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Preventing Falls in Hospitalized Patients: State of the Science

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1. Introduction

Although hospital falls have been decreasing over the past several years, they remain a significant problem.¹ Patient falls are the most common adverse events reported in hospitals.^{2–5} Each year, roughly 700,000 to 1 million patient falls occur in U.S. hospitals resulting in around 250,000 injuries and up to 11,000 deaths.⁶ About 2% of hospitalized patients fall at least once during their stay.^{7,8} Approximately one in four falls result in injury, with about 10% resulting in serious injury.⁹

Inpatient falls result in significant physical and economic burdens to patients (increased injury and mortality rates and decreased quality of life) as well as to medical organizations (increased lengths of stay, medical care costs, and litigation).^{10,11} In 2008, Centers for Medicare & Medicaid Services (CMS) stopped reimbursing hospitals for fall-related injuries.¹² Given significant financial pressure, hospitals are seeking a “silver bullet” to fall prevention.¹³

Hospitals employ various “guidelines” for fall prevention.^{14–16} In general these include: 1) identify patients who are at high risk of falling and 2) use clinical judgment to decide which of a multitude of fall prevention strategies to utilize to reduce fall risk. Not surprisingly, there is considerable heterogeneity among the guidelines which adds to confusion on the “right approach” to fall prevention; this is promoting the uptake of time- and labor- intensive

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approaches to fall prevention into “standard of care.”¹⁷ The lack of clarity of prevention guidelines may add to the cognitive burden of patient care and potentially increases patient risk.^{18–20}

Although there is a growing body of research on fall prevention in community dwelling elderly, findings from these studies are not necessarily generalizable to the hospital environment.¹⁷ Hospital patients have a myriad of acute and chronic illnesses which limit judgement and mobility and they must navigate a new and unfamiliar environment. Furthermore, staffing and even unit design considerations may play into fall risk. Short lengths of stay offer a brief window of time to conduct interventions, rendering some strategies (e.g. exercise programs) impractical. The unique organizational culture and leadership structures of hospitals require specific implementation strategies. Thus, it is imperative to examine fall prevention intervention strategies specific to the hospital setting.

2. Study designs

While this manuscript is by no means a complete review of study designs, the goal is to familiarize the reader with the strengths and limitations of the types of research often used to test fall prevention interventions.

2.1. Quality Improvement Studies

Many studies on fall prevention in hospitals take the form of a quality improvement (QI) study. The goal of QI studies is *not* to generate generalizable knowledge but to share the results of a programmatic change on health outcome such as falls.²¹ Many QI studies employ an uncontrolled before-after design conducted on single nursing unit (or group of units).

There are several reasons why most QI studies should not be viewed as “evidence” of effectiveness of a fall prevention strategy. First, these studies are in general less rigorous than research studies. Pronovost and Wachter state QI studies “commonly lack clarity regarding the study population, interventions and co-interventions, outcome measurement and definitions...and what data are available may be poor in quality.”²² QI interventions frequently contain multiple components, often not well described, which can change thorough the study. In addition, many of these interventions are led by a “champion” and it is difficult to know how much the intervention was dependent on the “champion.” Also, without a control group it is difficult to distinguish the effect of intervention from underlying secular trends in falls. Finally, the incentive to publish a negative QI study is low, so the possibility of publication bias is high. This may explain why Hempel found the intervention effect for fall prevention across historical control studies (often QI) was 0.77 (95% Confidence Interval = 0.5–1.18) whereas the intervention effect for fall prevention in studies with concurrent controls (often research) was 0.92 (95% Confidence Interval = 0.65–1.30).²³

In sum, we view QI studies as analogous to “case reports.” These studies are important for hypothesis generation they do not serve as “evidence” that a fall prevention strategy is effective outside of the context of the quality improvement initiative.

2.2. Research: Randomized Studies

Controlled trials represent a much stronger study design. Randomization and outcome assessment can occur at the patient level or at a larger level—often the nursing unit. Such designs are referred to as cluster randomized controlled trials (cRCTs). Traditionally cRCTs were conducted using a parallel design, meaning once randomized, study units remain intervention and control conditions through the duration of the study. A stepped wedge is a newer design where all units in the study transition from control to experimental conditions at regular intervals, called “steps,” which controls for underlying secular trends.²⁴ This type of design is particularly advantageous when evaluating a clinical or policy strategy has been “made” but can be rolled out at flexible dates.

There are several advantages to employing a cluster- rather than a patient-randomized study for hospital fall prevention. First, the possibility of contamination of the intervention onto control patients is lessened when conducted by geographically separated staff. Second, although an intervention may be effective at the patient-level (e.g., none of the patients fell who had the intervention), the total number of falls a unit experiences may remain the unchanged because the intervention was not applied to the “right” patients or so much attention was paid to the intervention patients on the unit that “different” patients fell. Thus an intervention could be efficacious for individual patients but not effective in practice.

In a cRCT units should be followed for several months prior to randomization to establish baseline rates and then randomized to intervention and control conditions using methods that would assure baseline fall rates are similar between intervention and control units. Follow-up should be long enough to minimize the study novelty, and to allow units to establish stable fall rates. To minimize ascertainment bias is important that the visibility of the study remain approximately equal between intervention and control units. To address secular trends in fall rates the effect of the intervention should be tested using the interaction of the slope of the rate of falls in the unit type (intervention or control) and the time (before and after the initiate the intervention).

2.3. Research: Non-randomized studies

Although randomized controlled studies yield the highest level of evidence, some universally applied interventions (e.g., national policy changes) cannot be studied in a controlled manor.²⁵ In such cases, useful evidence can be derived from large, credible parallel or before-and-after studies where the effect size cannot easily be attributable to confounders, and where efforts have been made to control for secular trends.²⁶

3. Single Fall Prevention Interventions

3.1. Fall risk identification

The use of fall risk prediction tools is widespread, but their value in hospital fall prevention interventions is questionable.^{27–29} First, it is important distinguish between fall risk assessments and fall prediction or screening tools. Risk assessments usually consist of a checklist of risk factors for falls, but do not provide a score or value for the patient’s fall

risk. Predictive tools use these known risk factors to calculate a score for the patient's risk of falling, with established cutoffs to identify risk level.

Some tools have demonstrated acceptable sensitivity and specificity in single studies, but the reported predictive values of these tools vary by study design, setting, and population.^{27,28,30} Further, a patient's risk for falling is transitory, requiring periodic reassessment. Few tools have been validated specifically with older hospital patients, and a recent systematic review concluded that existing tools do not have sufficient specificity and sensitivity to be effectively used in this population.³¹

The lack of evidence supporting the use of predictive tools led to 2013 National Institute for Health and Care Excellence (NICE) guidelines which explicitly recommended *against* the routine use of fall prediction tools, instead advising that all inpatients over the age of 65 be considered at high-risk.³² The Agency for Healthcare Research and Quality (AHRQ) cautions that it is more important to identify and address a patient's specific fall risk factors than to determine their risk for falling.³ Despite this, fall risk screening tools are frequently used to identify patients for intervention,²³ often, relying on "home-made" tools without established psychometric properties.⁴ While these tools have the potential to tailor fall prevention strategies to specific patient risk factors,³³ they predict falls no better than nursing judgement.³⁴

3.2. Alarms

Alarm systems are designed to reduce falls by alerting staff when patients attempt to leave a bed or chair without assistance. They can also function as a reminder to patients to call for assistance before getting up. There are several types of alarm systems in use, including pressure mats, infrared movement detectors, cord-activated alarms, and wearable devices.³⁵ Alarms are disruptive and may be especially disturbing to cognitively impaired patients, contributing to confusion and agitation. They also restrict mobility and independence; in US nursing homes, alarms are considered a type of restraint and facilities can be penalized for indiscriminate use of the devices.³⁶

There is now strong evidence that alarms are ineffective as a fall prevention maneuver in hospitals.^{37,38} A large cRCT tested the effectiveness of bed/chair alarm systems to prevent falls in 16 general medical, surgical and specialty units in a US community hospital.³⁷ Although the intervention successfully increased alarm use, there was no significant effect on falls or physical restraint use. In an RCT performed in three acute wards in a UK hospital, Sahota et al. found that alarms did not reduce fall rates and were not cost-effective.³⁸ AHRQ has cautioned there is an overreliance on alarms as a fall prevention measure,³ yet alarms remain in use by over 90% of nurse managers.³⁹

There are a few possible explanations for the ineffectiveness of alarms as a fall prevention strategy. Reliance on alarms assumes staff have enough time to intervene prior to a fall, which could be only a matter of seconds. Alarms may decrease vigilance by giving staff a false sense of security. Finally, the Joint Commission has expressed concerns about excessive hospital noise leading to general "alarm fatigue".⁴⁰

Although the current body of evidence does not support the effectiveness of alarms as a fall prevention measure in hospitals, there is promising new technology that may better predict and prevent falls.^{41,42} These new systems and devices have the potential to serve as effective and sustainable fall prevention strategies.

3.3. Sitters

Sitters, also known as companions or ‘specials’, are a potentially effective yet costly fall prevention strategy. Sitters provide one-to-one surveillance for patients deemed at high risk for falls and may additionally provide therapeutic care. Guidelines for the use of sitters and their duties, qualifications, and training vary among hospitals.^{43,44}

There is indirect evidence of sitter effectiveness, but no RCTs of sitters as a single intervention have been performed to date. The evidence supporting effectiveness of sitters has been limited to small observational studies conducted in a single hospital—each with its own definition of what constitutes a sitter.^{45–48} In addition to the limited evidence of effectiveness, there is the possibility that sitters may have an adverse effect on patient care; for example, to save on costs, existing staff may be utilized as sitters, potentially placing other patients at risk. Despite the lack of evidence, sitters are recommended in numerous fall prevention guidelines.⁴⁹

Sitters represent a considerable expense, with annual costs of over \$1 million reported.^{45,50} These costs are rising and are typically not reimbursable by third-party payers.^{45,51} Due to their expense, hospitals are increasingly interested in reducing sitter use without negatively impacting patient safety. Several initiatives have successfully reduced sitter use without increasing fall rates.^{43,52}

In sum, patient sitters are costly and hospitals discourage their use. Although not studied rigorously, whether sitters prevent falls is not well established.⁴³ Feil found that more than 4 of 5 falls which occurred with a sitter present were unassisted,⁴⁹ reinforcing the hypothesis that sitters are not a panacea for hospital falls.

3.4. Intentional Rounding

In an effort to increase patient satisfaction and reduce patient harm, many hospitals have instituted intentional rounding. Rounding is a proactive approach to meeting patient needs that involves bedside checks at regular intervals, usually every one to two hours. The quality of evidence for rounding is weak, with most of the literature consisting of QI studies.^{53,54} Difficulties with adherence and sustainability of rounding initiatives are widely reported,^{55–57} and introduction of the practice is often perceived as a top-down approach which restricts staff autonomy.⁵⁷ Other barriers include increased workload, competing priorities, poor documentation, inadequate education, and lack of staff buy-in.^{55,56} Thus, even if stronger evidence supporting the effectiveness of rounding is produced, the feasibility of the strategy as a sustainable fall prevention practice is uncertain.

3.5. Patient Education

There is some evidence that education is an effective component of multifactorial interventions,⁵⁸ but the body of evidence on their effectiveness as a single intervention is limited. Haines et al. performed an RCT of a multimedia education intervention combined with one-on-one follow up from a health professional. While the intervention did not significantly reduce fall-related outcomes overall, subgroup analysis of cognitively intact patients who received the intervention showed a 50% reduction in fall rates.⁵⁸ When the same intervention was tested in a cluster RCT in 8 hospital rehabilitation wards, a significant reduction in rates of falls and falls resulting in injury.⁵⁹ These results may be explained by the fact that patients in rehabilitation wards tend to be more cognitively intact than those in acute settings. Thus, although patient education is potentially effective in reducing hospital falls for certain patients, it is not suitable for patients with cognitive impairment—a common risk factors for inpatient falls.⁶⁰

3.6. Environmental Modifications

The physical environment can be an important contributor to falls. Of a total of 538 hospital falls resulting in death or permanent loss of function that were reviewed by The Joint Commission, 209 (39%) identified the physical environment as part of the root cause.⁸ Small studies have explored the impact of a variety of environmental modifications. One RCT found fewer falls occurred on vinyl flooring compared to carpet, but the findings were limited by a small sample size and low fall rate during the 9-month trial.⁶¹ A cRCT found no evidence that low-low beds reduced rates of falls or injuries from falls.⁶² Other interventions have included visual cues (e.g. signage, wristbands), lighting, and the use of special rooms for high-risk patients.^{63–65} Some of these fall prevention efforts have resulted in patient harm; for example, in 2005 the FDA issued a recall of enclosed beds after reports of patient injury and death from entrapment.⁶⁶

3.7. Physical Restraints

There is considerable controversy surrounding the use of physical restraints in hospital settings.^{5,67} Patients who require restraints suffer a loss of dignity and autonomy; furthermore, restraints may also cause agitation, delirium, pressure ulcers, deconditioning, strangulation and death.^{68,69} Data suggest that restraints may not protect, but actually increase risk of falling, or sustaining an injurious fall.^{70–72}

Unfortunately, on the part of both health professionals and patients, there is a perception that restraints reduce the risk of falling, and they are often employed as a “last resort” to protect patients from falling.^{67,73,74} This perception of physical restraint effectiveness as a strategy to prevent falls has persisted despite the increasingly restrictive regulations and standards from CMS and The Joint Commission limiting their use.^{75,76}

3.8. Non-Slip Socks

Non-slip socks are often provided to hospitalized patients under the assumption that they will provide additional traction to prevent patient falls. In contrast to manufacturers' claims, research has cast doubt on the slip-resistant properties of these products.⁷⁷ The small body of research on non-slip socks has not provided evidence of their efficacy as a fall prevention

strategy.⁷⁸ Further, non-slip socks carry the risk of spreading drug-resistant infection in hospitals.⁷⁹ Given the lack of evidence of effectiveness and potential to spread infection, a patient's own footwear remains the safest option for fall prevention.

4. Multifactorial Interventions

Given the multitude of factors contributing to falls, it is intuitive that multi-component interventions would be most effective in improving fall outcomes. Although fall prevention guidelines typically recommend the use of multicomponent interventions,^{3,14,16,32} there have been relatively few controlled trials of multi-component interventions. Of these, some have found a reduction in fall rates^{80,81} while others reported no intervention effect.^{82,83} Barker et al. recently conducted the largest cRCT of a hospital fall prevention intervention to date in 24 wards in 6 Australian hospitals (n=46,245 admissions). Despite successful implementation of the 6-PACK program, the intervention did not produce lower rates of falls or fall-related injuries.⁸³

The limited number of high-quality studies and heterogeneity among intervention sites make it challenging to combine studies for quantitative overviews. In a 2012 Cochrane review⁸⁴, pooled analysis of four small multicomponent RCTs revealed an overall reduction in fall rate ratio (0.69, 95% CI 0.49–0.96) but not injurious falls. However, three of the cited studies included subacute care units and the fourth was conducted in a single geriatric orthopedic unit. A 2012 meta-analysis of six acute care interventions found a statistically significant, but small reduction in fall rates (OR 0.9, CI 0.83–0.99) (DiBardino).⁸⁵ A 2013 updated review² supported the evidence for multicomponent interventions, additionally identifying factors associated with success. It should be noted that none of these analyses did not include the most recent negative results of the 6-PACK trial; this information will be included in a forthcoming Cochrane Review.

The current body of evidence on multi-factorial interventions is limited in several respects. The heterogeneity of components, delivery characteristics, and target populations make it difficult to identify which specific components are effective. Implementation is a key component of any successful patient safety initiative, but there is a lack of reporting on how interventions were implemented in published studies.²³ Finally, the body of evidence also tends to be limited to older populations with a longer length of stay.⁵

5. Conclusion

Although decreasing, hospital falls are a significant patient safety problem. While there is a growing literature on strategies to prevent these events, most are uncontrolled quality improvement studies. Even though a number of successful quality improvement programs have been described, most controlled studies of fall prevention have been “negative.” This is typical for any “emerging science.” Thus, there is an urgent need for well-designed research studies in hospital fall prevention.

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Synopsis:

Falls in hospitalized patients are a pressing patient safety concern, but there is a limited body of evidence demonstrating the effectiveness of commonly used fall prevention interventions in hospitals. This article reviews common study designs and the evidence for various hospital fall prevention interventions. There is a need for more rigorous research on fall prevention in the hospital setting.

Key Points:

- Falls in hospitalized patients result in significant burdens to patients and medical organizations
- Despite the multiplicity of “positive” quality assurance demonstrations of fall prevention interventions, these studies should not be viewed as “evidence” of effectiveness
- Few controlled interventions exceed usual care in preventing hospital falls when tested rigorously
- There is a pressing need for large, well-designed trials of hospital fall prevention interventions