IMAGE Protocol

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I. Study Overview:

A. Summary: This is an Implementation/Effectiveness hybrid study, where Aim 1 evaluates the implementation process and Aim 2 evaluates the effectiveness of a clinical protocol. The protocol in this study is a two step protocol to identify and manage geriatric syndromes in the Emergency Department (ED). Step 1 is nurse screening for geriatric syndromes using three previously validated tools: the Brief Delirium Triage Screen (Delirium screen), the 4 Stage Balance Test (4SBT), and the Identifying Seniors at Risk score (ISAR). Step 2 is management of patients who screen positive either by admission to the hospital or further investigation and treatment in the ED Observation Unit (Obs Unit).

For Aim 1, Implementation, the process will be evaluated qualitatively and quantitatively. Data will be collected on the actions and perceptions of hospital staff. The implementation procedures done will follow Lean Six Sigma processes, which is the standard implementation process of our hospital system. We will also monitor the implementation process using aggregate quality data from the ED, currently already collected monthly as part of QI measures. *No identifying information on staff will be collected as part of the study.*

Table 1: Study specific abbreviations and definitions.

4SBT	4 Stage Balance Test. A fall risk assessment
DMAIC	Define, Measure, Analyze, Improve, Control. Part of the Lean Six Sigma methodology.
CFIR	Consolidated Framework for Implementation Research (CFIR)
ED/EM	Emergency Department/ Medicine
EMR	Electronic Medical Record
HRQoL	Health Related Quality of Life
ISAR	Identifying Seniors at Risk Score
OARS	Older Americans' Resources and Services Activities of Daily Living questionnaire.
Obs Unit	Emergency Department Observation Unit
PROMIS	Patient Report Outcomes Measurement Information System- a HRQoL scale.
PT	Physical therapy or therapist
QI	Quality improvement
Sustainability Survey	Measurement Instrument for Sustainability of Changed Work Practices

For Aim 2, Effectiveness, data will be collected prospectively from patient participants in before and after cohorts.

B. Intervention: The two-step intervention will begin with the patient's primary ED nurse screening for geriatric syndromes. The ED physician will then determine if multidisciplinary intervention is needed and the appropriate level of care (eg, dementia may cause a positive delirium screen, but may not require evaluation if cognitive status is at baseline). Patients requiring multidisciplinary assessment will be either admitted or assigned to the Obs Unit for geriatric assessments based on standard care of their medical problems. These assessments are in addition to usual care for the patient's underlying medical complaint. Geriatric consultation involves evaluation by the hospital's geriatric consultation team: a board certified geriatrician, a geriatric nurse practitioner, and fellows. PT assessments are done by hospital PTs. Medication reviews are completed by ED pharmacists and include confirmation of medication list and dosages and assessment of possible medication interactions or potentially

inappropriate medications using standard criteria.[1] The case management team includes nurse case managers and licensed social workers.

This intervention is already in place, however currently only 5% of older adults in the ED are receiving the screening and only 11% are placed in the Obs Unit for further assessment. Based on data from other institutions, this is likely an underutilized service and we are missing many older adults with acute needs. The goal of implementation is to increase nurse screening to >80% and protocol compliance to >80%.

C. Rationale for study: The data collected for Aim 1 is partly from our baseline ED metrics but also data collected as a result of our accreditation as a Level 1 Geriatric ED. As part of that process, we have to track dispositions, 72 hour return rates, morbidity and mortality reports, readmissions, and geriatric screening rates. This is current monthly report. Additionally, we have to do chart reviews to assess compliance to our geriatric quality protocols. The intervention in question is included as part of our geriatric protocols. This intervention is not "new", it has been ongoing since 2015. However, a formal implementation process is needed as education and accreditation have not been able to increase our screening and compliance rates above 5%. For this reason, Dr. Southerland took 80 hr of Lean Six Sigma Green Belt training in 2017-2018.

The research in this study that would not be done normally as part of normal QI at OSU is Aim 2, evaluating the effectiveness of the protocol. Aim 2 will involve recruiting and consenting patients for prospective analysis to determine the impact of the protocol on patient centered outcomes.

Table 2: Study Timeline

Months	Study Phase	Aim 1: Implementation	Aim 2: Effectiveness
0-3	**Startup**	- Lean team training	Enrollment preparation
3-15	**Baseline**	- Work flow analyses	- Enroll for baseline cohort (n=150)
16-32	**Preparation/ Implement-ation**	- Process data collection and Implementation surveys. Lean Six Sigma rapid process improvement	- Follow up and baseline data analysis
33-56	**Maintenance/ Sustainability**	- Continue process data collection - Withdrawal of implementation strategies; Sustainability survey at months 44 and 56.	-Enroll post implemen-tation cohort (n=230) - Data collection and analysis

II. Aim 1 Protocols

A. Specific Aim: Develop, implement, and sustain a two-step intervention providing ED geriatric assessments by combining 1) ED nurse-based screening for geriatric syndromes of all older ED patients with 2) multidisciplinary geriatric assessment in an ED Obs Unit. We will use mixed-methods approaches and the CFIR framework to identify resource, organizational, patient, staff, and administrative factors that affect protocol adherence.[2-4] We will use Lean Six Sigma processes to overcome barriers. We will track effects of the protocol in reference to ED quality metrics, staff work flow, and work culture.

Hypothesis 1a: Implementation: Lean Six Sigma processes will i) increase ED nurse-based screening rates to >80% older adults in the ED and ii) increase protocol fidelity in the Obs Unit to >80%.

Hypothesis 1b: Sustainability: After 6 months of >80% screening, we will characterize the necessary elements for sustainability by systematically withdrawing implementation support strategies. We hypothesize that attention to CFIR elements during implementation will result in routinization and institutionalization that does not significantly decrease with withdrawal or time, as assessed by sustainability surveys.[5]

B. Subjects: ***Aim 1*** will include analysis of aggregate ED EMR data on ED patients ≥65 overall (1a) and in the ED obs unit (1b). ED staff and Lean team members are also study subjects for **Aim 1**. All ED and obs unit physicians, midlevel providers, nurses, pharmacists, and involved consultants/stakeholders are eligible, yielding an estimated 260 people. While staff participation in the implementation process and surveys is voluntary, participation in the education and protocol is mandatory.

C. Data Collection: 1) Monthly **aggregate EMR data** on all ED patients is collected as part of general quality measures. This includes: Obs Unit census, patient demographics, geriatric screening results, consultation rates for the multidisciplinary geriatric services, and dispositions from the ED. 2) **Staff Surveys** will be sent electronically using REDCap (Vanderbilt University, TN).[6,7] There will be at least 2 types of staff surveys: the Implementation survey in Preparation and Implementation phases and the Sustainability scale survey. 3) **Observational data**: Trained observers will perform work flow analyses per usual practice.[8] The first workflow analysis has already been done and was determined to be IRB exempt as it is a standard QI analysis done for QI purposes.

The only time that identifiable staff information will be used for research purposes will be using staff emails to send out surveys. In keeping with prior practices, all surveys sent to nursing staff will be approved by nursing leadership in addition to the IRB. Individual respondents' emails will be used to allow for paired comparison of survey responses for the sustainability survey at 12 and 24months after implementation. Otherwise all survey information will be aggregated without identifiers. Survey completion is voluntary and will not affect their work opportunities or be reported to their supervisors. Similarly, staff who are observed during workflow analyses will not have their names reported, but instead will be listed as RN-A1, RN-A2, tech-A1, etc.

D. Aim 1 Timeline/ Methods:

F.7.i: *Preparation* (3 months): Mirroring the normal process at our site, we will convene a Lean implementation team including: study PI, Obs Nurse Champion, ED Nurse Educator, and representatives from pharmacy, safety, geriatrics, case management, and informatics. All personnel have prior Lean training/experience or will receive training. Standard Lean processes will be followed, such as use of a Gantt chart for task management. The Lean team will review current data and identify barriers to implementation. A staff survey (Implementation Survey) will identify beliefs and domains for improvement. Based on prior studies using the CFIR,[2,4] domains of interest will be: 1) beliefs about capabilities, 2) professional role/identity; 3) barriers/facilitators to screening; 4) attitudes; and 5) social influences. Education will consist of 2 hours of nurse training, led by our ED nurse educator (Peg Gulker)

who has Geriatric Emergency Nurse Education (GENE) certification.[9] Select nurse champions who self-identify as interested in assisting with the process will also complete the GENE course and/or online modules (Geri-EM.com).

F.7.ii: *Implementation (12 months):* We will use the Lean Six Sigma DMAIC process (Define, Measure, Analyze, Improve, and Control) and rapid cycles of process improvement. Key enablers and barriers will be identified from the data obtained during Preparation. Team workshops will be used to generate solutions. These generated solutions are tested and results measured using aggregate EMR reports. These reports are summarized in the form of A3 sheets, tracked, and discussed during weekly team meetings, which can generate additional issues and new improvement cycles. At 6 months into this process, the Implementation Survey will be re-administered to assess changes and identify further areas of focus. The implementation team will also assess the added burden to staff and look for any adverse outcomes on ED metrics, such as ED length of stay and admission rates.

F.7.iii: *Maintenance and Sustainability (32 months)*: Maintenance*:* After the goals of >80% screening rate with > 80% protocol fidelity is achieved for 6 months, implementation will be considered successful. The Control/Maintenance phase of the DMAIC process begin. All new nurses and staff will receive the geriatric training. Existing staff will have annual training to review and reinforce their geriatric knowledge. The Lean team will continue to meet monthly, but rapid cycle process improvement will halt unless concerning trends are noted. Sustainability*:* At 12 and 24 months after Maintenance phase initiation, we will assess the degree of routinization and institutionalization among all 180 ED nurses via a Sustainability survey (estimated response rate 70%).[5] Implementation support will be withdrawn in a stepwise fashion in 3 month blocks. For example, fidelity audits may be decreased from weekly to monthly to semi-annually. If concerning trends are noted in the monthly aggregate EMR data, these processes will be reinstated and the Lean team will be reconvened. Per STARI guidelines,[10] we will monitor for any contextual changes that occur during this time that may affect results and any adaptations to the protocol. Reporting continued maintenance of a program as the only measure of sustainability is insufficient, as program adaptation may also signal further benefits or sustained improvement.[11]

III. Aim 2 Protocol

A. Specific Aim: To reduce the decline in functional status and health related quality of life (HRQoL) commonly seen after older adults experience an ED visit**.**[12-14] We will recruit cohorts pre and post implementation.

Hypothesis 2a: The intervention will reduce the decline in functional status seen after ED visits. Secondary outcomes include health-related quality of life, ED revisits, and results of the multidisciplinary assessments.

Hypothesis 2b: Patients will be satisfied with the protocol as assessed by thematic analysis of qualitative subject interviews of intervention patients.

B. Participant Selection: Adults ≥65 years assigned to the Obs Unit at the discretion of the treating physician will be enrolled **(n=380)**. Patients may be in Obs as part of an Obs protocol (e.g., chest pain) or in response to a positive geriatric screening test. Patients with delirium or dementia will be enrolled with an LAR and patient assent. Exclusion criteria are need for inpatient care, non-English speaking, acute psychiatric issues, prisoners, unable to follow-up, or unable to consent and no LAR.

Study personnel will monitor the Obs Unit electronic tracking board (7am-11pm M-F and select weekends) to identify and recruit 380 patients (150 pre and 230 post cohorts).

C. Data Collection: A survey and chart review will be completed during the Obs stay (Table 3). Follow up phone interviews will occur at days 30±3 and 90±5. In simulations with research staff, survey completion required 8-10 minutes of patient time. Patient data will be collected in REDCap, which has built in scoring tools for PROMIS measures. Chart abstraction will be done by research coordinators and will use standard methods (including training of abstractors, standardized forms, code book, etc).[15]

Data collection definitions:

OARS:[16] (Primary Outcome) An assessment of activities of daily living (functional status) commonly used in ED studies. We will obtain 4 timepoints: Premorbid (patient report of function 1 week prior to ED visit), at the ED visit (day 0), and at days 30 and 90. A change of ≥3 points or death between is a significant decline.[12,17]

HRQoL: The Patient Reported Outcomes Measurement information System (PROMIS) is endorsed by the NIH and PCORI. We will use the Global Health v1.2 (10 questions). A 3 point change is clinically meaningful.[18]

New services: Number of new or increased outpatient services (e.g., home health therapies, referral for community interventions, equipment).

New geriatric syndrome[19] diagnoses of delirium, impaired cognition, fall risk, or elder mistreatment.

Geriatric clinic referral: Referrals to the Falls Prevention, Polypharmacy, or Geriatrics Clinic.

Pharmacist recommendations: Number of medication related problems/interactions.[1,20]

Positive geriatric interventions: ≥1 of: new services, diagnoses, referrals, or pharmacist recs.

ED revisits and hospitalizations: Any ED revisits or unscheduled hospitalizations within 90 days.[21]

Patient satisfaction: interview data with themes of positive patient outcomes or satisfaction.

Table3: Patient level data collected for Aim 2.

	Chart review	Patient interview
Day 0	- Demographics and zip code - Charlson Comorbidity Index - Observation protocol - Geriatric screening scores - Geriatric assessments - New geriatric syndromes - Geriatric clinic referrals - Medication recommendations - New services - Disposition and length of stay	- OARS and HRQoL - Current level of care - Falls in the past month - Current home health and community resources - (subset) semi-structured interviews.
Days 30, 90	- Clinic referrals and follow-up - ED revisits and	- OARS and HRQoL - Current level of care

	hospitalizations	- Falls since last contact - Home health and community resources used

Qualitative data: At least 20 patients in the post cohort will be selected for semi-structured interviews. Interviews will be led by a trained researcher coordinator. Purposeful sampling will be used to provide a mix of genders, ages, and Obs Unit dispositions. To assess patient satisfaction, (Aim 2b), a trained researcher will conduct in-person, semi-structured interviews with intervention patients. In addition to Likert-type questions, we will solicit brief descriptions of clinical exemplars of how this intervention produced a positive patient outcome. See interview guide. Maximum variation/ heterogeneous purposive sampling will provide a mix of genders, ages, and observation dispositions. This interview will add an additional 20 minutes to the patient's participation time, and so we expect that some participants may decline this portion. With 230 patients in the post implementation cohort, we should have sufficient volume to get at least 20 patients to participate in the qualitative data collection.

D. Follow up: The participants will be followed for 90±5 days. The follow up interviews will be done over the phone. If the participant prefers, these can be scheduled by email to allow them to choose an appropriate and easy time. Email reminders can also be sent if the participant prefers that communication strategy. LAR or caregivers are invited to be present at during the follow up calls. If the participant and the LAR/caregiver give antithetical answers to a question, both answers will be recorded to track how often this occurs, but only the LAR's answers will be used for the final analysis. All participants will be mailed a Thank you Card from the PI for participating at the end of study enrollment.

IV. Data Analysis

A. Aim 1a outcome definition: **Screening rate** is defined as the percentage of ED patients ≥ 65 years old who have documentation *of all 3 screens* (4SBT, ISAR, Delirium). **Protocol Fidelity** is the percentage of screen positive patients in the Obs Unit who receive *all appropriate consultations* as noted on EMR data. Secondary outcomes include the number of cycles required to reach 80% screening, any protocol adaptions, and fidelity to Lean methods. Fidelity to Lean will be measured by (1) Lean documents, (2) completion of ≥2 rapid improvement cycles, and (3) representation from both leadership and frontline employees at meetings.

Aim 1b outcome definition: We will characterize the necessary elements to maintain screening rates >80%. We will use X-bar and R-charts to evaluate for special process variation as we withdraw implementation support. Any support withdrawal that leads to significant decrease in screening rates will be considered necessary and the Lean team will address the problem. For sustainability, we will summarize and report the mean total and subsection scores at each timepoint. The main outcome is the change in scores over time. Secondarily, any mean subscores < 3.0 on the Sustainability Survey will be considered areas of weakness in the protocol and reported as possible threats to sustainability.[22]

Analysis: Monthly summary statistics on geriatric patient visits, screening and consultation will be recorded. For **Hypotheses 1a.i and1a.ii** (*Implementation*) we will calculate the proportions for screening rate and protocol fidelity with 95% CIs monthly using aggregate data. Success is predefined as a point estimate >80% for each outcome for 6 months. The Staff Implementation Surveys (both pre- and post-implementation) will be thematically analyzed used Atlas.ti (Cleverbridge, Inc, Chicago, IL) a qualitative data analysis program, and categorized within the CFIR framework. This data will be used to further the implementation process. Additional assessments of implementation will include: the number of improvement cycles, generated solutions and protocol adaptations, and Lean fidelity. Lean fidelity will be assessed as a yes/no variable at conclusion of implementation. For **Hypothesis 1b**, (*Sustainability*) we will compare the total mean scores (primary outcome) between the 2 years taking into account linked responses by the same nurses in both years using a mixed model. We will compare individuals' scores over time using a paired t-test or Sign Rank test.

B. Aim 2: Participant representativeness will be assessed by comparison to demographics of all ED patients. The *primary outcome* for Aim 2a is the proportion of patients in the pre and post cohort with a significant (≥3 point) decline in Functional Status (OARS) from day 0 to day 90. We will compare proportions with decline in the pre- and post-group using a Chi-square test (primary analysis). Also, logistic regression modeling will be used to compare the functional decline between the pre and post intervention groups univariately and while controlling for initial ED HRQoL, demographic factors (age, race, average socioeconomic status from zip code census tract), Charlson Comorbidity Index score,[23] number of services used and any other significant factors varying between the two cohorts. The total number of covariates will not exceed 12, given we estimate 122 subjects with functional decline. A similar secondary analysis will be done using the 30 day timepoint data.

Secondary outcomes for 2a: Dichotomous secondary outcomes will be analyzed using proportions and chi-square tests between pre- and post-intervention groups and with exploratory logistic regression models. Count data will be explored using either Poisson or negative binomial regression. *Exploratory analyses* will use similar methods to compare the pre-intervention group to the post- subgroup who received all 3 screens.

F.12.ii *For Aim 2b*, interviews will be transcribed verbatim and entered into Atlas.ti. We will conduct manifest content analysis of the descriptions using phrases and sentences as our unit of analysis.[24,25] We will categorize the exemplars and analyze for appropriateness and perceived outcomes based on the level of detail provided. Analysis will include open and axial coding procedures using techniques of constant comparison and questioning within and across cases.[26,27] The coding schema will be created with consensus on coding definitions and grouping codes into code families/categories. Dual coding with negotiated consensus will be performed on 20% of the data to add rigor to the analysis. Themes will be reported per current guidelines.[28,29]

V. References

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