STUDY PROTOCOL

Screening instruments to predict adverse outcomes for undifferentiated older adults attending the emergency department: Protocol for a prospective cohort study [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background: The number of older adults with complex medical comorbidities and functional impairment is increasing throughout the world. Frail older adults frequently attend the Emergency Department (ED) and are at increased risk of adverse outcomes following presentation. A number of screening tools exist that aim to screen older adults for frailty and identify those at risk of functional decline, unscheduled readmission, institutionalisation and mortality. We propose to determine the predictive accuracy of four commonly used screening tools, namely the Identification of Seniors at Risk Screening (ISAR), Clinical Frailty Scale (CFS), Program of Research to Integrate Services for the Maintenance of Autonomy (PRISMA 7) and InterRAI ED, to determine adverse events at 30 days and six months among older adults who present to the ED.

Methods and analysis: This is a prospective cohort study where patients over the age of 65 will have four screening tools (ISAR, CFS, PRISMA 7, InterRAI ED) performed by face-to-face interview with a research nurse during their index visit to one Irish ED. Older adults will be included if they are willing and able to provide written informed consent, have a Manchester Triage Category 2-5 and are resident in the hospital catchment area. Demographic information will be collected at the index visit. A telephone follow up will occur at 30 days and six months, completed by a research nurse who is blinded to the initial assessment. Outcome data will include mortality rates, ED
re-attendance, hospital readmission, functional decline and institutionalisation. We will analyse the risk of adverse outcomes using multivariable logistic regression and we will report adjusted risk ratios (RR) with 95% CI.

**Dissemination:** Study findings will be disseminated through publication in peer-reviewed journals and presentations at relevant academic and clinical conferences. National and International gerontology conferences will be targeted.

**Keywords**
Frailty, Emergency Department, Screening Tools, Older Patients

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Introduction

The number of people over the age of 60 is predicted to double by 2050 as per the World Health Organisation (United Nations, Department of Economic and Social Affairs, Population Division, 2019). The rise in an older population will increase pressures on an already overcrowded ED system. Older adults are frequent attenders in the ED and have increased 30-day mortality compared with their younger counterparts (Shen et al., 2015). A recent systematic review by Morley et al. (2018) explored the causes and consequences of, and solutions to, ED crowding. They found that the presentation of older adults with urgent and complex needs are one key causal factor of ED overcrowding. Early physician assessment was associated with decreased length of stay in the ED. It is difficult to resource an ED with early physician assessment for all ED attendees, particularly in departments with long waiting times for assessment (Morley et al., 2018). It is necessary to target these resource intensive assessments to those at most risk of adverse outcomes. Frailty identification may provide an efficient and effective means to highlight older adults most likely to benefit from urgent ED physician assessment.

Frailty is a common condition affecting community dwelling adults over the age of 65 (Roe et al., 2017). Frail older people are at increased risk of adverse outcomes including mortality and institutionalisation (Fried et al., 2001; Rockwood & Mitnitski, 2007). Frail older patients are at greater risk of presenting to ED, having longer length of stay in hospital, and have a higher rate of adverse outcomes following hospital attendance (Hoeck et al., 2012; Roe et al., 2017; Rochat et al., 2010). Ellis et al. (2011) have shown the benefits of comprehensive geriatric assessment in this population with patients more likely to be alive and in their own homes after this intervention. Healthcare organisations should target this resource-intensive intervention at older frail patients who have been identified at the highest risk of future adverse events. Frailty screening tools are one such method to identify those who are frail and require more robust and detailed assessment which may not be routinely performed in the busy ED setting. There has been a number of observational studies validating various frailty screening tools. A recent systematic review by Jørgensen & Brabrand (2017) including four studies on older people in the ED examined the predictive accuracy of the CFS, Deficit Accumulation Index, ISAR and The Study of Osteoporotic Fracture frailty index. These screening tools used did not accurately predict those who were at risk of ED re-attendance at 30 days Jørgensen & Brabrand (2017). Lewis et al. (2019) have reviewed the Fried, CFS and SUHB (Stable, Unstable, Help to walk, Bedbound) Scales in an older population who presented to ED in Australia. These tools predicted future adverse outcomes for patients (death, poor self-reported health and quality of life, requirement for community services post discharge and readmittance to ED) although each tool identified a different prevalence of frailty (Lewis et al., 2019). O’Caomhín et al. (2019) completed a cross-sectional study comparing the diagnostic accuracy of the CFS, ISAR and PRISMA-7 frailty screening tools in the ED setting when compared to comprehensive geriatric assessment. They found that the area under the ROC curve (AUC) ranged from 0.78 for ISAR to 0.88 for Prisma 7. However, there has been no study which longitudinally investigates commonly used frailty screening tools in the Irish ED population. We propose to assess the predictive accuracy of four screening tools which are in use in the Irish healthcare setting to predict adverse outcomes in older adults at 30 days and six months; the CFS, ISAR, PRISMA 7 and InterRAI ED.

Methods

Study design

This is a prospective cohort study which will adhere to the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) standardised reporting guidelines to ensure the standardised conduct and reporting of this research (Von Elm et al., 2007). Data collection and follow-up will take place during the period of September 2019 to November 2020 (inclusive). Data will be entered on Excel Version (2016). The hard copies of the questionnaires and consent forms will be kept in a locked cabinet in a building and office requiring swipe card access.

Ethics

Ethical approval for the study has been granted by the Research Ethics Committee, Quality and Safety Department, University of Limerick Hospital Group (Ref. 062/19). Written informed consent will be obtained from all participants prior to recruitment to the study, in line with the Data Protection Act 2018 (Section 36(2)) (Health Research Board, 2018) Regulations 2018.

Setting

The study will take place at the ED of the University Hospital Limerick (UHL). UHL is a Model 4 university teaching hospital which caters for the general medical, surgical, and emergency treatment of patients in the catchment areas of Limerick, Clare and North Tipperary. Model 4 hospitals have a 24/7 ED which functions 365 days a year and are tertiary referral centres for the relevant region. UHL has 438 inpatient beds and serves a population of approximately 400,000 people.

Population of interest

All adults aged ≥65 years who present to the ED at UHL between September 2019 and April 2020 (inclusive) will be considered eligible for participation in the study provided that they meet the following criteria:

Inclusion criteria. We will include patients over the age of 65 who have a Manchester Triage Category of 2 to 5 (Mackway-Jones, 1997). They must have capacity and willingness to provide written informed consent to take part in the study. We will obtain consent from a nominated carer or next of kin for those with a suspected or documented cognitive impairment. This assessment may be recorded in the patients chart or otherwise will be performed with the baseline Montreal Cognitive Assessment (MOCA) by the research nurse (Nasreddine et al., 2005). They must be a resident in the hospital catchment area and not enrolled in other related studies.

Exclusion criteria. Patients will be excluded if neither the patient nor the carer can communicate in English sufficiently to
complete consent or baseline assessment. Patients will be excluded if they present outside of research nurse (RN) operational hours. Similar to other studies, the RN is operational between the hours of 8am and 5pm Monday - Friday. Therefore, individuals who present to the ED and are discharged outside of these hours will not be included in the study. Patients who are acutely unwell and unable to answer the questionnaire will also be excluded.

Index visit to the ED
The RN will complete a baseline demographic questionnaire which will include age, sex, and socioeconomic status. Baseline comorbidities will be obtained as part of the Charlson Comorbidity Index which is a 21-item condition checklist (Charlson et al., 1994). Functional status will be documented in the form of the Barthel Index which is a 10-item questionnaire relating to functional ability (Mahoney & Barthel, 1965).

Frailty screening tools
Four frailty screening tools will be administered at the index visit.

**CFS.** The CFS was developed by Rockwood in Dalhousie and classifies patients on a scale from robust to severely frail as assessed by the healthcare professional (Rockwood et al., 2005). It is one of the most widely used frailty screening scales. It was initially a seven-point scale which was revised to a nine-point scale in 2007. The nine-point scale will be administered in our study.

**PRISMA-7.** The PRISMA 7 consists of seven questions which are completed by the patient or a family member. A score of 3 or more indicates frailty (Raîche et al., 2008). It is a common screening tool that is recommended by the British Geriatric Society and Asia-Pacific Clinical Practice Guidelines for the Management of Frailty (Dent et al., 2017).

**InterRAI ED.** The InterRAI ED is a standardised clinical data assessment tool which is performed electronically based on the InterRAI Care Systems. It assesses the patient with regard to their cognitive, psychological, and physical function prior to admission with particular emphasis placed on falls, dyspnoea, and pain (Gray et al., 2013).

**ISAR.** The ISAR is a six-question screening tool which is completed by the patient or a family member. A cut-off of more than 2 identifies those at higher risk of adverse outcomes. (McCusker et al. (1999)). A recent systematic review found that this tool had a modest predictive accuracy at predicting ED return and emergency hospitalisation at six months following the index visit (Galvin et al., 2017).

Follow-up assessment
Follow up telephone interviews at 30 days and six months will be completed by the RN who will be blinded to the baseline assessment. All withdrawals will be reported. Participants will be asked via telephone to complete a follow up questionnaire (see Extended data) (Leahy et al. (2020)) including the Barthel Index and healthcare utilisation (GP visits, home care support, public health nurse visit, allied health use etc). Hospital admission, ED re-presentation will be ascertained from the hospital database. Deaths and admission to nursing home will be documented.

Sample size
When considering sample size for logistic regression, a recommended rule of thumb is n = 100+50i, where i is the number of predictor variables in the final logistic regression model (Bujang et al. (2018)). Therefore, a sample size of at least 400 is necessary, based on the number of independent variables to be included in the model.

Statistical analyses
Descriptive statistics will be used to describe the baseline characteristics of the cohort. These will include proportions, percentages, ranges, means and standard deviations and medians and interquartile ranges (where data are not normally distributed). We will analyse risk of adverse outcomes using multivariable logistic regression and we will report adjusted risk ratios (RR) with 95% CI. SPSS Software Version 26 and R Software will be used in the analysis.

Dissemination
Study findings will be disseminated through publication in peer-reviewed journals and presentations at relevant academic and clinical conferences. National and International gerontology conferences will be targeted. Lay findings will be disseminated via our recently established PPI group (Conneely et al., 2020). Anonymised data will be available in a data repository to enable accessibility.

Study status
Data collection and follow-up is ongoing. Study completion is expected in October 2021.

**Discussion**
Older patients are at higher risk of adverse outcomes after presentation / admission to the ED. It is necessary to streamline services to ensure that older patients most at need obtain comprehensive geriatric assessment in a timely fashion. Therefore, it is essential that a quick but accurate screening process is available to stratify these patients and predict those who are at greater risk of adverse outcomes.

We propose a prospective cohort study to determine the predictive accuracy of four frailty screening tools, the CFS, ISAR, PRISMA-7 and Inter-Rai ED, which are already commonly used in the Irish healthcare setting. These tools need to be feasible for non-specialists to complete rapidly in a busy, time restrained ED environment.

The major strength of this study is its prospective and longitudinal nature. It focuses on an area of key importance to health service provision for older people and will inform healthcare planning. The outcome measures for the study will include future adverse events (death, rehospitalisation, falls, institutionalisation). These are of key importance to patients and healthcare organisations. Data on adverse outcomes will be directly
identified by an RN via telephone conversation with the patient or next of kin or from hospital records. The RN will be blinded to the initial frailty screening tool results when identifying the outcome measures. All frailty screening will be carried out during the same assessment period so that a change in the status of the patient is not likely. Limitations of the study also need to be acknowledged. While the study participants are representative of the general ED older adult population, subgroups including those with acute confusion, dementia and the critically unwell were excluded. Furthermore, the population are recruited during weekday operational hours. Finally, the RN has experience in frailty screening so the screening process may not be entirely reflective of an ED nurse population.

Data availability

Underlying data

No underlying data are associated with this article.

Extended data

Open Science Framework: SOAED- Screening instruments to predict adverse outcomes for undifferentiated older adults attending the emergency department. https://doi.org/10.17605/OSF.IO/XR3S6 (Leahy et al. 2020).

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

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Von Elm E, Altman DG, Egger M, et al.: The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Ann Intern Med. 2007; 147(8): 573-577. Published Abstract | Publisher Full Text
This is a clearly written protocol for a prospective cohort study aiming to compare 4 frailty identification tools (ISAR, CFS, PRISMA 7 and interRAI ED) in patients over the age of 65 attending an Irish ED.

The design is feasible and the information obtained could provide fresh insights as to which one adds more value in the local context to predict clinically relevant outcomes for the older person.

Consequently, results could inform local quality improvement processes and inspire others to do the same.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Geriatrics, Gerontology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
Abstract
You might consider changing the sequence of the 3 selection criteria to place “willing and able to provide written informed consent” last. Placed first seems to make this the major criterion!

“Outcome data will include mortality rates, ...” This does not seem to match the previous sentence (on the nurse's interview), nor the remainder of the sentence which seems to cover the content of the nurse's interview. Mortality rates are evidently calculated after all of the data are assembled. Alternatively you could say “outcome data will include rates of mortality, ED re-attendance, ...”. But if you are describing the coverage of the nurse interview, you might consider placing morality last in the list of variables to be collected and not mention rates.

Introduction
Parag 1, 3rd sentence: the mention here of increased 30-day mortality is not relevant to the theme of this paragraph (crowded EDs), but it would fit nicely in the second paragraph. Consider moving.

Was the Jorgensen systematic review of screening tests able to adjust predictive validity for the interventions that were given between the screening and the outcome (and will you be able to control for any such interventions in your proposed study)?

The whole dilemma facing predictive validity comparisons is that any interventions undertaken based on results of the screening tests will, if effective, tend to contradict the prediction. You do not mention blinding the physician to the results of the four screening tests: will the medical team have any knowledge of the screening results? If so, how will you adjust analyses for differences in their therapeutic interventions which could work to reduce the predictive validity of the screens?

Last part of the Introduction section: might it also be a benefit of this study to help standardize screening across EDs in Ireland? I agree this may be implied in your final sentence, but is it not worth stating explicitly?

Methods
Hard copies of questionnaires... Would data not be collected using tablets or laptops?

Inclusion criteria paragraph:
First sentence conflicts with previous paragraph which referred to patients 65 and over; now it's those aged over 65.
Index visit to the ED... The exclusion criteria did not mention patients who are regular visitors to the ED (which was implied in the introductory section). So, presumably the “index visit” is just their first visit during the recruitment period rather than their first visit ever?

Who administers the questionnaires at the index visit? Presumably not the nurse who does the follow-up interviews? Will the order of administering the four screening tests be randomised for each patient? If questions are common to more than one of the screens, will the questions be repeated?

[Is the INTER RAI a screening tool or a larger frailty assessment?]

The logistic analysis would benefit from more detailed description. There are several outcomes (GP visits, Barthel, home care, death, etc.) Are these each used in separate logistic analyses? If so, how will you compare the various screening tests, some of which may predict one outcome better than another? Is one outcome considered more important than others? Are you using continuous scores on the screens, although at least one of them proposes a cut-off score? Are you running analyses separately for each of the 4 screening tests, or will you include one and then see if adding others improves the prediction odds ratio?

Study Status... Given the claim that data were to be collected from Sept 2019 to April 2020, did you get caught out by Covid? Is there a major delay in completing the study? Too few patients participating? What happened?

Discussion
First paragraph: do you have some sort of triage in mind following the screening, given the lack of resources to administer comprehensive geriatric assessments to everyone?

Second paragraph: “… tools need to be feasible for non-specialists to complete…” But you mentioned previously that the INTER-RAI is a clinical tool; does Rockwood’s method need input from the doctor?

Third paragraph: this mentions falls as an outcome that was not mentioned in the Methods section.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.
Reviewer Expertise: Epidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.