews is to determine the attitudes of staff regarding the feasibility of implementing STEADI to add context to the data collected from patient surveys. (**Table A.2.3 and A.2.4**) Staff (Physicians and Clinic Operation Managers) will be asked to walk through the STEADI intervention and describe how each piece was implemented to assess fidelity (**Attachment E.1-E.2.**) Physicians will answer questions regarding ease of implementation, fidelity, communication, and time spent implementing STEADI. Clinic operations managers (those who manage day-to-day operations of the respective clinics) will answer questions about how implementation affected the work flow of clinics. Each interview will take, on average, 45 minutes to complete based on the staff role.

Table A.2.1 Summary of data collection methods under this OMB request

Data Collection Method	Data Collected	Respondent Type	Administration	Rounds of Data Collection
<i>To Assess Fall Risk and Eligibility for Study</i> <i>STEADI Stay Independent Fall Risk Screener</i>	Questions to determine study eligibility (fall risk)	Older Adults attending a selected clinic	Paper forms to be filled out in the waiting room of clinic	1 round
<i>To Assess Impact of STEADI</i> Patient Surveys	Self-reported falls, fall-related injuries, and participation in recommended interventions	All patients (treatment and control) who completed the STEADI Falls Risk Screener and agreed to participate in the study	Web surveys followed up with mail and phone surveys for non-respondents, falls tracking log to be filled out by patients when they experience a fall	4 rounds over 1 year
<i>To Assess Feasibility and Fidelity of Implementation</i> Process Evaluation	Attitudes and concerns about STEADI implementation (fidelity, ease of use, time,	Clinic staff (physician, physician assistants, etc.) implementing STEADI	In-person or telephone interview	1 round

Interviews-Physicians/physician assistants/Nurse practitioners	communication between providers and nurses, provider efficacy, patient engagement)			
Process Evaluation Interviews-Clinic operations managers	Attitudes and concerns about STEADI implementation	Clinic operations managers at clinics where STEADI is being implemented	In-person or telephone interview	1 round

Table A.2.2 Patient Surveys Crosswalk of Questions with Indicators

Questions	Questions Description	Indicator
Baseline survey questions 1-2	Falls and fall injuries in the past 12 months	Falls in the past year
Baseline survey question 3	In general would you say your health is	General health at baseline
Baseline survey questions 4-7, 10-14	Attitudes about falling (how likely are you to fall, how important is falling, are you afraid of falling etc.)	Fall prevention perceptions and attitudes, to understand patient characteristics that facilitate adherence to recommended fall interventions
Baseline survey questions 8-9	How physically active older adults are at baseline	Physical activity
Baseline survey questions 15-22	Fall prevention activities at baseline (Physical Therapy, Occupational Therapy, etc.)	Baseline fall prevention activities
Baseline survey 23-34	Fall risk factors including use of medications linked to fall risk, alcohol, marijuana use, and other health related risk factors	Fall risk factors at baseline
Baseline survey 35-36	Race and ethnicity	Race and ethnicity
Follow-up survey question 1	General health	Change in health status compared to baseline survey
Follow-up survey question 2-9 and falls tracking log	Number of times fallen since last surveyed, number of injurious falls since last survey, and	Number of falls, injurious falls, and medically significant falls

	medical attention required	
Follow-up survey questions 10-16	Recollection of discussions about fall prevention activities with health care provider	Fall prevention activities recommended by health care professional
Follow-up survey questions 17-33	Specific fall prevention activities patient engaged in since last survey	Adherence to provider recommendations for fall prevention
Follow-up survey questions 34-44	Medications patients take since last survey and alcohol and marijuana use	Increases or decreases in patient medication use
Follow-up survey (last survey only) question 45-46	Perceptions and attitudes of falls	Fall prevention perceptions and attitudes change from baseline

Table A.2.3 Process evaluation data collection efforts

Research Question	Construct	Method Type(s)	Provider Interview	Clinic Operations Manager Interview	EHR Data
How is fall prevention being implemented?	Ease of use Time Perceived efficacy Patient engagement	Qualitative	X		
		Qualitative	X	X	
		Qualitative	X		
		Qualitative	X		
To what extent is fall prevention being implemented as designed?	Fidelity	Quantitative and Qualitative	X		X

Table A.2.4 Process Evaluation Interviews Crosswalk of Questions with Indicators

Questions	Questions Description	Indicator
Physician interview questions 1-2	Implementation of STEADI and changes in work flow	Fidelity
Physician interview questions 3-5 and 11-12	Ease of use of STEADI and communication between providers	Barriers and facilitators to implementing STEADI
Clinic operations manager	Ease of use of STEADI	Barriers and facilitators to

questions 1-8		implementing STEADI
Physician interview questions 6-10	Time taken to implement different components of STEADI	STEADI implementation time
Clinic operations manager interview questions 9-13	Time taken to implement different components of STEADI	STEADI implementation time
Provider interview questions 13-19	Perceived knowledge, awareness, and engagement of patients attitudes towards falls and fall prevention	Perceived efficacy and patient engagement

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

Patients will have the opportunity to respond to the baseline and follow-up patient surveys via a self-administered web-based survey (also called computer-assisted web interview, or CAWI). CAWI technology minimizes respondent burden by 1) automatically providing text fills within questions and handling skip patterns based on responses to each question; 2) allowing respondents to complete the survey at a convenient time; 3) allowing respondents to stop and re-enter the survey if needed; and 4) capturing data in real-time, thereby eliminating the need for manual data entry.

Patients who do not complete the self-administered web survey or the mailed paper self-administered questionnaire (SAQ) will be called to attempt to complete the questionnaire via telephone with a trained telephone interviewer. Further, if a respondent receives the paper SAQ but does not wish to complete the paper version of the survey, he/she can call a toll-free line and complete the survey via telephone. Similar to CAWI technology, computer-assisted telephone interviewing (CATI) technology helps minimize respondent burden with built-in functionality that moves through skip patterns seamlessly to increase efficiency. CATI tailors the sequence of the questions based on the answers of the respondent, resulting in few – if any – skip errors, and automatically provides text fills within questions based on responses to each question. Data collected via CATI are also automatically stored electronically, eliminating the need for manual data entry.

This data collection will supplement data collected from the EHR. The only data collected via survey will be information that cannot be obtained from the EHR.

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

No effort has been identified to collect data for the evaluation of STEADI in a primary care setting within the CDC. Prior data was collected in one health care system in New York State. However, this study was not a randomized control trial and measured falls leading to emergency department (ED) visits and hospitalizations only (Johnston 2018). The proposed study will randomize patients to either intervention or control groups and is able to not only collect data on ED visits and hospitalizations, but will also capture data on falls not treated medically.

CDC conducted the study, Older Adult Safe Mobility Assessment Tool (OMB# 0920-1005), with the goal of creating and evaluating a mobility planning tool to promote readiness to adopt mobility-protective behaviors in older adults. This project tested how to effectively word fall and motor vehicle crash prevention tips for older adult audiences but did not evaluate fall prevention and did not examine the impact on injury outcomes.

Other similar studies include the Strategies to Reduce Injuries and Develop confidence in Elders (STRIDE) study funded by the National Institute on Aging (NIA) in partnership with the Patient Centered Outcomes Research Institute (PCORI). STRIDE will compare the effects of an evidence-based multifactorial falls intervention implemented in a primary care setting with usual care. The proposed study differs from STRIDE as the proposed study evaluates fall prevention based specifically on CDC's STEADI initiative to determine which components are most effective at reducing falls in addition to evaluating the entire intervention.

The data collection proposed in this project is necessary, as it is the first federal effort to determine specifically which of the STEADI components are effective at reducing falls in older adults.

CDC is currently the only federal agency focused on integrating public health and clinical care of falls. CDC reached out to other federal agencies and other national organizations in December 2018 that have an interest in the prevention of older adult falls. Based on these discussions, there are no similar data collections that have been conducted or are underway, as confirmed via searches of electronic databases and discussions with stakeholders and federal partners. We have shared the project design with the Administration for Community Living (ACL) and the National Council on Aging (NCOA) through partnership calls, and presentations at the NCOA annual meeting in May 2018, and the Gerontological Society of America annual conference in November 2018. We plan to share the data from this project during partner calls and at scientific meetings and webinars,

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

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

A.6. Consequences of Collecting Information Less Frequently

This data collection effort will be part of a comprehensive evaluation of STEADI. The planned frequency of data collection for the *patient survey* is necessary to capture falls that were not medically treated and to determine whether patients adhered to the recommended interventions. The baseline *patient surveys* will be collected at time zero following the STEADI fall risk screening and at 4, 8, and 12 months post baseline. Collecting less frequently (longer time period between surveys) could result in recall problems for older adult patients leading to inaccurate data. If these data are not collected, CDC will be unable to determine whether STEADI is effective and which components of STEADI are effective at reducing the number of falls and fall injuries in the primary care setting. Without this information, it will be impossible to assess the impact of STEADI. *The patient fall logs* is not required, it is provided to help accurately fill out the patient surveys. Recall of falls has been shown to be most accurate when data

is collected weekly or monthly to avoid recall bias (Ganz 2005). If data is collected less frequently, it could lead to either an over or under estimation of falls. The *process evaluation interviews* will occur once during the study period. If this data were not collected, CDC would not know what barriers existed in implementing STEADI in the selected primary care clinics of a health care system. Additionally, CDC would not have information on implementation factors that may affect the impact of STEADI.

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

This request fully complies with 5 CFR 1320.5. There are no special circumstances.

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

A. Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on May 24, 2019 Volume 84, Number 101, pp 24150 (**Attachment F**) CDC received one non-substantive anonymous public comment (**Attachment F1**)

B. Efforts to Consult Outside the Agency

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

1. Reviewed the list of projects funded by the National Institute on Aging and found one project (STRIDE) directed at falls prevention in primary care settings. See section A.4. This project is sponsored by the Patient-Centered Outcomes Research Institute (PCORI), an independent, nonprofit, nongovernmental organization and is being conducted at ten clinical trial sites across the country including six academic medical centers (Mount Sinai, Johns Hopkins, University of Iowa, University of Pittsburgh, University of Texas, University of Michigan). CDC had a call with PCORI to discuss the design of their project and the design of the current data collection. The proposed study differs from STRIDE as the proposed study evaluates fall prevention based specifically on CDC's STEADI initiative to determine which components are most effective at reducing falls in addition to evaluating the entire intervention.
2. CDC is in regular contact with other federal agencies that have an interest in preventing older adult falls (e.g., ACL, 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.

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

The *patient surveys* involve repeated surveying, with the same or similar questions, of the same individuals four times over the course of a 12-month period. Keeping respondents engaged and motivated is important in order to obtain maximum retention of panelists and cumulative response rates. To improve survey participation rates for the baseline and follow-up surveys, respondents will receive an incentive with a value of \$3 per completed

survey, in the form of postage stamps. As there is one baseline and three follow-up patient surveys, each patient will receive up to \$12 of postage stamps for their participation in the study. Respondent attrition from the baseline survey through each subsequent follow-up survey would be detrimental to the patient surveys study data, as information on patient falls and adherence to the recommended interventions would be incomplete. A Cochrane Collaboration systematic review found that a monetary incentive doubled the odds of receiving response rates on a survey (Edwards et al., 2002). A study of the impact of incentives on multi-modal survey response rates found that the incentive had a greater effect on those aged 60 years and older ($p < .05$), increasing their response rate by 22.5% compared to an increase of 15% for those younger than 40, and 10.7% for those aged 40-59 (McGonagle et al., 2017).

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 G**). 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 research, unless otherwise compelled by law.

Patient Baseline and Follow-Up Surveys: To ensure privacy, personal identifiable information will not be collected during the survey. A randomly generated, numeric participant ID will be assigned to each respondent, which will be used to link the survey data with the patient's EHR record. After the completion of the follow-up surveys, only the participant 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, the link between the participant identification and the participant's personally identifiable information will be destroyed. 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 personal 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.

Provider Interviews: To ensure privacy, personal identifiable information will not be collected during the interviews. Each participant will be assigned an ID and their interview responses will not be stored with their identifying information. Personal identifiable information such as an email will not be shared outside the database.

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

A. Institutional Review Board (IRB). The study protocol has been reviewed and approved by Emory University's IRB. A copy of the Emory IRB approval letter is provided in **Attachment H**.

B. Justification for Sensitive Questions. The patient surveys and the provider interviews will not contain any sensitive items.

A.12. Estimates of Annualized Burden Hours and Costs

Table A.12.1 shows the estimated annualized burden hours for the respondents' time to complete the *Stay Independent Fall Risk Screener*, *patient survey consent*, *patient survey questionnaires*, and *provider interviews*. Total annualized burden is estimated at 1,578 hours.

Screener. The *Stay Independent Fall Risk Screener* takes an estimated 6 minutes to complete (30 seconds per question for each of the 12 questions). We expect that 12,105 patients will be screened to obtain the target sample size of approximately 3,000 patients who agree to participate in the study and receive the STEADI risk assessment or are assigned to the control group. Those patients who screen at high risk will be assigned, based on clinic attended and week of attendance, to one of three study arms or to the control group.

Survey Screener and Consent. The *survey consent screener* will take an estimated 12 minutes to complete, based on the number of items in the screener. We expect that 4,357 patients will screen at risk for a fall (36 percent) and that 3,705 patients (85 percent) will consent to participate in the *patient surveys*.

Patient Baseline and Follow-up Surveys. Of the 3,705 patients who consent to participate, an estimated 3,000 patients (81 percent) will complete the *baseline survey* and an estimated 2,688 patients (90 percent) will complete at least two of the three follow-up *patient surveys* in addition to the baseline over a 30-month period, on a rolling basis. Each survey will take an estimated 15 minutes to complete. The patients will also be asked to complete a falls tracking log during the 12 months of the study, to record any falls and medical care they receive as a result.

Patient Falls Tracking Log. Patients will be asked to recall information from the log during the follow-up surveys. Tracking falls in the Patient Falls Tracking Log is optional.

Provider, and Clinical Operations Manager Interviews. The *provider interviews consent screener* will take an estimated 5 minutes to complete, and the *provider interviews* will take an estimated 45 minutes to complete based on the number of questions and prompts included in the interview guide. We expect a total of ten physician/physician assistants/nurse practitioners and six of the clinic operations managers will complete the interviews.

Table A.12.1 Estimated annualized burden hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (hours)	Total Burden (hours)
Patient	Stay Independent Fall Risk Screener (Att. D)	4,035	1	6/60	404
	Consent Form (Att. C)	1,235*	1	12/60	247
	Patient Baseline Survey (Att. B1)	1,000	1	15/60	250
	Patient Follow-up Survey (Att. B2)	896	3	15/60	672
Physician/Physician Assistants/Nurse Practitioners	Provider Interview Guide/Consent (Att. E1)	3	1	50/60	3
Clinic Operations Manager	Operations Manager Interview Guide/Consent (Att. E2)	2	1	50/60	2
	Total				1,578

* This number includes the older adults who screen at risk for a fall and consent to participate in the study

Table A.12.2 shows the estimated annualized cost burden based on the respondents' time to complete the data collection forms. Average hourly wage rates were calculated using mean wages from the U.S. Department of Labor, Bureau of Labor Statistics https://www.bls.gov/oes/current/oes_stru.htm.

Table A.12.2 Estimated annualized burden costs

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (hours)	Average Hourly Wage Rate	Total Cost Burden
Patient	Stay Independent Fall Risk Screener (Att. D)	4,035	1	6/60	\$24.34*	\$9,821
	Consent Form (Att. C)	1,235	1	12/60	\$24.34*	\$6,012
	Patient Baseline Survey (Att. B1)	1,000	1	15/60	\$24.34*	\$6,085
	Patient Follow-up Survey (Att. B2)	896	3	15/60	\$24.34*	\$16,356

	B2)					
79Physician/ Physician Assistant/Nurse Practitioner	Provider Interview Guide/Consent (Att. E1)	3	1	50/60	\$101.63	\$254
Clinic operations Manager	Operations Manager Interview Guide/Consent (Att. E2)	2	1	50/60	\$47.29	\$79
	Total					\$38,607

* Average hourly wage rate calculated using mean wages for 00-0000 All Occupations from the National Compensation Survey: Occupational wages in the United States May 2017 “U.S. Department of Labor, Bureau of Labor Statistics:” [018](#).

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

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the project.

A.14. Annualized Cost to the Federal Government

It will take three years to conduct this data collection under contract HHSD2002013M5395. The total cost to the government over 3 years will be \$1,120,685. The annualized cost to the government will be \$373,562. (Table A.14.1). This includes \$358,562 in contract costs annually and \$15,000 in other federal costs, including salary, fringe, travel, and supply expenses related to the involvement of two federal employees to devote 5% FTE to the project.

Table A.14.1 Total Annualized Cost

Type of Cost	Description of Services	Annual Cost
Contractor	Data collection, data analysis, project management	\$358,562
Two technical monitors at 5% FTE each (CDC)	Study planning and contractor oversight	\$15,000
Total Annual Estimated Costs		\$373,562

A.15. Explanation for Program Changes or Adjustments

This is a new collection.

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

The exact start date for data collection activities is contingent on the OMB clearance date. Data from the provider interviews will be analyzed looking for common themes. The quantitative data from the patient surveys will be used in conjunction with EHR data from the selected clinics' health care system to provide counts for falls, fall injuries, and interventions undertaken to prevent falls. Risk ratios comparing the three intervention arms to the control group will be calculated for number of falls and fall injuries controlling for patient demographics (**Attachment I**).

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 Fall's webpage. The time schedule for the project activities are summarized in **Table A.16** below.

Table A.16: Project Time Schedule

Activity	Schedule
Consent and screen older adult patients into study.	Ongoing 1-18 months after OMB approval
Conduct baseline and follow-up surveys	Ongoing 1-30 months after OMB approval
Conduct provider interviews	Ongoing 6-18 months after OMB approval
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

There are no exceptions to the Paperwork Reduction Act.

REFERENCES

1. Centers for Disease Control and Prevention NCIPC. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. Accessed at www.cdc.gov/injury/wisqars Aug, 2019.
2. Florence, Curtis S., et al. "Medical costs of fatal and nonfatal falls in older adults." *Journal of the American Geriatrics Society* 66.4 (2018): 693-698.
3. Burns, Elizabeth, and Kakara, Ramakrishna "Deaths from falls among persons aged ≥ 65 years—United States, 2007–2016." *Morbidity and Mortality Weekly Report* 67.18 (2018): 509.
4. Johnston, Yvonne A., et al. "Implementation of the Stopping Elderly Accidents, Deaths, and Injuries initiative in primary care: an outcome evaluation." *The Gerontologist* (2018).
5. Ganz, David A., Takahiro Higashi, and Laurence Z. Rubenstein. "Monitoring falls in cohort studies of community-dwelling older people: effect of the recall interval." *Journal of the American Geriatrics Society* 53.12 (2005): 2190-2194.

6. Edwards P, Roberts I, Clarke M, DiGiuseppi C, Pratap S, Wentz R, Kwan I. Increasing response rates to postal questionnaires: systematic review. *British Medical Journal*. 2002;324:1183.
7. McGonagle KA, Freedman VA. The Effects of a Delayed Incentive on response rates, Response Mode, Data Quality, and Sample Bias in a Nationally Representative Mixed Mode Study. *Field Methods*. 2017;29(3):221-237.