Practices of falls risk assessment and prevention in acute hospital settings: A realist investigation

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SUMMARY OF RESEARCH

Background: Falls are the most common type of safety incident reported by acute hospitals (1), and can cause both physical (e.g. hip fractures) and non-physical harm (e.g. reduced confidence) to patients (2). The National Institute for Health and Care Excellence (NICE) guideline on falls in older people recommends that, in order to prevent falls in hospital, patients should receive a multifactorial falls risk assessment and be provided with a multifactorial intervention, tailored to address the patient's identified individual risk factors (3). It is estimated that such an approach could reduce the incidence of inpatient falls by 25-30% and reduce the annual cost of falls by up to 25% (1). However, there is substantial unexplained variation between hospitals in adherence to the NICE guideline, in terms of levels of assessments and interventions (2).

Aim: To determine how and in what contexts multifactorial falls risk assessment and tailored multifactorial falls prevention interventions are used as intended on a routine basis in acute hospitals in the NHS in England.

Methods: Realist evaluation (4), which is concerned with understanding for whom and in what circumstances complex interventions work and involves building, testing and refining the theories of how the intervention is supposed to work, provides an overall framework for the study (a fuller description of realist evaluation is given on page 7). Our project is comprised of three work packages (WPs):

WP1: A realist review of the literature will be undertaken. We will first identify theories concerning how and in what contexts multifactorial falls risk assessment and the implementation of tailored falls prevention interventions lead to a reduction in patients' falls risk. We will then test these theories systematically, using primary studies to determine whether empirical evidence supports, refutes, or suggests a revision or addition to the identified theories. As part of testing the theories, we will assess acute hospital Trust policies for adherence to the NICE guideline, to provide insight into whether the level of adherence reflects decisions made at the organisational level.

WP2: To further refine the theories, we will undertake a multi-site case study across three acute hospital Trusts, gathering data through ethnographic observation, interviews with staff and patients, and review of patient records and other documents.

WP3: We will translate the findings into actionable guidance that Trusts can use to inform their own falls risk assessment and prevention strategies.

BACKGROUND AND RATIONALE

Falls, generally defined as 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level,' (5) are the most common type of safety incident reported by acute hospitals (1). In 2017, approximately 250,000 patients in England were reported to have had a fall in hospital (2), although underreporting may mean that the true incidence of falls is higher (6, 7). Falls are most common in patients aged 65 years or older, representing 77% of inpatient falls (1). The majority of falls are the result of multiple interacting causes, most commonly age-related physiological changes, medical causes, medications, and environmental hazards (8).

Injurious falls are those which result in physical injury and can be categorised as minor (e.g. bruises, abrasions not requiring treatment), moderate (e.g. wounds or bruises that require attention), or serious (e.g. fractures, head or internal injuries requiring treatment) (6). Twenty-eight per cent of inpatient falls result in some level of harm and patients aged 65 years or older are more likely to be harmed (1). The proportion of falls resulting in any fracture ranges from 1% to 3%, with reports of hip fracture ranging from 1.1% to 2.0% (7). In 2015/2016, inpatient falls in England resulted in 2,500 hip fractures (2). Outcomes for patients who acquire hip fractures in hospital are far worse than for those in the community who acquire hip fractures, with significant differences in mortality (risk ratio (RR)=3.00; 95%CIs 1.05-8.57), discharge to long-term high-level nursing care facilities (RR=2.80; 95%CIs 1.10-7.09), and return to preadmission activity of daily living status (RR=0.17; 95%CIs 0.06-0.44) (9).

The human cost of falling also includes fear of falling and associated loss of confidence (2, 6). It can result in slower recovery (2), even when physical harm is minimal, and can have longer term consequences for the patient's health, as fear of falling may lead to restriction of activity and associated loss of muscle and balance function, increasing risk of falling (6). Falls can also be a cause of significant distress for families and staff (2, 7). Falls in hospital are a common cause of complaints (10) and can be a source of litigation (11). Falls in hospital are also associated with increased length of stay and greater amounts of health resource use (7). NHS Improvement has estimated inpatient falls cost the NHS and social care an estimated £630 million annually (1). **It is therefore a priority to reduce the number of patients who fall, and their risk of injury, in acute hospital settings.**

The traditional approach to managing falls in acute hospitals was to complete a falls risk prediction tool

(such as STRATIFY (12)). Such tools typically stratify patients according to their perceived risk of falling (high, medium, low) with interventions targeting individuals at high risk. There are, however, issues with this approach to risk evaluation for falls, in particular the issue of discrimination, where all patients on the unit are identified as high risk, and that having a score provides reassurance that action is being taken when actually it is not (13). Given the limitations of risk prediction tools, the NICE guideline on falls in older people states that falls risk prediction tools should not be used and instead a multifactorial falls risk assessment should be undertaken (3). Rather than categorising a patient according to their perceived risk of falling, this approach to assessment identifies individual risk factors for each patient which may make them at risk of falling and that can be treated, improved or managed during their stay. This may include: cognitive impairment; continence problems; falls history, including causes and consequences (e.g. injury and fear of falling); footwear that is unsuitable or missing; health problems that may increase their risk of falling; medication; postural instability, mobility problems and/or balance problems; syncope syndrome; and visual impairment. The NICE guideline states that a multifactorial falls risk assessment should be undertaken for all inpatients 65 years or older and inpatients aged 50 to 64 years judged to be at higher risk of falling due to an underlying condition. On the basis of this assessment, a multifactorial intervention should be provided for the patient, tailored to their individual risk factors. For example, if visual impairment is identified, it might be decided that an optician visit should be arranged if the patient has lost their glasses or, if there is no known reason for poor eyesight, an ophthalmology referral is made (14). In this way different patients, who have different risk profiles, will receive different interventions for reducing their risk of falls. NICE published a surveillance report in May 2019 (15); while the guideline will now be updated, the new evidence that was identified relating to preventing falls in older people during a hospital stay is consistent with current recommendations and therefore this guidance will remain the same.

Preventing inpatient falls completely would only be possible with unacceptable restrictions to patients' independence, dignity, and privacy (7, 10). **Nonetheless, it is estimated that the introduction of multifactorial falls risk assessment and interventions, as recommended by the NICE guideline, could reduce the incidence of inpatient falls by 25-30% and reduce annual cost of falls by up to 25%** (1). Despite the NICE guideline being updated to include these recommendations in 2013, the latest National Audit of Inpatient Falls (NAIF) report noted substantial unexplained variation between hospitals in levels of assessments and interventions (2). The NAIF found a decrease in the number of Trusts using falls risk prediction tools between 2015 and 2017 but 34% of Trusts are still using such tools. Improvement was found in a number of assessment indicators but rates for some indicators remain concerningly low. This includes cognitive impairment assessment (58.5%), despite the fact that cognitive impairment is associated with more than twice the risk of falling (6). Rates also remain low for delirium assessment (39.7%), medications assessment (47.8%), and vision assessment (46.2%) (2). In interventions, there was improvement in presence of care plans where required for cognitive impairment and delirium, although rates remain low (43.7% and 48.7% respectively), but no overall significant change in the presence of tailored continence care plans (66.9%) or mobility care plans (78.8%) for those patients who require them.

Given this variation, there is a need to understand the contextual factors that support and constrain the use of multifactorial falls risk assessment and tailored falls prevention interventions in an acute hospital setting, in order to improve practice. Below we consider the empirical evidence regarding the effectiveness of multifactorial falls prevention interventions.

Evidence for multifactorial falls assessment and interventions

There is limited high quality research on preventing inpatient falls (16), with the majority of existing research focusing on falls prevention in community dwelling adults (6), despite the fact that fall rates are higher in hospital than in the community (14). An updated Cochrane systematic review of interventions for preventing falls in older people in care facilities and hospitals was published in 2018, with searches conducted up to August 2017 (17). This included 95 randomised controlled trials (RCTs), 24 of which were conducted in hospitals. In preparing this proposal, we reran the search on Medline, EMBASE, CENTRAL, and CINAHL, date limiting the search from 2017 to 2019. This identified one additional RCT of a hospital falls prevention intervention, a conference abstract for which no study publication could be located (18).

Of the 24 RCTs conducted in hospitals included in the Cochrane review, six evaluated multifactorial interventions. The pooled results of five of these studies suggest multifactorial interventions may reduce the rate of falls in hospitals (rate ratio (RaR)=0.80; 95%CIs 0.64-1.01), particularly in rehabilitation or care of the elderly wards (RaR=0.67; 95%CIs 0.54-0.83), but the quality of these studies was judged low. There was also significant heterogeneity in the results and significant intervention heterogeneity. For example, while a multidisciplinary team approach has been shown to be an important factor in falls prevention (7), in only one

study was the assessment undertaken by a multidisciplinary team (19); in three studies assessments were nurse-led (14, 20, 21) and one study did not specify who undertook the assessment (22). Two studies included use of a multifactorial falls risk assessment (14, 19), in line with the NICE guideline (3), but two used falls risk prediction tools (20, 22). Some included provision of written information for the patient (19), in line with the NICE guideline (3), while others incorporated other forms of patient education (21, 23).

We also searched CENTRAL, ClincialTrials.gov, and WHO ICTRP for any ongoing trials of falls prevention interventions. This revealed that the majority of ongoing trials continue to focus on community dwelling adults. We identified only one ongoing RCT of a hospital falls prevention intervention, evaluating the impact of non-slip socks (ACTRN12617001226392).

Therefore, existing evidence on how to successfully implement the NICE guideline on falls prevention in hospitals is limited. Further research is needed that explores the impact of different contextual factors (such as multidisciplinary assessment vs nurse-led assessment) on the conduct of multifactorial falls risk assessment and implementation of tailored falls prevention interventions.

Understanding the context of falls risk assessment and prevention

Given the limited literature on inpatient falls prevention, in this section we draw on a broad range of literature on risk assessment and adherence to clinical guidelines, to provide the theoretical context for the proposed study.

Assessing and responding to a patient's risk of falling can be characterised as cognitive activities associated with decision making. The process of judgement involves the integration of different aspects of information about a person, object or situation to arrive at an overall evaluation (24). In the context of falls prevention, this refers to the process through which a patient's risk factors for falling in hospital are identified. On the basis of this judgement, a decision should then be made about interventions to reduce the risk of falling. Thus, we can see the implicit theory, or chain of reasoning, underlying the NICE guideline as being that a multifactorial falls risk assessment allows the healthcare professional who undertakes the assessment to identify the patient's individual risk factors for falling in hospital. On the basis of this they are able to select and implement interventions that respond to those risks, leading to a reduction in the patient's falls risk (see Figure 1).

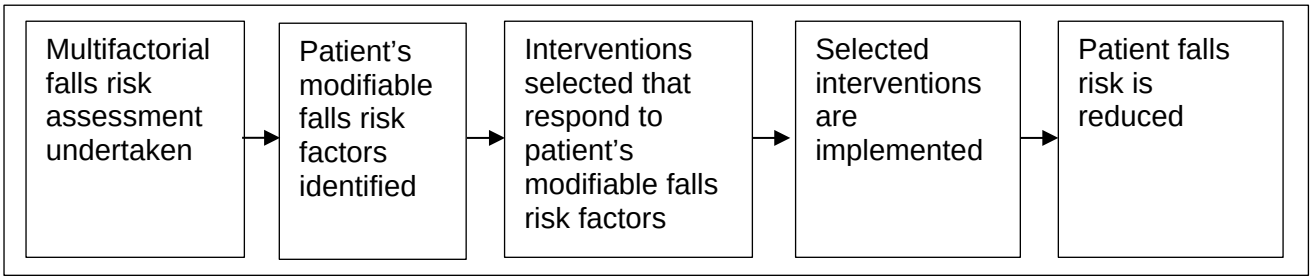

Figure 1: An initial theory of multifactorial falls risk assessment and prevention

There are a number of points where this implementation chain of falls risk assessment and intervention selection could fail. The first relates to whether a falls risk assessment is undertaken, what kind of assessment is undertaken, and what that assessment covers. Falls risk assessment is one of a number of risk assessments that are undertaken when a patient is admitted to hospital and during their inpatient stay. One study of risk screening and assessment forms to prevent harm to older people, undertaken across 11 Australian healthcare providers, found that hospitals used between 8 and 27 (median 11) standard assessment forms that included 150-586 data capture items (median 354) (25). The use of multiple risk assessment forms was associated with high workload burden, with completion of initial assessments being reported to take between 40 minutes and two hours, with most of this work being undertaken by nursing staff. Given the number of assessments healthcare staff are required to undertake, this may lead some staff to prioritise certain risk assessments over others, based on their perception of the patient's greatest area of risk. A study of adherence in the emergency department to those aspects of the NICE guideline on falls in older people concerned with responding to patients who present following a fall found that staff perceived that it was not possible to be familiar with all guidelines and certain guidelines would be prioritised within the department (26). When patients presented with multiple health issues, these other issues may take priority, particularly when time is limited.

In terms of what kind of assessment is undertaken, tools to support falls risk assessment can be categorised

into falls risk prediction tools and falls risk assessment tools (27). Using formal, structured assessment tools may improve decision making as they encourage healthcare professionals to focus on relevant information in a consistent fashion (28). However, despite the proliferation of tools such as risk assessment forms in healthcare, often driven by attempts to improve quality and safety, their content, form, and use have received limited attention within the healthcare literature, leading to calls for 'formacology' as a new subfield of improvement research (29). Falls risk assessment forms are part of the patient record, as are the care plans that are established following the undertaking of a falls risk assessment; as we move to a paperless NHS and as the introduction of electronic patient records (EPRs) increases across NHS acute hospitals, it is timely to ask how the digitisation of such forms affects the process and outcome of falls risk assessment. This is an area where impact appears to be variable; a US study of the impact of implementation of an EPR on nursing care outcomes, where the EPR included a falls risk assessment tool, found that introduction of the EPR did not lead to a statistically significant increase in documentation of falls risk, nor did it lead to a decrease in fall rates (although these changes did occur in relation to hospital acquired pressure ulcers) (30), while in another US study, the addition of a falls risk assessment tool to an EPR in the emergency department, when implemented with a falls prevention strategy and staff education, led to a 48% decrease in the rate of falls (31). There are also questions about how the digitisation impacts integration of falls risk assessment into the workflow. In the study of adherence to the NICE guideline in the emergency department, ease of accessing tools to support assessment was seen as an important contextual factor (26). This reflects broader literature on guideline adherence, where ease of access of tools and the extent to which they are integrated into the workflow has been shown to be important across a number of settings (32).

Other contextual factors that may influence which assessments are undertaken are knowledge and education of staff. For example, in the FallSafe falls prevention quality improvement project, while the proportion of patients receiving cognitive assessment and lying and standing blood pressure (BP) checks continued to be significantly higher than at baseline after the project ended, the improvements were not sustained at the levels achieved when there was active project support and dedicated local lead time (33). However, undertaking cognitive assessments and lying and standing BP checks are not standard nursing competencies, so new staff would require training in order to enable the improvements to be continued. This also points to staff turnover as a potential constraining factor.

Another factor that may influence attention to falls prevention and the completion of falls risk assessments are specific quality improvement initiatives focusing on falls prevention. However, previous research has highlighted how focusing on certain quality indicators may improve an organisation's performance, but when attention then moves elsewhere, performance may decline, raising questions about how to sustain that performance (34). Strategies that may work to keep attention on falls prevention are safety huddles (35) and intentional rounding (36); there is some evidence that such strategies reduce falls in hospitals, although evidence on the impact of safety huddles tends to come from single site quality improvement projects and the evidence regarding intentional rounding is considered to be weak (37). More generally, a positive safety culture has been found to be associated with a lower rate of falls (38). The role of senior staff such as the ward manager has also been identified as a key factor for success in both the FallSafe quality improvement project (10) and the emergency department study described above (26). While a number of assessments and interventions were introduced as part of FallSafe, 'the main mechanism of improvement' was considered to be 'educating, inspiring and supporting' a member of ward staff to lead local improvement on their own wards, but the support of the FallSafe lead's line manager was important (10).

The second point where the implementation chain can break down is in the identification of interventions that respond to the patient's falls risk factors. One factor that may influence this is related to the number of risk assessments that nursing staff have to undertake. This may produce a cognitive burden on staff, having to integrate relevant information located across multiple forms to inform their decision making, which can lead staff to focus on completing assessment forms, rather than ensuring the appropriate interventions are selected (25). Literature on guideline adherence identifies consistency with other guidelines as a contextual factor (39) and selecting appropriate interventions can be particularly challenging when the interventions suggested by different assessments conflict, e.g. mobilising the patient to reduce pressure ulcer risk while reducing the opportunities for the patient to fall. It may also depend on the extent to which the risk assessment form or local protocols guide the selection of interventions. A trial included in the Cochrane falls prevention review, but categorised as a social environment intervention (targeting staff members and changes in the organisational system), was Fall TIPS, a computerised decision support-based multifactorial assessment and tailored intervention that guides falls risk assessment and then presents corresponding interventions tailored to patient-specific areas of risk (40). Once the recommended interventions are reviewed, tailored if needed, and approved, Fall TIPS prints a bed poster, patient education handout, and care plan. In a cluster RCT

across four US hospitals, use of Fall TIPS was found to result in a statistically significant reduction in falls in patients over 65 years old (rate difference=2.29 per 1000 patient days; 95%CIs 0.63-3.95). While the nature of the assessment and the suggested interventions do not fulfil all requirements of the NICE guideline, these results point to the potential for computerised decision support to assist multifactorial falls risk assessment and prevention.

Even if appropriate falls prevention interventions are identified, they will not necessarily be implemented. At the individual, or 'micro', level, motivation to follow local protocols regarding falls prevention interventions may be influenced by their perceived impact; if healthcare professionals perceive that it makes a difference to patient care, they are more likely to follow the protocol consistently (32, 41). Without such motivation, healthcare professionals may struggle to overcome the inertia of previous practice (41). Patient responses may also support or constrain implementation of falls prevention interventions. It has been found that patients prefer multifactorial falls prevention interventions, possibly valuing availability of multiple options and/or tailoring of these approaches to their individual needs (42). However, several interview studies, undertaken in Australia (43) and the US (44, 45), suggest patient adherence to inpatient falls prevention strategies depends on a range of contextual factors including patient willingness to ask for assistance and speed with which assistance is provided. Some patients may not wish to 'bother' staff (44) or may not accept they are at risk of falling (43, 45-47), suggesting communication between healthcare professionals and patients regarding their falls risk and the importance of falls prevention is key in reducing falls. In the literature on guideline adherence, patient behaviours have also been shown to motivate or demotivate adherence (39) and the findings of one of the studies included in the Cochrane falls prevention review support this idea (23). The intervention, based on the Health Belief Model (48), was an education programme delivered by physiotherapists to patients and staff. The authors suggest that the finding of fewer falls as the intervention period increased could be due to the intervention resulting in a growing safety culture. When the trial finished, focus groups were conducted with a number of clinical staff who were involved in the trial (49). The findings from these suggest that the education created a positive culture around falls prevention and facilitated a teamwork approach where patients and staff worked together to prevent falls. When patients were proactive and empowered to engage in falls prevention strategies, such as ringing the bell for assistance, staff felt that their falls prevention efforts were being supported and this motivated them to change practice.

The FallSafe quality improvement project provides insight into some of the practical organisational, or 'meso', level challenges that can occur when trying to implement falls prevention interventions. For example, in trying to ensure that walking aids could be provided for patients who were admitted over weekends when no physiotherapy input was available meant addressing issues of cross professional working, equipment supply, and equipment storage (10). Wider social, cultural, and political, or 'macro', level contextual factors that may influence the implementation of falls prevention interventions include economic constraints on the healthcare budget, malpractice liability, and policies that incentivise or disincentivise the improvement of particular outcomes or adherence to particular guidelines, which will influence organisational regulations, rules, and policies, the availability of necessary resources, and the priority given to guideline implementation (39).

Summary

In summary, we currently know that there is variation in adherence to the NICE guideline. On the basis of literature on risk assessment and adherence to clinical guidelines, we can make assumptions about the contextual factors that influence this. However, we lack knowledge of how falls risk assessment and prevention happens in practice, how the content and form of artefacts to support falls risk assessment influence this process, and the specific combinations of factors that support and constrain adherence to the NICE guideline.

Evidence explaining why this research is needed now

There is a consistent rise in falls and recurrent falls with age and in acute hospital settings older adults are at increased risk of falling (6). A rising population of older people means that it is likely that the proportion of older people in hospitals will increase over coming years, making the challenge of falls prevention in hospital wards more pressing (50). Similar demographic trends in all developed nations mean that this is a global challenge. The importance of falls prevention to NHS England is indicated by the recent introduction of a Commissioning for Quality and Innovation (CQUIN) indicator 'Three high impact actions to prevent Hospital Falls', which aims to stimulate key components of a multifactorial falls risk assessment by requiring that 80% of older adults have lying and standing BP recorded at least once, no hypnotics/antipsychotics/anxiolytics without documented rationale, and mobility assessment documented and walking aid provided if required

within 24 hours of admission. As described above, it is estimated that the introduction of multifactorial falls risk assessment and interventions, as recommended by the NICE guideline, could reduce the incidence of inpatient falls by 25-30% and reduce annual cost of falls by up to 25%. However, there is currently significant unexplained variation in the extent to which the NICE guideline is being implemented.

Despite the importance of this topic, there is limited high quality research on preventing inpatient falls (16), and a lack of research on the effects of context on the success of interventions for preventing inpatient falls (51). Both NICE (3) and the Cochrane falls prevention review (17) call for more research on multifactorial interventions in hospitals. There is also limited research on the patient's experience of falls risk assessment and prevention in hospital settings (45). Using a realist approach, this research will provide insight into the contextual factors that support and constrain adherence to the NICE guideline, paying attention to the patient experience of this process. This will produce evidence which Trusts can draw on to inform their own falls risk assessment and prevention strategies, with the potential to reduce frequency of falls in older adults and thereby reduce both human suffering and healthcare costs.

AIMS AND OBJECTIVES

Aim: To determine how and in what contexts multifactorial falls risk assessment and tailored falls prevention interventions are used as intended on a routine basis in acute hospitals in the NHS in England.

Objectives:

1. To use secondary data to develop a programme theory that explains what supports and constrains routine use of multifactorial falls risk assessment and falls prevention interventions;
2. To refine the programme theory through mixed method data collection across three acute hospital Trusts; and
3. To translate the programme theory into guidance to support multifactorial falls risk assessment and prevention and, in turn, adherence to the NICE guideline.

RESEARCH PLAN/METHODS

Design and theoretical/conceptual framework

Falls risk assessment and prevention can be characterised as a complex intervention (7), by which we mean that it is an intervention aimed at producing change in the delivery and organisation of healthcare services and which comprises a number of separate components that may act both independently and interdependently (52, 53). Some of these components are organisational and social and can impact the extent to which falls risk assessment and prevention interventions are successfully introduced and subsequent process and patient outcomes. The study of complex interventions requires a strong theoretical foundation, to make explicit often implicit assumptions regarding how and why the intervention will provide the desired impact (54) and how this is influenced by context (55). Realist evaluation (4) offers a framework for understanding for whom and in what circumstances complex interventions work. It involves building, testing and refining the underlying assumptions or theories of how the intervention is supposed to work. Realist evaluation has been used for studying the implementation of a number of complex interventions in healthcare (56-58), including standardised care approaches such as clinical guidelines (32).

From a realist perspective, interventions in and of themselves do not lead to outcomes. Rather, it is how recipients of the intervention choose to make use of, or not, the resources that an intervention provides that determine outcomes, and such choices are highly dependent on context. For example, whether the introduction of a form for multifactorial falls risk assessment leads to the use of tailored falls prevention interventions and a subsequent reduction in falls depends on if, and how, nurses use that form, a choice that may vary according to contextual factors such as workload, confidence in their ability to undertake the assessment, and belief in the value of the assessment and associated interventions. Therefore, a realist approach is suitable when studying interventions where uptake and subsequent impacts have been found to be variable. Realist approaches are concerned with constructing programme theory that details how intervention components trigger responses in recipients (intervention mechanisms) within particular contexts to generate outcomes, described as Context Mechanism Outcome Configurations (CMOCs).

WP1: Realist review (Months 1-15)

Objective

- To use secondary data to develop a programme theory that explains what supports and constrains routine use of multifactorial falls risk assessment and falls prevention interventions (Objective 1).

Summary of method

We will undertake a realist review. Realist review is a literature review method that represents a divergence from traditional systematic review methodology (59). It starts by identifying programme theories and then uses empirical evidence to systematically evaluate these, allowing us to compare how an intervention is intended to work with how it actually works.

Realist reviews are useful when considering the literature regarding interventions where there is limited primary research for two reasons; firstly, in contrast to systematic reviews, a range of sources of data can be considered as evidence, enabling reviews to make use of, for example, reports of local evaluations and quality improvement initiatives that have not been subject to peer-review (60); secondly, because the key unit of analysis in a realist review is the intervention mechanism, literature concerning other interventions that have the same underlying mechanism are deemed relevant, so a wider breadth of evidence is available (60, 61). For example, we may be able to draw on studies of other risk assessment interventions or studies of interventions for increasing guideline adherence.

The methods presented here are based on those that three of us (RR, JW, and PG) have successfully used in a recently completed realist review of the impact of networked health IT on patient safety (HS&DR 16/53/03). RAMESES guidelines will be followed to ensure quality of the conduct and reporting of the review (62). Realist approaches can be thought of as consisting of three phases: theory elicitation, theory testing, and theory refinement, and we use this structure to describe the process of the realist review.

Phase 1: Theory elicitation

Search strategy: To identify programme theories, or theory fragments, searches will be designed by an information specialist with expertise in realist reviews (JW). The databases to be searched include:

- Ovid Medline and Medline In-Process & Other Non-Indexed Citations
- Ovid Health Management Information Consortium
- EBSCO CINAHL

We will undertake the following searches:

Practitioner theories: Programme theories are likely to be found in editorials, comments, letters, and news articles (60), so searches will be undertaken, using a filter (set of search terms) to limit the search to these publication types (see example in Appendix 1). In addition to searching the databases listed above, searches will be run on Google, and websites of relevant professional organisations (e.g. Royal College of Nursing) and professional journals (e.g. Nursing Times, Health Service Journal). We will also search for reports of quality improvement projects, such as FallSafe, including searching NHS Trust websites.

Academic theories: The discussion sections of empirical studies often include the authors' theories about why the intervention did or did not achieve the desired effect (63). Therefore, studies of falls prevention interventions will be searched for, using existing systematic reviews as a starting point (Appendix 2). In preparing this proposal, we searched Cochrane, CINAHL, the CRD HTA database, Epistemonikos, and Medline for systematic reviews on fall prevention, which identified 155 unique records. We also searched Prospero for ongoing systematic reviews, identifying one on the effectiveness of falls prevention interventions on falls outcomes for hospitalised adults (CRD42017058887) and one on the effectiveness of multi-factorial and multi-component interventions for the prevention of falls for adults in hospital settings (CRD42019143208).

Substantive theories: We will undertake a search for relevant substantive theories on risk assessment and guideline adherence, in addition to reviewing articles retrieved in the 'academic theories' search for reference to substantive theory.

Review strategy: A 'liberal accelerated' approach to screening will be taken, where one reviewer reviews all records/full text papers and a second reviewer reviews records/full text papers excluded by the first reviewer (64). This approach is less time and resource intensive than having two reviewers review all records/full text papers while maximising inclusion, increasing the number of records/full text papers retained in comparison to a single reviewer (65). Because the purpose of this phase of the review is to identify and catalogue programme theories and theory fragments, rather than to assess their validity, selection will be based on relevance to the topic of the review (59, 60). All retrieved records will be screened based on title and abstract. Reviewers will ask: 1) Is this about falls risk assessment and/or falls prevention interventions in the acute

hospital setting? and 2) Does it potentially contain ideas about how falls risk assessment and prevention works, for whom, and in what circumstances? Full text copies of all potentially relevant papers will be retrieved. Reviewers will read the papers to determine whether they contain ideas about how falls risk assessment and prevention happens, the contextual factors that support and constrain this, and/or the consequences of this (the outcomes). A PRISMA flow chart detailing the review decision process for Phase 1 will be developed.

Included studies from the 'practitioner theories' and 'academic theories' searches will be imported into NVivo and coded as context, mechanism, and outcome. A 10% random sample of papers will be coded by a second reviewer for consistency. Our experience of undertaking realist reviews suggests that individual studies are unlikely to provide us with fully formed CMOCs or to even contain information about all three elements of context, mechanism, and outcome (63). Therefore, we will draw together coded data from multiple studies in order to configure a series of CMOCs. These will combine to provide an initial programme theory. Narrative summaries of each of the substantive theories identified will be written and we will compare the CMOCs with the substantive theories, using the substantive theories to fill in any remaining gaps in the CMOCs. Given that falls risk assessment and prevention is likely to be supported or constrained by contextual features at the micro, meso, and macro level, we will adopt Westhorp's approach of 'layering' theories, in order to develop an initial programme theory that considers the influence of context at all three levels (66, 67).

The initial programme theory will be summarised in both diagrammatic and narrative form (68, 69). To prioritise CMOCs for testing in Phase 2, we will draw on methods we used in a previous realist study (70). We will first identify a sub-set of possible CMOCs to test, based on the feasibility of testing them, undertaking initial scoping searches to gauge the extent of the available literature, and based on their potential for informing practice (e.g. if a CMOC contains contextual factors that constrain the conduct of falls risk assessment that are not amenable to change, it will not be taken forward for testing). We will discuss the remaining sub-set of CMOCs with our lay researchers and our advisory board and ask them to rank them in order of priority; those CMOCs which have the highest ranking across both groups will be taken forward to the next stage.

Phase 2: Theory testing

Search strategy: Searching will be purposive and iterative, driven by the prioritised CMOCs, in order to identify empirical studies relevant to testing of the initial programme theory (60). Health and multidisciplinary databases to be searched include:

- Ovid Medline and Medline In-Process & Other Non-Indexed Citations
- EBSCO CINAHL
- Ovid EMBASE
- Web of Science Core Collection
- ProQuest Applied Social Sciences Index & Abstracts

An initial scoping search suggests there is limited empirical evidence from the hospital setting, with existing research tending to focus on the community setting. Therefore, initial searches will be limited to the hospital setting but, where there is an absence of literature, searches will be broadened out to include literature from the community setting and care homes. We are aware of the currently funded NIHR Health Technology Assessment multi-centre cluster randomised controlled trial to evaluate the Guide to Action Care Home fall prevention programme in care homes for older people (FinCH), the final report for which is due to be submitted in December 2019, and will draw on the findings of this study. We may also broaden our search to include literature concerning other interventions that are based on the same mechanisms as those within the initial programme theory (61). For example, we have discussed our study with Susanne Coleman, who is currently undertaking an NIHR funded realist evaluation of pressure ulcer risk assessment, the findings of which are likely to be relevant to testing our initial programme theory. We will be open to including a range of documentary sources, including reports of quality improvement projects.

An additional source of evidence is the policies of acute hospital Trusts regarding falls risk assessment and prevention, which are often publicly available via Trust websites. Therefore, we will also use Google to retrieve these documents.

Review strategy: As in Phase 1, a 'liberal accelerated' approach to screening will be taken. Relevance of each study to testing the initial programme theory will be assessed pragmatically against key inclusion criteria concerned with the context (acute hospitals) and the intervention (falls risk assessment and/or falls prevention interventions). Priority will be given to those studies that meet all inclusion criteria but we will also include studies which match the intervention criteria but not the context criteria (e.g. studies about falls risk assessment in care homes) and studies which match the context criteria and are concerned with interventions

that have the same underlying mechanism (e.g. studies about pressure ulcer risk assessment in acute hospitals). A PRISMA flow chart detailing the review decision process for Phase 2 will be developed.

Studies deemed to be relevant will be appraised using the Mixed Methods Appraisal Tool (MMAT) (71). As in Phase 1, included studies will be imported into NVivo and coded as context, mechanism, and outcome.

For the Trust policies on falls risk assessment and prevention, we will create an Excel spreadsheet to assess adherence to the different elements of the NICE guideline. This will be based on the NAIF, capturing information on whether or not a falls risk prediction tool is recommended, the assessments to be undertaken, and the interventions to be implemented following assessment, and whether the interventions are tailored to the patient's individual risk factors.

Phase 3: Theory refinement

Data synthesis: Coded data for each study will be compared in turn with the initial programme theory to determine whether the findings support, refute, or suggest a revision or addition to the CMOCs. This will be done through discussion, initially by the two researchers and Principal Investigator (PI), then with the wider project team. The results of the survey of Trust policies will provide insight into whether the level of adherence reflects decisions made at the organisational level.

The resulting programme theory will be summarised in both diagrammatic and narrative form (68, 69). Following the methods used at the end of Phase 1, to prioritise CMOCs for testing in WP2, we will first identify a sub-set of possible CMOCs to test, based on the feasibility of testing them and their potential for informing practice. We will also discard those CMOCs for which the realist review has already revealed strong evidence. We will discuss the remaining sub-set of CMOCs with our lay researchers and our advisory board and ask them to rank them in order of priority; those CMOCs which have the highest ranking across both groups will be taken forward to WP2.

Outputs

- A realist review of falls risk assessment and prevention;
- A programme theory that explains what supports and constrains routine use of multifactorial falls risk assessment and falls prevention interventions;
- Detail on the extent to which acute hospital Trust policies adhere to the NICE guideline; and
- A prioritised list of CMOCs for testing in WP2.

WP2: Multi-site case study (Months 16-21)

Objective

- To refine the programme theory through mixed method data collection across three acute hospital Trusts (Objective 2).

Summary of method

The Cochrane falls prevention review suggests that a mixed methods approach be used for understanding the impact of multifactorial falls prevention interventions (17). Realist evaluation is an explicitly mixed method approach; while it does not employ particular methods of data collection, a mixture of qualitative and quantitative methods is encouraged, to gather data on the processes and contexts of an intervention as well as its impacts (60). To refine the programme theory, we will undertake a multi-site case study with embedded units of analysis (72). Multi-site case studies enable the identification of commonalities across settings, thus increasing the generalisability of the findings, and provide an understanding of the impact of context on work practice. The method of the multi-site case study, based on methods used by one of us (DD) in a previous study of practices of patient assessment (73), is as follows:

- In addition to having *multiple case sites* (Trusts), data will be gathered across *multiple wards* in each case site.
- *Multiple methods* of data collection – ethnographic observations, semi-structured interviews, and review of patient notes – will be used in each case site. In addition, we will collect examples of documents used to support falls risk assessment and prevention and routinely collected data on number of falls and falls-related harms. Using multiple methods of data collection can provide a richer view of the setting; for example, observations will reveal the everyday, taken-for-granted aspects of falls risk assessment and prevention while the interviews will focus on participants' perceptions (74).
- The views of *multiple stakeholders* regarding falls risk assessment and prevention will be sought: we will interview a range of staff at both the ward and organisational level, and patients and their carers.

The specific details of data collection, including sampling, and analysis will depend on the CMOCs resulting

from WP1 that are to be tested. Additionally, it might be appropriate to add further data collection methods, e.g. if one of the CMOCs suggests the safety culture to be an important factor, we may choose to add a safety culture questionnaire (75). The data collection protocol will be revised and further specified at the end of WP1, in light of the CMOCs to be tested and in collaboration with our lay researchers. However, based on the literature presented above and discussions that we have had with staff in our case sites who have responsibility for falls prevention, we have constructed the following tentative CMOCs which we use to illustrate the description of our methods:

1. When staffing levels are low and/or workload is high (context), nursing staff select which risk assessments they will undertake for particular patients, based on their perceptions of the patient's particular vulnerabilities (mechanism), leading to certain patients not receiving a falls risk assessment (outcome).
2. When nursing staff are required to undertake a large number of different risk assessments (context), this creates a cognitive burden so that nursing staff find it difficult to integrate the information from the different risk assessments to determine which interventions should be prioritised for the patient (mechanism), leading to a standard bundle of interventions being provided to all patients (outcome).
3. When attention is drawn to weaknesses in local falls prevention practices, e.g. through local or national audits or an adverse event (context), quality improvement initiatives are introduced and attention is focused on falls prevention (mechanism), leading to more complete falls risk assessments and adherence to protocols for falls prevention (outcome).
4. If falls prevention is emphasised as a priority by the ward manager (context), practices such as safety huddles and nursing handovers can be used as an opportunity to maintain nursing staff attention on falls prevention (mechanism), leading to more complete falls risk assessments and adherence to protocols for falls prevention (outcome).
5. If patients do not adhere to falls prevention advice (context), nursing motivation decreases (mechanism), leading to fewer falls risk assessments being undertaken (outcome).

Sampling of case sites

Data will be collected across three NHS acute Trusts in England (Leeds Teaching Hospitals Trust, Manchester University Foundation Trust, Calderdale & Huddersfield Foundation Trust), with two wards per Trust. Trusts have been selected to ensure variation in key NAIF indicators, the health IT in place, and to include both teaching and district general hospitals (Table 1).

Table 1: Case site characteristics

Site	NAIF indicators (%)							EHR	Hospital type
	Delirium	Continence CP	BP	Medication	Vision	Call bell	Mobility aid		
Leeds	10	82	39	43	56	80	69	Locally developed	Teaching
Manchester	8	100	31	50	25	75	100	Locally developed/ AllScripts	Teaching
Calderdale	67	67	8	7	13	50	17	Cerner Millennium	District general

Delirium = been assessed for presence/absence of delirium or documented diagnosis of delirium; Continence CP = continence or toileting care plan, tailored to patient (not generic); BP = measurement of lying and standing blood pressure; Medication = an assessment for medication that increase falls risk; Vision = any assessment of vision; Call bell = call bell is in sight and in reach of patient; Mobility aid = appropriate mobility aid in reach

Wards will be selected to ensure variation in contextual factors the CMOCs suggest influence falls risk assessment and prevention. For example, based on CMOC 3, we would try to select wards that vary in their performance in local audits of falls assessment and prevention practice. We anticipate that in each hospital we will include one care of the elderly ward and one specialist ward that often has a high proportion of older patients, such as Orthopaedics or Vascular, as the experience of team members suggests that practices of falls risk assessment can differ in these two types of setting. However, the likelihood of observing falls risk assessments will also influence our choice of wards (e.g. falls risk assessments are likely to be more

frequently observed on wards with a higher turnover of patients, wards with more patients who are 65 years or older, and on admissions wards).

The number of case sites in a multi-site case study depends on the number of aspects of the context that are anticipated to impact on the phenomenon of interest (76), while also involving a trade-off between breadth and depth of investigation (77). Three case sites will enable identification of organisational level factors that impact on falls risk assessment and prevention while providing confidence in the generalisability of findings that are consistent across sites. By sampling across clinical areas in each site, we will be able to distinguish between those differences that are due to clinical area and those that are due to Trust/unit level factors.

Sampling within case sites

Sampling of observations: In determining how many periods of observation are necessary to provide an adequate overview of current practice within a particular setting, it is important to ensure that a range of time periods is observed and that there is adequate time for the participants to become comfortable with the presence of the researcher (77). We also want to ensure that we observe different staff members performing falls risk assessments. Ten 4 hour periods of observation will be conducted per ward (total = 240 hours), covering day, evening/night, and weekend shifts. Discussion with those at the case sites with responsibility for falls prevention suggest that practices for falls risk assessment and prevention are not static and may change in response to events such as a patient on the ward having an injurious fall or in response to local or national audits, as described in CMOC 3. Therefore, in order to be able to capture such changes in practice, data collection will be conducted at each case site concurrently, with two 4 hour periods of observation being undertaken in each ward per month over five months.

Sampling of interviews: There is no consensus regarding how many interviews are necessary to provide an adequate understanding of attitudes and experiences within a particular setting. It is dependent on the range of participants to be included, the purpose of the interviews, and whether other forms of data will be gathered. It is necessary to balance the desire for data saturation with the need to keep the data set to a manageable size. In order to understand the impact of both the micro level and meso level context on practices of falls risk assessment and prevention, we will interview staff at both ward level (doctors, nurses, pharmacists, physiotherapists, occupational therapists, and healthcare assistants, 8 per ward, total = 48) and organisational level (Directors of Nursing/Chief Nurses, members of falls prevention teams, 4 per Trust, total = 12). We will interview patients and/or their carers, where the patient is either aged 65 years or older or aged 50 to 64 years and judged to be at higher risk of falling due to an underlying condition (5 per ward, total = 30). Where possible, these will be the same patients whose care has been observed.

Sampling of patients for record review (medical and nursing record): On each ward, the medical and nursing record for 10 patients will be reviewed (total = 60). Where possible, these will be the same patients who participate in the interviews and/or have their care observed. This number has been chosen on the basis that it is a feasible amount of data to collect within the timeframe of the study and will provide enough data for quantitative analysis to be undertaken.

Data collection

Ethnographic observation: Ethnography is the study of people in their environments where the researcher participates in the setting in order to collect data (77). Ethnographic methods, such as non-participant observation, have been used in previous realist evaluations as part of the process of theory testing and refinement (32, 57), and the importance of observation for determining how and if standardised care approaches such as guidelines are used in practice has been demonstrated (32). In addition, ethnographic observation is important for getting a sense of how practices of falls risk assessment and prevention fit within the broader context of work (78, 79) and for capturing those aspects of the context that cannot easily be measured, such as the culture of an organisation.

In each case site, two researchers will conduct observations independently in the same ward and at similar times. An observation protocol will be developed, based on the CMOCs being tested and with input from our lay researchers, which will define what the researchers should pay attention to. The researchers will record observations in fieldnotes. Following in the ethnographic tradition, the researchers will, at least in the early stages of the study, keep the scope of the notes wide, on the basis that what previously seemed insignificant may come to take on new meaning in light of subsequent events (77), and will give special attention to the indigenous meanings and concerns of the people studied (80). In addition, the researchers will record incidents of observer effects (e.g. participants asking ‘What are you writing?’) to allow analysis of whether participants’ awareness of the researchers’ presence changed over time (74). The researchers will regularly compare their notes to ensure that they are capturing the necessary information at an appropriate level of

detail and to reflect on what they are observing and identify necessary additions to the observation protocol. Fieldnotes will be written up in detail as soon after data collection as possible.

For the first two observation periods in each ward, researchers will undertake general observations, to become familiar with staff and the work of the ward. They will seek to understand the routines of the ward, to determine when in the day falls risk assessments are most likely to be undertaken Following this, the researcher will select a bay to observe where there is at least one patient who is at risk of falling (i.e. aged 65 years or older or aged 50 to 64 years and judged to be at higher risk of falling due to an underlying condition). For these patients, attention will be paid to any assessments that are undertaken, any interventions in place for reducing falls risk, and interactions between staff, patients and carers. In this, we draw on methods used by one of us (DD) in a previous study of practices of patient assessment (73). To ensure that we observe falls risk assessments, we will use the record reviews to determine when a patient is due to next have a falls risk assessment (following the initial assessment, falls risk assessments are typically expected to be undertaken weekly). If we struggle to observe falls risk assessments, we will talk to staff to develop our understanding of where and when we can best capture these assessments.

It is important to understand how falls prevention practice is shaped by the organisation of clinical work and other practices for ensuring patient safety; therefore observations of nursing handovers, safety huddles, multidisciplinary team meetings, intentional rounding, and board rounds will also be undertaken and attention will be paid to other artefacts that support falls prevention, such as electronic whiteboards that indicate which patients are at risk of falling. Training sessions on falls prevention that take place within the site will be attended.

Staff interviews: Interviews with staff are an important complement to ethnographic observation, providing an opportunity for the researcher to ask questions about aspects of practice that might not be immediately intelligible to an observer, as well as for gaining interviewees' reasoning about falls risk assessment and prevention. Semi-structured interviews will be conducted with staff towards the end of the data collection period. As an iterative approach will be taken to data collection and analysis, these interviews will be used to discuss revisions to the CMOCs. For this purpose, the interviews will be conducted using the 'teacher learner cycle' (81). Here, the interviewer describes, through their interview questions, the candidate theories to the interviewee who is then invited to comment, expand and discuss the theories based on their experience of the intervention. For example, CMOC 3 would lead to questions about the interviewee's experience of quality improvement initiatives related to falls prevention and the impact of those initiatives. Based on CMOC 4, this may be followed by questions about whether the changes were sustained and, if so, what supported that, with questions about the role that safety huddles and handovers play in supporting that. Through this process, the interviewer channels the interviewee's responses to the task of developing and refining the theories. The interviewer proceeds to formalise the interviewee's theories, based on the information they have given, and the interviewee is then invited to comment on that formalisation. Consequently, the interview is a vehicle for enabling key participants to revise and expand the theory. The interviews will also be used to gather interviewees' perceptions about how adherence to falls risk assessment and prevention guidance could be improved. An interview topic guide will be established, based on the CMOCs, with the research team agreeing revisions to the guide in light of emerging themes. All interviews will be audio recorded and transcribed verbatim.

Patient and carer interviews: Semi-structured interviews will be conducted with patients and/or their carers. An interview topic guide will be established, based on the CMOCs and with input from our lay researchers. All interviews will be audio recorded and transcribed verbatim.

Record review: A form will be developed for recording information from the patient record. While this may vary according to the CMOCs to be tested, we intend to base it on the NAIF, capturing information on the assessments undertaken, how frequently, and the care plans in place. This will be done prior to observing a patient's care, so that the observations can be used to determine if the care plans are enacted.

Documents: Copies of materials such as forms and protocols that staff are observed to use when undertaking falls risk assessment and/or falls prevention activities will be collected, along with copies of Trust level policy/guidance documents and training materials concerning falls risk assessment and prevention.

Routinely collected data: Routinely collected data on number of falls and falls-related harms per ward per month will be obtained.

Data analysis

To analyse the data, we will use methods that we have used for theory testing in a previous realist evaluation (82). An iterative approach to data collection and analysis will be taken, to enable ongoing refinement and testing of the theories and the gathering of further data in light of such revisions. As a first step in analysing

the data, we will produce a series of matrix displays, based on the case dynamics matrices described by Miles & Huberman (83), to facilitate cross-case analysis and obtain an overview of the data. One matrix display will be produced for each CMOC being tested, keeping analysis focused on theory testing. Each matrix display, with one patient per row, will summarise the mechanisms anticipated by the CMOC (whether or not it was triggered), other mechanisms that appeared to be at play, contextual factors anticipated to trigger the mechanisms (whether or not they were present), other contextual factors that appeared to exert influence, and anticipated and unanticipated outcomes. The matrix displays will facilitate discussion, initially between the two researchers and PI and then with the wider project team, to determine whether the data support, refute, or suggest a revision or addition to the CMOCs. We anticipate that, as we scrutinise the matrix displays, further questions will become apparent, prompting a return to the data for further information.

Analysis of qualitative data: Where further information is required from the field notes and/or interview transcripts, the data will be indexed in NVivo, using codes relevant to the questions and inductive codes to capture other aspects of the contexts, mechanisms, and outcomes relevant to the CMOCs. In addition, we will conduct a data analysis session with our lay researchers, to gain their perspective on the qualitative data.

Analysis of quantitative data: Quantitative data will consist of, for each ward, data from the record review forms, concerning which assessments were undertaken, how frequently they were undertaken, and which care plans were in place, and data from the field notes, concerning whether those care plans were enacted. Descriptive statistics will be produced, broken down by ward. Following this, and following the approach that we took in a previous realist evaluation (70), specific analyses will be undertaken as they relate to the testing of the CMOCs. The nature of these analyses will heavily depend on the CMOCs that are developed, but the intention would be to undertake inferential analysis where possible, to test the theories. For instance, it may be possible to undertake factorial analysis of variance, or correlation and appropriate regression analysis but other analyses may also prove to be possible.

While we will also gather routinely collected data on number of falls and falls-related harms as contextual data, we do not anticipate undertaking quantitative analysis of these data, because there may be differences in falls rates between wards that are unrelated to the effectiveness of their falls prevention practices (e.g. due to age of patients on the ward).

Outputs

- An account of how falls risk assessment currently happens in practice, including detail of the form and content of artefacts that are used to support falls risk assessment and the role that EPRs play in the conduct of falls risk assessment; and
- A revised programme theory, with supporting data, that explains what supports and constrains routine use of multifactorial falls risk assessment and falls prevention interventions.

WP3: Development and dissemination of guidance (Months 22-24)

Objective

- To translate the programme theory into guidance to support multifactorial falls risk assessment and prevention and, in turn, adherence to the NICE guideline (Objective 3).

Summary of method

The third and final WP consists of the following three activities:

1. Presentations will be given at each of the case sites, reporting the results of the project. These are intended to be interactive sessions, to encourage discussion about the implications of the findings in terms of how to support multifactorial falls risk assessment and prevention. We will seek advice from the case sites regarding useful formats for dissemination of guidance (e.g. textual or more visual, such as short videos).
2. Guidance materials will be developed. The nature of this guidance will depend on the findings and on what our case sites tell us would be most helpful. Possible forms of guidance are discussed further under ‘Dissemination, outputs and anticipated impact’.
3. Having developed the guidance, we will hold a knowledge mobilisation event in order to gain feedback on the guidance. Who this event is targeted at will depend on who the guidance is most relevant to, which could be policymakers, commissioners, Trust level staff, ward level staff, patients and carers, or a combination of such stakeholder groups.

Outputs

- Guidance materials that Trusts can use to inform their own multifactorial falls risk assessment and prevention strategies.

ETHICS/REGULATORY APPROVALS

We propose to carry out data collection across three NHS hospital Trusts, involving staff and patients in the study. The research team has considerable relevant experience in carrying out qualitative research in such settings. NHS research ethics and HRA approval will be sought.

PATIENT AND PUBLIC INVOLVEMENT

A group of lay researchers, recruited via Leeds Older People's Forum, will be established and led by DW. The lay researchers will: at the end of Phase 1 of the realist review, present their views on the programme theory and on which of the CMOCs should be prioritised for testing in later stages of the review; at the end of WP1, present their views on which of the CMOCs should be prioritised for testing in WP2; contribute to the development of the observation protocol and the patient/carer interview topic guide for WP2; contribute to the analysis of WP2 data. We will also invite our lay researchers to present our findings with us. Training will be provided on realist evaluation and qualitative data analysis.

To evaluate our PPI, we will use a matrix developed by the Yorkshire & Humber Patient Safety Translational Research Centre for measuring PPI, on a scale of 1 to 6, against the six national standards for involving the public in research (inclusive opportunities; working together; support & learning; communications; impact; governance). Every six months (timed to take place shortly before each progress report is due), we will use the matrix as a basis for reflective discussions between the research team and the lay researchers and come to a consensus on how our PPI activities score against each standard. To measure performance against the standard of impact, at the beginning of the study, we will agree with our lay researchers the intended purpose of their involvement and the expected outcomes, so that discussions can explore to what extent those outcomes have been achieved. A summary of these discussions will be included in the PPI section of the progress reports, which we will invite our lay researchers to write. Given the expectation in the national standards of working together, these plans for evaluating PPI will be reviewed and revised with our lay researchers.

SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK

Success of the project as it progresses will be measured against completion of the milestones described above. Success criteria at the end of the project will be:

- Completion of the main outputs: a realist review of falls risk assessment and prevention; detail on the extent to which acute hospital Trust policies adhere to the NICE guideline; an account of how falls risk assessment currently happens in practice, including detail of the form and content of artefacts that are used to support falls risk assessment and the role that EPRs play in the conduct of falls risk assessment; a programme theory that explains what supports and constrains routine use of multifactorial falls risk assessment and falls prevention interventions; and actionable guidance that Trusts can use to inform their own multifactorial falls risk assessment and prevention strategies; and
- Dissemination of the findings to a range of relevant stakeholders, including our case study sites and the Manchester Falls Collaborative.

We are not aware of any barriers to the proposed work at present. A potential barrier to the proposed research is lack of willingness of NHS staff to participate in the research, either due to lack of time or other concerns. In previous studies, we have found use of ethnographic observations for data collection to be beneficial, as it does not require participant time away from their normal activities. Another risk is that staff change their behaviour due to the presence of the researcher. Our experience of undertaking similar studies suggests the importance of emphasising to staff that we are not there to assess their practice but instead wish to understand the challenges that they experience and having adequate time in the field to allow staff to become familiar with the researcher; allowing staff to see our fieldnotes is also a strategy for allaying any concerns.

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APPENDIX 1

Example search strategy: Theories of fall prevention in hospitals

30-09-2019
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to September 27, 2019>

1 Accidental Falls/ or exp Hip Fractures/pc (24006)
2 fall*.tw. (199205)
3 (slip? or trip?).tw. (19867)
4 or/1-3 [falls] (225262)
5 Risk Assessment/ (248485)
6 risk assessment*.tw,kw. (62496)
7 (fall* adj3 (assessment* or screen* or prevent* or predict*)).tw. (9295)
8 exp Accident Prevention/ (83051)
9 or/5-8 [assessment or prevention] (366394)
10 Hospitalization/ (101099)
11 Subacute Care/ (961)
12 Hospital Units/ (9935)
13 Inpatients/ (20256)
14 ((acute or sub-acute or subacute or hospital) adj3 (care or ward$1 or hospital)).tw. (943655)
15 ((rehabilitation or geriatric) adj (ward$1 or hospital$1 or unit$1 or department$1)).tw. (9072)
16 inpatient*.tw. (99901)
17 or/10-16 [hospital] (1059398)
18 4 and 9 and 17 [Fall assmt & prevention in hospitals] (2657)
19 (policy or policies or guideline* or recommendation* or position).ti. (197585)
20 guideline/ or practice guideline/ (32607)
21 policy/ or public policy/ or exp health policy/ (134747)
22 (theor* or concep* or logic).ti. (198480)
23 ((theor* or concep* or logic) adj (framework* or model* or analy* or evaluat*)).ab. (69671)
24 or/19-23 [Policy, Guideline or overt Theory] (571958)
25 Comment/ (805608)
26 Letter/ (1044110)
27 Editorial/ (503334)
28 news/ or newspaper article/ (214005)
29 "Comment on".ti. (25911)
30 (letter* adj3 editor*).ti. (15062)
31 opinion*.ti. (14773)
32 (view or views).ti. (52851)
33 or/25-32 [Discussion papers Hidden Theory] (2038947)
34 24 or 33 [Theory Search] (2551853)
35 4 and 9 and 34 (1051)
36 18 and 34 (141)

APPENDIX 2

Example search strategy: Systematic reviews of falls prevention in hospitals

30-09-2019
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to September 27, 2019>

1 Accidental Falls/ or exp Hip Fractures/pc (24006)
2 fall*.tw. (199205)
3 (slip? or trip?).tw. (19867)
4 or/1-3 [falls] (225262)
5 Risk Assessment/ (248485)
6 risk assessment*.tw,kw. (62496)
7 (fall* adj3 (assessment* or screen* or prevent* or predict*)).tw. (9295)
8 exp Accident Prevention/ (83051)
9 or/5-8 [assessment or prevention] (366394)
10 Hospitalization/ (101099)
11 Subacute Care/ (961)
12 Hospital Units/ (9935)
13 Inpatients/ (20256)
14 ((acute or sub-acute or subacute or hospital) adj3 (care or ward$1 or hospital)).tw. (943655)
15 ((rehabilitation or geriatric) adj (ward$1 or hospital$1 or unit$1 or department$1)).tw. (9072)
16 inpatient*.tw. (99901)
17 or/10-16 [hospital] (1059398)
18 4 and 9 and 17 [Fall assmt & prevention in hospitals] (2657)
19 limit 18 to (meta analysis or "systematic review") (56)
20 (Literature review* or (systematic adj2 review*) or (realist adj2 review*) or (narrative adj2 review*) or (critical adj2 review*) or scoping review* or synthesis or meta-analys* or "meta analysis").ti. (507485)
21 18 and 20 (71)