Paramedic-coached ED Care Transitions to Help Older Adults Maintain their Health

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1. PROJECT SUMMARY / ABSTRACT

Older adults use the emergency department (ED) as an important source of acute care, making 20 million ED visits annually. Most older adults who visit the ED do not have conditions of sufficient severity to warrant hospital admission; thus, they are treated and discharged home. Unfortunately, older adults do poorly after being discharged home from the ED, with 20% having repeat ED visits within 30 days. The ED-to-home transition has been identified as a cause for these avoidable poor outcomes, but ED-focused interventions to improve this transition have had inconclusive outcomes and have suffered from feasibility, sustainability and scalability problems.

Coleman's Care Transition Intervention (CTI) has been **validated and is widely used** to improve the hospital-to-home transition, decreasing both hospital readmissions and costs. The CTI uses coaches, usually nurses or social workers but also lay people, to support patients who are being discharged home by transferring skills to activate patients. Applying the CTI to the ED-to-home transition is a natural extension, but it has not been evaluated in this unique and demanding setting.

In this study, **we will test our overall hypothesis that the community-based, paramedic-coordinated ED-to-home CTI will improve community-dwelling older adults' post-ED health outcomes and reduce costs**. We will evaluate CTI process outcomes by testing if participants randomized to the CTI 1) demonstrate better understanding of red flags that indicate a worsening of their condition, 2) implement required medication changes more frequently, 3) and follow up with their primary care physicians more rapidly after ED discharge, as compared to patients in the control group who receive usual care. We will also evaluate the effectiveness and cost-effectiveness of the CTI by testing if participants randomized to the CTI have 1) improved Patient Activation Measure scores 30 days after discharge, 2) have decreased frequency of ED visits, and 3) decreased health care costs within 30 days of ED discharge. To assess this, we will also measure differences in PCP, specialist, and urgent care visits. Additionally, we recognize that the CTI will not eliminate all repeat ED visits. Thus, we will identify factors independently associated with repeat ED visits among CTI recipients such that future programs can ensure their needs are adequately addressed.

2. PURPOSE OF THE STUDY AND BACKGROUND

2.1. PURPOSE OF THE STUDY & AIMS

The emergency department (ED) is an important source of acute care for the 40 million older adults (age≥65) living in the US. In 2010, older adults made 20 million ED visits, 11 million of which resulted in the patient being discharged home.[1] Older adults do poorly after being discharged home from the ED, with approximately 20% of these patients needing a repeat ED visit within 30 days.[2,3,4,5,6,7,8,9,10] ***With the older adult population doubling by 2040, the frequency of these adverse events will increase unless interventions improve older adults' ED-to-home transitions***.

Frequent hospital readmissions led to the development, validation, and widespread implementation of the Coleman Care Transitions Intervention (CTI) to improve the hospital-to-home transition.[11,12,13] In contrast, only a few programs have been tested to improve ED-to-home transitions for older adults, which are almost as frequent as hospital-to-home transitions (11 vs. 13.5 million/year).[14] Unfortunately, these ED-focused programs have demonstrated little success.[15,16,17,18,19,20,21,22]

Our multi-disciplinary team, which has a history of successful academic-community collaborations to study the care delivered to acutely ill older adults, includes researchers and community partners. Building upon our extensive experience in geriatric emergency medicine and prehospital medicine, as well as Coleman's work, we will apply the CTI to the ED setting, utilizing ambulance-based paramedics to improve the ED-to-home transition. ***Overall, we hypothesize that our community-based, paramedic-***

coordinated, patient-centered, ED-to-home CTI program will improve older adults' post-ED outcomes. We will test this hypothesis in four aims:

1. Implement a community-based, paramedic-coordinated, patient-centered, ED-to-home CTI program in Madison, WI and Rochester, NY for older adults treated in the ED and discharged home.

2. Assess the process outcomes of our ED-to-home CTI program for older adults treated in the ED and discharged home, as compared to usual care.
   Hypothesis 1A: More CTI participants will demonstrate understanding of their ED discharge instructions, red flags that indicate a worsening of their condition, and how to respond to the red flags four days after ED discharge.
   Hypothesis 1B: More CTI participants will implement medication changes made in the ED within four days of ED discharge.
   Hypothesis 1C: CTI participants will have shorter time-to-follow-up with their primary providers.

3. Determine the effectiveness and cost-effectiveness of the ED-to-home CTI program for older adults treated in the ED and discharged home, as compared to usual care.
   Hypothesis 2A: CTI participants will have increased patient activation 30 days after discharge.
   Hypothesis 2B: CTI participants will have lower odds of repeat ED use within 30 days of discharge.
   Hypothesis 2C: CTI participants will have lower estimated healthcare costs within 30 days of discharge.

4. Identify biomedical and psychosocial factors independently associated with repeat ED visits within 30 days of ED discharge among ED-to-home CTI program participants.
   Hypothesis 3A: Biomedical factors associated with increased odds of repeat ED visits include increased age, increased number of comorbidities, impaired cognition, and limited functional status.
   Hypothesis 3B: Psychosocial factors associated with increased odds of repeat ED visits include reduced social connectedness, increased anxiety symptoms, and increased depressive symptoms.

In this study, we will apply evidence-based findings to evaluate a program to help older adults remain healthy and independent after ED care. We will address a significant deficiency in the delivery of quality care for a uniquely vulnerable population: the ED-to-home transition of acutely ill older adults who do not require hospital admission. We will use an innovative approach by adapting the widely used CTI, which has been validated for hospital-to-home transitions, and deliver the services using paramedics, an underused, highly-skilled, and highly-respected resource present in all communities. This evidence will guide further efforts to optimize older adults' health following an ED visit, including dissemination and implementation of this ED-to-home CTI program and development of new approaches to target patients with repeat ED visits.

2.2. BACKGROUND

EDs Care for A Large and Growing Number of Older Adults

EDs are critical sources of acute, unscheduled care in the United States, with 28% of all acute illness encounters occurring in an ED.[23] In 2009, older adults (age≥65) in the US accessed the ED for care 20 million times, a 27% increase from 2001.[1] Of these ED visits, 11 million (55%) did not require inpatient hospitalization and were discharged home after ED care.

ED patients discharged home are not traditionally considered at risk for poor outcomes, as they do not have an illness of sufficient severity to warrant hospital admission. However, older adult ED patients are medically complex, with 33% having 3 or more chronic conditions and 41% taking 5 or more medications; additionally, they have poor outcomes such as readmission, nursing home placement, or death.[24,25] In the 30 days after an ED visit, approximately 20% of older adults return to the ED for further care.[2,3,4,5,6,7,8,9 9] Many consider these poor outcomes to be avoidable. [26,27]

Of notable concern is the under-studied ED-to-home transition, during which patients suddenly assume responsibility for their acute health needs within the context of their broader lives, a disruption that requires modification of daily routines and lifestyles. Research has found that older adults have difficulty with this responsibility and with prioritizing their health and non-health obligations.[28,29,30] Patients experience challenges during this ED-to-home transition because the nature of the emergency care system precludes planned transitions, requires rapid discharge to make room for new patients, and is isolated from the PCP, home health, and social services. These challenges can be categorized into: 1) education and engagement and 2) follow-up.[8,11,31]

Education and engagement: Prior to ED discharge, providers give the patient/caregiver verbal and written information, a process that lasts an average of 4 minutes.[32] Unfortunately, 78% of patients have deficient comprehension[33] and those with impaired cognition, common among older ED patients, are at greater risk of poor comprehension.[33,34,35,36] Reasons for poor comprehension include instructions being provided *without*: 1) accounting for health literacy;[37] 2) including all necessary domains, such as medication changes (29%); [32] 3) giving patients opportunities to ask questions (43%);[32] and 4) confirming understanding (90%).[32,38] Failure of ED providers to identify cognitively impaired patients further complicates the older adult's discharge.[39]

This failure to provide quality discharge instruction has broad implications. Older adults with limited health literacy are known to have increased risk of having repeat ED visits.[40] Without clear information, medication changes may not be well-understood, leading to incomplete or incorrect therapy. Also, red flags, symptoms for which patients should seek medical attention, may not be well-understood, leading to patients either inappropriately delaying care or accessing care unnecessarily.[11]

Follow-up: Patients are told to call their PCPs to obtain follow-up after ED discharge, as routine follow-up visits may prevent complications, such as deteriorating health status or a return visit to the ED.[4,22] Unfortunately, studies have found that PCP follow-up appointments occur in as few as 32% of patients within 30 days of ED discharge.[41,42,43] Explanations for this include barriers such as financial constraints, lack of transportation, functional limitations, and incomplete instructions related to follow-up care.[32,38,44,45,46] Also, given the challenges patients face prioritizing their activities after ED discharge, without clear instructions and available PCP appointments, these follow-up visits often do not occur.[28]. *The poor outcomes in this large and highly vulnerable population reflect avoidable morbidity and result in substantial avoidable costs; thus, they require investigation and intervention.*

COLEMAN'S CARE TRANSITIONS INTERVENTION (CTI)

The CTI is a four-week long program designed to empower and support patients being discharged from the hospital (www.caretransitions.org). The program was designed to be low-cost, low-intensity, and capable of being implemented in a wide variety of settings. Furthermore, it recognizes the joint role of patients and family caregivers as participants in a quality transition. The *program uses a care transitions coach, who can be a nurse, social worker, or community worker*, who provides one visit in the hospital prior to hospital discharge, as well as one home visit and three phone calls after hospital discharge to help patients manage their health and address their needs. During these visits, the coach uses motivational interviewing to provide education, models behaviors, and take part in role-playing to help patients care for themselves more effectively. The coach focuses on the "Four Pillars" of the program, which address the key deficiencies in transitions identified by Coleman (Table 1).**[47]** Coleman demonstrated that the hospital-to-home CTI is effective at reducing hospital readmissions and cost-effective.[12,13] Thus, the program has been widely disseminated and implemented.[48,49]

The CTI has not been tested for the ED-to-home transition. However, our preliminary work has shown that the problems seen in the hospital-to-home transition are present in the ED-to-home transition; thus, *we believe that the CTI can be appropriately and seamlessly applied to the ED-to-home transition.*

Table 1: Conceptual Model of the Care Transitions Intervention: The Four Pillars

	Medication Self-Management	Follow-Up	Red Flags	Patient-Centered Record
Goal	Know medications & have a system to take them	Schedule appropriate follow-up visits	Know indications that a condition is worsening and how to respond	Understand and manage a personal health record
Hospital Visit	Discuss importance of knowing medications	Recommend PCP follow-up	Discuss symptoms and drug reactions	Explain the personal health record
Home Visit	Reconcile medications; correct discrepancies	Emphasize importance of follow-up visit; practice and role-play questions for the PCP	Discuss symptoms and side effects of medications	Review discharge summary; encourage patient to share health record with PCP
Follow-Up Calls	Answer any remaining medication questions	Provide advocacy in getting appointment, if needed	Reinforce when / if PCP should be called	Discuss outcome of PCP visit

While the CTI reduces hospital readmissions, it does not eliminate them. We anticipate some patients discharged from the ED will return for repeat care despite the CTI. We do not know which factors are independently associated with repeat ED visits. *This study will identify the factors associated with repeat ED visits among CTI recipients such that their needs can be adequately addressed.*

THE EMERGENCY MEDICAL SERVICES SYSTEM (EMS) AND COMMUNITY PARAMEDICINE

The ambulance-based EMS system is a unique component of the health care system. It is staffed with paramedics who traditionally provide in-home assessment, acute treatments, and transport to an ED immediately after a call for assistance.[50,51,52] This service is uniform throughout urban, suburban, and rural communities and is available, regardless of day of week, time of day, or location.

Although the EMS system's potential to improve community health was recognized 20 years ago in the "EMS Agenda for the Future," the role has only recently gained acceptance, being called community paramedicine or mobile integrated health care. [53,54,55,56] EMS providers have indicated a desire to participate in programs to promote community health.[53,57,58] EMS providers are performing blood pressure screening and health education; educating on topics such as driving under the influence; delivering immunizations; performing home safety evaluations and fall risk assessments; assisting with advanced care directives programs; screening for elder abuse and neglect; and identifying patient's needs and referring to other community programs

2.3. PRELIMINARY WORK

Dr. Shah and his team have worked to understand the supports and constraints that influence the older adult's transition from the ED to the community. They recently completed a qualitative study of older adult ED patients who were discharged, with in-home interviews after ED discharge.[59,60] They found the issues faced by patients immediately after ED discharge must be addressed through multiple strategies, a role that the CTI coach can play. Specifically, they found that older patients: 1) want to be healthy, but do not define health as a biomedical construct; 2) desire independence, but want assistance; 3) are busy with family commitments / life interests, but recognize that constraints exist; and 4) have tremendous difficulty obtaining follow-up care with their primary care physicians as well as acute illness care. Given the context in which these individuals live their lives, repeat ED visits may result without the appropriate support and empowerment. *These issues map directly to the Four Pillars of the CTI, demonstrating the value of the CTI conceptual model in the ED-to-home transition*.

Dr. Kind and her team in Madison, WI have extensive experience studying the hospital-to-home transition of older adults. She is among the national leaders in care transitions for older adults. *Her expertise with aging, aging specific issues in care transitions, and care transitions will directly enhance our ability to demonstrate the value of the CTI model in the ED-to-home transition.*

In Rochester, NY, collaborators Lifespan and VNS have been delivering the CTI program for patients transitioning from the hospital to home for 4 years. They have reduced hospital admissions by approximately 50%. *Their experience has shaped this proposal and supports its feasibility.* Finally, Dr. Coleman originally developed the CTI and is the sole provider for coach training. He has worked with an ED to implement the CTI for patients discharged home from the ED and found no new feasibility challenges as compared to the hospital-to-home program. [61] Also, by providing training for all coaches, Dr. Coleman's group has an expertise critical to effectively train the paramedic coaches.

3. STUDY DESIGN

3.1. OVERVIEW

We will perform a randomized controlled trial of community-dwelling, older adult ED patients being discharged home to test the effect of a community-based, paramedic-coordinated, ED-to-home transitions program that has been validated in other settings.

In performing this program evaluation, we will adapt the hospital-to-home CTI program to the ED-to-home transition, and then we will test its outcomes. Specific research activities include:

- We will *identify, hire, and train* paramedics to serve as the CTI coaches.
- We will *enroll* 2400 older adults (age≥60) being discharged home from the ED at the University of Wisconsin Hospital & Clinics (1200 subjects) and the University of Rochester (UR) Medical Center-Strong Memorial Hospital or Highland Hospital (1200 subjects combined).
- We will *enroll* up to 2400 primary caregivers of the patient subjects being discharged home.
- We will *randomize* enrolled subjects to receive either the ED-to-home CTI (intervention group) or usual care (control group).
- We will perform research assessments at baseline (in the ED) and again via phone 4 and 30 days after discharge. We will also collect additional data from medical and administrative records to test our hypotheses, as well as from up to one informal caregiver per enrolled older adult (Figure 1).

Intervention group subjects (CTI program) will receive one home visit and up to 3 telephone calls to support their transition and provide coaching, as per the CTI guidelines. Control group subjects (usual care) will receive no additional services. All study procedures will be standardized at both sites.

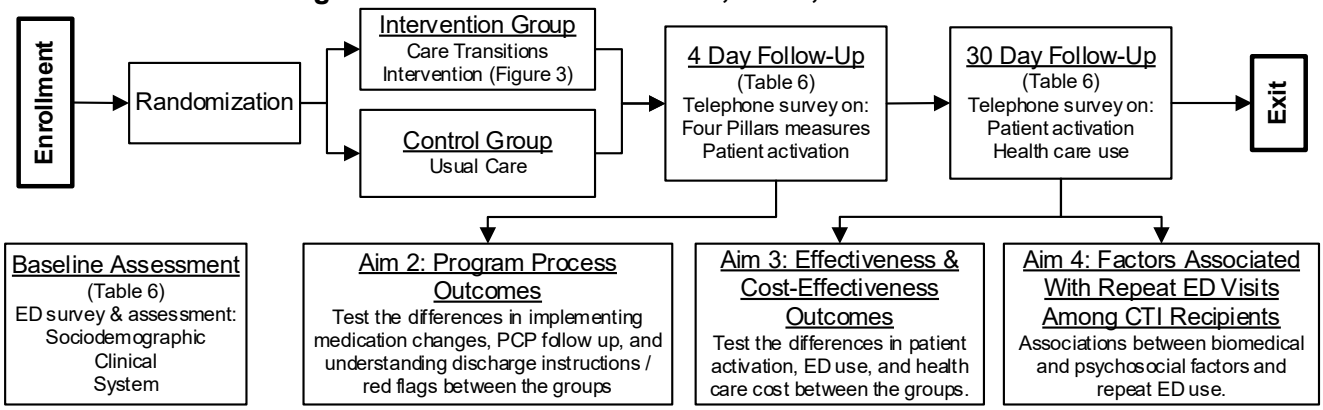
Our analyses will provide empiric evidence on the value of this intervention, thereby guiding the dissemination and sustainability of such a program to improve older adults' health after ED care.

3.2. RATIONALE FOR STUDY DESIGN AND MEASURES

We chose a randomized controlled trial, as it is the most rigorous study design and will allow us to directly compare the intervention against usual care. The alternatives, a parallel cohort study or pre-post- study, would not have the same level of rigor, which would undermine study findings. The consequence of this weaker design is that the findings would be less likely to be integrated into practice, thereby wasting the resources and the efforts by the participants. Given the existing literature, we decided that a high quality randomized controlled trial would be appropriate.

The primary outcomes chosen—process, effectiveness, cost effectiveness—allow us to develop the scientific evidence to test this intervention. The robust measures are patterned on Coleman's initial work and can speak to the value proposition for this model. The specific measures are as follows:

Figure 1: Research Framework, Aims, and Processes



Socio-demographic measures (Table 2, Section 1): Standard characteristics will be collected to compare the intervention and control groups and if necessary include these factors as covariates in our analyses. Health system structural factors will also be collected.

ED care & CTI program clinical measures (Table 2, Section 2): We will collect the chief complaint and final diagnosis to evaluate differences between the intervention and control groups and to perform sub-analyses on specific conditions (e.g., injury). We will collect discharge information for our outcomes assessment. Finally, we will measure the elapsed time for the clinical activities (e.g., coaching) to assist with sustainability and dissemination.

Covariates (Table 2, Section 3): Factors that may affect older adults' outcomes and will be collected to include in our analysis. Cognitive status, depression, anxiety, and social isolation are associated with worse outcomes and are critical measures.[62,63,64,65,66]

Outcomes (Table 2, Section 4): To determine the ***fidelity*** of the CTI and the ***acceptability*** of the program to patients and caregivers, we must evaluate the Four Pillars and program satisfaction. This will occur through telephone surveys performed 4 and 30 days after ED discharge. Additionally, as part of the CTI, the coaches measure patients' progress in skill transfer. This information will also be collected.

The CTI aims to improve ***patient activation***, which is measured as having the skills, knowledge, and motivation to participate as effective members of the care team.[67] We will use the Wallston Perceived Health Competency Scale.

Upon study exit, we will measure our ***primary outcome***, ***health care use*** within 30 days of ED discharge, through survey and administrative data from both local health systems and the insurers. We will also measure the costs of health care as well as the CTI program.

We will check the Social Security Death Index for death within 30 days for all subjects.

If a subject ***withdraws*** during follow-up, we will clarify the level of withdrawal that the subject is requesting—cessation of subject contact or removal from the study. If the subject requests cessation of contact, we will continue to review the subject's medical record to obtain health care use (e.g., ED use) outcomes. If a subject is ***admitted to a skilled nursing facility***, which occurs in less than 2% of ED patients discharged home, we will track that outcome and measure those costs, but we will not survey those subjects.

3.3. RATIONALE FOR INTERVENTION

We will implement and test the CTI for the intervention group because of its demonstrated effectiveness and cost-effectiveness, its applicability to the ED patient discharged home, its efficiency, particularly relating to activities in the ED, and its widespread use. We have chosen to use community-based

paramedics as the coaches for the CTI because these individuals are highly trained, available in all communities, and are highly respected by patients. Thus, paramedics are able to perform these visits in follow up to ED visits rapidly. Given that the CTI program has been tested using lay people, trained paramedics should be able to perform the required duties.

Table 2: Measures			
	Measures	**Time**	**Source/Approach**
1. Demo - graphic	Patient age, gender, marital status, race, ethnicity, education level, primary language, home ownership, living status, home address	ED	Patient survey
	Patient relationship with PCP	ED	Patient survey
	Insurance plan / number	ED	Epic review
	Primary Care Medical Home certification level	ED	Health systems
2. Clinical	New home services (since ED visit)	Day 30	Patient survey
	ED medications prior to assessment, chief complaint, final diagnosis (ICD-10), discharge medications, and instructions	ED	Epic review
	CTI Coaching & Services Forms* Personal Health Record (PHR) Home Visit/PHR Discussion Checklist Follow-up Phone Calls Checklist Patient Activation Assessment Medication Discrepancy Tool Care Transitions Measure - 3	CTI Coach home visit & coach follow up calls	CTI program records
3. Covariates	Medical history, including Charlson Comorbidity Index	ED	Patient survey
	Healthcare: Medications, home services, ED / hospital use	ED	Patient survey/ Epic review
	Health Status: Short Form-12[68]	ED	Patient survey
	Disability Status: ADL[69]	ED	Patient survey
	Cognition: Short Blessed Test (BOMC)	ED	Patient survey
	Social Isolation: PROMIS Social isolation short form	ED	Patient survey
	Depression: PHQ-9	ED	Patient survey
	Anxiety: GAD-2	ED	Patient survey
	Health literacy	ED	Patient survey
4. Outcomes			
	Family Caregiver Activation in Transitions	ED, Day 30	Caregiver survey
	Understanding of red flags	Day 4	Patient survey
	Medication changes implemented	Day 4	Patient survey
	Follow up with PCP, specialists, urgent care	Day 4, 30	Patient survey / Epic review
	Wallston's Perceived Health Competency Scale (PHCS)	ED, Day, 30	Patient survey, Caregiver survey
	Healthcare use within 30 days of discharge	Day 30	Patient survey / Epic review
	Death within 30 days of discharge (Social Security Death Index)	Day 30	Death Index
	Patient experiences of continuity	Day 30	Patient survey
	Cost of healthcare and CTI program	Day 30	Health systems, study
	Program satisfaction	Day 30	Patient, caregiver survey

*All forms copyrighted by Dr. Eric Coleman

4. CHARACTERISTICS OF THE RESEARCH POPULATION

4.1. SUBJECT CHARACTERISTICS

Number of Subjects: We propose to enroll 2400 ED patient subjects into the study, with 1200 of the enrollments coming at UW and 1200 at UR Medical Center-Strong Memorial Hospital or UR Medical Center-Highland Hospital. Of the 2400 subjects, 1200 will be randomized to the intervention group and 1200 to the control group. We will also enroll up to one informal caregiver per ED patient, resulting in up to 2400 additional subjects. Thus, the total number of subjects potentially enrolled in this study is 4800.

Gender and Age of Subjects: All patient subjects will be age 60 years and older, as this is a concern of the older adult population. Both men and women will be enrolled.

Informal caregiver subjects must be age 18 or older, and will be either male or female, depending on who is identified by the patient subject.

Racial and Ethnic Origin: Individuals of all races and ethnicities will be included.

Vulnerable Subjects: Older adults are the focus of this study as these problems are not as prevalent for younger individuals; thus evaluating transitional care for them is of likely little benefit and any developed knowledge may not be translatable to older adults. We will implement safeguards to protect this population:

1. The study staff will not be directly providing ED clinical care to the participants, thus eliminating any potential coercion.
2. Decisional capacity will be evaluated by the RA obtaining consent to ensure that participants understand the risk and benefits of the study before obtaining informed consent, unless the Health Care Power of Attorney has already been activated. The decisional capacity evaluation process that will be used has been approved by the UR IRB. It assesses the potential subject's understanding of the study. This process is more conservative than the UW IRB policy "Research with Adult Participants Lacking Capacity to Consent" (Section II) as all subjects will be tested in this minimal risk study. The PI (Dr. Shah, emergency medicine), co-I (Dr. Kind, geriatrician), and project director (McDowell, psychology degree, extensive community health/social work experience working with vulnerable populations) will ensure that all RAs who conduct the capacity assessment will be fully trained.
3. Informed consent to participate in the study will be obtained from patients. Patients without decisional capacity will be included if a caregiver with responsibility for the patient's health care consents to participation in the study. Priority of decision makers is as follows: 1) research power of attorney, if present; 2) court appointed guardian; 3) power of attorney for healthcare; 4) next of kin in the following order: spouse or registered domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, or close friend.
4. Informed consent will be obtained from the caregiver if present in the ED. The caregiver will be assessed for decisional capacity using the same methods as with the patient subject. Caregivers without decisional capacity will not be eligible to join study.

4.2 INCLUSION AND EXCLUSION CRITERIA

Patient Inclusion Criteria	Patient Exclusion Criteria
Age≥60 years	Previous study participation
English speaking	Active enrollment in or discharge to hospice
Dane County, WI or Monroe County, NY resident	Homelessness
UW or UR affiliated PCP	Behavioral health treatment as primary reason for ED visit
Independent home dwelling (no prisoners, nursing home, assisted living)	Participation in a transition care team program or intensive care management patient
Discharge home from the ED	ESI 1 patient (highest acuity, assigned by ED staff)
Have a working telephone	Unable to obtain consent from patient or proxy

Caregiver Inclusion Criteria	Caregiver Exclusion Criteria
Age≥18 years	Unable to obtain consent / no decisional capacity
English speaking	
Able to understand and complete informed	

consent	
Have a working telephone	

4.3 DISCUSSION OF SUBJECT POPULATION

We have chosen this subject population because the existing literature has indicated that this is the group that is of greatest risk after being discharged from the ED. We have limited the population as per the exclusion criteria to: 1) maximize study rigor; 2) eliminate conflict with existing programs; 3) protect patient autonomy and safety. We are enrolling only English-speaking subjects because, based on our previous studies, it is rare for older adult ED patients at these two EDs to not speak English and no individual group (e.g., Spanish-speaking) requires translators with great frequency. We considered excluding patients who could not fully participate in the ED CTI due to barriers such as sensory limitations or impaired cognition. However, with our goal to maximize external validity and understand factors that lead to repeat ED visits in patients receiving the CTI, we have elected to retain these patients and account for them in our analysis. We are excluding ESI 1 patients for multiple reasons: 1) these patients have high acuity conditions and often are receiving life-saving interventions; 2) these patients are rarely discharged home; 3) these patients are rarely able to provide informed consent for a study such as this. Thus, we have elected to exclude them rather than unnecessarily expend time and effort to assess them, approach the care team, and approach the patient.

5. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

5.1 METHOD OF SUBJECT IDENTIFICATION AND RECRUITMENT

All study procedures will be standardized at both sites. Subjects will be identified and recruited using processes based on published best practices refined by our team.[70,71] Following the inclusion criteria, we will recruit subjects each day in the ED at UW Hospital and Clinics and UR Medical Center-Strong Memorial Hospital and UR Medical Center-Highland Hospital. To ensure variability in the time of day at which patients present, a random time table will be created and recruiting will start at that time, and continue until a subject is enrolled.

Recruitment Model: An Emergency Department Research Associate (RA), who is a staff person employed by the Department of Emergency Medicine, will monitor the HealthLink /eRecord trackboard for eligible patients. These staff members have a broader role in the ED. They (RAs) complete duties as assigned by the Department Chair as it relates to the overall mission of the Department of Emergency Medicine (e.g., research, clinical operations such as quality improvement, communication, & process monitoring, etc.). These RAs under the direction of the ED clinical providers will approach subjects for study recruitment purposes as described below.

When a potentially eligible patient is identified, the RA will ask the primary clinical team as to whether they anticipate the patient being discharged home. If the clinical team indicates that the patient will likely be discharged home, the RA will then approach the patient and their family / informal caregivers to confirm eligibility and explain the study.

All participating patient subjects, regardless of assignment to intervention or control group, will be asked to complete three research surveys. The first survey will be completed in the privacy of their ED room and will take about 15 minutes to complete. The other two surveys will be completed over the telephone at approximately day 4 and day 30 at a time that is convenient for the subject. These survey follow-up calls will take about 10 minutes to complete and assess outcome measures. All questions are voluntary. Subjects are free to refuse to answer any survey questions they are uncomfortable with.

Patient subjects randomized to the intervention arm (CTI program) must agree to one paramedic coach home visit and up to 3 follow up phone calls to deliver CTI program clinical care over 30 days. The paramedic coach home visit will ideally occur within 24 hours of ED discharge and take approximately 1 hour. This home visit will be scheduled at a time that is convenient for the subject. During the home visit the paramedic coach will review the subject's medications, educate on red flags and emphasize provider follow-up. The phone calls will reinforce the coaching information. These interactions are organized around the validated and nationally implemented CTI program.

In the event a participating subject is admitted to the hospital directly from the initial ED visit (i.e., the primary team changes its mind based on developing results), then the subject (and caregiver where applicable) will be removed from the study because they no longer meet study eligibility criteria.

Caregiver subjects will be asked to complete an ED survey and one follow up research survey by phone at approximately day 30. The ED survey will take approximately 15 minutes to complete, and the call will take approximately 10 minutes to complete and will assess outcome measures. All questions will be voluntary.

Randomization: Randomization will occur at the site-level and occur after the treatment team has indicated that the patient will be likely discharged home, and the subject or legally authorized representative (LAR) has consented to participate on the study and the baseline survey has been completed. At that point, the subject will be randomized. This will be a stratified randomization, based upon whether or not an informal caregiver provides significant support for the patient.

In the infrequent event that the patient is admitted after consenting for the study and being randomized (but before being discharged and leaving the ED), the patient subject (and caregiver where applicable) will be withdrawn from study as an investigator initiated withdrawal because the subject no longer meets eligibility criteria (i.e hospital admission).

5.2 PROCESS OF CONSENT

For consent, we have developed an approach (in conjunction with the UR IRB) to minimize coercion and undue influence. Consent will only be performed by individuals who are listed on the IRB application and who are IRB approved and authorized to obtain consent. The process has been established to provide enough information to allow a thoughtful decision and ensure enough time to allow a considered decision. Because this study includes vulnerable subjects (older patients, patients with potentially diminished capacity), previously implemented processes are being used. We estimate that less than 2% of the participating subjects will lack decisional capacity (~10% of older adult ED patients lack decisional capacity, and the vast majority are admitted to the hospital, thus excluded from this study), but have built mechanisms to ensure they are identified.

Process:

All study procedures will be standardized at both sites. After a potentially eligible patient (and caregiver where applicable) is identified, the RA will ask the primary clinical team whether they anticipate the patient being discharged home. If the clinical team indicates that the patient will likely be discharged home, the RA will then approach the patient and their family / informal caregivers to confirm eligibility. In the privacy of the subjects' ED room the RA will explain the study, its benefits and the potential risks of participation. The ED patient will then be given the combined consent and HIPAA authorization form and allowed as much time as they need to read it and ask questions. If the patient agrees to participate, decisional capacity will be evaluated by the RA to ensure that participants understand the risk and benefits of the study before obtaining informed consent. The decisional capacity evaluation used has previously been approved by the UR IRB. It assesses the potential subject's understanding of the study. This process is more conservative than the UW IRB policy "Research with Adult Participants Lacking

Capacity to Consent" (Section II). The patient will be involved in the consent process as much as possible and will be asked to provide assent by the researchers. The subject's assent will be required and will be documented on the consent form. This documentation will will be retained in the subject's research record. Surrogates (LAR) will be informed that their decisions should be based upon what the surrogate believes is consistent with the subjects wishes if they possessed capacity, and if a subject's wishes cannot be determined, surrogate decisions should be based upon what the surrogate believes to be in the subject's best interest.

If the patient lacks decisional capacity, the RA will discuss the study further with a LAR present in the ED. If no LAR is present, then the subject will not be included in the study. Priority of decision makers is as follows: 1) research power of attorney, if present; 2) court appointed guardian; 3) power of attorney for healthcare; 4) next of kin in the following order: spouse or registered domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, or close friend. If the LAR agrees to study participation, the study coordinator will confirm decisional capacity of the LAR and then ask the LAR to sign the combined consent and HIPAA authorization form. If the LAR lacks decisional capacity, then the subject will not be included in the study. The patient and the LAR will be given a copy of the signed consent forms.

Informed consent will be obtained from caregivers present in the ED. Caregivers will be assessed for decisional capacity using the same methods as with the patient subject. Caregivers without decisional capacity will not be eligible to join study.

In cases where the capacity of the subject is in doubt, the RA will consult with an ED physician or clinician investigator.

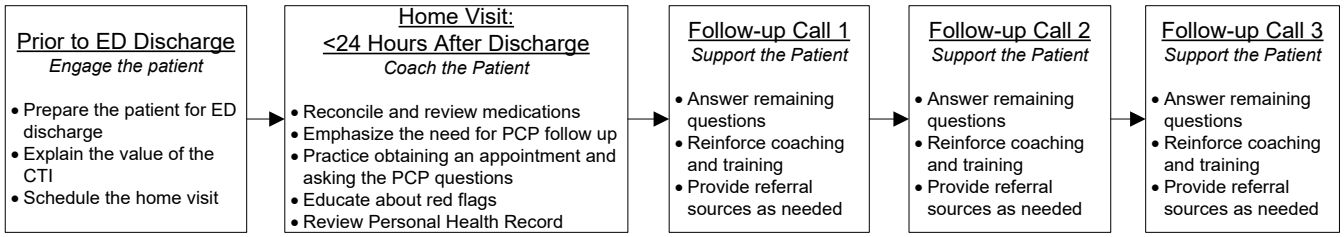
After completing informed consent, the patient (and caregiver when applicable) will be asked to complete the baseline survey. When the baseline survey is complete, the patient will be informed of their randomization. If the patient is randomized to the control group, the RA will schedule the 1st follow-up call at a convenient time for the patient. If the patient is randomized to the intervention group, the RA will ask the patient for a convenient time, within the next 24 hours, for the paramedic coach to make the home visit. The RA will schedule the visit and give the patient a reminder card with a photo of the coach and the time the home visit is scheduled. For those patient subjects who lack capacity, the LAR (surrogate) will be required to attend the paramedic coach home visit.

6. METHODS

6.1. CTI CLINICAL PROGRAM & ITS PROCESSES (only for the INTERVENTION GROUP)

We are adapting a validated and widely used program for a new setting. The only revision is to minimize the coaching in the ED to avoid prolonging the patients' discharge process as that would notably impede ED operations, inhibiting dissemination and implementation. Thus, the review of the four pillars of the CTI model, which is typically covered in the hospital, will occur during the first home visit, which will ideally occur within 24-48 hours.

Figure 3: Care Transitions Intervention Processes



Paramedic Coach Identification: The paramedic coaches will be considered part of the research team and will be fully trained in accordance with the UW IRB and UR IRBs. Participating paramedic coaches will be will be identified and selected to participate based on their level of EMS experience and their interest in the research objectives. The paramedic coaches will be paid as subcontracted providers by the UW Dept. of Emergency Medicine. They will not have an appointment registered with the University of WI Human Resources. Therefore an Individual Investigator Agreement (IIA) will be completed for each paramedic coach. IIAs have been obtained and the requisite human subjects training for each coach has been completed. The paramedic coaches are now officially included as members of the study team and listed on the 'key personnel' and 'roles' pages of the protocol application.

Training: The paramedic coach will be trained following the existing national standard created by Dr. Coleman. The paramedic staff will complete the on line training, then go to Denver, CO to receive the full training, and then will shadow coaches in Rochester, NY and Madison, WI to better understand the process. The coaches will also take part in the monthly training updates that are delivered by Dr. Coleman's CTI staff via webinar.

Processes:
After the patient returns home, the paramedic coach will perform the home visit, within 24-48 hours ideally. During this visit, the coach will follow the program as they have been trained by Dr. Coleman and his staff. They will coach the patient to reconcile medications; emphasize the importance of provider follow-up and practice obtaining an appointment and asking the PCP questions at the visit; review red flags due to medications and the acute condition; and develop the Personal Health Record. As per the CTI, the paramedic will not do the work for the patient, but will coach and educate the patient and/or caregiver. During the CTI program's follow-up calls (up to 3, not related to research activities), the paramedic coach will further coach and support the patient and/or caregiver.

If the subject expresses need for assistance beyond coaching or the coach identifies clinical issues, then he/she will coach the subject to call his/her provider to obtain further guidance. If the subject is unable to do so, then the paramedic coach will call the PCP directly or 911 to request an ambulance for evaluation and transport to an ED. Because the coach is a paramedic and has extensive medical training, he/she has the expertise to recognize medical issues and summon assistance.

All CTI program documentation will be securely retained within the study files in the UW Department of Emergency Medicine and the UR Department of Emergency Medicine. If the patient subject consents to the communication, a status summary will be sent to their primary care provider for inclusion in their medical record. This information will be sent using secure, HIPAA compliant email systems. Because all UW enrolled subjects will be patients of UWHealth, the UW email system will be used and is HIPAA compliant. Because all UR enrolled subjects will be patients of UR Medicine, the UR email system will be used and is HIPAA compliant.

6.2. USUAL CARE (CONTROL) GROUP

The usual care group patients will receive the routine UW and UR discharge educational materials from the ED staff. There may be an effect from the research survey calls, but that would only decrease the magnitude of the anticipated differences between the control and intervention group.

6.3. RESEARCH PROCESSES

The informed consent, baseline survey and randomization will be completed in the ED by the study RA. To facilitate scheduling the coach home visits the RA will know the coach's weekly availability. For those subjects randomized to the intervention group, the RA will schedule the coach home visit within 24 hours of ED discharge ideally and then send the paramedic coach the appointment time, patient's contact information and ED discharge summary via email. To ensure that all PHI is communicated securely, UW coaches will be provided with UW Department of Medicine email addresses and at UR the coaches will also be provided with UR email addresses. Thus, all communication will be within each institution's secure, HIPAA compliant email system.

Blinded research staff will be responsible for all research surveys for the patient and caregiver. These are intended for all subjects (control and intervention group) and independent of the clinical CTI program delivered to the intervention group.

Patient subjects will be contacted *four days after ED discharge*. The RA will telephone the subject and complete a survey that evaluates the program fidelity and initial outcome measures (Table 2). We chose this time point because patients should have made medication changes (e.g., started an antibiotic) and contacted their provider for follow up by then. We anticipate that the survey will take no longer than 10 minutes to complete.

Patient subjects will be re-contacted *thirty days after ED discharge.* The RA will re-contact all subjects and complete a final survey. We anticipate that the survey will take no longer than 10 minutes to complete the telephone survey. The RA will inform subjects of the research phone numbers from which all calls will be made. It is anticipated that providing this information will re-assure subjects and give an increase sense of comfort knowing who is calling them.

If, at the time the follow-up assessments are due (Day 4 and Day 30) the patient subject is either in the ED or inpatient in the hospital, research staff will go to the ED or inpatient hospital floor and request permission from the attending health care provider to visit the patient to complete the followup survey. If the provider states the research visit is inappropriate the RA will leave the ED/inpatient area immediately. The patient subject can decline the RA visit and study survey at any time. This change in data collection does not apply to the Caregiver subject.

Caregiver subjects will be re-contacted *thirty days after ED discharge*. The RA will re-contact all subjects and complete a final survey. We anticipate that the survey will take no longer than 10 minutes to complete the telephone survey. The RA will inform subjects of the research phone numbers from which all calls will be made. It is anticipated that providing this information will re-assure subjects and give an increase sense of comfort knowing the who is calling them.

The RA will conduct a medical record review at the end of the study. We have built a lag time because we recognize that it can take months for the medical record to be fully updated with care episodes, discharge diagnoses, etc. The collected data are represented in Table 2.

Records Management: All data will be maintained initially on paper and then entered in REDCap, an electronic data management system on a secure server maintained by the UW Department of Medicine. The PI and coordinator are responsible for monitoring data quality in conjunction with the study team. Reports will be generated and reviewed regularly to show the status of all subjects and bring forward any problems with study processes and data completeness.

Individuals who decline to participate will not have any identifiable information retained. We will retain the following variables to compare those participating to those who decline to participate: 1) age up to 89 years and age range for subjects ≥ 90 years, 2) sex, 3) race, 4) chief complaint, 5) reason for declining study participation.

All documentation will be stored in the UW or UR Department of Emergency Medicine locked office space. No later than the end of the study, the forms will be scanned and stored on secured network drives at UW and the paper copies will be destroyed.

Table 3: Schedule of Activities

Paramedic-coached ED Care Transitions to Help Older Adults Maintain their Health								
↓ Activity → Day	0	1	2	3	4	5		30
Recruitment								
Patient and Caregiver (CG) Identified, Recruited & Randomized in ED								
Research Activities								
Control & Intervention Groups								
Patient Baseline & Follow-up Survey Calls								
CG Baseline & Follow-up Survey Calls								
Clincial Activities								
Intervention Group								
Coach Homevisit								
Coach Follow-up Patient Calls - TBD								

EFFICACY ASSESSMENTS

To evaluate the program, the RA who calls the subject will complete the following measures:

1. Care Transitions Measure: The CTM includes the 3 major domains that patients have identified as critically important to their experience with coordination out of the hospital. This will serve as a proxy measure for actual changes.
2. Medication Changes: Survey asking if medication changes are implemented (e.g., new medications started, old medications stopped). If not applicable, then that will be recorded. The date of change will also be queried.
3. Understanding of Red Flags: The discharge instructions from the ED will be abstracted for key red flags. Subjects will be asked to list the red flags for which they are monitoring their condition, and will be asked to explain the meaning of the red flag. The RA will record the subject responses verbatim. Two physicians will review the responses and score the level of understanding on a Likert scale.
4. Follow up with PCP: PCP follow up will be assessed in three different manners. The primary measure will be the time to in-person PCP follow-up (e.g., clinic or home visit). The secondary measures will be time to any PCP follow up (e.g., in-person or phone) and the third approach will be contact with PCP within the time recommended by the ED (e.g., phone or in person) follow-up.
5. Patient Self Efficacy: Wallston's Perceived Health Competency Scale (PHCS) is a domain-specific

measure of self-efficacy. It assesses perceptions of self-efficacy specific to health-related situations but is not limited to any single behavior.

6. Patient Activation Measure: The Coleman Patient Activation Measure will be the primary measure for this assessment. A 1 point change in score is considered clinically significant for the Coleman measure.

6.5 COSTS TO THE SUBJECT

Subjects will not incur any costs for participating.

6.6 PAYMENT FOR PARTICIPATION

Subjects will not be paid for participation.

6.7 RETURN OF INDIVIDUAL RESEARCH RESULTS / MANAGEMENT OF HEALTH FINDINGS

As part of this study, we may identify new health information. During the consent process, we will obtain permission to disclose this information to each subject's PCP. This will be done via a template letter that will be sent by the study staff by standard postage mail to the PCP summarizing performance on the various tests. If the subject declines to allow us to provide this information to their PCP, then the disclosure will not occur.

As part of the surveys in the ED or via phone, we may identify certain findings that require physician review. For the surveys completed in the ED, the findings will be reviewed with the treating physician. For the phone surveys, these findings will be reviewed by the physicians overseeing this study at either the Rochester or Madison sites and action will be taken as clinically appropriate.

As part of the CTI coaching, the coach may identify clinical issues. Then, he/she will coach the subject to call his/her PCP to obtain further guidance. If the subject is unable to do so, then the coach will call the patient's provider or 911 for direct ED transport. By using trained providers (paramedics) with extensive clinical knowledge and having continual physician availability by phone, this decision will be maximally supported.

7. SUBJECT WITHDRAWALS

All subjects will be advised in the written informed consent forms that they have the right to withdraw from the study at any time without prejudice. Withdrawal will only occur if the subject indicates that he / she no longer wishes to participate. For subjects who withdraw from the study, we will clarify the level of withdrawal. For those who wish their records to be fully expunged from the study, we will destroy all information except for the consent form, but add a note indicating the date and time of withdrawal. For those who wish to cease participating in the CTI program and follow up activities, we will request permission to retain them in the study and continue medical record review until the end of study chart review.

8. SAFETY AND REPORTABLE EVENTS

The level of risk in this supportive care behavioral intervention is low, and no published literature regarding this widely implemented intervention has reported any problems. All research team members will be involved in safety monitoring.

8.1 UNANTICIPATED PROBLEM DEFINITION

An unanticipated problem is an event that includes any symptom, illness, or experience, which develops or worsens during the course of the study and that changes the subject risk/benefit ratio and that is directly related to subjects' participation in the study.

8.2 RECORDING UNANTICIPATED PROBLEMS

During the study follow up calls, research staff will assess if any unanticipated problems have occurred. All unanticipated problems whether observed by the staff, elicited from or volunteered by the subject, will be documented. Each unanticipated problem will include the date of onset, brief description of the experience, the relationship to CTI and any action taken with respect to the CTI.

8.3 SERIOUS ADVERSE EVENT

A serious adverse event is defined as any adverse medical experience that results in any of the following outcomes: 1) death; 2) is life-threatening; 3) requires inpatient hospitalization; 4) results in persistent or significant disability/incapacity; 5) requires medical or surgical intervention to prevent permanent impairment or damage.

8.4 RESPONSIBILITIES FOR REPORTING SERIOUS ADVERSE EVENTS

Any negative reactions that arise during the course of this study will be discussed in the weekly research team meetings. All adverse events will be reviewed to determine if a change in protocol is necessary.

If a serious adverse event related to study activities occurs, it will be reported to the NIH and the University of Wisconsin IRB within 24 hours. If the event took place at the University of Rochester site, it will also be reported to the University of Rochester IRB as well as the University of Wisconsin IRB.

9. RISK/BENEFIT ASSESSMENT

9.1 POTENTIAL RISKS

One risk involves any stress caused by the survey questions or assessments, either through the questions themselves or frustration or fatigue from completing the questions. This risk is moderate, because the questions are standard questions asked by health care providers. However, the risk can be mitigated and made less likely by taking appropriate steps described in the “Protection Against Risk” section.

Another risk involves the release of confidential information regarding the medical conditions for which subjects will be assessed and from the medical record reviews. Release of information can cause social or psychological harm. However, the risk for this is extremely unlikely due to the procedures used to mitigate this issue that are described in the “Protection Against Risk” section.

A third risk is that the study team may be able to identify issues of depression or suicidal thoughts from the surveys. Identification of these issues would require contacting appropriate individuals for intervention (e.g., your ED provider, your health care team).

A fourth risk is identification of abuse or neglect. Home visits will occur as part of this study and child abuse or neglect may be observed during a visit. We are required by state law to report this to the appropriate authorities. This may include reporting to local law enforcement or protective service agencies, resulting in legal or social risks to subjects or other members of their household.

In home visit situations where the paramedic coach identifies that a home environment requires mandatory reporting to authorities the paramedic coach will report as mandated and also communicate their findings to the study Principal Investigator (PI). Additionally, in situations where it is unclear whether mandatory reporting requirements are triggered the paramedic coach will communicate their findings to the study Principal Investigator to further discuss the case. If deemed necessary the research team will communicate concerns to the patient’s primary care physician for appropriate follow-up by the PCP.

A final risk is that we may refer subjects to their primary care providers or an ED for additional care. Following these referrals will be dependent upon the subject inclination to accept the referral.

9.2 PROTECTION AGAINST RISKS

Stress: The risk from the stress of the questions will be mitigated by requesting consent to ask the questions, by asking the questions at times of their choosing, and offering to terminate the screening at any point that subjects request.

Release of Confidential Information: To prevent the unintentional release of confidential information for any of the human subjects included in the research study, all data will be stored in locked offices. All electronic data will be stored on secure networked computers / networked drives, as per policy. Only investigators and research staff directly involved in the project will be given access. All identifiers will be stripped from the database at the earliest possible time. For patient data, identifiers will be eliminated upon completion of follow up and data abstraction.

Different Levels of Care: In terms of the acute event, that will be protected against in two ways. First, the ED staff will have completed its primary medical care before consent is requested or assessment is performed. Thus, participation cannot impact ED medical care. Second, in the ED, participation cannot harm medical care because the research staff operates independently of the ED physician. Participation can benefit medical care only from the standpoint that new needs may be identified and addressed, thus improving the health of the older adult.

Depression or Self Harm: To mitigate this risk, we will contact appropriate others to intervene (e.g., the ED provider, their health care team).

Elder or child abuse or neglect: If either abuse or neglect is observed during the coach's' home visit, we are required by state law to and will report this to the appropriate authorities.

Referral to PCP or ED: If needed from a clinical standpoint, the subject may be referred to their PCP or an ED. It will be up to the subject to decide if they wish to act up on this referral.

9.3 POTENTIAL BENEFITS TO SUBJECTS

Subjects in the study who receive the intervention may benefit by having more intensive support during the ED to home transition.

9.4 ALTERNATIVES TO PARTICIPATION

Subjects may elect to not participate.

10 CONFIDENTIALIATY OF DATA AND INFORMATION STORAGE

While the study is underway, all data will be identifiable. However, we will take many actions to maximally protect the data and mitigate the risk of breach of confidentiality.

1. For data collection purposes, identifiers will be used to label all collection forms. These forms will be initially stored in secure URMC or UW Department of Emergency Medicine offices and will be destroyed once the data are uploaded into REDCap the electronic data management system.
2. All data will be maintained in REDCap, an electronic data management system application on a UW Madison School of Medicine and Public Health server and maintained by its IT staff.
3. Only the PI and research staff with direct reasons for access will be allowed to access the data.
4. No identifiable data will be kept from those subjects who were ineligible for the study or who chose not to enroll.

5. For analysis procedures, all subjects will be assigned an automatically generated identification code in the RedCap system. This code will be used for data linkage purposes during analysis. Data will be reported as group data so that no individual could be identified.
6. After study completion, direct identifiers will be removed from the datasets. Only an auto-generated REDCap assigned subject number will be used for data linkage purposes. These limited datasets will be retained on limited access, secure UW servers.
7. Limited analysis datasets will be kept for 7 years after completion of the study, or longer to allow for secondary analysis after the study is complete.
8. All members of the study team will complete either a UW or URMC CITI and HIPAA training.

11 RESEARCH INFORMATION IN MEDICAL RECORDS

We will not add research information in medical records.

12 DATA ANALYSIS AND MONITORING

12.1 SAMPLE SIZE DETERMINATION

This study is designed to have adequate power to *test the primary hypotheses that the CTI will result in lower odds of repeat ED use within 30 days of discharge compared to the control group* (Hypothesis 2B). Based on published data, we expect 20% of the subjects in the control group to have at least 1 repeat ED visit within the 30-day follow-up period. In order to detect a 5% absolute decrease in the frequency of repeat ED visits with 80% power using a Chi-square test at a two-sided significance level of 5%, we will need 860 subjects per group. We anticipate approximately 25% attrition over the 30-day follow up period. As such, a final sample size of 1200 subjects in each group will be recruited for participation. We also calculated the minimum detectable effect size testing individual biomedical and psychosocial factors predicting repeat ED visit in Aim 4 for intervention group only. With an expected 15% baseline proportion of repeat ED visit, the sample size of 860 in the intervention group will have 80% power to detect an odds ratio (OR) of 1.3 per standard deviation of a normally distributed predictor. Similarly, 80% power is available to detect an OR ranging from 1.6-1.7 for a binary predictor prevalent in 30-50% of subjects.

We will also have to adjust for clustering by site in most of the analyses below.

12.2 PLANNED STATISTICAL ANALYSIS

Through the analytic methods used in Aims 2 and 3, we will assess differences between groups related to process outcome measures (Aim 2) and will assess the effectiveness and cost-effectiveness of the ED-to-home CTI (Aim 3). In Aim 4, we will identify predictors of repeat ED use among intervention group subjects. We will characterize of our study sample using descriptive statistics and corresponding measures of variation. We will assess for differences between groups at baseline despite randomization in key characteristics (e.g., demographics, comorbidities) using t-tests for continuous variables and Chi-square tests for categorical variables, using Fisher's exact test where appropriate. These comparisons will enable the identification of covariates to be controlled in our multivariable analyses. If distributional assumptions associated with a particular statistical procedure are violated, we will use appropriate transformations or non-parametric alternatives. Primary analyses will be performed under the intent-to-treat principle, keeping subjects in the group to which they were originally randomized, regardless of compliance or adherence to study procedures. We will conduct sensitivity analyses among subjects who complete all study procedures to evaluate the effect of the intervention among those who complete all study-related procedures. Hypothesis-driven comparisons will be made to control the family-wise type I error rate at 0.05 (two-sided) for the primary hypothesis.

Caregiver Subject Analysis: Although not an original aim of the study, we have obtained permission from the NIH and will perform a limited analysis of caregiver activation. This was only recently added to

the CTI. To compare the caregiver activation between the control and intervention groups, we will administer the FCAT. The FCAT will be scored as 1-6 points per question, for a score ranging from 10-60. We assume that 30% of participants will have caregivers with them, the average score will be 30, and we will look for a 5 point difference. Our sample size will allow a power of >0.8 for a t-test (alpha=0.05).

Hyp 1A: More program participants will demonstrate understanding of their ED discharge instructions, red flags that indicate a worsening of their condition, and how to respond to the red flags three days after ED discharge.
Hyp 1B: More program participants will implement medication changes made in the ED within three days of ED discharge.
Hyp 1C: Program participants will have shorter time-to-follow-up with their primary care physicians.
Hypothesis 1A & 1B: Binary outcomes such as patients' understanding of their ED discharge instructions, red flags and how to respond, and accurate implementation of medication changes, will be compared between intervention and control group using chi-square tests. Estimates of differences between study groups and associated 95% confidence intervals will be provided overall and by study site. A separate multivariable logistic regression model will also be fitted for each of the outcome variables in hypotheses 1A and 1B. This will allow us to evaluate the effect of the intervention on each of these outcome variables while controlling for potential confounding variables, if necessary. **Hypothesis 1C**: Time-to-follow-up visit with primary care physicians will be compared between groups using the Log-Rank Test. Cox regression model will be fitted to compare the survival function after adjusting for potential confounding variables such as demographics, comorbidities etc., if necessary. A hazard Ratio and 95% confidence interval will be estimated. Because we have the issue of competing outcomes present (rehospitalization and follow up), we will have to account for it through the cumulative incidence function.[72]

Hyp. 2A: Program participants will have increased patient activation 30 days after discharge.
Hyp. 2B: Program participants will have lower odds of repeat ED use within 30 days of discharge.
Hyp. 2C: Program participants will have lower estimated healthcare costs within 30 days of discharge.

Hypothesis 2A & 2B: To evaluate difference in subjects' self-care competency, Wallston scores will be compared between intervention and control groups using the Wilcoxon Rank Sum test. Any repeat ED use and the number of ED visits during the 30-day follow up period will be compared between intervention and control groups using the Chi-square test and ANOVA as appropriate. To adjust for potential baseline differences between intervention and control subjects, a multiple logistic regression model will be constructed with repeat ED use as the dependent variable, study intervention group as the primary independent variable, and any covariates that were found to be imbalanced at baseline in our bivariate analyses. Multicollinearity between predictor variables will be assessed using multiple correlations (variance inflation factors). We will use the log likelihood ratio to assess overall model fit. We will also check for overdispersion and use Generalized Estimating Equation (GEE) to provide robust estimates of standard errors. Possible interaction effects between the covariates will be inspected and stratified analyses will be performed if there are significant interaction effects. Standard diagnostic measures for logistic regression such as Pearson residual and deviance residual will be used to check the goodness-of-fit of the regression model assumptions and identify any outliers.

Hypothesis 2C: The proposed economic assessment considers the financial costs and benefits of the CTI. Consistent with standard terminology,[73] we define *financial benefits* for this study as the consequences of the CTI that are related to health services cost, expenses, salaries, revenues, and other fiscal issues. It is important to recognize that adoption of the CTI will include both fixed (e.g., implementation) and variable (e.g., dependent on units of care delivered/patients served) costs. Dissemination of the program will require additional resources to cover CTI implementation. Hence, we

include fixed and variable costs in our analysis while excluding costs associated with the research. We will evaluate the economic impact of CTI from the perspective of health care system/insurers, including both the cost of the CTI and the expected healthcare cost reduction due to altered use of ED, hospital, and office visits. Impact on direct healthcare costs (and hence analysis from the insurer perspective) will be most critical to the adoption and dissemination of this care model since insurance organizations (dominant stakeholders through control of payment), are unlikely to reimburse for CTI care unless they assess it as at cost-neutral or better.

The occurrence of events contributing to healthcare costs (e.g., ED visits) will be ascertained from clinical information systems at both health systems. We will estimate the following CTI expenses for the intervention group: hardware and/or software investments; maintenance costs; direct and indirect costs for training; personnel salary and benefit costs, etc. We will estimate the value of direct healthcare resources saved or expended, including both fixed and variable costs. We will use Medicare reimbursement schedules to assign costs to events because of their national scope, relevance to older populations, and alignment with the true costs of care rather than inflated costs or discounted insurance plan reimbursements. We will calculate total direct costs for each individual by taking the product of the costs per visit (price) and utilization by visit type, and summing across categories of utilization for that individual. We will then estimate unadjusted and adjusted incremental costs. The adjusted cost approach uses multivariable regression models to eliminate the effects of differences in population characteristics across comparison groups, if appropriate. To do so, we will estimate the program's monthly and annual costs using multivariable models and then will calculate the incremental cost of the CTI. All prices will be calculated in 2015 dollars. Using collected data, we will extrapolate the costs of running the program and expected benefits over 12-month period and annually. Finally, we will make economic projections of the program's financial sustainability and scalability. We will conduct a series of sensitivity analyses by modifying local wages, population case-mix and program effectiveness to estimate boundaries to program's sustainability and optimal operational conditions.

To test the hypothesis that individual in the treatment group will have lower health care costs within the 30-days of ED discharge, we will first calculate total direct costs for each individual by taking the product of the costs per visit (price) and utilization by visit type, and summing across categories of utilization for that individual. We expect to find that total health care expenditures will exhibit a right skewed distribution with no negative measures and a nontrivial number of zeros. Consistent with the literature, we will log transform total spending to generate a normal distribution and use the box cox and GLM family test to find the distribution to best in our data. We will use the recycled predications method to re-transform estimates back from the log scale and compare average health care spending in the treatment and control groups.

Hyp. 3A: Biomedical factors associated with repeat ED visits include increased age, increased number of comorbidities, impaired cognition, and limited functional status.
Hyp. 3B: Psychosocial factors associated with repeat ED visits include reduced social connectedness, increased anxiety symptoms, and increased depressive symptoms.

To evaluate the relationship between biomedical and psychosocial factors with the occurrence of repeat ED visits among intervention subjects we will conduct bivariate analyses between patient characteristics and the primary outcome measure (repeat ED visits within 30 days). To do this we will conduct bivariate analyses with potential predictor variables and the dependent variable (repeat ED use) using two sample t-tests for continuous variables or Chi-Square tests for categorical variables, using Fisher's Exact test where appropriate. We will then identify independent predictors of repeat ED visits by fitting a multiple logistic regression model with biomedical and psychosocial factors identified in the bivariate analysis as independent variables. Model fitting statistics such as Akaike's Information Criteria and difference in log likelihood will inform the development of the final regression model. Standard diagnostic measures such

as residual plots will be used to assess the goodness-of-fit of the regression model assumptions and identify any outliers.

Missing Data: Inference based on the proposed method is valid provided that missing data follows the missing completely at random (MCAR) assumption. However, the occurrence of missing data may depend on the observed response and such as missing at random (MAR) mechanism will generally bias the estimates. Sensitivity analysis will be performed to examine the MCAR assumption. If it is deemed to be severely violated, we will report treatment effects using weighted GEE that addresses the MAR mechanism.[74,75] Biased estimates may arise if missing data does not follow the MAR mechanism, or non-ignorable non-response (NINR). Although unanticipated in this study, we will examine this potential NINR using the mixture model approach.[76]

Future Planned Analysis: We are requesting to retain the data in an identified form for 10 years after completion of this study for future analyses of health care utilization and claims data from subjects' health insurance providers so as to understand if a paramedic coach reduces health care use and costs. We will keep the deidentified data indefinitely.

12.3 DATA AND SAFETY MONITORING

The data safety and monitoring plan should be commensurate with the risks of the study, as well as the size and complexity of the study. This plan includes monitoring procedures with structured adverse event (AE) and serious adverse event (SAE) determination, monitoring and reporting systems with standardized protocols and forms for referring and/or treating study participants who experience adverse events. AEs should be reported to the IRB, the NIA Program Officer.

Appendix A details the NIA approved plan.

13.0 REFERENCES

1 Albert M, McCaig LF, Ashman JJ. Emergency department visits by persons aged 65 and over: United States 2009-2010. NCHS data brief, no 130. Hyattsville, MD: National Center for Health Statistics. 2013.

2 Moons P, DeRidder K, Geyskens K, et al. Screening for risk of readmission of patients aged 65 years and above after discharge from the emergency department: predictive value of four instruments. European Journal of Emergency Medicine. 2007; 14:315-323.

3 McCusker J, Cardin S, Bellavance F, Belzile E. Return to the emergency department among elders: Patterns and predictors. Academic Emergency Medicine. 2000;7(3):249-259.

4 Caplan GA, Brown A, Croker WD, Doolan J. Risk of admission within 4 weeks of discharge of elderly patients from the emergency department. The DEED study. Discharge of elderly from emergency department. Age & Ageing. 1998; 27: 697-702.

5 Hastings SN, Schmader KE, Sloane RJ, Weinberger M, Goldberg KC, Oddone EZ. Adverse health outcomes after discharge from the emergency department -- incidence and risk factors in a veteran population. Journal of General Internal Medicine. 2007;22:1527-31.

6 Pines JM, Mullins PM, Cooper JK, Feng LB, Roth KE. National trends in emergency department use, care patterns, and quality of care of older adults in the United States. Journal of the American Geriatrics Society. 2013;61(1):12-7.

7 Friedmann PD, Jin L, Karrison TG, et al. Early revisit, hospitalization, or death among older persons discharged from the ED. American Journal of Emergency Medicine. 2001;19(2):125-129.

8 Guttman A, Afilalo M, Guttman R, et al. An emergency department-based nurse discharge coordinator for elder patients: does it make a difference? Acad Emerg Med. Dec 2004;11(12):1318-1327.

9 Lowenstein SR, Crescenzi CA, Kern DC, et al. Care of the elderly in the emergency department. Annals of Emergency Medicine. 1986;15:528-35.

10 Rosenberg M, Rosenberg L. Improving outcomes of elderly patients presenting to the emergency department. Annals of Emergency Medicine. 2011;58:4979-481.

[11] Coleman EA, Berenson RA. Lost in transition: challenges and opportunities for improving the quality of transitional care. Ann Intern Med 2004;141:533-6.
[12] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: The care transitions intervention. Journal of the American Geriatrics Society. 2004; 52:1817-1825.
[13] Coleman EA, Parry C, Chalmers S, Min SJ. The Care Transitions Intervention: Results of a Randomized Controlled Trial. Archives of Internal Medicine. 2006;166:1822-8
[14] Available at: http://www.cdc.gov/nchs/data/nhds/3firstlisted/2010first3_numberage.pdf. Accessed on August 3, 2014.
[15] Hwang U, Shah MN, Han JH, et al. The care span: Transforming emergency care for older adults. Health Affairs. 2013;32:2116-2121.
[16] Graf CE, Giannelli SV, Herrmann FR, et al. Identification of older patients at risk of unplanned readmission after discharge from the emergency department. Swiss Medical Weekly. 2012;141:w13327.
[17] Hastings NS, Oddone EZ, Fillenbaum G, Sloane RJ, Schmader KE. Frequency and predictors of adverse health outcomes in older Medicare beneficiaries discharged from the emergency department. Medical Care. 2008; 46: 771-777.
[18] Keyes DC, Singal B, Kropf CW, Fisk A. Impact of a new senior emergency department on emergency department recidivism, rate of hospital admission, and rate hospital length of stay. Annals of Emergency Medicine. doi: 10.1016/j.annemergmed.2013.10.033.
[19] McCusker J, Dendukuri N, Tousignant P, et al. Rapid two-stage emergency department intervention for seniors: impact on continuity of care. Academic Emergency Medicine. 2003;10:233-243.
[20] Mion LC, Palmer RM, Meldon SW, et al. Case finding and referral model for emergency department elders: a randomized clinical trial. Annals of Emergency Medicine 2003;41:57-68.
[21] Runciman P, Currie CT, Nicol M, Green L, McKay V. Discharge of elderly people from an accident and emergency department: evaluation of health visitor follow-up. J Adv Nurs 1996;24:711-8.
[22] Caplan GA, Williams AJ, Daly B, Abraham K. A randomized, controlled trial of comprehensive geriatric assessment and multidisciplinary intervention after discharge of elderly from the emergency department--the DEED II study. J Am Geriatr Soc. Sep 2004;52(9):1417-1423.
[23] Pitts SR, Carrier ER, Rich EC, Kellerman AL. Where Americans get acute care: increasingly it's not at their doctor's office. Health Affairs (Millwood). 2010;29:1620-9.
[24] Wilson IB, Schoen C, Neuman P, et al. Physician-patient communication about prescription medication nonadherence: a 50-state study of America's seniors. J Gen Intern Med. 2007;22(1):6-12.
[25] Kellerman AL, Hsia RY, Yeh C, Morganti KG. Emergency Care: Then, Now, And Next. Health Affairs. 2013;32:2069-2074.
[26] Nunez S, Hexdall A, Aguirre-Jaime A. Unscheduled returns to the emergency department: an outcome of medical errors? Qual Saf Health Care. 2006;15:102-108.
[27] Chassin MR, Galvin RW. The urgent need to improve health quality. Institute of Medicine National Roundtable on Health Care Quality. JAMA. 1998;280:1000-5.
[28] Sellers CR, Duckles JM, Shah MN, Seshadri S, Salerno S, Elliot A, Christensen T. What makes for "successful" transitions from the emergency department to home and community among older adults? International Journal of Qualitative Methods. 2013; 12: 815-816.
[29] National Transitions of Care Coalition. Improving transitions of care: Emergency department to home. 2009. Retrieved August 24, 2011. http://www.ntocc.org/Portals/0/ImplementationPlan_EDToHome.pdf.
[30] Greiner A. White space or black hole: What can we do to improve care transitions? Issue Brief #6. ABIM Foundation. June 2007. Accessed July 1, 2014.
[31] Hastings SN, Helfin MT. A systematic review of interventions to improve outcomes for elders discharged from the emergency department. Academic Emergency Medicine. 2005; 12:978-986.
[32] Vashi A, Rhodes KV. "Sign right here and you're good to go": A content analysis of audiotaped emergency department discharge instructions. Ann Emerg Med. 2011;57:315-322.
[33] Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. Patient comprehension of emergency department care and instructions: Are patients aware of when they do not understand? Ann Emerg Med. 2009; 53(4): 454-461.
[34] Han JH, Bryce SN, Ely EW, Kripalani S, et al. The effect of cognitive impairment on the accuracy of the presenting complaint and discharge instruction comprehension in older emergency department patients. Ann Emerg Med. 2011; 57(6):662-671.

[35] Stiell A, Forster AJ, Stiell IG, vanWalraven C. Prevalence of information gaps in the emergency department and the effect on patient outcomes. CMAJ. 2003; 169: 1023-8.
[36] Samuels-Kalow ME, Stack AM, Porter SC. Effective discharge communication in the emergency department. Annals of Emergency Medicine. 2012;60:152-159.
[37] Herndon JB, Chaney M, Carden D. Health literacy and emergency department outcomes: A systematic review. Annals of Emergency Medicine. 2011;57:334-345.
[38] Rhodes KV, Vieth T, He T, et al. Resuscitating the physician-patient relation: emergency department communication in an academic medical center. Ann Emerg Med. 2004;44:262-267.
[39] Han JH, Zimmerman EE, Cutler N, et al. Delirium in older emergency department patients: recognition, risk factors, and psychomotor subtypes. Academic Emergency Medicine. 2009;16:193-200.
[40] Baker DW, Gazmararian JA, Williams MV, et al. Health literacy and use of outpatient physician services by Mediare managed care enrollees. Journal of General Internal Medicine. 2004;19:215-220.
[41] Katz EB, Carrier ER, Umscheid CA, Pines JM. Comparative effectiveness of care coordination interventions n the emergency department: a systematic review. Annals of Emergency Medicine. 2012;60:12-23.
[42] McCusker J, Roberge D, Vadeboncoeur A, Verdon J. Safety of discharged seniors from the emergency department to the community. Healthcare Quarterly. 2009;12 (Special Issue): 24-32.
[43] Barlas D, Homan CS, Rakowski, et al. How well do patients obtain short term follow up after discharge from the emergency department. Ann Emerg Med. 1999;34:610-614.
[44] Kyriacou DN, Handel D, Stein AC, et al. Brief report: Factors affecting outpatient follow up compliance of emergency department patients. J Gen Intern Med. 2005;20:938-942.
[45] Murray MJ, LeBlanc CH, Clinic follow up from the emergency department: do patients show up? Ann Emerg Med. 1996;27:56-58.
[46] Cheung PT, Wiler JL, Lowe RA, Ginde AA. National study of barriers to timely primary care and emergency department utilization among Medicaid beneficiaries. Annals of Emergency Medicine. 2012; 60:4-10.
[47] Parry C, Coleman EA, Smith JD, Frank JC, Kramer AM. The Care Transitions Intervention: A Patient-Centered Approach to Facilitating Effective Transfers Between Sites of Geriatric Care. Home Health Services Quarterly. 2003;22(3):1-18.
[48] McGarry BE, Smirnow AM, Wendland M, Bartock B, Cohen E, Chirico J, Beckman H. Reducing hospital readmissions: The effect of a 3 year community-based discharge coaching intervention of elderly and non-elderly adults. Presented at Academy Health 2014.
[49] Personal communications, Annie Wells, Lifespan of Rochester, September 9, 2014.
[50] Shah MN. An analysis of the forces affecting the formation of the emergency medical services system. American Journal of Public Health.
[51] Roush William R., ed. Principles of EMS Systems. American College of Emergency Physicians. Washington DC, 1994.
[52] Caprio TV, Shah MN: Approach to the Geriatric Patient. In: Emergency Medical Services: Clinical Practice and Systems Oversight, 5th ed. (Brice J, Cone DC, Delbridge T, Myers B, ed.). In Press.
[53] Garrison GH, Foltin GL, Becker LR, et al. The role of emergency medical services in primary injury prevention. Ann Emerg Med. 1997; 30: 84-91.
[54] EMS Agenda for the Future. National Highway Transport Safety Administration / Health Resources & Services Administration. Washington, DC, 1996.
[55] Delbridge TR. Bailey B. Chew JL Jr. Conn AK. Krakeel JJ. Manz D. Miller DR. O'Malley PJ. Ryan SD. Spaite DW. Stewart RD. Suter RE. Wilson EM. EMS agenda for the future: where we are ... where we want to be. EMS Agenda for the Future Steering Committee. Ann **Emerg** Med. 31(2):251-63, 1998
[56] https://www.youtube.com/watch?v=iCTZI47aRss&feature=youtu.be&utm_source=8.19.14_MIH-CP+video+email+to+members&utm_campaign=MIHCP+-+Video&utm_medium=email. Accessed August 25, 2014.
[57] Jaslow DS, Marsh RL. Primary injury prevention in emergency medical services. Acad Emerg Med. 1999; 6: 465.
[58] Lerner EB, Fernandez AR, Shah MN. Do EMS providers think they should participate in disease prevention? Prehospital Emergency Care. 2009; 13: 64-70. PMCID: PMC2713580.
[59] Sellers CR, Duckles JM, Shah MN, Seshadri S, Salerno S, Elliot A, Christensen T. What makes for "successful" transitions from the emergency department to home and community among older adults? International Journal of Qualitative Methods. 2013; 12: 815-816.

[60] Duckles J, Sellers C, Seshadri S, Lampo D, Shah MN. It's a balancing act: Understanding relational strategies of community dwelling older adults navigating post-emergency care and health in the context of everyday life. International Journal of Qualitative Methods. 2014. In press.
[61] Personal Communication, Sue Rosenbek, Lead Dissemination and Training, Care Transitions Program, University of Colorado Denver.
[62] Tomaka J, Thompson S, Palacios R. The relation of social isolation, loneliness, and social support to disease outcomes among the elderly. J Aging Health. 2006;18:359-384.
[63] Hawkley LC, Thisted RA, Cacioppo JT. Loneliness predicts reduced physical activity: cross-sectional & longitudinal analyses. Health Psychol. 2009;28:354-363.
[64] Strawbridge WJ, Cohen RD, Shema SJ, Kaplan GA. Successful aging: predictors and associated activities. Am J Epidemiol. 1996;144:135-141.
[65] Menec VH. The relation between everyday activities and successful aging: a 6-year longitudinal study. J Gerontol B Psychol Sci Soc Sci. 2003;58:S74-82.
[66] Tilvis RS, Kahonen-Vare MH, Jolkkonen J, Valvanne J, Pitkala KH, Strandberg TE. Predictors of cognitive decline and mortality of aged people over a 10-year period. J Gerontol A Biol Sci Med Sci. 2004;59:268-274.
[67] Von Korff M, Gruman J, Schaefer J, Curry SJ, Wagner EH. Collaborative Management of Chronic Illness. Annals of Internal Medicine. 1997;127 (12): 1097–102.
[68] Ware JE Jr, Kosinski M, Keller SD. A 12-item short form health survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996; 34:220-233.
[69] Katz S, Downs TD, Cash HR, Grotz RC. Progress in development of ADL. Gerontologist. 1970; 10:20-30.
[70] Mody L, Miller DK, McGloin JM, et al. Recruitment and retention of older adults in aging research. Journal of the American Geriatrics Society. 2008; 56: 2340-2348.
[71] Marcantonio ER, Aneja J, Jones RN, et al. Maximizing clinical research participation in vulnerable older persons: identification of barriers and motivators. Journal of the American Geriatrics Society. 2008; 56: 1522-1527.
[72] Varadhan, Evaluating health outcomes in the presence of competing risks: a review of statistical methods and clinical applications. Med Care. 2010 Jun;48(6 Suppl):S96-105.
[73] Health care cost, quality, and outcomes. ISPOR Book of terms. Ed. ML Berger. International Society for Pharmacoeconomics and Outcomes Research. Lawrenceville, NJ. 2003. p.173-174
[74] Robins JM, Rotnitzky A. Semiparametric Efficiency in Multivariate Regression Models with Missing Data. Journal of the American Statistical Association. 1995;90, 122–129
[75] Preisser JS, Lohman KK, Rathouz PJ. Performance of Weighted Estimating Equations for Longitudinal Binary Data with Drop-Outs Missing at Random. Statistics in Medicine. 2002;21:3035–3054.
[76] Fitzmaurice GM, Laird NM. Generalized linear mixture models for handling nonignorable dropouts in longitudinal studies. Biostatistics. 2000;1:141–156.

APPENDIX A
DATA AND SAFETY MONITORING PLAN

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1.0 PARTICPANT SAFETY

1.1 Potential Risks and Benefits for Participants

Potential Risks

The potential subject risks associated with this study are as follows:

1. Stress caused by the survey questions or assessments: Either through the questions themselves or frustration or fatigue from completing the questions, this risk will be present. Although we anticipate this risk, it is expected to be commensurate with what participants would experience outside of the research study because the questions are standard questions asked by health care providers. However, the risk can be mitigated and made less likely by taking appropriate steps described in the "Protection Against Risk" section 1.3 below.
2. Identification of issues of depression or suicidality: Through the survey instruments, depression or suicidality may be identified. Identification of these issues would require contacting the appropriate individuals for intervention, such as the ED provider or the health care team.
3. Identification of abuse or neglect: Home visits will occur as part of this study and abuse or neglect may be observed during a visit. We are required by state law to report this to the appropriate authorities. This may include reporting to local law enforcement or protective service agencies, resulting in legal or social risks to subjects or other members of their household. This risk is disclosed in the consent document.
4. Release of confidential information: Through the surveys and assessments and medical record reviews, confidential information will be collected. Release of identifiable information outside the study team presents a potential risk of social or psychological harm. However, the risk for this is extremely unlikely due to the procedures used to mitigate this issue that are described in the "Protection Against Risk" section and we are not collecting sensitive information about participants.
5. Referral to primary care or ED provider: Based on the findings of the study, we may refer subjects to their primary care or an ED provider. Acceptance of this referral will be dependent on the subject, but this referral may occur, leading to further evaluation of health conditions. This referral may result in added costs to the subject.
6. Incorrect delivery of the intervention: If the Care Transitions Intervention is delivered incorrectly, a result may be an increased use of ED or hospital services. That would include increased cost and a burden on subjects. Although we anticipate this risk, it is expected to be commensurate with what participants would experience outside the research study when they receive the Care Transitions Intervention as part of their care.
7. Risk of delayed medical care: With the enrollment of subjects in the ED, there is a chance that medical care could be delayed due to the enrollment process. This risk is somewhat limited due to the planned process, which includes communication with care team who will not be able to determine if the patient will be discharged home until critical medical care is complete. However, it must be monitored.

Potential Benefits

The services provided through this study may have benefits as follows:

1. Identification of unrecognized medical conditions: Through the research protocol, medical conditions not recognized by the subject may be identified. For instance, depression, medication errors, or development of acute medical problems may be identified and then receive care either through the coaching of the patient/caregiver or through notification of the patient's primary care provider / ED provider.
2. Health education: Through the coaching provided, patients may better understand their health, develop better processes to manage their health, and even experience better health.

1.2 Adverse Event, Serious Adverse, Unanticipated Problem Event Collection and Reporting

The research team will use the NIA approved definitions of adverse event (AE) and serious adverse events (SAE). These definitions are as follows:

Adverse Event

Definition: Any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

Examples of AEs for this study include:

- Stress from completion of the survey instruments
- ED visit without hospitalization or other SAE criteria (below)
    - Note: a repeat ED visit without hospital admission occurs in up to 20% of older adults who have an index visit. Given the high incidence of this event (up to 20%) and the fact that it does not meet the NIA's definition of a SAE, we are considering it an AE, not a SAE.

Serious Adverse Event

Any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

Unanticipated Problem (UP)

This is any incident, experience, or outcome that:

- Is unexpected, in terms of nature, severity, or frequency, given (a) the research procedures and (b) the characteristics of the study population;
- Is related or possibly related to participation in the research (i.e., reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Event Collection

Events for investigation will be collected through three mechanisms:

1. During research activities, any voluntary responses that identify an AE or SAE will be flagged by study staff for review.
2. During research activities, there will also be a systematic collection of AEs and SAEs. As part of the chart review at UW, we will be collecting death, hospitalizations, ED use, and health care utilization. Furthermore, through patient/caregiver surveys we will be collecting the same

information to particularly identify death, hospitalization, ED use, and health care utilization at non-UW facilities. These AEs and SAEs will be flagged by study staff for review.
3. Independent notification, such as through an unsolicited letter or telephone call, of any events that meet AE or SAE criteria will be flagged by study staff for review.

For each of these events, the staff will record a brief description of the experience, the date of onset, the date of resolution, severity, expected, relationship to study treatment, and outcome of this event. The research team will utilize the NIA approved flow sheets and forms to identify and track potential AEs and SAEs.

Events will be reviewed (within one business day of collection) to determine if they meet criteria for an AE or SAE, as well as whether the AEs/SAEs are UP. Depending on the categorization, the following review will occur (See Figure 1):

Any AE will be reviewed within 5 business days of categorization (as above):

1. The information regarding the subject will be accessed and the NIA tracking form will be completed.
2. The site PI designee (who must be a clinician with relevant expertise) will be notified to determine if the event is unexpected, related to participation in the research, or places participants at a greater risk of physical or psychological harm than was previously known or recognized.
3. If the AE is related but expected, then the PI will report the event to the Independent Safety Officer and the NIA with the monthly reports.
4. or not unexpected, then the PI will report the event to the Independent Safety Officer and the NIA with the monthly reports.
5. If the AE is unexpected, the governing IRB will be notified within 10 business days of categorization.
    a. The other site investigators will be notified promptly for report to their IRB.
6. The event will be discussed on the weekly study oversight call.

Any SAE will be reviewed within 1 business day of categorization (as above):

1. The information regarding the subject will be accessed and the NIA tracking form will be completed.
2. The site PI designee (who must be a clinician with relevant expertise) will be notified to determine if the event is unexpected, related to participation in the research and places participants at a greater risk of physical or psychological harm than was previously known or recognized.
3. The overall PI will be notified without unblinding the PI.
4. The NIA and Independent Safety Officer will be notified within 1 business day of categorization.
5. The governing IRB will be notified within 1 business day if the SAE constitutes an UP and is immediately life-threatening or severely debilitating to other participants.
6. If it is unexpected, related, or possibly related, the other study investigators and sites will be notified promptly.
7. The PI will provide a final update to the NIA and Independent Safety Officer within 14 business days of the event for all SAE cases, unless the investigation is still ongoing.
8. The event will be discussed on the weekly study oversight call.

Grading Criteria

We will utilize the NIA approved grading criteria, as indicated on the event forms including:

Severity

- 1 = Mild- Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.
- 2 = Moderate- Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning
- 3 = Severe- Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating

Study Relatedness

- 1 = Definitely related- The adverse event is clearly related to the study procedure – i.e. an event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.
- 2 = Possibly related- An adverse event that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors.
- 3 = Not related- The adverse event is clearly not related to the study procedure - i.e. another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically implausible.

Expectedness

- Unexpected - nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol, consent form, or relevant research literature.
- Expected - event is known to be associated with the intervention under study.

Event Actions

As a result of the event and the event investigation, a number of different actions may occur, including the following:

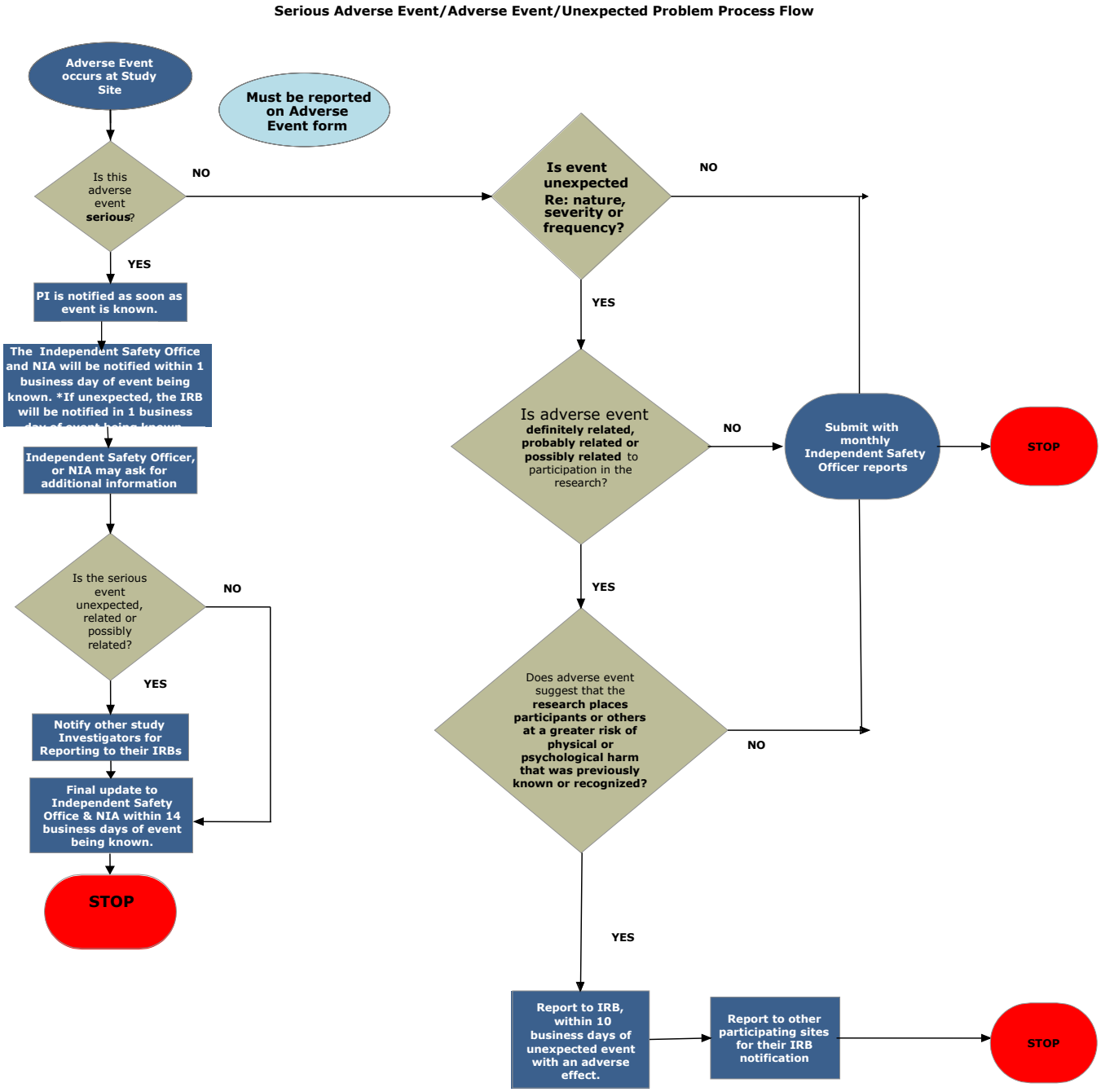
- Changes to the protocol
- Modification of consent documents
- Additional training of study staff
- Termination of the study

As these changes are occurring, the study may need to be stopped. This study will use the following stopping rule:

In the event that a SAE is unexpected and related to the research processes, new enrollment and interventions will be halted but ongoing follow up procedures will continue. This level of intervention is justified because the follow up is a brief survey of health status and satisfaction and lacks any intervention. This decision will be confirmed with the Independent Safety Officer, the UW-IRB, and the NIA.

Once the event has been investigated, then the study team, in conjunction with the Independent Safety Officer, will determine if the event actions proposed are sufficient to address the SAE that was unexpected. Once it has been sufficiently addressed and approved by the governing IRB, then the study will be restarted.

Figure 1


Serious Adverse Event/Adverse Event/Unexpected Problem Process Flow
Adverse Event occurs at Study Site
Must be reported on Adverse Event form
Is this adverse event serious?
NO
YES
PI is notified as soon as event is known.
The Independent Safety Office and NIA will be notified within 1 business day of event being known. *If unexpected, the IRB will be notified in 1 business
Independent Safety Officer, or NIA may ask for additional information
Is the serious event unexpected, related or possibly related?
NO
YES
Notify other study Investigators for Reporting to their IRBs
Final update to Independent Safety Office & NIA within 14 business days of event being known.
STOP
Is event unexpected Re: nature, severity or frequency?
NO
YES
Is adverse event definitely related, probably related or possibly related to participation in the research?
NO
Submit with monthly Independent Safety Officer reports
STOP
YES
Does adverse event suggest that the research places participants or others at a greater risk of physical or psychological harm that was previously known or recognized?
NO
YES
Report to IRB, within 10 business days of unexpected event with an adverse effect.
Report to other participating sites for their IRB notification
STOP

1.3 Protection Against Study Risks

This randomized controlled trial involves the use of data on living subjects. Maximal efforts will be employed to ensure that subjects are appropriately selected, are exposed to minimal physical, psychological, social and legal risks.

Informed Consent Process

For completion of the informed consent process, we have developed IRB-approved processes to minimize coercion and undue influence. Consent will only be performed by individuals who are listed on the IRB application and who are IRB approved and authorized to obtain consent. The process has been established to provide enough information to allow a thoughtful decision and ensure enough time to allow a considered decision. All study procedures will be standardized at both sites.

The consent process is as follows:
After a potentially eligible subject is identified and research assistant (RA) is given permission to approach the individual, the RA will then approach the patient (and their caregivers where applicable) to confirm eligibility and interest in volunteering for the study. In the privacy of the subjects' ED room the RA will explain the study, its benefits and the potential risks of participation. The ED patient will then be given the combined consent and HIPAA authorization form and allowed as much time as they need to read it and ask questions.

Additionally, in the instances where the patient would like their caregiver/family member to participate, the RA will obtain informed consent from caregivers present in the ED utilizing the same processes as used for the subject as described above.

All subjects will be given a copy of their completed informed consent. Copies of the IRB approved consent forms are included with this plan. All subjects will be reminded that they can request to be removed from the study at any time.

Protection against Risks

The following processes will be implemented to protect subjects from study risks:

Stress: The risk from the stress of the questions will be mitigated by requesting consent to ask the questions, by asking the questions at times of their choosing, and offering to terminate the screening at any point that subjects request.

Depression or Self Harm: This risk is limited as we are not enrolling patients with primary psychiatric complaints. If we identify incidental depression or self-harm issues we will contact appropriate others to intervene (e.g., the ED provider, their health care team).

Elder or child abuse or neglect: This risk is limited as we are not enrolling patients with primary abuse/neglect complaints. If either abuse or neglect is observed during the coach's' home visit, we are required by state law to and will report this to the appropriate authorities.

Release of Confidential Information: To prevent the unintentional release of confidential information for any of the human subjects included in the research study, all data will be stored in locked offices. All electronic data will be stored on secure networked computers / networked drives, as per policy. Only investigators and research staff directly involved in the project will be given access. All identifiers will be stripped from the database at the earliest possible time. For patient data, identifiers will be eliminated

upon completion of follow up and data abstraction.

Referral to PCP or ED: There is no way to prevent this risk, as this is the hypothesized outcome of the study and it is very common (up to 20%) currently without the program being tested. One could further argue that this is a benefit. If needed from a clinical standpoint, the subject may be referred to their PCP or an ED. It will be up to the subject to decide if they wish to act upon this referral.

2.0 INTERIM ANALYSIS

No interim analysis of the study was proposed in the original funded grant proposal to consider this study for early termination, and thus no interim analysis is planned for this protocol. Furthermore, to achieve the final aim of the funded proposal the full sample size is needed. Early termination would limit our ability to achieve that aim.

3.0 DATA AND SAFETY MONITORING

3.1 Frequency of Data and Safety Monitoring

This data safety and monitoring plan is commensurate with the risks as well as the size and complexity of the study. This plan outlines the appropriate oversight and monitoring of the conduct and progress of the study to ensure that important information that may affect the safety and welfare of subjects is collected, recognized, and acted upon quickly while still ensuring the validity and integrity of the data. This monitoring plan includes structured adverse event (AE) and serious adverse event (SAE) determination, monitoring and reporting systems with standardized protocols and forms for referring and/or treating study participants who experience adverse events. AEs will be reported to the NIA Program Officer and the Independent Safety Monitor. UP will be reported to the reviewing IRB in accordance with its reporting policies.

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. The Independent Safety Officer will act in an advisory capacity to the NIA to monitor participant safety, data collection and evaluate the progress of the study.

Section 1.2 includes the full details of AE and SAE collection and action.

From a quantitative standpoint, the following will occur:

1. A **monthly** report to the Independent Safety Officer and to the NIA Project officer will be sent for review to further monitor subject safety. This will include monthly and cumulative data to identify trends in the events between the intervention and control groups.
2. A cumulative data and safety monitoring annual report will be sent to the Independent Safety Officer, the NIA Project officer, and reviewing IRBs (at the time of continuing review).

3.2 Content of Data and Safety Monitoring Report

The monthly Data and Safety Monitoring Report will summarize the safety metrics described in this plan. Specifically, by site it will include the number of subjects enrolled, randomized, active, completed, and discontinued from the study. Furthermore, it will include the events, the grading, the determination (related to research procedures), and the outcome.

Templates of this report are provided.

3.3 Independent Safety Officer Membership and Affiliation

The following individual has accepted the position of Independent Safety Officer for this protocol pending review and approval by the NIA. Should there be any questions regarding the independence of the Independent Safety Officer it will be addressed and corrected if necessary at that time.

We are proposing either of the two individuals listed below to act as the Independent Safety Officer who will conduct these reviews is listed below. Neither Dr. Adit Ginde nor Dr. Raj Shah have any direct involvement with the study, investigators or intervention. Their detailed CVs/biosketches are included with this submission.

Name: **Adit Arun Ginde, M.D., M.P.H.**
Title: Associate Professor of Emergency Medicine
Organization: University of Colorado School of Medicine
Department of Emergency Medicine
12401 E. 17th Avenue, B215
Aurora, CO 80045
Telephone: (720) 848-6777
Email: adit.ginde@ucdenver.edu

3.4 Conflict of Interest for Independent Safety Officer's

The Independent Safety Officer will adhere to the NIH Conflict of interest reporting requirements. The Independent Safety Officer will have no direct involvement with the study investigators or intervention. The Independent Safety Officer will sign a Conflict of Interest (COI) Statement which includes current affiliations and any other relationship that could be perceived as a conflict of interest related to the study and / or associated with commercial interests pertinent to study objectives. He will complete this COI annually.

This COI report will be submitted to the NIA project officer in the annual report. The approved NIA COI statement will be used.

3.5 Protection of Confidentiality

All subject reports and subsequent discussions are confidential. Only investigators and research staff directly involved with the project will have access to identifiable subject information.

All data reports will be presented in a blinded manner to the Independent Safety Officer to assure protection of confidentiality for all participating subjects. At no time will the Independent Safety Officer know the identity of any study subjects.

3.6 Independent Safety Officer Responsibilities

The Independent Safety Officer responsibilities include:

1. Review the plans for data safety and monitoring
2. Recommend subject recruitment be initiated after receipt of a satisfactory protocol
3. Review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator.
4. Help ensure the safety of the study participants through data monitoring and advising the study team;
5. Report to NIA on the safety and progress of the trial
6. Make recommendations to the NIA Project Officer and the Principal Investigator concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study.

Templates for Reports

Table 1: Participant Enrollment Status by Site

Data as of:_____

Date of report:_____

Site:_____

	N	%
Enrolled		100
Active		
Completed		
Discontinued from Study		100
Lost to follow- up		
SAE/AE/UP		
Withdrew Consent		
Other		

Table 2: Incidence of Adverse Events

Data as of:_____

Date of report:_____

Intervention Group

Outcome	Total N=n*	Total N=Events***	Total N= (%)**
Overall			
ED Re-admission			
Hospitalization			
Death			
Other			

Control Group

Outcome	Total N=n*	Total N=Events***	Total N= (%)**
Overall			
ED Re-admission			
Hospitalization			
Death			
Other			

Table 3: Severity of Adverse Events

Data as of:_____

Date of report:_____

Intervention Group

Preferred Term*	Total N=Mild n** (%)***	Total N=Moderate n (%)	Total N=Severe n (%)
Overall			
ED Re-admission			
Other			

Control Group

Preferred Term*	Total N=Mild n** (%)***	Total N=Moderate n (%)	Total N=Severe n (%)
Overall			
ED Re-admission			
Other			

Listing 1: Serious Adverse Events by Site

Data as of:_____

Date of report:_____

Intervention Group

Site	Participant ID	Onset Date	Stop Date	Expected (Y/N)	Relationship to Intervention*	Outcome**	Description of SAE

* *Definite, Possible, Not Related*

** *Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present – no treatment
Residual effect(s) present- being treated
Subject died

Control Group

Site	Participant ID	Onset Date	Stop Date	Expected (Y/N)	Relationship to Intervention*	Outcome**	Description of SAE

* *Definite, Possible, Not Related*

** *Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present – no treatment
Residual effect(s) present- being treated
Subject died