PATIENT FALLS IN ACUTE CARE

INPATIENT HOSPITALS: A PORTFOLIO

OF RESEARCH RELATED TO

STRATEGIES IN REDUCING FALLS

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Signed Statement

This portfolio contains no material which has been accepted for the award of any degree or diploma in any university or other tertiary institution and to the best of my knowledge and belief contains no material previously published or written by another person except where due reference has been made in the text.

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Introduction to Portfolio
Introduction

Despite a myriad of studies on fall prevention, patient falls continue to be a long-term problem experienced by health care organisations world-wide. Falls impose a heavy burden in terms of social, medical, and financial outcomes,\(^1\) and continue to pose a threat to patient safety.\(^2\) Because the potential for a fall is a constant clinical safety issue in every health care organisation,\(^3\) protecting the patient from falls and subsequent injuries, and ensuring that the patient care environment facilitates, are fundamental aspects in providing quality care.\(^4\) Moreover, the current international focus on creating a culture of quality care and patient safety requires the implementation of fall prevention programs that decrease the risk of falls.\(^5\)

As with other international health care organisations, the National University Hospital (where the principal investigator is working), has been challenged with the issue of how to prioritise and implement quality initiatives across all disciplines. Faced with persistent patient falls that affect care outcomes, fall prevention has been a priority initiative at the hospital since 2003. In response, a nursing task force was established in an attempt to resolve this problem. A root cause analysis undertaken by this task force revealed that the hospital protocol on fall prevention was outdated and not evidence-based. Furthermore, many nurses did not understand the importance of fall prevention, while the administration of the fall prevention program was instituted on an ad hoc basis rather than as a standard of care for all patients. The challenge for this task force, as with other
health care professionals, was not only in finding an intervention that was effective, but also identifying who would benefit from its implementation.

Although the need to apply current best practices to reduce patient falls is clear from the task force results, evidence of the effectiveness of fall prevention interventions in acute care hospitals is lacking in literature. In addition, there are no published studies on fall prevention in Singapore to support changes in nursing practices. Thus, it becomes apparent that research on fall prevention is greatly needed in Singapore so that an evidence-based fall prevention program can be developed.

This topic coincides with the Doctor of Nursing course, which requires the student to gain knowledge through scholarly research on contemporary issues in nursing by undertaking two separate projects related to a single area of interest. Undertaking the two research projects on fall prevention in an acute care inpatient hospital as part of the doctoral studies provided an opportunity to address this deficit in a way that could raise awareness of the importance of fall prevention in Singapore hospitals. This research also provides a platform for the first body of research into fall prevention to be conducted within the Singapore health care environment, which is essential, as international studies are not always necessarily applicable to the Singapore context due to differences in educational preparation, skills-mix, organisational culture and nursing practices.
Significance of the Research

The two research studies contained in this portfolio are believed to be the first in-depth study of fall prevention in Singapore. The significance of this research offers new insights on the validity of fall-risk assessment tools and the effectiveness of multi-targeted fall prevention interventions within the context of acute care inpatient hospitals. This portfolio also provides recommendations on how this research can contribute to a reduction in the number of patient falls in Singapore hospitals.

Portfolio Structure and Overview

This portfolio into patient falls in acute care inpatient hospitals describes the researcher’s journey in the evaluation of various fall-risk assessment tools and exploration of strategies to reduce patient fall rates. As a journey, it is presented in five sections that represent significant points within the portfolio, and is designed to assist the reader navigate through the portfolio.

Section 1: This section of the portfolio addresses a number of important issues on falls and falls prevention. Firstly, it depicts how falls have been defined in literature and notes the inconsistencies in definitions that have been used. Secondly, it describes the incidence, risk factor, circumstances and impact of falls. Thirdly, it explores existing fall-risk assessment tools and fall prevention strategies. Lastly, two research studies are presented from the background review of contemporary literature.
Section 2: Based on Section 1, this section recounts the report of the first research study entitled ‘Evaluation of three fall-risk assessment tools in an acute care inpatient hospital’. The aim of this study was to evaluate the predictive validity of three fall-risk assessment tools, namely the Morse Fall Scale, STRATIFY, and Hendrich II Fall Risk Model. The study highlighted that Hendrich II Fall Risk Model (with a cut-off score of $\geq 5$) and Morse Fall Scale (with a cut-off score of $\geq 25$) were the only two tools that had strong sensitivity values to identify patients at high risk of falls. However, only the Hendrich II Fall Risk Model had acceptable specificity compared to the Morse Fall Scale. Thus, the Hendrich II Fall Risk Model provides the best predictive validity and reliability compared to Morse Fall Scale and STRATIFY.

Section 3: Based on Section 2, this section relates the report of the second research study entitled ‘A randomised control trial evaluating the use of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital’. This double-blind randomised controlled trial was designed to compare two fall prevention interventions: a) universal multiple interventions, and b) targeted multiple interventions. The purpose of this study was to determine the effectiveness of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital. The findings revealed that a targeted multiple intervention strategy is linked to the reduction in the mean number of falls, a reduction in the relative risk of recorded falls, and a longer mean time to the first fall in the intervention group.
**Section 4:** This section provides a summary of the two research studies and the implications of the research on nursing practices, as well as further research in the area of fall prevention in acute care inpatient hospitals. It also provides strategies for translating the research evidence.

**Section 5:** This section contains a copy of a peer reviewed publication that was generated from this portfolio.
Section 1

Background Literature Review and Context of Research
Section 1

This section establishes the context for research and defines the field of study—that is, fall prevention in acute care in-patient hospitals. This section guides the reader through the principal investigator’s initial review of contemporary literature, categorising the information under the following seven sub-headings: definition of falls, incidence of falls, risk factor for falls, falls circumstances, impact of falls, fall-risk assessment, and fall prevention strategy. Two research studies are identified as a result of this background literature review.

Definition of Falls

In many of the reviewed studies, the concept of a fall was taken for granted, and no definition was given.\textsuperscript{2-5} In those studies that had a definition of what constitutes a fall, the definition varied between studies. For example, Hitchco and colleagues defined a fall as ‘a sudden unexpected descent from a standing, sitting or horizontal position, including slipping from a chair to the floor, patients found on the floor, and falls that occur while the patient is assisted by hospital staff’\textsuperscript{11} (p.117). Chu and colleagues defined a fall as ‘an event which results in a person coming to rest unintentionally on the ground or other lower level, not due to any intentional movement, a major intrinsic events (e.g., stroke) or extrinsic force (e.g., forcefully pushed down, knocked down by a car’\textsuperscript{12} (p.61). The lack of a consistent definition of a fall has, to some extent, hampered the comparison of studies. There is a need for a consistent standardised definition of falls that can be used universally.\textsuperscript{13-15} A published consensus statement recommends that a fall be
defined as ‘an unexpected event in which participants come to rest on the ground, floor, or lower level’ 16 (p.1619).

**Prevalence of Falls**

Falls are the most frequently reported critical incident in acute care inpatient hospitals,17, 18 accounting for as much as 40% of the hospital incident reports. 19, 20 Furthermore, at least 10% of elderly patients experience a fall during an acute care stay in hospital.21 The incidence of patient falls is likely to continue to increase as the population ages, particularly when many elderly patients have physical and cognitive limitations, and are unfamiliar with the hazardous surroundings of the hospital.2

**Incidence of Falls**

Studies on fall rates in acute care inpatient hospitals are limited, and wide variation in fall rates have been reported between 2.2 and 8.9 per 1,000 patient days depending on patient population and disease type.11, 21-27 A retrospective cross-sectional study on falls in Singapore showed that patient fall rates ranged from 0.68 to 1.44 per 1,000 patient days.25 This is lower in comparison with studies carried out internationally. Research also shows that fall rates vary from one clinical specialisation to the next. In Switzerland, Halfon and colleagues22 reported that departments such as gynecology, obstetrics, pediatrics and intensive care reported no falls, while falls were frequent in medical units. A retrospective study conducted by Kerzman and colleagues26 in Israel found there was a higher
incidence of falls in elder care, psychiatric and rehabilitation than in surgical, medical and paediatric units. Another recent retrospective study conducted by Fischer and colleagues\textsuperscript{24} found higher falls rate in psychiatry, medicine and oncology than in surgery, gynecology, obstetrics and paediatrics, while a four-month prospective study conducted by Hitcho and colleagues\textsuperscript{11} in the same hospital reported higher fall rate in medicine, neurology and oncology than in orthopedic, gynecology, obstetrics and paediatrics units.

Differences in fall rates could result from variations in the definition of a fall, the methods of reporting falls, the methods of analysis,\textsuperscript{15} and patient characteristics across the settings; rehabilitation ward compared to a gynaecological or obstetric ward where patients are characteristically quite different, and therefore the difference in fall rates will be a function of these differences. Several of the studies\textsuperscript{24,26} are retrospective, relying solely on data from either medical records or risk management databases, which are often incomplete. These factors could explain some of the differences in the incidence rate of falls, thus rendering comparisons problematic.\textsuperscript{14} In addition, studies on fall rates in acute care are limited, and the data is inadequate to set a benchmark that determines an acceptable level of falls.

**Risk Factors for Falls**

A risk factor is defined ‘as a characteristic or situation found significantly more often among individuals who subsequently experience a certain adverse event than individuals not experiencing the event’\textsuperscript{28} (p.15). The likelihood of falling
increases with the number of risk factors. Approximately 80% of the patients in acute care hospitals have at least two risk factors for falls. Several case-control studies have been performed to identify the risk factors for falls among hospital inpatients. Risk factors include: history of falls, age (over 65 years), gender, medication use, impaired mental status, increased toileting needs, impaired mobility, sensory impairments, and environmental hazards. These risk factors form the domains of the fall-risk assessment tools.

**History of Falls**

History of falling was a positive predictor of future falls in three case-control studies, and one descriptive study. In a study conducted by Hendrich and colleagues, a history of falling seemed to be significant risk factor, as other studies also reported. However, when the sample size was increased from 338 to 1,135 patients (fallers and non-fallers) in a recent study, it became clear that many of the risk factors reported in previous studies overestimated the importance of certain risk factors. Hendrich and colleagues pointed out that when large numbers of non-fallers (control patients) were tested against patients who fell, the significance of a history of falls became insignificant. A history of falls only appeared to be significant because it was always paired with a ‘real’ risk factor. If patients were falling often, the fall risk factor was the true ‘root’ cause of why they were falling, and not the fact they have a history of falls.
The percentage of fallers that are reported in studies who fall more than once is variable. A prospective descriptive study reported that about 25% of the first falls were followed by at least one more fall.\textsuperscript{11} Another retrospective descriptive study reported that 11% of the patients fell more than once.\textsuperscript{24} No research has focused on the difference in risk factors for falls between one-time fallers and recurrent fallers.

**Age and Gender**

In several descriptive studies, age was found to increase an individual’s risk of falling, with the elderly (aged 65 years and older) at greater risk than younger patients.\textsuperscript{11, 24, 26} Yet, age has not been identified as a risk factor for falls in case control studies,\textsuperscript{30, 31, 33} as it is not just the elderly who fall in acute care hospitals. The elderly, as noted, account for the overwhelming majority of those who fall, but results of recent studies suggest that younger patients in specialised areas, such as medicine, neurology and oncology, also have an increased risk of falling. Age appears to be a risk factor because it often correlates with the true risk factor of impaired gait and mobility.\textsuperscript{30, 35}

Reports on gender are contradictory. For instance, a case-control study\textsuperscript{32} and a descriptive study\textsuperscript{36} identified male patients as being more likely to fall, while another three studies,\textsuperscript{11, 37} two descriptive studies and a case control study,\textsuperscript{30} identified female patients as being more prone to falling.
Medication Use

The relationship between medication use and falls has been examined in many studies. Hendrich and colleagues\textsuperscript{32} found a significant increase in risk from anti-epileptics and benzodiazepines. In a study by Wagner,\textsuperscript{38} an analysis was undertaken to determine the effect of using benzodiazepines and the occurrence of hip fractures in the elderly. After controlling for potential confounders (age, sex, race), it was determined that the incidence of hip fractures appears to be associated with benzodiazepines use. Multivariate results from a case-control study conducted by Krauss and colleagues,\textsuperscript{30} revealed that the use of sedatives/hypnotics (odd ratio = 4.3; confidence interval = 1.6-11.5) and diabetic medications (odd ratio = 3.2; confidence interval = 1.3 -7.9) increased the risk of falling.

The common medications associated with fall risk include those that act on the central nervous system such as sedatives/hypnotics and tranquilizers, and benzodiazepines.\textsuperscript{2,11, 30, 32, 38} Patients receiving three or more psychoactive medications are particularly at risk of falling. Other medications associated with an increased risk of falls include anti-epileptic,\textsuperscript{32} digoxin, beta-blockers, anticoagulants,\textsuperscript{11} diuretics and anti-hypertensives.\textsuperscript{2} Drug effects and reactions may affect cognition and balance, thus contributing to patient falls.\textsuperscript{35}
Impaired Mental Status

Impaired mental status was the most commonly identified risk factor associated with increased risk of falling in case-control studies.\textsuperscript{31-33} Impaired mental status was most commonly described as confusion, disorientation, and agitation, but the results of a large case-control study\textsuperscript{32} reported that symptomatic depression might increase a patient’s risk of falling. Moreover, impulsive behaviour due to cerebral insult might influence a stroke patient’s risk of falling.\textsuperscript{29,32}

Impaired Mobility

Impaired mobility was a commonly identified risk factors associated with an increased risk of falling in several case-control studies.\textsuperscript{30-34} Impaired mobility was most frequently described as a general weakness or impaired gait,\textsuperscript{33} gait/balance deficit, decreased mobility of the lower limbs, any lower extremity problem,\textsuperscript{30} and needing assistance with ambulation.\textsuperscript{34}

Increased Toileting Needs

Increased toileting needs were cited in two-case-control studies on individuals with frequent urination, incontinence, nocturia, urgency, and diarrhoea or toileting needs related to the use of cathartics.\textsuperscript{31,32}
Sensory Deficits

Sensory deficits were also found to increase a patient’s risk of falling, and were described as dizziness and vertigo. Impaired vision related to cataract, glaucoma or macular degeneration was found to increase the risk of falling in the elderly.

Environmental Hazards

Environmental hazards such as poor lighting, slippery floor surfaces, and ill-fitting footwear were estimated to contribute to approximately 10% of the falls in hospitals. The risk of environmental hazards contributing to falls is greatest for patients with poor ambulation and transfer mobility, which can result from a mismatch between the patient’s mobility capabilities and the design of the surrounding environment. For example, patients with poor gait are at greatest risk of balance loss and falls when walking on slippery or waxed floors than those with normal gait. Likewise, patients with poor transfers are at greatest fall risk when standing up from low-seated chairs.

Fall Circumstances

Location and Activity at Time of Falls

The majority of falls occur from, or near, the patient’s bed, and these account for up to half of all falls. Another common fall location is the bathroom. About 50% of falls occur while getting out of bed or ambulating to and from the bathroom or bedside commode. Elimination-related falls were common among the elderly (65 years and older), and usually occurred at night.
Time of the Day

The time of the day that patient's fall varies between studies. Halfon and colleagues\textsuperscript{22} identified morning and evening as the highest risk time, and identified ambulating as the highest risk activity. Fischer and colleagues\textsuperscript{24} reported that 39\% of falls occurred at night, with 31\% in the evening, and 30\% during the day. Similarly, Hitcho and colleagues\textsuperscript{11} found 59\% of falls occurred at night, and 42\% occurred in the day and evening. Donoghue and colleagues\textsuperscript{37} reported 50\% of falls occurred in the morning and early afternoon, and 31\% at night. On the other hand, Kerzman and colleagues\textsuperscript{26} found that falls occurred around the clock. A major limitation in all these studies was the lack of a standardised definition of day, evening, and night, which caused comparison problems.

In summary, there are several limitations to the studies on risk factors for falls, and falls circumstances that make it difficult to compare and draw conclusions. Firstly, the studies were performed on different populations. Morse et al,\textsuperscript{33} Krauss et al.\textsuperscript{30} and Hendrich et al.\textsuperscript{32} conducted their study in a general hospital population, while Oliver et al. conducted their study on an elderly population. Secondly, the studies were performed on variable sample size, ranging from 100 fall patients and 100 control, to 355 fall patients and 780 control.\textsuperscript{32} Thirdly, the literature describes a large number of prospective descriptive studies on fall risk factors that contribute to the general knowledge of fallers, but may overestimate fall risk factors when non-fallers (control) are not used.\textsuperscript{35} Finally, although
impaired mobility was the only risk factor identified in every study, each of the studies expressed the notion of impaired mobility in a different way.

**Falls Injuries Rate**

About 60%-70% of the falls resulted in no injuries at all with 30%-40% resulting in minor and moderate injuries, and 3-6% resulting in major injuries.$^{11, 24, 25, 30}$ Minor injuries include: pain/swelling, abrasions/skin tears, bleeding, lacerations/perforations/punctures, minor contusions, and reddened area on skin. Moderate injuries include: contusions/haematoma, and neck sprain, while typical serious injuries include: excessive or serious bleeding or laceration, cranial bleeding fracture or dislocation, and haematoma or contusion.$^{11, 22, 29}$

Few studies$^{11, 22, 27, 29}$ have evaluated the predictors of fall-related injuries, while existing evidence is contradictory. A case-control study conducted by Krauss and colleagues$^{30}$ reported that patients who fell in the bathroom were more likely to suffer an injury than those who fell in patient hospital rooms. In addition, patients with visual impairments were more likely to suffer an injury than those who did not have a visual impairment. A prospective descriptive study by Hitcho and colleagues,$^{11}$ found that females were more likely to suffer an injury, and that patients who were confused or disoriented were less likely to be injured than alert and oriented patients. In addition, elimination-related falls increased the risk of the elderly suffering a fall-related injury.$^{11}$ Oncology patients were found to have
the highest rate of injury, which was related to anaemia, thrombocytopenia and risk of pathologic fracture.\textsuperscript{11}

Fischer and colleagues\textsuperscript{24} reported that patients aged 75 years old, and those on the geriatric floor were more likely to sustain serious fall-related injuries. However, Vassallo et al.\textsuperscript{41} found that injuries were unpredictable, and none of the patient characteristics studied were able to distinguish patients who fell and sustained no injury from those patients prone to injury after a fall.

**Impact of Falls**

Hospital falls have implications for both the patient and hospital. For the patient, a fall can cause serious discomfort, injury and delayed recovery. Ultimately, a fall could result in morbidity, mortality, and early placement in a nursing home.\textsuperscript{17} The effects of falls extend beyond physical injury. Tinetti et al.\textsuperscript{42} and Wilson \textsuperscript{39} reported that elderly patients can acquire impaired mobility from an injury, fear from a lack of self-confidence, or restriction in ambulation, either self-imposed or imposed by family members in an attempt to prevent subsequent falls. Such restrictions will, in turn, precipitate further decline in function, which contribute to an increased risk for falls.\textsuperscript{43} For example, Friedman et al.\textsuperscript{44} found that falls and a fear of falling shared the same prediction. Individuals who developed one of these outcomes were at risk of developing the other, resulting in a spiralling risk of falls, fear of falling, and functional decline. Furthermore, Salkeld et al.\textsuperscript{45} found that 89% of elderly women would rather be dead than experience the loss of
independence that results from a hip fracture and subsequent admission to a nursing home.

Patient’s relatives are also affected by a fall. They may be concerned for the safety of their relative (the patient), or the relative’s ability to remain independent with the possibility of long-term care. \[^{46}\] When a fall occurs, the patient’s relatives are often angry and feel that the fall should not have happened in a hospital and that staff are therefore negligent. \[^{47}\] This can lead to a loss of confidence by the public in the ability of the health care system to provide safe services, \[^{48}\] and the staff, in turn, feel guilty and concerned. \[^{47}\]

For the hospital, a fall results in loss of revenue where fall-related injuries or complications increase the patient’s length of stay. \[^{39}\] Patients who fall and sustain an injury are reported to have hospital charges of over $US 4,200 (or approximately SGD $6,720 dollars) higher than those who do not fall. \[^{18}\] In a prospective study conducted in four institutions in Finland in 2002, the average cost per fall was Euro 944 (or approximately SGD $1,859). \[^{49}\] No research has been conducted in Singapore on the cost of falls. The costs incurred as a result of fall-related injuries are substantial in terms of the use of health care services, and waiver of hospital charges, subsequently placing an enormous pressure on health care systems. \[^{50}\] It also exposes staff and the hospital to complaints, coroner’s inquests and litigation. \[^{47}\] Hence, prevention of falls in acute care inpatient hospitals is an important patient and public health care issue. \[^{11}\] The risk of falling can never be totally eliminated but can be significantly reduced through the
implementation of an effective fall prevention program, which is essential for the holistic care of patients.\textsuperscript{46} The fall prevention program is comprised of two components: fall risk assessment tools to identify patients who are likely to fall, and the fall intervention strategies to prevent patients from falling.\textsuperscript{51}

**Fall Risk Assessment Tools**

A major strategy in all fall prevention programs is to identify those patients at high risk of falling, which is usually done with the aid of a fall-risk assessment tool.\textsuperscript{52} The use of fall-risk assessment tools allows early identification of those patients at high risk of falling, so that appropriate interventions can be instituted to minimise risk.\textsuperscript{53, 54} The fall-risk assessment tool provides nurses with objective data to increase awareness of a patient’s risk of falling.\textsuperscript{55} In addition, the fall-risk assessment tool enables nurses to use time and scarce resources more efficiently.\textsuperscript{56} By using a fall-risk assessment tool, nurses can identify an individual patient’s risk factors, and initiate a more effective fall-prevention intervention rather than reacting after a fall.\textsuperscript{31} To ensure that staff time is not wasted on tools that are not effective, fall-risk assessment tools need to be able to accurately identify the high risk of falls for most of the patients. To enable this, tools need to possess the following characteristics: evidence-based with a few items that are simple, logical, and easy scoring of total scores; a short completion time; user-friendly with high degree of staff compliance rates; high internal and external validity and reliability.\textsuperscript{57, 58}
A range of fall-risk assessment tools used to predict the probability of falling has been described within the fall literature. However, a large portion of this literature was based on fall-risk assessment tools that were developed based on the fall risk factors recommended in the literature. Moreover, these tools were developed as part of the quality improvement project, and used in conjunction with the fall prevention program. The methods used in the development of many of these tools have not been described. During the initial review of fall literature, only five studies were identified that described the development of tools that were based on rigorous research design, using either a case-control or cohort methodology, and included information on the validity of the tool.

Sensitivity refers to the total number of fallers correctly identified as high risk, while specificity refers to the total number of non-fallers correctly identified as low risk. A total of seven studies included information from the developers of the tool on its accuracy in the setting in which the tools were developed. The sensitivity of the tools ranged from 43% to 90%, while the specificity ranged from 38% to 83%. A low to moderate sensitivity could imply that too many patients who fall are classified as low risk. Likewise, a low to moderate specificity may imply that too many patients who do not fall are classified as high risk.
A total of eight studies\textsuperscript{65-72} included information on the validation of tools in other settings. The Morse Fall Scale and the STRATIFY were the tools that had been subjected to extensive evaluation in many settings. The sensitivity of the tools ranged from 60\% to 83\%, while the specificity ranged from 47\% to 81\%.\textsuperscript{65-72} Both sensitivity and specificity were much lower when tested outside the setting the tools were developed in. Although, these tools were validated with high accuracy, when tested outside the setting in which they were originally validated, the predictive accuracy could not be reproduced, and suffered from low specificity. These results could imply that fall-risk assessment tools might not be effective when used outside the setting in which the tool was developed.\textsuperscript{73} This might occur because of different characteristics, as well as, operational differences between environments.\textsuperscript{66} This is of concern to staff who want to use the fall-risk assessment tool as part of the fall prevention program,\textsuperscript{73} as it could result in a waste of resources. Oliver and colleagues\textsuperscript{31} pointed out that ward design, nursing philosophy, skills-mix, and patient population vary from unit to unit. Thus, a prospective validation of fall-risk assessment tools is necessary before using it in clinical practice.\textsuperscript{58} Myers also recommends that fall-risk assessment tools require evaluation on its predictive validity in different clinical settings before using it.\textsuperscript{73}
**Fall Prevention Approach**

Strategies used to prevent falls can be categorised into single and multiple interventions.\(^\text{10}\) Given that patient falls are usually the result of a combination of risk factors, strategies that incorporate multiple interventions are more likely to be effective than single interventions.\(^\text{74}\) The most common strategy used to reduce falls in acute care inpatient hospitals is a program of multiple intervention strategies targeted at risk factors involving: patient assessment; risk identification; medication review; eliminating environmental factors such as slippery floor, obstacles etc; educating patients regarding personal risk of falling; providing physical assistance to high risk patients during activities such as mobilisation and self-care; and increasing staff awareness of the risks of patients falling.\(^\text{8}\) For example, after identifying the risk factors for falls in a specific population, generic multiple interventions for all patients at risk of falling are implemented.

Multiple intervention strategies have been implemented in acute care inpatient hospitals in different ways. For example, some studies instituted a set of ‘Standard Interventions’ to all patients at risk of falls.\(^\text{3, 21, 75-78}\), while another assumed all patients were at some risk of falling and implemented a set of ‘Standard Precautions’ to all patients plus a set of ‘Strict Fall Precautions’ to patients identified at risk of falling.\(^\text{5}\) Three studies used different levels of interventions where, as the patient’s assessed fall risk increased, so did the number of interventions implemented.\(^\text{2, 4, 79}\)
All the studies utilised the pre-test and post-test design except for one that utilised a quasi-experimental design. Majority of the pre-test and post-test design studies were conducted as part of the quality improvement projects. The reports on the results of these studies are contradictory. A large number of the pre-test and post-test design studies were able to demonstrate a reduction in fall rate, ranging from 20% to 38%. There was also a study that demonstrated a 77% reduction in the number of falls resulting in serious injuries. However, two studies demonstrated an increase in fall rate. A study by O’Connell and Myers showed an increase in fall rates from 12.05 falls per 1,000 bed days in the pre-test period to 13.22 falls per 1,000 bed days in the post-test period. Another study by McFarlane-Kolb also showed an increase in fall rates from 5 in the pre-test cohort to 10 in the post-post test cohort.

Although a large number of the studies on multiple intervention strategies in acute care inpatient hospitals have demonstrated a fairly impressive result, health care professionals need to be cautious about applying these types of fall prevention interventions without first weighing up the limitations of all these studies. Firstly, many of the studies utilised self-developed fall-risk assessment tools that had not been tested for validity, reliability, and clinical feasibility. Thus, these tools may have poor sensitivity and reliability. Secondly, the cause and effect relationship between the interventions and the reduction in falls, and fall-related injuries, cannot be established with the use of pre-test and post-test design. Thus, the evidence base supporting these interventions is weak. In addition, the absence of
a concurrent control group in the pre and post-test designs could pose a threat to internal validity.\textsuperscript{79,82}

Although, multiple intervention strategies for acute care inpatient hospitals are widely implemented, systematic reviews have shown no consistent evidence for fall prevention.\textsuperscript{9,47} Recently, two additional randomised controlled trials have shed light on this issue. Healey and colleagues\textsuperscript{83} examined the effects of targeted risk factor reduction in elderly care wards of a general hospital. The result showed a 30\% relative risk reduction in falls in the intervention wards as compared with the control wards. Haines and colleagues\textsuperscript{84} also reported that a targeted fall prevention program in a sub-acute setting resulted in a 30\% reduction in falls but not a reduction in serious injuries. However, these studies were conducted in sub-acute hospitals, and in elderly population. Gillespie\textsuperscript{85} notes that, while these results are encouraging, they need to be verified in other settings.

**Limitations in the Fall Research**

There are many limitations that indicate a need for further research into fall events in acute care inpatient hospitals. Firstly, most of the studies concerning falls are descriptive and fail to provide the level of evidence required to underpin nursing practice. This is a considerable limitation, in that these descriptive studies do not provide any direction for nursing practice. In addition, a large proportion of these studies have been retrospective in nature. Retrospective studies rely on the quality
of documentation of health care professionals and the memory of past fallers to determine the relationship between risk factors identified and the fall episode.

Secondly, there is no standard universal definition of a fall that outline the methods of identifying when a fall has occurred, the details recorded, and the methods of analysis. This ambiguity in definition leads to a lack of consistency in the literature in the preparation of a fall typology.

Thirdly, it is difficult to compare and draw conclusions from the studies on fall-risk assessment tools because of small sample sizes and differing designs, patient populations, and facilities. In addition, there is limited replication and testing in different settings and across populations. Finally, although multiple interventions are widely implemented in acute care inpatient hospitals, there have been no adequate randomised controlled trials to assess their effects.

**Conclusion**

The aim of the first section was to establish the context and define the focus of the research— that being, fall prevention in acute care inpatient hospitals. A review of the incidence of falls, risk factors of fall, fall circumstances and impact of falls were outlined. The fall-risk assessment tools and fall prevention interventions were also discussed. Best practice advocates for the early identification of patients at high risk of falling with the aid of a fall-risk assessment tool, and the institution of appropriate interventions to minimise the risk of falls.
Only a few fall-risk assessment tools have been developed using rigorous research design, and tested for validity and reliability, despite the large number of tools currently available for use. Although, these tools have been validated with high accuracy, when tested outside the setting in which they were originally validated, the predictive accuracy could be reproduced and were reported to have low specificity. This may occur because of different patient characteristics, as well as operational differences between environments. A prospective validation of fall-risk assessment tools is necessary before using it in clinical practice. Myers also asserts that fall-risk assessment tools require evaluation of predictive validity across different clinical settings before being used. For these reasons, study one of this portfolio focuses on prospective evaluation of fall-risk assessment tools.

Performing a fall risk assessment is only useful if there are appropriate interventions available. However, the evidence-base to support targeted multiple interventions in acute care inpatient hospitals is weak. There have been no adequate randomised controlled trials to assess the effect of targeted multiple interventions. Only large randomised control trials conducted recently in sub-acute hospitals have demonstrated that targeted multiple intervention programs have been successful in reducing the incidence of falls. Several authors have highlighted that these results are encouraging but need verification in other contexts. Thus, study two of this portfolio focuses on randomised control trials that evaluate the use of a targeted multiple intervention strategy in reducing the number of falls.
REFERENCES


31. Oliver D, Britton M, Seed P, Martin FC. Development and evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly


Section 2: Study 1

Evaluation of Three Fall-risk Assessment Tools in an Acute Care Inpatient Hospital
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Abstract

**Background:** Assessments for the risk of patients falling have been widely performed in hospitals for several decades using specific screening tools. A valid and reliable tool is essential to identify the level of fall-risk for every patient if fall prevention strategies are to be targeted effectively. Unfortunately, a review of the literature has revealed that few fall-risk assessment tools have been validated. The tools that have been validated appear to be reasonably accurate within the setting in which they were developed, but less so in other settings, thus limiting their generalisability. Two authors highlighted the need to establish the validity, reliability, and the clinical utility of these tools in a variety of clinical settings before using it.\textsuperscript{1, 2} This knowledge is essential to inform and direct nurses in selecting an evidence-based fall-risk assessment tool for use in a clinical setting.

**Objective:** The objective of this study was to evaluate the predictive validity of three fall-risk assessment tools, namely the Morse Fall Scale, STRATIFY, and Hendrich II Fall Risk Model.

**Method:** The Morse, St Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY), and the Hendrich II fall-risk assessment tools were validated in inter-rater and validity studies. The probability of disagreement and kappa values, and sensitivity, specificity, positive and negative predictive values
of the assessment tools with the associated 95% confidence intervals was assessed.

**Results:** A total of 144 patients were recruited for the inter-rater reliability study. The probability of disagreement was between 2.8% and 9.7%, and the 95% confidence intervals ranged from 1.1% to 15.7% for all tools. The kappa values were all higher than 0.80. In the validity study, 5,489 patients were recruited to observe 60 falls. The Morse Fall Scale (with a cut-off score of ≥25) and the Hendrich II Fall Risk Model (with a cut-off score of ≥5) had strong sensitivity values of 88% and 70% respectively. However, in comparison with the Morse Fall Scale (specificity = 48.3%), only the Hendrich II Fall Risk Model had a more acceptable specificity (61.5%).

**Conclusion:** The Hendrich II Fall Risk Model is potentially useful in identifying patients at a high risk of falls in acute care facilities.
SECTION 2

Section 2 provides the report of the first study entitled ‘Evaluation of three fall-risk assessment tools in an acute care inpatient hospital’. This section is comprised of five sub-sections that encompass an introduction to the study, a literature review on fall-risk assessment tools, a description of the methodology used, a description of the results, and a discussion of the major findings and their implications.

Introduction

In Section 1 of this portfolio the background literature review of patient falls in acute care inpatient hospitals is provided. The literature review reveals that research, to date, has not provided evidence that is necessarily meaningful for nurses working in acute care hospitals in order to decide which assessment tool would help them to identify patients at high-risk of falling. The nursing assessment of patients’ risk of falling has been widely performed in hospitals for several decades using specific screening tools. A valid and reliable tool is essential to identify the level of fall-risk for every patient if fall prevention strategies are to be targeted effectively. Unfortunately, a review of the literature highlighted that few fall-risk assessment tools have been validated. Tools that have been validated appear to be reasonably accurate within the development setting, but less so in other settings, thus limiting its generalisability. Two authors have highlighted the need to establish the validity, reliability, and the clinical utility of these tools to a variety of clinical settings prior to the tools being used.1,2
In Singapore, there are no accepted fall-risk assessment tools available, and thus different tools are used. The fall-risk assessment tools used in the study hospital were developed based on experiential data, and have not been tested for validity and reliability. No work has been done in Singapore on the validity and reliability of fall-risk assessment tools. This study evaluated the fall-risk assessment tools in an acute care inpatient hospital in Singapore.

Following is a review of the literature on the fall-risk assessment tools used by nurses in acute care inpatient hospitals. From the outcome of this review, three fall-risk assessment tools are identified for further evaluation in this study.

**Literature Review**

Many health care professionals use fall-risk assessment tools to identify patients at high-risk of falling. For a fall-risk assessment tool to be useful, it must be quick and easy to administer, have the ability to identify patients who are likely to fall without providing too many false positives. It should also produce consistent results when used by different people. Eleven studies were identified that described the development of the fall-risk assessment tools used by nurses in acute care inpatient hospitals.\textsuperscript{4-14} Most of these tools have been developed based on expert opinion\textsuperscript{9-12}, or adaptation of an existing tool.\textsuperscript{5} Examples of these tools include the Conley Scale,\textsuperscript{7} John Hopkins Hospital Fall Risk Assessment Tool,\textsuperscript{12} Stanford Fall Risk Tool,\textsuperscript{6} Fall Risk Category Scale, Fall Risk Assessment Scale,
and the Estimated Fall Risk Scale.\textsuperscript{8} There were also other tools, known only as Fall Risk Assessment Tools.\textsuperscript{4, 10, 11, 14}

The content of these tools varies considerably with respect to the number of items (ranging from 7 to 17). The risk factors commonly assessed by these tools included:

- history of falls
- advanced age
- changes in mental state
- altered elimination
- impaired mobility
- medications.

One of the nursing fall-risk assessment tools was simply a risk factor checklist,\textsuperscript{13} while several have scores arbitrarily assigned to the risk factors based on convenience and the tool developer’s own judgment.\textsuperscript{5, 6} Only two of the tools had scores attributed to the risk factors based on statistical tests.\textsuperscript{7, 8} Furthermore, most of these tools had not been evaluated in relation to the validity and inter-rater reliability. Of those that had been validated, the reported sensitivity value varied from 43\% to 79\%, and specificity varied from 40\% to 70\%.\textsuperscript{7, 9, 14} Only two studies reported good inter-rater reliability of above 80\%.\textsuperscript{7, 9}

There are three limitations in the studies on the 11 nursing assessment tools. First, the lack of a control group with a non-faller population to serve as a comparison
can result in under or over estimation of the importance of risk factors.\textsuperscript{1} Second, an additional risk factor was added to the content of one tool following validation,\textsuperscript{7} which could invalidate the performance of that tool.\textsuperscript{15} Third, the varied sensitivity and specificity values make it difficult to compare and assess the quality of the studies. These limitations need to be considered when comparing the findings of different fall-risk assessment tools.

Stronger evidence on nursing fall-risk assessment tools has been provided by five prospective and retrospective case-control\textsuperscript{16-18} or cohort studies.\textsuperscript{19} These risk assessment tools are the Morse Fall Scale, STRATIFY,\textsuperscript{17} Scott and White Fall Risk Screener,\textsuperscript{19} the Hendrich Fall Risk Model,\textsuperscript{18} and the Hendrich II Fall Risk Model.\textsuperscript{20}

\section*{Morse Fall Scale (MFS)}

\textbf{Description of the Tool}

The Morse Fall Scale was developed to assist clinicians in assessing the likelihood of a patient falling. Morse and her colleagues\textsuperscript{16} used a database of 100 patients who fell, and compared these patients with 100 randomised controls in an urban 1,200-bed hospital. The data were examined for significant variables that could differentiate between the two groups. As such, six key predictors of falls were identified: history of falling, presence of secondary diagnosis, intravenous therapy, use of ambulatory aids, gait, and mental status. These variables formed the domains of the MFS, and each domain in the scale was scored as follows:
History of Falling: This domain scored 25 if the patient had fallen during a present hospital admission or if there was an immediate history of physiological falls, such as from seizures or an impaired gait prior to admission. If the patient had not fallen, this domain scored 0.21

Secondary Diagnosis: This domain scored 15 if more than one medical diagnosis was listed on the patient’s chart. If the patient had no secondary diagnosis, this domain scored 0.21

Ambulatory Aid: This domain scored 0 if the patient was able to walk without a walking aid even if assisted by a nurse, used a wheelchair, or used a bed rest and did not get out of bed at all. If the patient used a stick or walker, this domain scored as 15. If the patient ambulated clutching onto furniture for support, then this domain scored 30.21

Intravenous Therapy: This domain scored 20 if the patient had an intravenous apparatus or a heparin lock instead. If not, this domain scored 0.21

Gait: This domain scored 0 if the patient was able to walk with their head erect, characterising a normal gait, with their arms swinging freely at their sides, and striding without hesitation. A patient was considered to have a weak gait when they stooped but were able to lift their head while walking without losing balance. The patient’s steps would be short or they might shuffle in this domain and scored
10. This domain scored 20 if the patient had an impaired gait, evidenced when
the patient had difficulty rising from a chair, attempted to get up by pushing on
the arms of a chair/or by using several attempts to rise. The patient’s head would
be down, and he or she would watch the ground. Because the patient’s balance is
poor, the patient might grasp onto furniture, a support person, or walking aid for
support and is unable to walk without assistance.21

**Mental Status:** Mental status was measured by checking the patient’s own self-
assessment of his or her own ability to ambulate. The patient was asked, ‘Are you
able to go the bathroom alone or do you need assistance?’ The patient was rated
as ‘normal’, and scored 0 when the patient’s reply indicated a judgment of his or
her own ability that was consistent with the nursing orders. If the patient’s
response was not consistent with the nursing orders or the patient’s response was
unrealistic, the patient was then considered to have overestimated his or her own
abilities and be unaware of their limitations, then this domain scored 15.21

**Scoring and Risk Level:** The scores were then tallied and assigned a risk level; 0-
24 no risk, ≥25 low-risk, 25-50 medium risk, and ≥51 high-risk. The MFS can be
set differently for each particular health care setting or unit so that fall prevention
strategies are targeted to those most at risk. 21
Evaluation of Tool

The MFS had been evaluated for its validity and reliability using a number of methods by the development authors. Discriminant analysis identified 81% of patients from the control group who fell, while computer modelling techniques using a simulated hospitalised population in hospital increased the discriminant function to 83%. The inter-rater reliability was 96%. A prospective validation study in 16 patient care units across two institutions was conducted to assess patients’ risk of falling. Three types of patient care units were utilised that included: acute medical, and surgical, long-term geriatric and rehabilitation areas. A total of 2,689 patients were recruited over a 4-month period, and were rated for fall-risk using the MFS. The results revealed that of the 2,689 patients, 1,265 (47.1%) ranked as low-risk of falls (≤ 25), 734 (27.35%) ranked as medium-risk (25-40), and 690 (25.5%) as high-risk (≥51). Of the 147 falls, 10 (6.8%) falls were from the low-risk group, 24 (16.3%) falls were from the medium-risk group, and 113 (76.9%) falls were from the high-risk group. Majority of the falls were from the high-risk group. Thus, the authors concluded that the Morse Fall Scale is an effective predictor of falls and a feasible tool for nurses to use in clinical areas.²²

The MFS was further evaluated in two other studies first, in a Canadian validation study, where the MFS was compared with the Functional Reach Test and the primary nurses’ clinical judgment assessment to identify elderly individuals at
high-risk of falls, and second, in an Australian study, where the MFS was validated in two aged care wards of an acute care hospital.

The first study was conducted over a three-month period involving 98 patients from a rehabilitation unit and a geriatric medical ward in a general hospital. The research nurses assessed all existing patients and all subsequent new admissions to the study wards for fall-risk using the three tools. The inter-rater reliability for the MFS was determined by having each research nurse blindly evaluate identical sets of 10 charts at two separate times. In this study, patients with scores of 45 or more on MFS were considered at high-risk of falls. The MFS had a sensitivity of 72% and a specificity of 51%. The positive and negative predictive values were 38% and 81% respectively. The result of the inter-rater reliability was not reported.

In the second study, the MFS was used as part of the fall prevention program wherein 1,059 patients admitted to the wards were assessed for fall risk by the same rater. Patients with scores of 45 or more on MFS were considered at high-risk of falls, and assigned to fall prevention intervention. The findings revealed that the MFS had a sensitivity of 83%, a specificity of 39% and a positive predictive value of 18%. Information on the inter-rater reliability was not reported. The authors concluded that further work was necessary to improve the sensitivity and specificity of the tool before it is used widely.
Strengths and Limitations

There were two strengths in the study by Morse et al.\textsuperscript{22} on the MFS. First, a chart audit was supplemented by patient examinations and observations of the environment. The aim of the chart audit was to verify or add missing information from the chart. Second, the MFS provided a score range from 0 to 120, which helps cater for changes in a patient’s condition.\textsuperscript{15}

There were four limitations to the studies conducted by Morse et al.,\textsuperscript{22} Eagle et al.,\textsuperscript{23} and O’Connell and Myers\textsuperscript{24} on the MFS. First, Morse and colleagues\textsuperscript{22} did not provide information regarding how the risk factors used for data collection were identified. Moreover, the data collection was retrospective and, therefore, was difficult to ascertain if the chart contained complete and accurate information. Second, different statistical tests were used to evaluate the predictive validity of the tool, which makes a comparison of the results extremely difficult. Despite these limitations, the MFS has been validated in different international contexts beyond the initial instrument development work. However, in these studies, conflicting evidence on the validity and reliability of the MFS has been reported.\textsuperscript{23, 24}

Third, in the validation study conducted by Eagle and colleagues,\textsuperscript{23} the MFS was completed retrospectively using information from the chart rather than assessing the patients. Hence, the MFS was not used correctly.\textsuperscript{15} In addition, while the nurses and the raters were blinded to the patients, it is not known if the raters, who
were using clinical judgment, had previously used the MFS and/or other methods to rate the patient’s risk of falling. This presents a threat to validity that is difficult to control.\textsuperscript{15} Moreover, the data on patients’ falls was collected from patient incident reports, and it is uncertain whether it included all the falls. The small sample size \((n=98)\) may have exposed the result of a Type II error.\textsuperscript{25}

Fourth, in the validation study conducted by O’Connell and Myers,\textsuperscript{24} the MFS classified over 70\% of the patients who did not fall as high-risk for falls, which indicates that there could be a number of other specific factors that distinguish fallers from non-fallers that are not listed or assessed in the MFS. In addition, the validation data was extracted from the assessment carried out on admissions as part of the fall prevention study. Those patients who were assessed as being high risk were included in the multiple strategies fall prevention program, which would probably explain the high false positive rate.\textsuperscript{24} Defloor and Grypdonck pointed out that evaluation of the predictive validity of a risk assessment tool is not possible if the risk assessment tool is used in combination with effective preventive measures.\textsuperscript{26}

**St Thomas’s Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY)**

**Description of the Tool**

Oliver and colleagues developed the British STRATIFY tool to predict which elderly patients would fall during a hospital stay, using a prospective case-control methodology. In phase I, they examined 116 patients who fell and 116 control
patients over a three month period, all of whom were at least 65 years old, and identified five key predictors of falls: history of falls, dependency in transfer and mobility, primary nurse’s judgment when a patient was agitated, frequent toileting, and visual impairment. These predictors of falls formed the domains of the STRATIFY tool.\textsuperscript{17}

A risk assessment score (range from 0-5) was derived, and rating 1 point for presence or 0 point for absence for each of the five domains. The transfer and mobility score (range 0-6) was obtained by combining the transfer and mobility sections of the Barthel index, each with ranges 0-3. A score of 3 or more was considered to predict a high-risk for falls.\textsuperscript{17}

**Evaluation of the Tool**

The reported sensitivity and specificity values of phase I with a score of 3 or more were 93\% and 88\% respectively. In phase 2, the tool was prospectively evaluated on a cohort of elderly patients in the same unit in which the tool was developed. The STRATIFY score was obtained by interviewing the patient’s primary nurse each week over an eight week period for all inpatients in the unit. The risk assessment tool was completed 395 times on 217 patients, and 71 falls occurred in the week after assessment. The sensitivity and specificity values were 93\% and 88\% for a score of 2 or more. For a score of 3 or more, the reported sensitivity and specificity values were 69\% and 96\% respectively. The positive and negative predictive values were 62\% and 98\% for a score of 2 or more. For a score of 3 or
more, the positive and negatively predictive values were 80% and 93% respectively.¹⁷

In phase 3, the tool was evaluated prospectively on a cohort of elderly patients in two other hospitals. The STRATIFY score was obtained by the ward nurses within 24 hours of admission, and weekly over a eight week period for all inpatients in the unit. The risk assessment tool was completed 446 times on 331 patients, and 79 falls were observed. The sensitivity and specificity values for a score of 2 or more were 92% and 68% respectively, and for a score of 3 or more were 54% and 88% respectively. The positive and negative predictive values were 39% and 98% for a score of 2 or more. For a score of 3 or more, the positive and negative predictive values were 48% and 90% respectively.¹⁷

Four studies have further evaluated the STRATIFY tool. First, a prospective validation cohort study was carried out in four acute medical units of two teaching hospitals in Canada, with the objective of determining if the tool predicted the number of falls. The tool was validated after modifications to the items score, and provided an operational definition for each item. The STRATIFY score was obtained by the ward nurses for all patients within 24-48 hours of admission into the hospital. A total of 620 patients over the age 65 years were admitted during a 6-month period. A receiver-operating characteristic curve was generated to show the sensitivity and specificity for predicting fall. The tool was found to have very good inter-rater reliability of 78% with a sensitivity of 94% and specificity of
41% for a score of 3 or more. No information was provided on the positive and negative predictive values.\textsuperscript{27}

Second, a prospective validation\textsuperscript{28} comparing the STRATIFY and Fall Risk Assessment Scale for Elderly (FRASE) was conducted. The study took place in the orthopaedic unit of an acute general hospital. Within the prospective group, a total of 60 patients were assessed on the first operative day for their risk of falling by two experienced senior orthopaedic nurses using the STRATIFY and FRASE. The two nurses were blinded to each other’s rating. Patients who were assessed for their risk of falling had fall prevention interventions implemented. The sensitivity and specificity values of STRATIFY were 50% and 76% respectively. No information was provided on the positive and negative predictive values. The inter-rater reliability of the STRATIFY tool was 84\%.\textsuperscript{28}

Third, a study completed by Coker and Oliver\textsuperscript{29} examined the predictive validity of the STRATIFY tool prospectively using a cohort design. The data was collected in an academic healthcare centre in a 24-bed Geriatric Assessment and Rehabilitation Unit involving 432 patients. The assigned nurse completed the STRATIFY tool within 24 hours of the patient being admitted or transferred to the unit. In this study, the reported sensitivity and specificity at a score of 3 and more were 36% and 85% respectively. The positive predictive and negative predictive values were 45% and 79%. For a score of 2 and more, sensitivity was 66%, specificity 47%, and positive predictive value 30%, and negative predictive
value 80%. The inter-rater reliability of the tool was established by nurses scoring their assigned patients using the tool during the same afternoon. This was followed by the nurses assigning scores to all of the other patients in the unit with whom they had worked but had not assigned that day. The inter-rater reliability was 74%.  

Fourth, a prospective validation study, comparing the effectiveness of the STRATIFY, Downton, Tullamore and Tinetti tools, was conducted in two acute medical wards admitting predominately elderly patients. A single clinician prospectively completed the medical assessments and four nursing fall-risk assessment tools on admission of 135 patients. The clinician completing the tool was blinded to the occurrence of falls that occurred after tool completion. Patients with scores of 2 or more on the STRATIFY were considered to be high-risk, and were followed-up until discharged, and those who fell at least once were classified as fallers. The sensitivity was 68% while the specificity was 66%. The positive predictive and negative predictive values were 28% and 92% respectively.  

**Strengths and Limitations**

There were three strengths in the studies by Papaionnou et al. 27, Jester et al. 28, Coker and Oliver, 29 and Vassallo et al. 30. First, Papaionnou and colleagues 27 included a different score for each item, which is important in optimising
prediction. In addition, each of the items was provided with a definition and hence, each question in the tool could be interpreted in the same way.

Second, Coker and Oliver\textsuperscript{29} utilised a prospective cohort methodology that involved 432 patients, indicating that a rigorous research design was being used, which helped to strengthen the study. Lastly, the study by Vassallo and colleagues\textsuperscript{30} was conducted prospectively and the assessor who completed the tool was blinded to the occurrence of falls, thus reducing the risk of bias.

There were five limitations to the studies conducted by Oliver et al.,\textsuperscript{17} Papaioannou et al.,\textsuperscript{27} Coker and Oliver,\textsuperscript{29} Jester et al.,\textsuperscript{28} and Vassallo and colleagues.\textsuperscript{30} First, several authors\textsuperscript{1, 27, 31, 32} raised doubts on the methodology used in the Oliver et al.\textsuperscript{17} study. Little information was given on how the items for the tool had been identified.\textsuperscript{1} These items were not clearly defined, and consequently subject to varying interpretations that could compromise reproducibility. Each item must be clearly defined so that it can be clearly interpreted consistently in the same manner.\textsuperscript{27} In addition, Oliver et al.\textsuperscript{17} developed a score of yes/no for all the items in the tool, which was simple to use and easily incorporated into the daily nursing care, however, predictions could be weakened by the absence of a score for each item, as certain patient characteristics can have a greater value in predicting falls.\textsuperscript{31, 32} The scoring system incorporated the nurse’s clinical judgment and hence, the inter-rater reliability needed to be checked before adopting the tool for use.\textsuperscript{32} Using the number of falls as the unit of analysis rather
than patients as an outcome could inflate the predictive validity. This approach would duplicate the number of patients who fell more than once.\textsuperscript{31} Furthermore, the patient in the next bed was not blinded to the study but was used to serve as a control for each patient who fell. This not only creates a bias in the study but also duplicates the data recorded for each patient.\textsuperscript{33} Some controls might be in the hospital for a very short time. It would be better to choose controls who have been in hospital for the same duration of time as the faller but who had not fallen.\textsuperscript{31} Despite the weaknesses, Altman maintained that the external validation of the STRATIFY tool in the second hospital was useful, and suggested that further evaluation of the tool in other settings would be beneficial.\textsuperscript{31} Several of these limitations had been strengthened in the Canadian validation study.\textsuperscript{27}

Second, in the validation study by Papaioannou et al.,\textsuperscript{27} the data on patient falls were collected from the patient incident reports, and it is uncertain whether it included all the falls. There is also a possibility that nurses completing the assessment form were influenced in how they responded to patients in terms of fall prevention strategies. It is not known whether this affected the true rate of falls. In addition, there is still room for error when changes to the items are made to the original tool. Moreover, the patient’s recall of information might not be accurate when the assessment is carried out 24 to 48 hours following admission.\textsuperscript{27}

Third, the low sensitivity and high specificity scores in the Jester et al.\textsuperscript{28} study indicated that the STRATIFY is better at classifying patients at low-risk for falls.
These results appear to be contradictory to an earlier study by Oliver et al. who reported a high degree of sensitivity of 93% and specificity of 88%. However, the results of this study must be viewed with caution because the Oliver et al. study was not conducted on hip fracture patients, and patients identified at risk of falling did not have a fall prevention strategy implemented. Moreover, the sample size was different; 60 for this study, and 217 in the Oliver et al. study\textsuperscript{17}.

Fourth, the low sensitivity and high specificity scores in Coker and Oliver\textsuperscript{29} validation study indicates that the STRATIFY is better at classifying patients at low-risk for falls. These results appear to be contradictory to an earlier study by Oliver et al. who reported a high degree of sensitivity of 93% and specificity of 88%.\textsuperscript{17} This may have occurred because of different patient characteristics (acute elderly versus Geriatric Assessment and Rehabilitation Unit), different predictions in the outcome of falls (number of patients who fall versus number of fallers). In addition, the data on patient falls was collected from the patient incident reports, and it is uncertain whether it included all the falls.

Lastly, in Vassallo and colleagues’ validation study,\textsuperscript{30} the sample size was small, and the STRATIFY tool failed to identify a high number of fallers as reflected by the low sensitivity score. In addition, changes in patient condition were not captured when the fall-risk assessment was conducted, which could account for the low predictive value.\textsuperscript{30}
Scott and White Fall Risk Screener

Description of the Tool

Yauk and colleagues undertook a 6-month retrospective study in response to the current fall-risk instruments that are often quite elaborate and represent something beyond the scope of what providers can do in a clinical setting.\(^\text{19}\) The aim of the study was to develop a fall-risk assessment tool that is useful, easy to use, and at the same time reduces, rather than increases, the workload of the nurses. A case-control methodology was used whereby 118 adult hospitalised fallers (cases) in the medical-surgical units of a tertiary hospital were compared to 236 randomly selected non-falling adults from the same units at roughly the same times (controls). The medical records of the subjects were reviewed for patient data at time of admission and at time of a first fall for cases or at midpoint of a hospital stay for controls. The variables were analysed using a bivariate relationship, and those found to be statistically significant were then analysed using multivariate analysis (i.e. logistic regression). The four significant predictors of falls on the Scott and White fall Risk Screener identified were: falls prior to admission (odd ratio: 2.4; CI 1.4 –3.9), disorientation at admission (odd ratio: 2.3; CI 1.2-4.5), needing assistance with ambulation (odd ratio: 2.1; CI 1.1-3.8), and lacking control of bowels (odd ratio: 3.7; CI 1.1 –11.8).
Evaluation of the Tool

The tool was evaluated in the population in which the tool was developed, and demonstrated good sensitivity of 91%, but an unacceptable low specificity of 37%. No information was reported on the inter-rater reliability of the tool.

Strengths and Limitations

There were two limitations in this study. First, data collection was retrospective and therefore, was difficult to ascertain if the chart contained complete and accurate information that could bias the outcome. Myers noted that this had the potential to overestimate or underestimate the presence of risk factors, and hence, the differences between the two groups. Second, the tool appeared to be developed based on incident reviews although insufficient information was provided in the article.

Hendrich Fall Risk Model

Description of the Tool

Hendrich et al used a retrospective case control methodology whereby all patients ($n=102$) who fell in a one month period was compared with a randomly selected sample of non-fallers ($n=236$) hospitalised in the same month. An instrument, constructed by Hendrich in her previous study, comprised of 22 risk factors found to be significant in the literature was used for the data collection. Patient charts were reviewed for risk factors present on admission and for fallers (cases), risk factors present in the 24 hour preceding the fall, and for non-fallers (controls), risk factors present at the mid-point length of stay. Logistic regression revealed
seven independent predictors of falls: confusion/disorientation; depression; altered elimination (incontinence); dizziness/vertigo; falls in the past; impaired mobility/generalised weakness; and the existence of diagnosed cancer. These predictors of falls formed the domains of the tool and were given the following scores: confusion/disorientation 3; depression 4; altered elimination (incontinence) 3; dizziness/vertigo 3; history of recent falls 7; impaired mobility/generalised weakness 2. A score of 3 or more indicates a high-risk for falls. In total, up to 22 points could be achieved.

Evaluation of the Tool

The sensitivity and specificity of the tool at the score of 3 or more were 77% and 72% respectively, indicating that those at high-risk were correctly identified as fallers, while those who did not fall were correctly identified as low-risk. The inter-rater reliability was 97%, however, it was not stated how the reliability had been calculated nor how many patients had been examined.\(^\text{18}\)

Strengths and Limitations

The strengths of this study are that the risk factors were identified from significant risk factors found in the literature, and that the controls were selected randomly from the population that gave rise to the cases. Furthermore, the tool was not developed in a specific setting but in a teaching hospital with a variety of clinical settings. The limitation of this study is that the data collection was retrospective, and therefore, it is difficult to ascertain if the charts contained complete and
accurate data, and that the sample size was small. No information in the literature on the evaluation of the tool outside the population in which the tool was developed.

**Hendrich II Fall Risk Model**

**Description of the Tool**

The Hendrich Fall Risk Model (HFRM) had been revised in a wider case-control study and is known as the Hendrich II Fall Risk Model. This study is one of the largest prospective case-control studies reported in fall research literature, and it examined 350 patients who fell and 780 control patients in an acute care tertiary facility. The items used for the tool were established through an exhaustive literature review. The study identified eight significant risk factors found to predict fall-risk: confusion/disorientation (odd ratio, 7.43), depression (odd ratio, 2.88), altered elimination (odd ratio, 1.67), altered-epileptics (odd ratio 2.89) or benzodiazepines (odd ratio, 1.70), gender (male) (odd ratio, 1.69), and the patient’s ability to rise from chairs (odd ratios from 2.16 to 10.12). A score of 5 or higher is considered to predict high-risk for falls.

**Evaluation of the Tool**

The sensitivity and specificity of the tool were 75% and 74% respectively, indicating that those of high-risk were correctly identified as fallers while those who were identified as low-risk did not fall. No information was reported on the
predictive values. Inter-rater reliability was measured in 17 randomly selected patients and was found to have 100% agreement.20

Strengths and Limitations

The study has several strengths. First, the tool was developed from one of the largest prospective case-control studies reported in literature on falls. Second, the use of random matching case/control of patients admitted to hospital on the same day, helped to solve the problem of over representation of some diagnosis.20 This has provided a heterogeneous population, representing the population of patients in acute care hospitals. Third, Hendrich and colleagues have taken into consideration the complexity of the acute care environment. They have provided a definition of all the items listed in the tool, and hence all the assessors can consistently interpret each item. Lastly, the tool was developed in a teaching hospital with a diverse acute care population, and therefore, it can be concluded that it is applicable to a variety of disciplines with adult population.

The main limitation of this tool was that it had not yet been validated outside the population in which the tool was developed. Rutledge et al.34 pointed out that the tool requires studies in similar settings to determine its validity and utility.

Optimal Fall Risk Assessment Tools

Based on the current evidence, even the tools that were developed using rigorous design have limitations, which limit the validity of the findings. From the evaluation of these tools, the Scott and White Fall Risk Screener was not selected
for further validation because the tool appeared to be developed based on incident reviews that have the potential to overestimate or underestimate the presence of risk factors. In addition, the specificity of the tool was very low at 37%, and there was no information reported on the inter-rater reliability of the tool. The Hendrich Fall Risk Model was another tool not selected for further evaluation because this tool has been revised in a wider case-control study, from 22 risk factors to 8 significant risk factors. The revised tool is known as the Hendrich II Fall Risk Model.

It appears that the Morse Fall Scale (MFS) and the ST Thomas Risk Assessment tool in the Falling Elderly Inpatients (STRATIFY) are two tools that have been developed using rigorous design, and prospectively validated in more than one clinical setting (refer Table 1). These findings have been acknowledged in the systematic review reported by Oliver and colleagues and Myers. Although, the Morse Fall Scale and STRATIFY has been validated with high accuracy and appears reasonably accurate within the development setting, when tested in other settings, the predictive accuracy could not be reproduced, and were reported to have low specificity. This may have occurred because of different patient characteristics, as well as operational difference between environments. Thus, limiting their use in clinical practice. To be useful in clinical practice, the tools must work in the settings in which it is to be used. It is necessary to prospectively validate these tools with large group of patients to achieve statistical significance before use in clinical practice.
Table 1: Summary of Fall Risk Assessment Tools

<table>
<thead>
<tr>
<th>Author</th>
<th>Cut-off score</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>Reliability (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morse Fall Scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morse et al.</td>
<td>-</td>
<td>83 (discriminant analysis)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>96</td>
</tr>
<tr>
<td>Eagle et al.</td>
<td>≥ 45</td>
<td>72</td>
<td>51</td>
<td>38</td>
<td>81</td>
<td>-</td>
</tr>
<tr>
<td>O’Connell &amp; Myers</td>
<td>-</td>
<td>83</td>
<td>39</td>
<td>18</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>STRATIFY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oliver et al.</td>
<td>≥ 3</td>
<td>93</td>
<td>88</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Phase I</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase II</td>
<td>≥ 2</td>
<td>93</td>
<td>88</td>
<td>62</td>
<td>98</td>
<td>-</td>
</tr>
<tr>
<td>Phase III</td>
<td>≥ 3</td>
<td>69</td>
<td>96</td>
<td>80</td>
<td>93</td>
<td>-</td>
</tr>
<tr>
<td>Phase III</td>
<td>≥ 2</td>
<td>92</td>
<td>68</td>
<td>39</td>
<td>98</td>
<td>-</td>
</tr>
<tr>
<td>Phase III</td>
<td>≥ 3</td>
<td>54</td>
<td>88</td>
<td>48</td>
<td>90</td>
<td>-</td>
</tr>
<tr>
<td>Papaioannou et al.</td>
<td>≥ 2</td>
<td>94</td>
<td>39</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>≥ 3</td>
<td>94</td>
<td>41</td>
<td>-</td>
<td>-</td>
<td>78</td>
<td></td>
</tr>
<tr>
<td>Jester et al.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coker et al</td>
<td>≥ 2</td>
<td>66</td>
<td>47</td>
<td>30</td>
<td>80</td>
<td>74</td>
</tr>
<tr>
<td>≥ 3</td>
<td>36</td>
<td>85</td>
<td>45</td>
<td>79</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Vassallo et al.</td>
<td>≥ 2</td>
<td>68</td>
<td>66</td>
<td>28</td>
<td>92</td>
<td>-</td>
</tr>
<tr>
<td>Scott &amp; White Fall Risk Screener</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yauk et al.</td>
<td>-</td>
<td>91</td>
<td>37</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hendrich Fall Risk Model</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hendrich et al.</td>
<td>≥ 3</td>
<td>77</td>
<td>22</td>
<td>-</td>
<td>-</td>
<td>97</td>
</tr>
<tr>
<td>Hendrich II Fall Risk Model</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hendrich et al.</td>
<td>≥ 5</td>
<td>75</td>
<td>74</td>
<td>-</td>
<td>-</td>
<td>100</td>
</tr>
</tbody>
</table>
The third tool, the Hendrich II Fall Risk Model is an evidence-based tool that can be used in diverse adult patient populations within acute care inpatient hospitals. This diverse adult population is similar to the study hospital, thus merits further evaluation. In addition, these three tools meet the criteria for the selection of an appropriate tool recommended by several authors.\textsuperscript{31, 37, 38} The criteria for tools includes: proven good sensitivity and inter-rater reliability, logical and simple useability, ability for evidence-based calculation of the total score, and have a threshold to start interventions. Further study is required to validate the three tools in the settings in which the tools will be used,\textsuperscript{1, 15, 36} so as to enable accurate identification of fall risk factors and to target interventions accordingly. For these reasons the three tools were selected for further evaluation in this study.
Methods

Aim of the Study

The aim of the study was to evaluate the validity of three pre-selected fall-risk assessment tools to identify patients at risk of falls, and to contribute to the international body of evidence on the validity and reliability of fall-risk assessment tools in acute care inpatient hospitals. The tool that has the best predictive accuracy will be used as an assessment tool for the second study.

Research Questions

Specific research questions were:

- What is the sensitivity, specificity, positive predictive value, and negative predictive value of the Morse Fall Scale, STRATIFY, and the Hendrich II Fall Risk Model fall-risk assessment tools in an acute care inpatient hospital?
- What is the inter-rater reliability of the Morse Fall Scale, STRATIFY, and the Hendrich II Fall Risk Model fall-risk assessment tools in an acute care inpatient hospital?
- Which of the three fall-risk assessment tools has the best predictive validity?
**Research Design**

**Descriptive Study**

A prospective descriptive design was the methodology used to conduct this study that involved two stages. Stage I was the inter-rater reliability component in which 144 observations were carried out independently by two research nurses using three fall-risk assessment tools (Morse Fall Scale, STRATIFY, and Hendrich II Fall Risk Model). Stage II was the validity component in which two research nurses assessed a total of 5,489 patients using the three assessment tools.

A prospective descriptive design was chosen for three reasons. First, a prospective design is more reliable than a retrospective design because of its ability to control and monitor the data collection method, and to measure the variables accurately and completely.\(^{33, 39}\) Second, as Polit and Hungler state, ‘the purpose of descriptive studies is to observe, describe, and document aspect of a situation’\(^ {39}\) (p.196). This study was concerned with the evaluation of fall-risk assessment tools. It involved describing the validity and reliability of the tools by utilising information collected from three fall-risk assessment tools through interviews with subjects, observations, and the enumeration of patient falls. Finally, this study is a starting point for a program of research on patient falls in acute care inpatient hospitals. Hence, it is necessary to understand the validity and reliability of fall-risk assessment tools, before considering whether or not change is required.
Setting

This study was conducted at the National University Hospital in Singapore, the nation’s only university hospital and only acute care tertiary hospital located in the western part of the country, serving a population of three million people. The hospital has 946 inpatient beds and offers a wide range of comprehensive health care services. This hospital was considered appropriate for this study for three reasons. First, it provided access to a large number of subjects, thus increasing the possibility of obtaining a significant number. Second, all patients admitted to the hospital were assessed for their fall-risk within four hours of their admission. Lastly, the subjects were easily accessible as this was the hospital where the principal investigator was working.

The study took place in 12 inpatient medical and surgical wards of the hospital. The size of the 12 wards ranged from 17 to 46 beds and admitted patients with medical and surgical conditions. Medical conditions included cardiac, respiratory, renal, oncology, gastro-enterology, endocrine, and neurology conditions while surgical conditions included general surgery, neurology, orthopaedic, and obstetrics and gynaecology. All the wards had a daily average occupancy of over 90% throughout the year. These wards were chosen because they formed the majority of the patient population in the study hospital, and the findings of this study provided a basis for changing or supporting current nursing fall-risk assessment tools.
Subjects

The subjects were newly admitted patients from 12 medical and surgical wards who met the inclusion criteria and exclusion criteria.

Inclusion Criteria

Patients with the following criteria were eligible for inclusion into the study:

- admitted into the study wards during the period of the study
- were 21 years or older (legal age to give consent)
- agreed to participate and gave consent.

Exclusion Criteria

Patients with the following criteria were excluded from the study:

- were already in the study wards before the start of the study
- fell before fall risk screening was carried out
- were unable to communicate and understand English, Mandarin, or Malay, whereby the study could not be explained, and consent could not be obtained. It was beyond the resources of the study to engage the services of professional translators.

Recruitment of Subjects

The subjects were recruited using convenience sampling from the list of name of all new admissions to the 12 study wards of the hospital. The two research nurses generated the name list from the Nauticus at the beginning of each workday. The Nauticus is the hospital-computerised system that provides health care
professionals with immediate and vital, real-time patient information such as patients’ demographic data, admission and discharge status, and follow-up appointments. From the name list, the day and the time of admission, and which ward the patient was admitted to, and the patient’s bed number could be determined. This process was important as it allowed the research nurses to locate all the new admissions to the hospital with minimal difficulty.

The recruitment of subjects was carried out daily on Monday to Friday, and on the next working day for Saturday, Sunday, and public holidays because of budget constraints to employ more research nurses. However, there were very few admissions to the hospital on weekends and public holidays. Those patients who agreed to participate in the study became the sample population.

**Convenience Sample**

Convenience sampling refers to selecting the most readily available patients as participants in a study.\(^{33, 39, 40, 41}\) Patients admitted to the 12 medical and surgical wards who met the inclusion criteria were the potential convenience sample. Convenience sampling was chosen for this study for the following reasons. First, in this study, the research nurses conducted participant interviews and observations to obtain data, therefore, convenience sampling is a desirable process that is often adopted.\(^{39}\) Second, a large number of subjects were required, and convenience sampling is an easy and efficient method of meeting this objective.\(^{39}\)
Advantages of Convenience Sampling

Using a convenience sample can be time efficient as there is no randomisation process, and all patients who fit the inclusion criteria can be considered eligible to participate in the study. The population participating in the research is obtainable or convenient to reach.\textsuperscript{41}

Disadvantages of Convenience Sampling

The main disadvantage of using a convenience sample is that it may not be a true representation of the total population because samples tend to be self-selecting, and therefore the findings cannot be generalised for the population as a whole.\textsuperscript{33}

Sample Size

A biostatistician attached to the Clinical Trial Epidemiology Research Unit (CTERU) assisted in the sample size calculation. A separate sample size was calculated for the reliability and the validity components of the study.

Inter-rater Reliability Study

Inter-rater reliability refers to the degree of consistency between scores that are obtained by two independent raters.\textsuperscript{42} It was anticipated that the probability of disagreement between two observers using these fall-risk assessment tools would be approximately 10%. Hence, a total of 140 observations were required to achieve a 95% Confidence Interval (CI) of 5% to 15% for the probability of disagreement.\textsuperscript{43} There is no standard to determine an acceptable reliability coefficient. However, the ideal reliability coefficient should be 90% or better if
the measures are to be used as a basis for making a decision.\textsuperscript{39} As such, the probability disagreement between the two observers was set at 10%.

\textbf{Validity Study}

The validity of a risk assessment tool is the degree to which the risk is correctly predicted, and is expressed as sensitivity, specificity, a positive predictive value, or negative predictive value.\textsuperscript{39} Sensitivity refers to the number of patients whose fall has been rated as high-risk, while specificity refers to the number of patients whose fall has been rated as low-risk. \textsuperscript{36} Positive predictive value refers to the total number of patients who rated as high-risk who then went on to fall. Negative predictive value refers to the total number of patients who did not fall and had rated as low-risk.\textsuperscript{36}

Myers \textsuperscript{1} analysed five assessment tools reported in various studies with sensitivity values ranging from 70\% to 77\% which were considered strong. It was anticipated that the sensitivity of these fall-risk assessment tools in settings under investigation is approximately 75\%. A total of 60 falls was required to complete the study in three months with a 95\% confidence interval of sensitivity of 63\% to 84\%.\textsuperscript{44} This was based on a total of 242 falls observed in the setting under investigation in the year 2004 (about 20 falls per month).
Study Duration

The study took six months to complete from July 2005 to December 2005. The duration of the study was divided into 2 stages: Stage I, the reliability component took one month to recruit 144 patients, while, Stage II, the validity component took 5 months to recruit 5,489 admissions in order to achieve the target of 60 falls.

Research Nurses Training

Two registered nurses who had no direct involvement with the patients in the study wards were recruited as independent assessors to assess the patients at risk of falling using the three fall-risk assessment tools. The two registered nurses were able to read and speak Mandarin and Malay fluently. Training on the use of each tool was provided to ensure that the two nurses assessed the patients and documented the data in a standard, accurate and consistent manner throughout the study. In addition, training was important for the collection of high quality data.39 If the two nurses were not similarly trained, a lack of consistency and accuracy could have occurred in their assessments and rating of the three tools, therefore, posing a major threat to internal validity.39,41 Training included practice sessions during which the comparability of the two assessors’ assessment and recording methods of fall-risk were assessed.39

The research nurses were provided with comprehensive information on the aim and purpose of the study, details of the three fall-risk assessment tools, and
training on the use of each of the three tools. The research nurses had the opportunity to assess ten patients, and an evaluation of their risk assessment technique was carried out. Further training was provided before data collection commenced where significant differences existed in the risk assessment results between the two research nurses. However, no significant differences were detected in the assessment process during training. It took two weeks for the research nurses to familiarise themselves with the process of fall-risk assessment and documentation.

**Ethical Considerations**

The research proposal was submitted for approval to the Research Higher Degrees Sub-committee of the Discipline of Nursing at the School of Population Health and Clinical Practice of the University of Adelaide, and the National Healthcare Group (NHG) Domain Specific Review Board (DSRB) (refer Appendix1). The DSRB comprises of representatives from all NHG institutions, who provides an independent and timely review of the ethical and scientific merit of research studies. As this study is a tool validation study, and poses no more than minimal risk to the patient, waivers of written consent were sought and approved by the review board. The research was given approval to commence in June 2005.

The ethical issues related to this research were for the protection of human rights, including: the right to self-determination, full disclosure of information, privacy, and protection from harm and discomfort.
The Right to Self-determination

The principle of self-determination means that prospective subjects have the right to decide voluntarily whether to participate in the study without coercion from the researcher, and to terminate their participation from the study at any point in time without risk of incurring any penalties or being prejudiced. It also means that prospective subjects have the right to refuse to give information, or to request for clarification of specific study procedures or the purpose of the study.\(^{39}\)

The potential subjects were informed that their participation in this study was entirely voluntary; that they could refuse and, even if they accepted, they could withdraw from the study at any time. Their decision not to take part or discontinue their participation in the study would not affect any medical/nursing care or any benefits due to them.

The Rights to Full Disclosure of Information

The principle of full disclosure of information means that the nature of the study was described in detail to the prospective subjects, which included the nature of the study, risks and benefits to the subjects, the researcher’s responsibilities, the subject’s right to refuse to participate.\(^{39}\) Information should not be misleading and withheld from subjects.\(^{41}\) A patient information sheet written in plain language was used as a guide to explain to the patients the purpose and details of the study. Opportunities to ask questions pertaining to the research were provided. The screening for fall-risk was carried out when the patients indicated an interest
in becoming involved in the research, and gave verbal consent. Verbal consent was sought from a patients’ spouse or immediate family member on behalf of patients who were unable to give their own consent for participation.

The Right to Privacy

The principle of privacy means that subjects have the right to expect their privacy will be maintained throughout the study, and that the data collected from the study will be kept in strictest confidence. This can be facilitated through anonymity or other confidentiality procedures.\textsuperscript{39}

Subjects were reassured that they would not be identifiable from the research. An identification code was used in lieu of the patient’s name to protect his or her identification when information related to the study needed to be disclosed. The data collected was kept in a filing cabinet inside a locked office, and only authorised personnel; the principal investigator, co-investigators and the biostatistician had access to the data. The data will be kept secured in a locked cabinet for 3 years following the completion of the study in line with the DSRB policy.\textsuperscript{46} The principal investigator will destroy the data after 3 years with a shredding machine.
The Right to Protection from Harm and Discomfort

The principle of protection from harm and discomfort means that subjects will be protected from physical and psychological harm, and that subjects will not be exploited. Hence, the principal investigator had carefully weigh the risk/benefit ratio for subjects against the benefits to the society in the design and conduct of the study. It was envisaged that any emotional trauma the patients might experience while participating in the study could be dealt with effectively by drawing on the principal investigator’s background in nursing. All patients were provided with the name and contact telephone number of the principal investigator should they wish to ask questions pertaining to the research, or appropriate counselling would be made available for those patients that might experience any difficulties during and after the fall-risk assessment procedure.

Data Gathering Instruments

Four instruments were used for data collection, which included: the demographic data form, the Morse Fall Scale, St Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY), and the Hendrich II Fall Risk Model.

Demographic Data Form

The principal investigator developed a form, based on a review of available literature, to collect demographic data on subjects. Demographic data was collected and categorised according to the discipline in which subjects were admitted, such as, age, gender, race, subject’s current condition, and subject’s fall
details, including date and time of fall, location of fall, and injury sustained to provide an overview of the study sample (refer Appendix 2).

Morse Fall Scale (MFS)

The MFS is comprised of the following criteria: history of falling, presence of a secondary diagnosis, use of an ambulation aid, intravenous therapy, type of gait, and mental status. The subjects were checked for each criterion on the instrument. The word ‘no’ was circled if the criterion was not present and ‘yes’ if the criterion was present. The words ‘no’/‘yes’ were translated into a numerical value, ranging between 0 and 25. The total possible score was 125. Based on the total scores, the subjects was categorised into ‘low’ (≤ 25), ‘medium’ (25-50), and ‘high’ (≥ 51) risk of falling.21 (refer Appendix 3)

St Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY)

The STRATIFY tool is comprised of the following criteria: history of falls as a presenting complaint, mental status including confusion, disorientation and agitation, visual impairment, need for frequent toileting, and transfer and mobility. The subjects were assessed for each criterion on the instrument. The word ‘no’ was circled if the criterion was not present and ‘yes’ if the criterion was present. The words ‘no’/‘yes’ were translated into a numerical value. The score for ‘yes’ was 1, and 0 for ‘no’, except for transfer and mobility where the score ranged between 0 and 3. The final transfer score was 1 if the total score ranged from 0-3 while the final mobility score was 0 if the total score ranged between 4
and 6. The total possible score was 5. A score of 3 or higher indicated a high fall risk.\textsuperscript{17} (refer Appendix 4).

**Hendrich II Fall Risk Model**

The Hendrich II Fall Risk Model tool is comprised of the following criteria: confusion/disorientation/impulsivity, symptomatic depression, altered elimination, dizziness or vertigo, gender (male), any prescribed anti-epileptics or Benzodiazepines, and the ‘get up and go’ test. The subjects were checked for each criterion on the instrument. If the criterion was absent, then ‘0’ would be circled, Where a criterion was present, a score that ranged between 1 and 4 was assigned. A total score of $\geq 5$ or higher indicated a high-risk of fall.\textsuperscript{20} (refer Appendix 5)

**Instrument Validity**

The validity of an instrument refers to the ability of an instrument to collect and measure data that is designed to measure.\textsuperscript{50} A work group, comprised of twelve Nurse Managers and Nurse Clinicians from the study hospital, reviewed the instruments. This was considered appropriate given their connection to the units, and knowledge in medical and surgical nursing. The work group was consulted in order to acquire constructive feedback regarding the content of the instruments, and the feasibility of using the instruments in the local setting. The three instruments were translated into Mandarin and Malay languages. This was to ensure that the interpretation of the meaning in the English, Mandarin and Malay
versions of the tool were consistent. The expert fluent in that particular language performed the translation, which was verified by another person.

**Pilot Study**

The instruments were piloted on a group of patients before data collection commenced. The aim of the pilot was to perform the fall-risk assessment on a small group of patients similar to those who would be asked to participate in the study. The sample group used for this process met the same specified inclusion and exclusion criteria for this study. The instruments were piloted over a four-week period. All patients who were admitted to the medical and surgical wards during the nominated four-week period were invited to participate in the pilot study. Forty patients met the inclusion and exclusion criteria and participated in the pilot study. There were no amendments made to the four instruments following the analysis of the pilot instruments.

**Advantages of a Pilot Study**

The objective of piloting the instruments before commencing data collection was to ensure the items on the instruments were easy for the patients to understand. It also ensured that the subjects shared the researcher’s interpretation of the terms in each item and what its overall meaning was. It was also used to gauge how long the process of fall-risk assessment would take the research nurses to complete. This was beneficial because if the process proved to be time-consuming and confusing, the items on the instruments could be modified before the study.
commenced, reducing the potential for subjects to drop out or research nurses collecting incomplete data. In addition, the pilot study allowed real data to enter into the database to determine any issues with coding and/or analysis.\textsuperscript{40}

**Disadvantages of a Pilot Study**

Although, there are benefits in conducting a pilot study of the fall-risk assessment tools before commencing the actual data collection, there are also disadvantages such, as recruiting additional manpower and time, and the extra time required to conduct the pilot study, and reviewing the outcomes of the study.

**Data Collection Procedure**

Data collection comprised of data collection forms preparation, assessing for fall-risk, monitoring for falls, and fall injuries.

**Preparation of Data Collection Forms**

The data collection forms was outsourced to a vendor for photocopying. The vendor was instructed to staple the three fall-risk assessment tools in different sequences and categorise them into 6 groups: A, B, C, D, and E & F (refer Appendix 6). A random list of subjects’ codes, and form groups were generated using an Excel spreadsheet, For example subject code 001 used form group D, and so on (refer Appendix 7) Stapling the three fall-risk assessment forms in different sequences was to minimise the two research nurses from being conditioned by the sequence of items, and rating the items without reading it.\textsuperscript{48}
Assessing for Fall-Risk

Assessing for fall-risk comprised of two stages; Stage I was the inter-rater reliability study, and Stage II was the validity study.

Stage I: Inter-rater Reliability Study

A total of 288 independent ratings were performed by two research nurses on a total of 144 subjects, using the three tools in three of the study wards. The two research nurses were blinded to the findings of each other to reduce bias. The research nurse’s knowledge of the others’ findings could consciously or unconsciously influence their performance or the recording and reporting of a patients’ fall risk. The data collected was analysed for its reliability before a decision was made to proceed on to Stage II of the data collection. This process was to ensure that the acceptable inter-rater reliability disagreement of 10% between the two nurses set at the beginning of the study was achieved. If the 95% Confidence Interval existed beyond 5% to 15%, further training and evaluation of the two research nurses’ risk-fall assessment processes would need to be provided, and data collection would need to be repeated. The estimated probability disagreement between the two research nurses was within 10%, and the Confidence Interval within 5% to 15%.

Stage II: Validity Study

The two research nurses generated a list of names from all the new admissions on the Nauticus at the beginning of each workday. Based on the list of names, the
research assistants visited the study wards daily to locate all the new admissions. Following the review of all the newly admitted patients, and discussion with the nurse managers, a decision was made with regard to the patients that the research nurses could approach. The benefit of discussing the patients with the nurse managers was that the research nurses had no knowledge of the patients’ background and condition. Patients in the wards could have had visitors or ongoing treatment being carried out, so it was thought appropriate to always check with the nurse managers before approaching the patients.

Patients in the study wards were considered for participation in the study based on the inclusion and exclusion criteria. Those patients identified as potential inclusions for the study were approached and had the study explained to them and were provided with a patient information sheet (refer Appendix 8) that outlined the purpose of the study, and what their involvement entailed. The patients were also given the opportunity to clarify anything that might be unclear. Once the patients agreed to participate in the study and gave verbal consent, they became the subjects.

Upon entry into the study, the research nurses reviewed the subjects’ medical records to gather information about their medical history and treatment, and at the same time record demographic data. A screening of the subjects for fall-risk followed this.
Screening of the subjects’ fall-risk was carried out by reviewing the subjects’ medical records. This was followed by interviewing the subjects with the three fall-risk assessment tools administered in the language the subjects could comprehend; English, Malay or Mandarin. In addition, screening of the subjects’ mobility status on the Hendrich II Fall Risk Model was determined by asking the subjects to perform the ‘get up and go test’. The screening was conducted at the subjects’ bedside. Each screening lasted approximately 20 minutes, including the administration of the instruments. The outcome of the screening was recorded on a data collection sheet. Screening of all new subjects for fall-risk was carried out daily within 24 hours of their admission to the ward on Monday to Friday, and the next working day, if the patient was admitted on a Saturday, Sunday, or public holiday.

**Monitoring for Falls**

Fall is defined as ‘an unexpected event in which the participants come to rest on the ground or lower level’[^49] (p.1,619). The principal investigator, who was not involved in the actual screening of the sample population, visited the study wards daily to follow-up all subjects entered into the study until the time of their first fall, discharge or death, whichever occurred first. For those subjects who fell, data was collected on: time of fall, location of fall, and activity at time of fall, and injuries sustained. The outcome of falls was classified according to the study hospital’s occurrence reporting system, which included: no injury, minor injuries, moderate injuries, and severe injuries. Minor injuries included soft tissue
swelling, contusions, bruises, and small skin tears that required little or no care or observation. Moderate injuries included sprains, large or deep lacerations requiring suturing and splinting. Severe injuries included fractures, and repair to fractures, and death. The data was collected from the subjects’ medical records and from interviews with the subjects and recorded by the principal investigator on a data collection form, which was developed based on a review of the literature, and the study hospital’s adverse event reporting system. Only data from subjects who fell following screening were included. The subjects exited from the study following the first fall, discharge or death.

**Monitoring for Falls Injury**

The principal investigator visited the study wards daily to follow-up those subjects who had sustained injuries following their falls. The outcome measures included subjects that required dressing or surgery, repairs to fractures, died, or received pain relief as a result of an injury. The data on the outcome of injuries sustained was gathered through observations, by reviewing a subject’s medical records and from interviews with the subject and ward nurses. The injuries sustained by the subjects were followed-up until the day of discharge from hospital or death.

**Data Collection Challenges**

There were three problems encountered in the data collection. First, the principal investigator was unable to observe some patients on their first fall following the
screening due to a short length of stay in hospital. Second, several new admissions were not recruited into the study because patients were not accessible in bed. They were either in operating theatres, x-ray departments or transferred to the Critical Care Unit, therefore, falls from this group of patients had to be excluded from the total count. Third, several high-risk patients fell before screening of the fall-risk could be carried out, and so the patients had to be excluded from the study. As a result, data collection took five months to recruit a total of 5,489 admissions in order to achieve the target of 60 falls.

Statistical Analysis

Data Coding

On collection of completed data form, each form was assigned a code number: 01, 02, 03 and so on. This process helped to preserve the anonymity and confidentiality of the subjects. In addition, it enabled the number to be recorded in the data file together with the data for reference if it was necessary to access the completed form from the data file.40

The quantifiable data from the completed data collection forms were coded. Coding is the process of assigning each response a numerical code that can be entered into the database in a form that can be easily analysed. 40 The coding corresponded to the question/item number, with responses numbered also. For example, discipline was listed as item 1 on the data collection form; the response to medical was coded as ‘1’, and surgery as ‘2’. Actual numbers such as the
subject’s age did not need to be coded. These codes were used to reference the data prior to entering it into the statistical software package.

Data Entry

The principal investigator discussed the database set-up with a biostatistician before data entry. This was to ensure that the biostatistician could assist with data analysis without too much difficulty. Once all the questions/items had been coded, the data entry assistant, who was employed full time for this study, entered the data directly into the Statistical Package for Social Science (SPSS) data editor spreadsheet at the end of each day. Once the data was entered into the SPSS data editor, data cleaning was performed before the data was analysed. Data cleaning is a process whereby the entered data was checked against the raw data, and any coding errors or discrepancies that were identified were rectified at once. This was important in ensuring the accuracy of numbers the computer would process, and the validity of data for analysis.

Data Analysis

Upon completion of data cleaning, statistical analysis was performed using Statistical Package for Social Science (SPSS Inc, Chicago, IL, and USA) version 14. According to the appropriate scale of measurement, descriptive statistics, such as frequency distribution (percentage), measure of central tendency (mean, median and mode), measures of dispersion (range), standard deviation), were used to analyse and describe the data. For example, frequency distribution was used in
this study to analyse data on a nominal scale such as disciplines, sex, race, current condition, and subjects’ fall details. Mean, median, standard deviation and range were used to analyse data on a ratio scale such as age.40

Inter-rater Reliability

The statistical tests applied to the data are determined by the attributes of the data collected. For nominal data, the measure of agreement between two assessors can be gauged by calculating the overall percentage of agreement. However, the percentage of agreement does not take into account the agreement that would be due to chance alone. Cohen’s kappa is a commonly used statistics to discount the proportion of agreement that is due to chance alone. Hence, Cohen’s kappa was used in this study to measure the agreement between the two assessors. The agreement between assessors on whether to classify subjects as ‘yes’ or ‘no’ as a risk for fall was displayed in a 2 x 2 contingency table, a cross tabulation was carried out, and the inter-raters agreement was calculated using Cohen’s kappa. The range of possible values of kappa is from –1 to 1, though it usually falls between 0 and 1. The nearer the value to 1, the more reliable the tool is. 51 The strength of agreement for Cohen kappa is: 0 = poor, 0.01–0.20 = slight, 0.21-0.40 = fair, 0.41-0.60 = moderate, 0.61-0.80 = substantial, 0.81-1 = almost perfect.52

The disagreement between assessors on whether to classify subjects as ‘yes’ or ‘no’ as a risk for fall was displayed in a 2 x 2 contingency table, a cross tabulation
was carried out, and the estimated probability disagreement between the two assessors was expressed as a percentage with a 95% confidence interval.

*Validity*

The ability of each of the three tools to predict who was likely to fall was examined by creating a 2 x 2 contingency table to illustrate which subjects with high and low scores fell or did not fall, and a cross tabulation was carried out. The predictive validity of the three tools was estimated by measuring the sensitivity, specificity, positive predictive value, and the negative predictive value of the three tools. Sensitivity was measured by the number of subjects with high-risk score who fell divided by the total number of subjects who fell. Specificity was measured by the number of subjects with low-risk scores who did not experience a fall divided by the total number of subjects who did not fall. A positive predictive value was measured by the number of subjects with high-risk scores who fell divided by the total number of subjects with high-risk scores. A negative predictive value was measured by the number of subjects with low-risk scores who did not fall divided by the total number of subjects with low-risk scores.
Results

This section presents the results of a prospective descriptive study conducted in two stages whereby different subjects were used for each stage of the study. Stage I was the inter-rater reliability component in which 144 observations were carried out independently by two research nurses using three fall-risk assessment tools. Stage II was the validity component in which two research nurses assessed a total of 5,489 subjects using the three fall-risk assessment tools.

Stage I: Inter-rater Reliability Study

The inter-rater reliability study was conducted from 15 July 2005 to 1 August 2005. Demographic data that included the disciplines of race, gender, and age were collected to provide an overview of the demographic characteristics of the subjects. Two research nurses performed independent fall-risk assessments on 144 subjects using the three fall-risk assessment tools. The data collected was analysed for probability of agreement and disagreement between the two assessors before the decision was made to proceed on to Stage II of the data collection.
Demographic Data

Recruitment and Discipline Demographics

A total of 144 subjects were recruited during the two-week data collection period. Of these subjects, 75% were admitted to medical wards, the remainder were admitted to surgical wards. Fewer subjects were recruited from the surgical wards because patients with surgical conditions account for only 35% of inpatient admissions in the study hospital. The majority of patients with surgical conditions are managed in the day surgery wards, following the global trend towards ambulatory care (refer Table 2).

Table 2: Recruitment and Discipline Demographics

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Number of Subjects ((n = 144))</th>
<th>Percentage ((100%))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td>108</td>
<td>75.0</td>
</tr>
<tr>
<td>Surgical</td>
<td>36</td>
<td>25.0</td>
</tr>
<tr>
<td>Total</td>
<td>144</td>
<td>100</td>
</tr>
</tbody>
</table>
Race

There were more Chinese (68.8%, $n=99$) subjects enrolled in the study than Malays (18.8%, $n=27$), Indians (11.8%, $n=17$) and other races (0.7%, $n=1$). The ethnicity of the subjects reflects the Singaporean population (refer Figure1).

Figure 1: Race of Subjects
Gender and Age Demographics

Of the 144 subjects recruited, 55.6% were male with a mean age of 55.5 years, while 44.4% of the subjects were female, with a mean age of 57.9 years. There was no statistically significant difference between male and female ages in the study. The mean age of all subjects combined was 56.5 years (refer Table 3).

Table 3: Gender and Age Demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number (%)</th>
<th>Mean (Age in years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>80 (55.6%)</td>
<td>55.48 (21-88) ± 17.69</td>
</tr>
<tr>
<td>Female</td>
<td>64 (44.4%)</td>
<td>57.86 (21-94) ± 18.20</td>
</tr>
<tr>
<td>Total</td>
<td>144</td>
<td>56.53 ± 17.89</td>
</tr>
</tbody>
</table>

Mean ± Standard Deviation
Distribution of Age Group of Subjects

The ages of subjects ranged from 21 to 94 years with the largest group of subjects aged between 50 to 64 years (34.7%, \( n=50/144 \)). The second largest group of subjects was aged between 65 to 79 years (20.8%, \( n=30/144 \)). The mean age of all the subjects combined was 56.53 years (refer Figure 2).

Figure 2: Distribution of Age Groups of Subjects

Mean age: 56.53
Inter-rater Reliability

A total of 288 independent simultaneous observation ratings were performed by two research nurses on 144 subjects, using the three fall-risk assessment tools in three of the study wards. The probability of inter-rater agreement for the three fall risk assessment tools was established using Cohen Kappa. It ranged from 0.86 to 0.89, indicating that the strength of agreement was almost perfect. The results appear to be consistent across the three tools and were not influenced by the various cut-off scores (refer Table 4).

The probability of inter-rater disagreement for the three tools ranged from 2.8% (95% CI: 1.1 - 6.9) to 9.7% (95% CI: 5.9 - 15.7). The STRATIFY reported the lowest inter-rater disagreement of 2.8% (95% CI: 1.1 - 6.9) with a cut-off score of \( \geq 3 \), while the MFS reported the highest inter-rater disagreement of 9.7% (95% CI: 5.9 - 15.7) with a cut-off score of \( \geq 51 \). Interestingly, the STRATIFY reported a narrower and wider inter-rater disagreement at higher and lower cut-off scores respectively. Conversely, the MFS reported narrower and wider inter-rater disagreement at lower and higher cut-off scores respectively (refer Table 4).
Table 4: Inter-rater Agreement / Disagreement of Fall Risk Assessment Tools

<table>
<thead>
<tr>
<th>Fall Risk Assessment Tool</th>
<th>At risk of fall (Cut-off score)</th>
<th>Cohen Kappa Value</th>
<th>Probability disagreement (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morse Fall Scale</td>
<td>≥ 25</td>
<td>0.86</td>
<td>4.2% (1.9 to 8.8)</td>
</tr>
<tr>
<td></td>
<td>≥ 51</td>
<td>0.80</td>
<td>9.7% (5.9 to 15.7)</td>
</tr>
<tr>
<td>STRATIFY</td>
<td>≥ 2</td>
<td>0.87</td>
<td>6.3% (3.3 to 11.5)</td>
</tr>
<tr>
<td></td>
<td>≥ 3</td>
<td>0.89</td>
<td>2.8% (1.1 to 6.9)</td>
</tr>
<tr>
<td>Hendrich II Fall Risk Model</td>
<td>≥ 5</td>
<td>0.87</td>
<td>6.3% (3.3 to 11.5)</td>
</tr>
</tbody>
</table>
Stage II: Validity Study

A total of 5,489 subjects were screened using the three fall-risk assessment tools during the five-month data collection period, from 16 August 2005 to 15 December 2005. Demographic data that included the disciplines race, gender, and age were collected to provide an overview of the demographic characteristics of subjects. The data collected was analysed for sensitivity, specificity, and positive and negative predictive values.

Recruitment and Discipline Demographics

Of these subjects, 65.9% (n=3616/5489) were admitted to medical wards and the remainder (34.1%, n=1871/5489) to surgical wards. The proportion of subjects admitted to the two disciplines was comparable to the inter-rater reliability, and this reflects the study hospital patients’ population (refer table 5).

Table 5: Recruitment and Discipline Demographics

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Number of Subjects (n=5489)</th>
<th>Percentage (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td>3,616</td>
<td>65.9</td>
</tr>
<tr>
<td>Surgical</td>
<td>1,871</td>
<td>34.1</td>
</tr>
<tr>
<td>Total</td>
<td>5,489</td>
<td>100</td>
</tr>
</tbody>
</table>
Race of Subjects

Of the 5,489 subjects who participated in the study, 68.8% \( (n=3735) \) were Chinese, 19% \( (n=1043) \) were Malays and 10.1% \( (n=552) \) were Indians, while 2.9% \( (n=159) \) of the subjects were from other races, which included ethnic minority groups such as Eurasians, and Sikhs, and subjects on work permits from Asian countries such as the Philippines, Indonesia, India, and Myanmar (refer Figure 3).

Figure 3: Race of Subjects
Gender and Age Demographics

Of the 5,489 subjects recruited, 51.8% were male with a mean age of 53.2 years, while 48.2% of the subjects were female with a mean age of 57.8 years. There was no statistically significant difference between male and female subjects. The mean age of all the subjects combined was 55.4 years (refer Table 6).

Table 6: Gender and Age Demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number (%)</th>
<th>Mean (Age in years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>2,842 (51.8%)</td>
<td>53.19 ± 18.8</td>
</tr>
<tr>
<td>Female</td>
<td>2,647 (48.2%)</td>
<td>57.78 ± 19.22</td>
</tr>
<tr>
<td>Total</td>
<td>5,859 (100%)</td>
<td>55.40 ± 19.1</td>
</tr>
</tbody>
</table>

Mean ± Standard Deviation
Distribution of Age Group of Subjects

Of the 5,489 subjects in the study, the majority (51.6%, \( n=2830/5489 \)) were between the age range of 50-79 years, while 20% (\( n=1125/5489 \)) of the subjects were between the age ranges 35-49 years, and 17.3% (\( n=952/5489 \)) were below the age of 34 years. The mean age of all the subjects combined was 56 years (refer Figure 4).

Figure 4: Distribution of Age Group of Subjects

Mean age: 56 years
Current Conditions of Subjects

Of the 5,489 subjects in the study, 64.3% \((n=3529/5489)\) were admitted for medical conditions, 32.2% \((n=1765/5489)\) for surgical conditions, and 3.5% \((n=195/5489)\) for other conditions (refer Figure 5).

Figure 5: Current Conditions of Subjects
Subjects Admitted with Medical Condition

Of the 64.3% \( (n=3529/548) \) subjects admitted with medical conditions, the majority of subjects were admitted for general medical (37.4%, \( n=1320/3529 \)), followed by cardiac (13%, \( n=460/3529 \)), oncologic (11.4%, \( n=403/3529 \)) and renal (9.7%, \( n=342/3529 \)) conditions (refer Figure 6).

Figure 6: Subjects Admitted with Medical Condition
Subjects Admitted with Surgical Condition

Of the 32.2% \((n=1765/5489)\) subjects admitted with surgical conditions, the majority of them underwent orthopaedic surgery (41.4%, \(n=731/1765\)), followed by general surgery (39.3%, \(n=693/1765\)), and gynaecologic surgery (6.9%, \(n=121/1765\)) (refer Figure 7).

Figure 7: Subjects Admitted with Surgical Condition
Demographics of Subjects who Fell

Of the 5,489 subjects recruited during the five-month data collection period, a total of 60 subjects fell once. There were more males subjects 68.3%, $n=41/60$) who fell compared with female subjects (31.7%, $n=19/60$). The ages of subjects ranged between 24 to 73 years, with a mean age of 62.7 years (refer Table 7).

Table 7: Demographics of Subjects who Fell

<table>
<thead>
<tr>
<th>Description</th>
<th>Frequency $(n=60)$</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>41</td>
<td>68.3</td>
</tr>
<tr>
<td>Female</td>
<td>19</td>
<td>31.7</td>
</tr>
<tr>
<td>Age *</td>
<td>62.7 $\pm$ 15.7</td>
<td>60 100</td>
</tr>
</tbody>
</table>

* Mean age $\pm$ Standard Deviation
Time and Location of Falls

Of the 60 subjects who fell, 51.7% \((n=31/60)\) fell between 2100 and 0700 hours, 33.3% \((n=20/60)\) between 0700 and 1400 hours, and 15% \((n=9/60)\) fell between 1400 and 2100 hours. The majority of subjects (71.7%; \(n=43/60\)) fell near their bed, 21.7% \((n=13/60)\) fell in the toileting area, and 6.7% \((n=4/60)\) fell along the corridor (refer Table 8).

Table 8: Time and Location of Falls

<table>
<thead>
<tr>
<th>Description</th>
<th>Frequency ((n=60))</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time of day</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2100 to 0700 hrs</td>
<td>31</td>
<td>51.7</td>
</tr>
<tr>
<td>0700 to 1400 hrs</td>
<td>20</td>
<td>33.3</td>
</tr>
<tr>
<td>1400 to 2100 hrs</td>
<td>9</td>
<td>15.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td><strong>Location of fall</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Near the bed</td>
<td>43</td>
<td>71.7</td>
</tr>
<tr>
<td>In the toileting area</td>
<td>13</td>
<td>21.7</td>
</tr>
<tr>
<td>Along the corridor</td>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>
Activity at Time of Falls and Fall Mechanism

Of the 60 subjects who fell, 25% \((n=15/60)\) of subjects fell while getting out of bed, and 8.3\% \((n=11/60)\) of subjects fell while climbing out of bed. Bathing, ambulating, sitting down or standing up, and using the toilet and beside commode followed this. Other activities included transfer from wheelchair to bed, wet floor, reaching for things and running to the toilet. The most common mechanism of the fall reported by subjects was a loss of balance \((46.7\%, n= 28/60)\). This was followed by a slip or trip, muscle weakness, and dizziness (refer Table 9).

Table 9: Activity at Time of Falls and Fall Mechanism

<table>
<thead>
<tr>
<th>Description</th>
<th>Frequency ((n=60))</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activity at time of fall</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambulating</td>
<td>6</td>
<td>10.0</td>
</tr>
<tr>
<td>Getting out of bed</td>
<td>15</td>
<td>25.0</td>
</tr>
<tr>
<td>Sitting down or standing up</td>
<td>5</td>
<td>8.3</td>
</tr>
<tr>
<td>Using bedside commode</td>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>Using toilet</td>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>Bathing</td>
<td>9</td>
<td>15.0</td>
</tr>
<tr>
<td>Climbing out of bed</td>
<td>11</td>
<td>18.3</td>
</tr>
<tr>
<td>Others</td>
<td>6</td>
<td>10.0</td>
</tr>
<tr>
<td><strong>Fall mechanism</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lost balance</td>
<td>28</td>
<td>46.7</td>
</tr>
<tr>
<td>Slipped or tripped</td>
<td>11</td>
<td>18.3</td>
</tr>
<tr>
<td>Dizziness</td>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>Muscle weakness</td>
<td>9</td>
<td>15.0</td>
</tr>
</tbody>
</table>
Outcome of Falls

Of the 60 subjects who fell, the majority (77.3%, \(n=44/60\)) resulted in no injury at all, while 13.4% \(n=8/60\) sustained a mild injury, 8.3% \(n=5/60\) a moderate injury, and 5% \(n=3/60\) severe injuries. Mild injuries included soft tissue swelling, contusions, bruises and small skin tears that required little or no care and or observation. Moderate injuries included sprains, large or deep lacerations requiring suturing and splinting. Severe injuries included fractures, requiring repair (refer Table 10).

Table 10: Outcome of Falls

<table>
<thead>
<tr>
<th>Injury</th>
<th>Frequency ((n=60))</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No injury</td>
<td>44</td>
<td>73.3</td>
</tr>
<tr>
<td>Mild injuries</td>
<td>8</td>
<td>13.4</td>
</tr>
<tr>
<td>Moderate injuries</td>
<td>5</td>
<td>8.3</td>
</tr>
<tr>
<td>Severe injuries</td>
<td>3</td>
<td>5.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>60</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
Fall Risk Assessment Tools

A total of 5,489 subjects were screened using the three fall-risk assessment tools during the five-month data collection, to achieve the target of 60 falls set at the beginning of the study. The subjects were identified to be at high-risk for falls at the cut-off scores recommended by the tool developers. The cut-off score for the Hendrich II Fall Risk Model was $\geq 5$, the Morse Fall Scale was $\geq 25$ and $\geq 51$ and STRATIFY was $\geq 2$ and $\geq 3$. The subjects were followed-up until the time of their first fall, discharge, or death, whichever occurred first.

Number of High-Risk Subjects

The proportion of subjects classified at high-risk for falls across the three tools ranged from 9.1% to 52.1%, with the Morse Fall Scale (with a cut-off score of $\geq 25$) classified as the highest proportion of subjects (52.1%) at high-risk for falls, and STRATIFY (with a cut-off score of $\geq 3$) classified as the lowest proportion of subjects (9.1%). The Hendrich II Fall Risk Model (with a cut-score off of $\geq 5$) was classified the second highest proportion of subjects at high-risk for falls (38.9%). The STRATIFY (with a cut-off score of $\geq 3$, 9.1%), and Morse Fall Scale (with a cut-off score of $\geq 51$, 9.3%) were the tools classified as the lowest proportion of subjects at high-risk for falls (refer Table 11).

Number of Falls

A total of 60 falls were observed during the five-month data collection period. Of the 60 falls, 53 (88.3%) falls were experienced by subjects classified to be at high-
risk for falls. The Morse Fall Scale (with a cut-off score of ≥ 25) identified the highest proportion of subjects classified to be at high-risk for falls ($n=53/60, 88.3\%$), while STRATIFY (with a cut-off score of ≥ 3) identified the lowest proportion of subjects classified to be at high-risk for falls ($n=15/60, 25\%$). The Hendrich II Fall Risk Model (with a cut-off score of ≥ 5) identified the second highest proportion of subjects classified to be at high-risk for falls ($n=42/60, 70\%$). Both STRATIFY (with a cut-off score of ≥ 2), and Morse Fall Scale (with a cut-off score of ≥ 51) identified as the third highest proportion ($n=33/60, 55\%$) of subjects classified to be at high-risk for falls (refer Table 11).

Positive Predictive Value
The positive predictive value across the three tools was low, ranging from 1.9% to 3%. The Morse Fall Scale had the highest (6.4%), and lowest positive predictive (1.9%) value with a cut-off score of ≥ 51 and ≥25 respectively (refer Table 11).

The results showed that the proportion of subjects classified at high-risk for falls recorded by Morse Fall Scale was higher with a cut-off score of ≥ 25 (88.3%, $n=53/60$) when compared to the cut-off score of ≥ 51 (55%, $n=33/60$). Although, the Morse Fall Scale (with a cut-off score of ≥25) classified as the highest proportion of subjects at high-risk for falls (52.1%), the positive predictive value was extremely low at 1.9%. However, when the cut-off score was raised to ≥51, the proportion of subjects classified to be at high-risk for falls was substantially
lowered from 52.1% to 9.3% but the positive predictive value was raised from 1.9% to 6.4% (refer Table 11).

Similar trends were recorded by STRATIFY; the proportion of subjects classified to be at high-risk for falls was higher at a cut-off score of ≥ 2 (n=33/60, 55%), and lower at a cut-off score of ≥ 3 (n=15/60, 25%). Similarly, the proportion of subjects classified to be at high-risk for falls by STRATIFY with a cut-off score of ≥ 2 was 24.5%, and the positive predictive value 2.4%. However, when the cut-off score was raised higher, to ≥ 3, the proportion of subjects classified to be at high-risk for falls dropped dramatically from 24.5% to 9.1%, while the positive predictive value was raised from 2.4 % to 3% (refer Table 11).

These results appear to suggest that low cut-off scores result in higher proportions of subjects classified at high-risk for falls, and lower positive predictive value. Conversely, high cut-off scores result in lower proportions of subjects classified at high-risk for falls, and higher positive predictive values (refer Table 11).
<table>
<thead>
<tr>
<th>Fall Assessment Tool</th>
<th>HFRM</th>
<th>MFS</th>
<th>MFS</th>
<th>STRATIFY</th>
<th>STRATIFY</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk of fall (cut-off score)</td>
<td>≥ 5</td>
<td>≥ 25</td>
<td>≥ 51</td>
<td>≥ 2</td>
<td>≥ 3</td>
</tr>
<tr>
<td>Number of subjects at high-risk for falls (%)</td>
<td>2134 (38.9%)</td>
<td>2859 (52.1%)</td>
<td>513 (9.3%)</td>
<td>1372 (24.5%)</td>
<td>497 (9.1%)</td>
</tr>
<tr>
<td>Number of high-risk subjects that fell (% of total number of falls: 60)</td>
<td>42 (70%)</td>
<td>53 (88.3%)</td>
<td>33 (55%)</td>
<td>33 (55%)</td>
<td>15 (25%)</td>
</tr>
<tr>
<td>Number of high-risk subjects that fell (total number of patients at high-risk for falls)</td>
<td>42 (2134)</td>
<td>53 (2859)</td>
<td>33 (513)</td>
<td>333 (1372)</td>
<td>15 (497)</td>
</tr>
<tr>
<td>PPV (%) (95% CI)</td>
<td>2.0 (1.5 - 2.6)</td>
<td>1.9 (1.4 - 2.4)</td>
<td>6.4 (4.6 - 8.9)</td>
<td>2.4 (1.7 - 3.4)</td>
<td>3.0 (1.8 - 4.9)</td>
</tr>
</tbody>
</table>
Number of Non-fallers and Negative Predictive Value

The proportion of subjects classified at low-risk for falls across the three tools was high, ranging from 47.9% to 90.9%. STRATIFY (with a cut-off score of ≥ 3) classified as the highest proportion of subjects (90.9%), and Morse Fall Scale (with a cut-off score of ≥ 25) classified as the lowest proportion of subjects (47.9%) at low-risk for falls. The negative predictive value across the three tools was high, ranging from 99.1% to 99.7% (refer Table 12).

Table 12: Number of Non-fallers and Negative Predictive Value of the Three Tools (n = 5489)

<table>
<thead>
<tr>
<th>Fall Assessment Tool</th>
<th>HFRM</th>
<th>MFS</th>
<th>MFS</th>
<th>STRATIFY (cut-off score) ≥ 5</th>
<th>≥ 25</th>
<th>≥ 51</th>
<th>≥ 2</th>
<th>≥ 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk of fall (%)</td>
<td>3355</td>
<td>2630</td>
<td>4976</td>
<td>4117</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of subjects</td>
<td>3337</td>
<td>2623</td>
<td>4949</td>
<td>4090</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of</td>
<td>3355</td>
<td>2630</td>
<td>4976</td>
<td>4117</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>subjects not ‘at</td>
<td>(61.1%)</td>
<td>(47.9%)</td>
<td>(90.7%)</td>
<td>(75%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>risk’ for falls (%)</td>
<td></td>
<td></td>
<td></td>
<td>(90.9%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of subjects</td>
<td>3337</td>
<td>2623</td>
<td>4949</td>
<td>4090</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘not at risk for</td>
<td>(3355)</td>
<td>(2630)</td>
<td>(4976)</td>
<td>(1117)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>falls who did not</td>
<td></td>
<td></td>
<td></td>
<td>(99.2 - 99.7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>fall (total number</td>
<td></td>
<td></td>
<td></td>
<td>(99.5 - 99.9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>of subjects ‘not at</td>
<td></td>
<td></td>
<td></td>
<td>(99.2 - 99.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>risk’ for falls)</td>
<td></td>
<td></td>
<td></td>
<td>(99.0 - 99.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPV (%)</td>
<td>99.5</td>
<td>99.7</td>
<td>99.5</td>
<td>99.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(99.2 - 99.7)</td>
<td>(99.5 - 99.9)</td>
<td>(99.2 - 99.6)</td>
<td>(98.8 - 99.3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sensitivity of Tools

The sensitivity value of the three tools at various cut-off scores ranged from 25% to 88.3%. The Morse Fall Scale (with a cut-off score of $\geq 25$) had the highest sensitivity value of 88.3%, followed by the Hendrich II Fall Risk Model with a sensitivity value of 70% (with a cut-off score of $\geq 5$). The STRATIFY had the lowest sensitivity value of 25% (with a cut-score score of $\geq 3$). Both the Morse Fall Scale, and STRATIFY had the lowest sensitivity values of 55% with a cut-off scores of $\geq 51$ and $\geq 2$ respectively (refer Table 13).

Table 13: Sensitivity Values of the Three Fall-risk Assessment Tools

<table>
<thead>
<tr>
<th>Fall Assessment Tool</th>
<th>HFRM</th>
<th>MFS</th>
<th>MFS</th>
<th>STRATIFY</th>
<th>STRATIFY</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk of fall (cut-off score)</td>
<td>$\geq 5$</td>
<td>$\geq 25$</td>
<td>$\geq 51$</td>
<td>$\geq 2$</td>
<td>$\geq 3$</td>
</tr>
<tr>
<td>Number of ‘high-risk’ subjects that fell (total number ‘high risk’ subjects)</td>
<td>42 (2134)</td>
<td>53 (2859)</td>
<td>33 (513)</td>
<td>33 (1372)</td>
<td>15 (497)</td>
</tr>
<tr>
<td>Total number of observed falls</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Sensitivity (%) (95% CI)</td>
<td>70.0 (57.5 - 80.1)</td>
<td>88.3 (77.8 - 94.2)</td>
<td>55.0 (42.5 - 66.9)</td>
<td>55.0 (42.5 - 66.9)</td>
<td>25.0 (15.8 - 37.2)</td>
</tr>
</tbody>
</table>
Specificity of Tools

The specificity values of the three tools at various cut-off scores ranged from 48.3% to 91.2%. The STRATIFY tool (with a cut-off score of \( \geq 3 \)) and Morse Fall Scale (with a cut-off score of \( \geq 51 \)), had the highest specificity value of 91.1% and 91.2% respectively. The Morse Fall Scale had the lowest specificity value of 48.3% with a cut-off score of \( \geq 25 \). The Hendrich II Fall Risk Model had a specificity value of 61.5% with a cut-off score of \( \geq 5 \) (refer Table 14).

Table 14: Specificity Values of the Three Fall-risk Assessment Tools

<table>
<thead>
<tr>
<th>Fall Assessment Tool</th>
<th>HFRM</th>
<th>MFS</th>
<th>MFS</th>
<th>STRATIFY</th>
<th>STRATIFY</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk of fall (cut-off score)</td>
<td>( \geq 5 )</td>
<td>( \geq 25 )</td>
<td>( \geq 51 )</td>
<td>( \geq 2 )</td>
<td>( \geq 3 )</td>
</tr>
<tr>
<td>Number of subjects ‘not at risk’ of falls and who did not fall (total number of subjects ‘not at risk’)</td>
<td>3337 (3355)</td>
<td>2623 (2630)</td>
<td>4949 (4976)</td>
<td>4090 (4117)</td>
<td>4947 (4992)</td>
</tr>
<tr>
<td>Total no of subjects who did not fall (total number of subjects)</td>
<td>5429 (5489)</td>
<td>5429 (5489)</td>
<td>5429 (5489)</td>
<td>5429 (5489)</td>
<td>5429 (5489)</td>
</tr>
<tr>
<td>Specificity (%) (95% CI)</td>
<td>61.5 (60.2 - 62.8)</td>
<td>48.3 (47.0 - 49.6)</td>
<td>91.2 (90.4 - 91.9)</td>
<td>75.3 (74.2 - 76.5)</td>
<td>91.1 (90.3 - 91.8)</td>
</tr>
</tbody>
</table>

Sensitivity and Specificity of Tools

The Morse Fall Scale had a high sensitivity (88.3%) and low specificity (48.3%) value at a lower (\( \geq 25 \)) cut-off score. Conversely, low sensitivity (55.0%) and high specificity (91.2%) values were seen at a higher (\( \geq 51 \)) cut-off score. The STRATIFY (with a cut-off score of \( \geq 2 \) and \( \geq 3 \)) had a low sensitivity (55%; 25%) and extremely high specificity (75.3%; 91.1%) value. The Hendrich II Fall Risk
Model (with a cut-off score ≥ 5) had the best balance between sensitivity (70%) and specificity (61.5%) values (refer Table 13).

**Overall Comparison of Tools**

The Morse Fall Scale (with a cut-off score of ≥ 25), and Hendrich II Fall Risk Model (with a cut-off score of ≥ 5) were the two tools able to identify a high proportion of fallers. Moreover, the proportion of high-risk subjects classified by the Morse Fall Scale (with a cut-off score of ≥ 25), and the Hendrich II Fall Risk Model (with a cut-off score of ≥ 5) were comparable. These two tools gave the best balance of subjects between a high-risk and low-risk for falls in comparison to the other tools, where a substantial proportion of subjects identified at low-risk for falls (refer Table 15).

Although, the Morse Fall Scale (with a cut-off score of ≥ 25) had a higher proportion of subjects at high-risk for falls, and sensitivity values than the Hendrich II Fall Risk Model (with a cut-off score of ≥ 5), the specificity value of Morse Fall Scale (with a cut-off score of ≥ 25) was much lower than that of the Hendrich II Fall Risk Model (with a cut-off score of ≥ 5). Thus, the Hendrich II Fall Risk Model (with a cut-off score of ≥ 5) provided a better balance than the Morse Fall Scale (with a cut-off score of ≥ 25), in term of sensitivity and specificity values, and proportion of subjects classified at high-risk of falls (refer Table 15).
Table 15: Comparison of the Three Fall-risk Assessment Tools \((n = 5489)\) and Observed Falls \((n = 60)\)

<table>
<thead>
<tr>
<th>Fall Assessment Tool</th>
<th>HFRM</th>
<th>MFS</th>
<th>MFS</th>
<th>STRATIFY</th>
<th>STRATIFY</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk of fall (cut-off score)</td>
<td>(\geq 5)</td>
<td>(\geq 25)</td>
<td>(\geq 51)</td>
<td>(\geq 2)</td>
<td>(\geq 3)</td>
</tr>
<tr>
<td>Number of ‘high-risk’ subjects that fell (total number of subjects ‘at risk’)</td>
<td>42 (2134)</td>
<td>53 (2859)</td>
<td>33 (513)</td>
<td>33 (1372)</td>
<td>15 (497)</td>
</tr>
<tr>
<td>Number of ‘not at risk’ subjects who did not fall (total number of subjects ‘not at risk’)</td>
<td>3337 (3355)</td>
<td>2623 (2630)</td>
<td>4949 (4976)</td>
<td>4090 (4117)</td>
<td>4947 (4992)</td>
</tr>
<tr>
<td>Sensitivity (%) (95% CI)</td>
<td>70.0 (57.5 - 80.1)</td>
<td>88.3 (77.8 - 94.2)</td>
<td>55.0 (42.5 - 66.9)</td>
<td>55.0 (42.5 - 66.9)</td>
<td>25.0 (15.8 - 37.2)</td>
</tr>
<tr>
<td>Specificity (%) (95% CI)</td>
<td>61.5 (60.2 - 62.8)</td>
<td>48.3 (47.0 - 49.6)</td>
<td>91.2 (90.4 - 91.9)</td>
<td>75.3 (74.2 - 76.5)</td>
<td>91.1 (90.3 - 91.8)</td>
</tr>
<tr>
<td>PPV (%) (95% CI)</td>
<td>2.0 (1.5 - 2.6)</td>
<td>1.9 (1.4 - 2.4)</td>
<td>6.4 (4.6 - 8.9)</td>
<td>2.4 (1.7 - 3.4)</td>
<td>3.0 (1.8 - 4.9)</td>
</tr>
<tr>
<td>NPV (%) (95% CI)</td>
<td>99.5 (99.2 - 99.7)</td>
<td>99.7 (99.5 - 99.9)</td>
<td>99.5 (99.2 - 99.6)</td>
<td>99.3 (99.0 - 99.5)</td>
<td>99.1 (98.8 - 99.3)</td>
</tr>
</tbody>
</table>

Summary of the Findings

The Morse, STRATIFY, and Hendrich II fall-risk assessment tools were validated in the inter-rater reliability and validity studies. In the inter-rater reliability study, two assessors using the three tools on a total of 144 subjects performed 288 independent simultaneous observations. The data was analysed for the probability of agreement and disagreement to determine the reliability of the tools before a decision was made to proceed on to Stage II. In the validity study, the two research nurses assessed a total of 5,489 patients using the three tools to achieve the target of 60 falls. The sensitivity, specificity, positive predictive value, and
negative predictive values of the assessment tools were assessed with the associated 95% confidence intervals.

Inter-rater Reliability

A total of 144 subjects were recruited from the medical (75%) and surgical disciplines (25%). Slightly more than 70% of the patients were above 50 years old, with the majority of subjects being aged between 50-79 years and a mean age of 56 years (SD 18). There were slightly more male than female patients. Chinese patients made up almost two-thirds of the subjects.

The inter-rater reliability for the three tools at various cut-off scores yielded a chance agreement of $k$ ranging from 0.80 to 0.89. Although the kappa coefficient of $>0.80$ is thought to be ideal, 0.81 to 1 is considered an almost perfect agreement between raters.\textsuperscript{52} The disagreement probability was good ranging from 2.8% to 9.7% (95% CI: 1.1%-15.7%).

Validity

A total of 5,489 subjects were screened using the three fall-risk assessment tools during the five-month data collection, to achieve the target of 60 falls. Medical patients made up the highest proportion (59.2%) of subjects recruited. The mean age for the validity study was 55 years (SD 19) and the median 56 years. The proportion of males to females was similar. The highest proportion of subjects by race was Chinese at 68% followed by Malays at 19%. The racial proportion was
similar to the inter-rater reliability study. Patients with medical conditions made up the highest proportion at 64.2%.

Sensitivity and Specificity of Tools
The MFS with a cut-off score of $\geq 25$ had the highest sensitivity (88%, 95% CI: 78 to 94), followed by Hendrich II Fall Risk Model with a cut-off score of $\geq 5$ (70%, 95% CI: 58 to 80). The sensitivity of MFS with a cut-off score of $\geq 51$, and STRATIFY with a cut-off score of $\geq 2$, were 55% (95% CI: 43 to 67) and STRATIFY with a cut-off score of $\geq 3$ had the lowest sensitivity of 25% (95% CI: 16 to 37). The specificity of all tools, except MFS, with a cut-off score of $\geq 25$ was more than 60%. Both MFS with a cut-off score of $\geq 51$ and STRATIFY with a cut-off score of $\geq 3$ had the highest specificity of 91% (95% CI: 90 to 92). The results suggest that lower cut-off scores resulted in high sensitivity and low specificity values. Conversely, higher cut-off scores resulted in low sensitivity and high specificity values.

Positive and Negative Predictive Values
The positive predictive value was below 10% and the negative predictive value was above 99% for all risk-fall assessment tools, suggesting that low cut-off scores result in a higher proportion of subjects classified at high-risk of falls, and lower positive predictive values. Conversely, higher cut-off scores resulted in a lower proportion of subjects classified at high-risk of falls, and higher positive predictive values.
Overall Comparison of Tools

Although, the Morse Fall Scale (with a cut-off score of $\geq 25$) had a higher proportion of subjects at high-risk of falls and sensitivity values, than the Hendrich II Fall Risk Model (with a cut-off score of $\geq 5$), the specificity value of Morse Fall Scale (with a cut-off score of $\geq 25$) was much lower than that of the Hendrich II Fall Risk Model (with a cut-off score of $\geq 5$). Thus, the Hendrich II Fall Risk Model (with a cut-off score of $\geq 5$) provided a better balance than the Morse Fall Scale (with a cut-off score of $\geq 25$), in term of sensitivity and specificity values, and proportion of subjects classified at high-risk of falls.
Discussion

This discussion section restates the research questions, and recapitulates the study design, before discussing the major findings of the study. The findings are related specifically to the research questions in order to provide answers and meet the aims of the study. Finally, the conclusion presents recommendations for further research in this area.

Restatement of the Problem

The purpose of this study was to evaluate the validity of three fall-risk assessment tools to identify patients at high-risk of falls. This study was designed to answer the following research questions:

- What is the inter-rater reliability of the Morse Fall Scale, STRATIFY, and the Hendrich II Fall Risk Model fall-risk assessment tools in an acute care inpatient hospitals?
- What is the sensitivity, specificity, positive predictive value, and negative predictive value of the Morse Fall Scale, STRATIFY, and the Hendrich II Fall Risk Model fall-risk assessment tools in an acute care inpatient hospitals?
- Which of the three fall-risk assessment tools has the best predictive validity?
Summary Description of Procedures

The study was conducted at a large tertiary acute care inpatient hospital in Singapore. It was a suitable setting for the study for three reasons. First, it provided access to a large number of subjects, thus increasing the possibility of obtaining a significant number. Second, all admitted patients to the hospital were assessed for their fall-risk within four hours of their admission. Third, subjects were easily accessible as this was the hospital where the principal investigator was working.

A prospective descriptive design was implemented from July 2005 to December 2005. For this design, a convenience sample was considered appropriate. The subjects were newly admitted patients from medical and surgical wards. The inclusion criteria for inpatients were that they needed to be 21 years of age or older, and agree to participate in the study. The exclusion criteria prevented patients who were already in the study wards before the start of the study, and who fell before the fall-risk assessment was carried out, from participating in the study.

The Morse, STRATIFY, and the Hendrich II fall-risk assessment tools were validated in inter-rater reliability and validity studies. In the inter-rater reliability study, two assessors used the three tools to assess the fall-risk for a total of 144 subjects, and performed 288 independent observations. In the validity study, the two nurses assessed a total of 5,489 patients with the three tools. The probability
of disagreement and kappa values, and sensitivity, specificity, positive predictive value, and negative predictive values of assessment tools with the associated 95% confidence intervals was assessed.

**Major Findings and their Significance to Clinical Practice**

A fall prevention program is provided to all patients admitted to acute care inpatient hospitals. Yet the program could be more efficient if it were able to predict the patients who were likely to fall, enabling appropriate preventive measures to be implemented. In this context, various fall-risk assessment tools have been developed to identify patients who are at high-risk of falls. What is of importance when using these tools to assess patients, is that they need to be capable of accurately identifying those at high-risk of falls. To do this, several authors have advocated for an ‘at risk’ tool that has a good predictive validity and reliability.27, 36, 53

**Inter-rater Reliability**

In this study, the inter-rater reliability for the three tools at various cut-off scores was almost at a perfect agreement between the two assessors. This means that similar evaluations were obtained using the assessment tools, thereby establishing them as reliable appraisal instruments. The study used the same two assessors to analyse the inter-rater reliability. Using the same research nurses to analyse the data could have been the reason behind achieving favourable results, as both assessors carried out the scoring on the same subject concurrently. Assessing the condition, verbalisations and actions of the subject simultaneously by both
assessors resulted in a consistent valuation. In addition, the two assessors received training by the investigator prior to carrying out assessments, ensuring a consistency in approach. Vassallo et al. reported that the STRATIFY assessment tool could be completed in its entirety and in a significantly shorter time than the other three tools being evaluated.\textsuperscript{30} Hendrich et al. on the other hand, focused on devising an assessment tool that was practical, user-friendly, and scientifically accurate.\textsuperscript{20} Within the context of this study, all three tools were relatively easy to use to evaluate the risk of falls in an acute care facility.

Access to a tool with good inter-rater reliability is important in clinical practice, as many nurses will use the tool to perform fall-risk assessments. The tool must be able to give the same results no matter which nurse uses it, to enable consistent fall-risk assessments to be conducted and the subsequent implementation of appropriate fall prevention measures. Hence, the inter-rater reliability should be ‘checked before the tool is adopted for use’\textsuperscript{54} (p.90).

**Validity**

**Sensitivity**

In the present study, the sensitivity of the Hendrich II fall Risk Model with a cut-off score of $\geq 5$ was 70\%. This finding is consistent with the work of Hendrich et al. who found sensitivity to be 74\% within the development setting.\textsuperscript{20} Using the tools as they were originally developed on a similar patient population as the original validation cohort, could account for the consistent results in this study.
In this study, the Morse Fall Scale had a high sensitivity of 88% with a lower cut-off score of ≥ 25. However, the sensitivity of the tool fell to 55% when the cut-off score was raised to ≥ 51. The apparent difference in the sensitivity value may be attributed to the cut-off score. A low cut-off score gives a high sensitivity, resulting in many patients classified as high-risk. In contrast, a high cut-off score gives a low sensitivity, resulting in many patients who would fall being missing.\textsuperscript{17} The clinical implication of low sensitivity is that a substantial number of patients who are at high risk of falling may not be receiving the required fall prevention intervention measures. It is for this reason that one of the most important aspects in the efficacy of the assessment tool is to correctly identify patients who are at a high risk of falling.\textsuperscript{30} Timely interventions can then be implemented to prevent falls. The findings of this study are not consistent with two other validation studies.\textsuperscript{23, 24} This study was conducted in an acute care hospital with a large sample size of 5,489 subjects, and validated with two different cut-off scores; ≥ 25 and ≥ 51. Differences in patient characteristics, cut-off scores, and sample sizes could have caused the inconsistency in results.\textsuperscript{17, 26}

The STRATIFY tool demonstrated low sensitivity in this study of 55% with a cut-off score of ≥ 2 and 25% with a cut-off score of ≥ 3. Previous validation studies demonstrated similar findings in respect to low sensitivity values that ranged from 36% to 68%.\textsuperscript{28-30} These findings are supported by Oliver’s notion that the ability of the tool to correctly classify or discriminate fallers and non-fallers ‘tend to diminish the more dissimilar the population from the one used in the original
validation cohort". The findings of this study appear to contradict an earlier validation study by Papaioannou et al. who reported a high sensitivity value of 94% for a cut-off score of $\geq 2$ and $\geq 3$. A high sensitivity value of 93% was also reported in Oliver’s validation study; however, both Oliver and Papaioannou’s validation studies were conducted with an elderly population over the age of 65 years. Moreover, the STRATIFY tool was also developed for an elderly population over the age of 65 years. In this study, 63% of the population was below the age of 65 years, and could have contributed to the apparent inconsistency of the results.

Specificity

The specificity of the fall-risk assessment tools to correctly classify non-fallers as ‘not at risk’ was high, ranging from 62% to 91% except for the Morse Fall Scale with a cut-off score of $\geq 25$. At this cut-off score, the specificity of the Morse Fall Scale was low at 48%. This is principally because of a high sensitivity value (88%), and a low-cut off score. As Oliver et al. have pointed out, there is a trade off between a score that confers high sensitivity and high specificity. A low cut-off score that yields a high sensitivity value would lose out on its specificity value. In contrast, a high cut-off score that yields a high specificity value would lose out on its sensitivity value. The low specificity value would lead to fewer patients being correctly identified in the ‘not at risk’ group, thereby resulting in a substantial number of potential non-fallers draining and diverting manpower and resources away from the potential fallers in the ‘at risk’ group.
The findings in this study relating to high specificity values of 75% at a cut-off score of 2 and 91% at a cut-off score of 3 for STRATIFY are not consistent with the previous studies. The difference in the findings could be due to the trade-off between the score that confers high sensitivity and high specificity. In this study, high specificity values yielded low sensitivity values, yet, the reverse occurred in previous studies.

**Predictive Values**

Low positive and high negative predictive values were seen across all assessment tools. There are two possible explanations for the low positive and high negative values in this study. The first could be attributed to the small number of fallers within the ‘at risk’ group. Low positive values were expected because only 60 falls were observed from a large population base of \( n=5489 \). In contrast, the high negative predictive values could be attributed to the large proportion of non-fallers in a generally large population base with a small number of fallers. The second could be attributed to the usual fall prevention strategies that have been implemented. Similar findings were seen in prospective studies that had fall prevention strategies carried out from the outset of the study.\(^{24, 30}\) A third explanation is that the positive and negative predictive values are dependent on the prevalence of falls in a population. The base fall rate in the study hospital was low ranging from 1.3 to 1.6 per 1,000 patient days.\(^{55}\) Thus, due to the large population base and miniscule incidence of falls, the positive and negative
predictive values may not be a good predictor for determining predictive validity of the three fall-risk assessment tools in this study.

**Determining Predictive Validity**

Both sensitivity and specificity are the most commonly used and recommended statistics for evaluating the predictive validity of risk assessment tools. A good and useful scale should have both high sensitivity and high specificity but in reality, when sensitivity goes up, specificity goes down.\(^{53}\)

As the primary aim of this study was to validate the three fall-risk assessment tools in an acute care facility, the published cut-off scores recommended by the tool developers were used. The determining factor for identifying patients at high-risk for falls is the sensitivity value. At the published cut-off scores, the Morse Fall Scale (≥ 51, high-risk only) and STRATIFY had very good specificity but poor sensitivity (below 60%). Even though the specificity of these studies was high, the low sensitivity renders it ineffective as a tool to predict patients at high-risk of falling. From this study, it has been established that the Hendrich II Fall Risk Model and Morse Fall Scale (with a cut-off score of ≥ 25) showed high sensitivity. Hence, its use in an acute care clinical setting warrants further consideration. The question is whether the Hendrich II Fall Risk Model or Morse Fall Scale (with a cut-off score of ≥ 25) has the best predictive validity. A comparison of specificity between the two presents the Hendrich II Fall Risk Model to be at 61.5\% compared to Morse Fall Scale (≥ 25) with a value of 48.3\%. 

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In this situation, the Hendrich II Fall Risk Model was the only fall-risk assessment tool with an acceptable specificity value. The Hendrich II Fall Risk Model has a similar cut-off score as that of the development study, that is a cut-off score of $\geq 5$. The positive predictive values and negative predictive values between the two fall-risk assessment tools mentioned above shows very little difference in predicting fallers or non-fallers.

Although the Morse Fall Scale at a cut-off score of $\geq 25$ shows a higher sensitivity of 88% because of the low specificity (48.3%), the Hendrich II Fall Risk Model with sensitivity of 70%, and specificity 61.8% will be a good screening tool because it provided a better balance in term of sensitivity and specificity provided the hospital has enough manpower and budget. When a hospital has less manpower and limited budget, the Morse Fall Scale at a cut-off score of $\geq 51$ is a good assessment tool to be used because the values of PPV (6.4%) and NPV (99.5%) of the tool are higher than the other four and the total number of patients ‘at risk’ is less. So the hospital can conduct interventions on the comparable less numbers of risk patients.

**Study Limitations**

There are five limitations to this study. First, the fall-risk assessment tool was performed only once. Hence, a change in a subject’s condition could explain the low positive predictive value of the tools. Second, the results obtained may not be reproducible in other units because of different patient and staff characteristics.
Third, two experienced nurses performed the ratings in the reliability study, and which may have influenced the results of the inter-rater reliability test. The results could yield different outcomes if the ward nurses who normally be using the tool performed the ratings. Fourth, subjects were not randomly selected which reduced the reliability and generalisability of the results. The results could have been compromised, as the subjects were self-selected; chosen because they were in the study wards and agreed to participate in the study. Finally, subject bias could have occurred among patients, whereby they answered queries differently depending on their medical condition on the day of assessment. Subjects could have had less motivation to respond to questions when in a state of discomfort or pain.

**Recommendations for Further Research**

There are three recommendations for further research. First, as the predictive validity of the fall-risk assessment tools is affected by characteristics of the population, it is necessary to validate the tools to determine the optimal cut-off scores before use, so that results could be generalised by this research. In addition, advanced statistic data should be used to compare the differences among the three tools as percentage data only is not enough to draw any conclusion. Second, preventive measures taken by nurses might have influenced the results by preventing some of the falls, further study is, therefore, required to control these interventions when testing the predictive validity of the fall-risk assessment tool using alternative designs.\(^\text{26}\) Finally, generalisability is hard to achieve in any small-scale single site research. A better way is to conduct an international research using multiple study sites.
Conclusion

Three fall-risk assessment tools were validated in an acute care inpatient hospital. Training on the use of assessment tools appeared to support good reproducibility in the assessment of all three tools. The Hendrich II Fall Risk Model (with a cut-off score of ≥ 5) and the Morse Fall Scale (with a cut-off score of ≥ 25) were the only two tools that had strong sensitivity values to identify patients at high-risk of falls. However, only the Hendrich II Fall Risk Model (with a cut-off score of ≥ 5) had an acceptable specificity value when compared to the Morse Fall Scale (with a cut-off score of ≥ 25).

This study found that the Hendrich II Fall Risk Model provided the best predictive validity and reliability when compared to the Morse Fall Scale and the STRATIFY fall-risk assessment tools. This study has shown that well validated tools with high predictive accuracy in one setting might not be reproducible in another, due to operational differences between environments, as well as, differences in patient and nurse characteristics. The results highlight the importance in validating the predictive accuracy of any tool before use in clinical practice. In addition, this study has provided evidence to support the use of the Hendrich II Fall Risk Model for the second research study investigating the effectiveness of targeted risk factor reduction to reduce the number of falls in acute care hospitals.
References


31. Altman D. Study to predict which elderly will fall will show difficulty in deriving and validating a model. British Medical Journal 1997;315(7118):1309.


Appendix 1

Validity and reliability of fall-risk assessment tools in acute care setting: Morse, STRATIFY, and Hendrich II tools

This is to inform you that the NHG Domain Specific Review Board has approved the above research project to be conducted in National University Hospital.

Documents reviewed are:

a) IRB/DSRB Application Form: Validity and reliability of fall-risk assessment tools in acute care setting: Morse, STRATIFY, and Hendrich II tools, Version dated 31 May 2005
b) Patient Information Sheet, Version 1 dated 17 June 2005
c) Data Collection Tool: Hendrich II Fall Risk Model 2004, Version 1 dated 17 June 2005

The approval period is from 17 June 2005 to 16 June 2006. Your study number is DSRB-A/05/195. Please use this code for all future correspondence.

Continued approval is conditional upon your compliance with the following requirements:

1. Only the approved Patient Information Sheet should be used.

2. No deviation from, or changes of the protocol should be implemented without documented approval from the NHG DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change of monitor or telephone number).
3. Any deviation from, or a change of, the protocol to eliminate an immediate hazard should be promptly reported to the NHS DSRB within 7 calendar days.

4. Please submit the following to the NHS DSRB:
   a. NHS DSRB Project Status Report Form — this is to be submitted 4 to 6 weeks prior to expiry of the stipulated period. The study cannot continue beyond the expiry date until re-approved by the NHS DSRB.
   b. Study completion or termination report

Yours best regards,

A Prof Gan Yoke Chin
Deputy Chairman
NHS Domain Specific Review Board A

Cc: Director of Research, NHG (as the only)
    Office of Biomedical Research, NHG
    Director of Nursing, NHG
Appendix 2

Code No: W______

Section A: Demographic

Instruction: Please indicate the correct number in the box provided

1. Discipline □ 1 = medical   2 = surgical

2. Age □ years old

3. Sex □ 1 = male 2 = female

4. Race □ 1 = Chinese 2 = Malay 3 = Indian 4 = Eurasian
   5 = Others _______(please specify)

5. Current Condition: □
   1 = medicine 5 = oncology
   2 = cardiology 6 = geriatric medicine
   3 = respiratory 7 = surgery
   4 = renal 8 = others (please specify) _________

Paste patient’s sticky label here

Date of Assessment __________________________ Name of Assessor __________________________
Section B: (to be completed only when patient fall)

1. When did the patient fall? Date: __________ Time: __________

2. Where did the fall occur? __________

3. What was the patient doing just prior to the fall? __________

4. What was the outcome of the fall?
   
   1. No injury
   2. Bruising
   3. Bleeding
   4. Soft tissue injury
   5. Fracture
   6. Subdural haematoma
   7. Others (please specify) __________
Appendix 3

MORSE FALL SCALE

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>CIRCLE NO/YES</th>
<th>SCORE</th>
<th>PATIENT SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient has a history of falling</td>
<td>No</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>2. Patient has secondary diagnosis</td>
<td>No</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>3. Patient uses ambulatory aids:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/bedrest/nurse assistant</td>
<td>Yes</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Crutch/cane/walker</td>
<td>Yes</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Holds on to furniture</td>
<td>Yes</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>4. Patient is receiving:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous therapy/heparin lock</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Patient gait is:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal/bedrest/wheelchair</td>
<td>Yes</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Weak</td>
<td>Yes</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Impaired</td>
<td>Yes</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>6. Patient’s mental status is:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oriented toward own ability</td>
<td>Yes</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Overestimates/forgets limitation</td>
<td>Yes</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL PATIENT SCORE:</strong></td>
<td></td>
<td></td>
<td>144</td>
</tr>
</tbody>
</table>
# Appendix 4

## STRATIFY Tool

<table>
<thead>
<tr>
<th>ITEM</th>
<th>VALUE</th>
<th>SUB_SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> History of Falls (HIST)</td>
<td>Did the patient present to hospital with a fall or has she fallen on ward since admission</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>If not, has the patient fallen within the last 2 months?</td>
<td>No</td>
</tr>
<tr>
<td><strong>2.</strong> Mental Status (MNTL)</td>
<td>Is the patient confused? <em>(i.e. unable to make purposeful decisions, disorganized thinking, and memory impairment)</em></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Is the patient disoriented? <em>(i.e. lacking awareness, being mistaken about time, place or person)</em></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Is the patient agitated? <em>(i.e. fearful affect, frequent movements, and anxious)</em></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>3.</strong> Vision (VISN)</td>
<td>Does the patient require eyeglasses continuously?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Does the patient report blurred vision?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Does the patient have glaucoma, cataracts or macular degeneration?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>4.</strong> Toileting (TOIL)</td>
<td>Are there any alterations in urination? <em>(i.e. frequency, urgency, incontinence, nocturia)</em></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td><strong>5.</strong> Transfer Score (TS)</td>
<td>Transfer means from bed to chair and back</td>
<td>0 = unable – no sitting balance; mechanical lift</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = major help (one strong skilled helper or two normal people; physical), can sit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = minor help (one person easily or needs supervision for safety)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = independent (use of aids to be independent is allowed)</td>
</tr>
<tr>
<td><strong>Mobility Score (MS)</strong></td>
<td>0 = immobile</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>1 = wheelchair independent including corners, etc</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2 = walks with help of one person (verbal or physical)</td>
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</tr>
<tr>
<td></td>
<td>3 = independent but may use aid, e.g. cane</td>
<td>3</td>
</tr>
</tbody>
</table>

**TOTAL SCORE** / 5

145
Appendix 5

Hendrich II Fall Risk Model © 2004

NOTE: This appendix is included on page 146 of the print copy of the thesis held in the University of Adelaide Library.
Appendix 6

Sequence of Stapling the Fall –risk Assessment Tool

<table>
<thead>
<tr>
<th>Appendix</th>
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<tbody>
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<td>A</td>
<td>1</td>
<td>Hendrich</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Morse Fall Scale</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>STRATIFY</td>
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<td>B</td>
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<td>STRATIFY</td>
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<td>Morse Fall Scale</td>
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<td>C</td>
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Appendix 7

Allocation of Subject Code to Fall-risk Assessment Tools

Patient Allocation
Ward 44

<table>
<thead>
<tr>
<th>Patient ID</th>
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<th>Taken</th>
<th>Returned</th>
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PATIENT INFORMATION SHEET

Validity and reliability of fall-risk assessment tools in acute care setting; Morse, STRATIFY, and Hendrich II tools

Fall is a common problem in the hospital, and patient may suffer from broken bone, head injury, bleeding, or loss of life as a result of fall. This is of concern to us as nurses, and measures must be carried out to reduce the number of fall. Assessment will help us to determine when and what measures must be implemented for our patients.

A number of studies in the West showed that risk factors changes with the unit or ward or different groups of patients, and it is recommended that the tools nurses use to identify patients who have a higher chance of falling must be evaluated within our context before using it to assess our patients.

We would like to invite you to participate in this research study to evaluate the usefulness of three fall risk assessment tools in predicting falls for patients admitted to the medical, surgical, and oncology ward during the period between July 2005 and January 2006.

You will be asked to answer several simple questions verbally regarding fall risk, and at the same time being observed by the interviewer. Please take your time to answer all the questions. The interview will take place at your bedside, and last no more than 5-8 minutes.

All data obtained during this study concerning you will be treated as confidential. All data will be coded and you will not be individually identified in any report based on this study.

Your participation in this study is entirely voluntary. You may refuse and even if you accept, you may withdraw from the study at any time during the interview. Your decision not to take part in this study or to stop your participation will not affect your medical/nursing care or any benefits to which you are entitled. If you decide to stop taking part in this study, please inform the interviewer immediately.

If you have any queries regarding this study, please direct them to Ms Emily Ang at telephone number 67724819.

Thank You

Emily Ang
Section 3: Study 2

Randomised Controlled Trial Evaluating the Use of a Targeted Multiple Intervention Strategy in Reducing the Number of Falls in an Acute Care Inpatient Hospital
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Abstract

Background: The literature indicates that nurses should assess for the risk of falls, communicate the risk, educate patients, their families and staff, and implement environmental safety interventions. The effectiveness of this approach is yet to be supported with scientific documentation. A targeted multiple intervention strategy seems to be effective in reducing patient falls for the elderly living in the community and residential facilities, or admitted to sub-acute hospitals. This strategy cannot be generalised for acute care inpatient hospitals because of variations in clinical practice, staffing, patient population, and environmental risks. Furthermore, this strategy has not been thoroughly evaluated in acute care inpatient hospitals using rigorous research design.

Objective: The objective of this study was to evaluate the effectiveness of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital.

Method: Of the 6,498 patients admitted to the eight medical wards during the data collection period, 1,822 subjects met the inclusion and exclusion criteria and were randomised into the ‘intervention’ (49.9%, n=910) or ‘control’ group (50.1%, n=912). The subjects in the control group received the usual universal multiple interventions, while subjects in the intervention group received a targeted multiple intervention strategy as well as the usual universal multiple
interventions. The subjects in the intervention and control groups were followed-up during their stay in hospital until the time of their first fall, they were discharged or death, whichever occurred first. The outcome measures included: the mean risk of falling, number of falls and fall injuries, and the severity of fall injury in each group.

**Results:** The incidence of falls in the intervention and control groups during hospitalisation were 0.4% (CI: 0.2 to 1.1) and 1.5% (CI: 0.9 to 2.6) respectively. The incidence of falls in the intervention group was significantly lower in comparison to the control group ($p=0.018$). The estimated relative risk of subjects falling in the intervention group was 71% lower than compared to the control group. Furthermore, subjects in the intervention group experienced a significantly longer mean time until their first fall, compared with subjects in the control group (14 days, CI: 1.2 to 16.8 compared to 6 days, CI: 2.8 to 5.2).

**Conclusion:** The use of a targeted multiple intervention strategy in an acute care inpatient hospital was linked to a reduction in the mean number of falls, a reduction in the estimated relative risk of falls, and a longer mean time until first fall in the intervention group.
SECTION 3

Section 3 provides the report of the second study entitled ‘Randomised controlled trial evaluating the use of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital’. This section is comprised of five sub-sections, which encompass: the introduction to the study, a literature review on fall prevention interventions, a description of the methodology used, an explanation of the results, and a discussion of the major findings and their implications.

Introduction

In Section 1, a review of the background literature on patient falls in acute care inpatient hospitals is presented, which revealed that the common approach to fall prevention in acute care inpatient hospitals is a program of multiple interventions. The effectiveness of this approach is yet to be supported with scientific documentation for verification.\textsuperscript{1, 2} The complexity of today’s health care environment requires nurses to select appropriate interventions for specific risk factors. This is important not only for patient safety, but also to optimise the use of time and scarce available resources. Currently, there is limited evidence available to assist nurses with making such decisions, as the research in literature on inpatient falls focuses on the evaluation of overall fall prevention programs.\textsuperscript{8}
In Singapore, a universal multiple interventions approach has been adopted in all hospitals. Although this approach offers a framework for nurses working in hospitals, and has been widely implemented for many years, nurses continue to discover patients who have fallen to the floor, and thus fall prevention in Singapore hospitals remains a challenge. While a ‘one size fits all’ solution to problems is rarely effective, there has been no rigorous research done in Singapore on fall prevention interventions.\textsuperscript{9} It has been suggested by Close that investment in non-evidence-based programs often results in a wasting of resources, and of the taxpayer’s money.\textsuperscript{10}

The targeted multiple intervention strategy seems to be effective in reducing patient falls.\textsuperscript{1, 3, 4} Most successful targeted multiple interventions strategy studies have been conducted on elderly people living in the community and residential facilities or admitted to sub-acute hospitals.\textsuperscript{5, 6} However, these interventions cannot be generalised to acute care inpatient hospitals because of variations in clinical practice, staffing, patient population, and environmental risks. Moreover, these interventions have not yet been subjected to thorough evaluation in acute care inpatient hospitals using rigorous research design. The purpose of this study was to determine the effectiveness of a targeted multiple intervention strategy used in an acute care inpatient hospital.
Literature Review

Performing fall-risk assessments is only useful if there are effective interventions available for patients identified as being ‘at risk’. Without these interventions, fall-risk assessment tools are of little benefit. Hence, it is imperative to implement fall preventive interventions once a fall-risk assessment is completed, and the patient has been identified as being high risk for falling. The current approach to fall prevention in acute care inpatient hospitals is to implement a program of generic or individually tailored multiple interventions.\textsuperscript{11}

Multiple Interventions

While the volume of literature covering the use of multiple interventions in acute care inpatient hospitals is extensive, most of this evidence is based on studies conducted as part of quality improvement projects and descriptive research reports, and outlines summaries of quality improvement projects.\textsuperscript{12-23} Throughout this literature, multiple fall prevention interventions are based on the notion that all patients are potentially at some risk of falling. Thus, generic interventions were implemented for all patients at risk of falls, and/or predetermined interventions for each level of risk were implemented for those patients identified at high risk of falling.

Generic Multiple Interventions

There are 12 studies\textsuperscript{12-23} that have evaluated generic multiple fall prevention interventions that were implemented for all patients. The common characteristics
of these studies are summarised under the following headings: assessment of fall-risk, communication of fall-risk, close monitoring of patients, interventions to reduce night falls, interventions to reduce bedside falls, environmental safety interventions, interventions to reduce fall injury, education on fall prevention, and evaluation of fall prevention programs.

Assessment of Fall Risk: Most of the studies established the risk factors for falls using a self-developed fall-risk assessment tool, except for eight studies that utilised a tool developed by others. For example, Barnett, McCarter et al., and O’Connell et al. used the Morse Fall Scale (MFS), Fonda et al. used Fall Risk Scoring System (FRASS), Sulla and McMyler, used the Hendrich II Fall Risk tool, while Sullivan et al. and Mosley et al. used tools that were developed by Spellbring and Berryman et al. respectively. Most studies assessed fall-risk upon admission, but reassessment of fall-risk varied across the studies, ranging from 12 hourly to daily assessments or when there was a change in the patient’s condition. There were studies that did not include the time of assessment and reassessment, with several studies not mentioning fall-risk assessments.

Communication of Fall Risk: The use of environmental cues varied both in kind and colour, and was used to increase patients, family members, and health care professionals awareness of fall-risk, to allow for easy identification of high-risk patients by health care professionals. Many studies used coloured armbands
and coding on the bedboard, nursing care plans, patient care records, patient allocation boards at the nurses’ station, and the traffic-light system. Posters were displayed in wards that incorporated a decision tree for the management of inpatient falls, with photographs of armbands, bed signs, and hip protector pads, to display correct application. A memory trigger sign was implemented to urge patients to use the ‘call-bell’ when needing assistance. A poster was placed on the door of a patient’s room if the patient had fallen while in hospital. This served as a reminder to the patient’s family and health care professionals of fall-risk. Patients who were potential fallers were identified to all the nurses during the handover of a shift.

**Close Monitoring of Patients:** Interventions that addressed close monitoring of patients included: regular checks of patients to see if assistance was required, providing assistance in toileting at regular intervals, use of ‘sitters’ to supervise patients, use of sensor alarm, and placing confused patients near the nurses’ station, and one-to-one nursing.

**Interventions to Reduce Night Falls:** Interventions that aimed at reducing night falls included: ‘glow in the dark’ commode seats and toilet signs, and night sensor light.

**Interventions to Reduce Bedside Falls:** One study included interventions that aimed at reducing falls at the bedside by reviewing toileting protocols and
practices for patients at risk of falling, using fitted bed sheets, reviewing the use of non-slip beside mats, using non-slip chair mats, using electric low beds that go within 12 cm of the floor, using bed alarms that sound when patients have moved out of their bed, and using bed poles to assist patients in transferring more independently.\textsuperscript{19}

\textit{Environmental Safety Interventions:} Most studies\textsuperscript{12, 15, 20} included interventions that addressed environmental safety, such as placing bedside accessories within easy reach, placing the bed in the lowest position, reducing clutter around the bed and in the ward or room,\textsuperscript{17, 19} using non-slip bathroom flooring,\textsuperscript{19} changing the floor cleaning process to reduce ‘high-shine, high wax’ finish,\textsuperscript{19} using non-slip socks and non-skid footwear,\textsuperscript{13} and ensuring adequate lighting at night.\textsuperscript{18} One study included an occupational therapist, who conducted a detailed environmental audit, and an equipment review panel to review the standard of equipment.\textsuperscript{16}

\textit{Intervention to Reduce Fall Injury:} Brandis et al.\textsuperscript{16} implemented the use of hip protector pads for those patients who had previously suffered a fall in order to minimise the risk of a bone fracture in subsequent falls.

\textit{Education on Fall Prevention:} Staff education programs varied across the studies. There was a study that included a written memorandum, publication of an article in the hospital newsletter, and presented information at unit meetings.\textsuperscript{16} Another study produced a resource pack for all wards, containing relevant information, an
up-to-date assessment form, care planning documentation, background evidence, and references. McCarter et al.\textsuperscript{13} incorporated fall prevention procedures into the hospital’s new employee orientation program to maintain the staff’s knowledge of fall prevention in the process of large employee turnover. In addition, a mandatory education was used on an annual basis to educate staff on fall prevention.\textsuperscript{13} Fonda et al.\textsuperscript{19} introduced a ‘fall prevention’ portfolio for every ward, which contained staff orientation brochures/folders, medical record alert sticker, protocols for after-fall reviews, and brochures for the patients’ families informing them about falls, and encouraging their involvement. Brandis et al.\textsuperscript{16} added documentation for a falls management plan decision tree into the ward manual, while Sullivan et al.\textsuperscript{14} developed a learning module for nurses that included a fall precaution practice guideline, and assessment tools for patients at risk of falls. Patient education also included measures for patients identified as having orthostatic hypotension, on how to minimise dizziness.\textsuperscript{15} Sulla and colleagues recruited unit nursing safety coaches to provide education to patient care assistant groups on specific interventions and their responsibilities for fall-risk patient groups.\textsuperscript{23}

\textit{Evaluation of the Fall Prevention Program:} Most of the studies reviewed presented implementation data that evaluated the outcomes of ongoing fall prevention programs through a comparison of results of before and after the implementation of the program. These studies yielded conflicting results. One study reported no change in fall rate,\textsuperscript{17} while another study reported an increase in
fall rates.\textsuperscript{20} Four studies reported a slight reduction in fall rates that ranged from 0.7\% to 3.4\%.\textsuperscript{13-15, 21} Five studies reported promising results having as much as a 17.3\% to 44\% decrease in fall rates,\textsuperscript{12, 16, 19, 25, 26} and one study reported a 77\% reduction in fall-related injuries.\textsuperscript{19} One study evaluated staff compliance with fall prevention measures rather than patient fall rate,\textsuperscript{18} while two studies did not report on the evaluation of the program.\textsuperscript{23, 27}

**Levels of Multiple Interventions**

There are four studies\textsuperscript{24-27} that implemented different levels of multiple interventions based on their assessed risk of falling. First, Poe and colleagues\textsuperscript{27} categorised the patients into three levels of fall-risk: low, moderate, and high risk, based on a fall-risk assessment tool created by the researchers. The patients received predetermined fall prevention interventions based on their level of risk, which included interventions to maintain a safe unit environment, assist in transfer, mobility and toileting, communicate fall-risk using flagging system, and close supervision. The number of interventions increased as the patient’s level of risk increased. The study also placed a great emphasis on staff education. However, the study did not include an evaluation of the effectiveness of multi-strategy interventions.

Second, Gowdy and Godfrey\textsuperscript{26} categorised patents into groups as either at ‘low’ or ‘high’ risk of falling. Patients identified as having a low-risk of falling (score of 1-3 points) were reassessed 12 hours later for their fall-risk, and given a
patient/family education brochure. Patients identified as having a high-risk of falling (score of ≥4 points) received additional fall interventions according to their assessed risk. The interventions included measures such as fall-risk alert bracelet/card, communication of fall-risk to patients, family members, and interdisciplinary members, environmental safety measures, offer of assistance for frequent toileting, use of assistive devices, use of diversional therapy to prevent wandering, a request for sitters as ordered by the doctor, consultation with a pharmacist for possible medication interactions, and referral to a physiotherapist for mobility problems related to daily living activities.

Third, Szumlas et al.\textsuperscript{25} initiated a fall prevention program that screened all patients for fall-risk on admission and thereafter every 24 hours, using a computerised fall-risk assessment tool. Patients were grouped into two categories according to fall-risk; the first category of fall-risk included a history of falls, impaired mental status and impaired mobility, while the second category included symptoms and/or diagnosis, eliminations, medications, and the environment. The fall prevention interventions were divided into a universal fall prevention interventions and strict precautions. The universal fall prevention interventions were implemented for all patients and included an orientation to the room, use of call light, placing bed in the low position with wheels locked; ensuring room was free of clutter and spills, placing items such as a call light, telephone, and personal items within easy reach, and providing adequate lighting. The strict fall precautions were additional precautions implemented for patients who met any of
the four indicators from the second category of fall-risk. The strict fall precautions involved placing a sign on the patient’s door reading ‘please help to prevent falls’, offering assistance hourly to the patient, while awake, to use the bathroom/commode, assessing the need for physical and occupational therapy, assessing consultation and discharge planning needs, performing hourly checks on patient’s condition, and assessing the need for one to one monitoring. In addition, all inpatient care and professional service managers were required to attend a one-hour training session to gain knowledge of the fall prevention program, and to understand their responsibility for fall prevention in the hospital. The results demonstrated a 20% reduction in total falls and a 15% reduction in the average hospital fall rate.

Fourth, Williams et al.\textsuperscript{24} developed a systematic, coordinated multiple strategy falls prevention program, and evaluated this in a before and after design study among 283 patients of three medical wards within a metropolitan tertiary hospital in Perth, Australia. The fall-risk prevention program included a fall-risk assessment that classified participants according to three levels of risk: low, medium and high. Appropriate interventions for the environment, mobility, communication and elimination were developed for each level of risk. The median age of participants was 79 years with 53% of the participants as female. The study for the intervention group lasted for 6 months, with a similar period for retrospective data analysis used to compare the incidence of falls prior to
implementation of the intervention. There was a significant reduction in falls from 0.95 to 0.80 (95% CI for the difference –0.14 to –0.16, \( p < 0.001 \)).

**Strengths and Limitations**

The pivotal strength in all the studies was the pragmatic aspect, in that the studies were conducted within a hospital utilising few resources. While several of the results were impressive and encouraging, these results need to be interpreted with caution for seven reasons. First, these studies utilised either a quality improvement methodology or descriptive research using a pre-test and post-test design, and consequently the direct cause and effect relationship could not be established. In addition, pre and post-test design study is relatively weak because it has no comparison group, making it especially vulnerable to threats of internal validity.\(^{28}\) Moreover, pre-test and post-test design are unable to control confounders such as change in staffing, case-mix, trends in fall-rate and so on, and thus the findings are of limited significance.\(^{29}\)

Second, an analysis of the participants’ compliance with each recommendation was not reported in the Fonda et al. study.\(^{19}\) This information is necessary in helping the reader to interpret the data to determine the success of the multiple falls prevention program. In addition, information about the falls and fallers, and the injury data collection system was not reported in the study, which prevents the reader from drawing firm conclusions from the study.\(^{30}\)
Third, most studies used self-developed fall-risk assessment tools that were not developed using rigorous research design, and had not been tested for validity and reliability.\textsuperscript{12-23} Thus, these tools could have poor sensitivity and reliability. Several studies used fall-risk assessment tools that were developed using rigorous research methodology. However, the researchers did not validate these tools to determine the validity and reliability in the setting in which the tool was used. A well-validated tool with high predictive accuracy in one setting may not be reproducible in another because of operational differences between environments, as well as, differences in patient and nurses’ characteristics.\textsuperscript{1}

Fourth, most of the research advised nurses to assess and communicate fall-risk, inform patients, family members and health care professionals of fall-risk, and implement environmental safety interventions. Yet, reviewers have concluded that evidence does not exist to guide health care professionals in implementing specific interventions that consistently reduce falls in acute care inpatient settings.\textsuperscript{1, 2, 11} In addition, several studies did not, or did not properly, define the specific multiple fall interventions used, while many researchers did not provide information on how specific multiple fall interventions were selected.

Fifth, the studies yielded conflicting results, with some studies reporting a reduction in the number of falls while others reported no change in fall rates. In those studies that reported a reduction in fall rates, the extent of the reduction was highly variable, ranging from 0.7% to 40% making a comparison of the fall rate
extremely difficult. Oliver observed that simply reporting fall rates before and after the intervention can render the significance or generalisability of the results as unreliable.\textsuperscript{29} Moreover, the results of these studies are specific to their setting, and cannot be applied to other settings.\textsuperscript{7}

Sixth, the O’Connell and Myers study was confounded by a second fall intervention study conducted simultaneously, and employing non-regular ward staff such as agency staff, casual pool staff, and staff from other wards. These confounders could have affected the results.\textsuperscript{20}

Finally, Morse\textsuperscript{31} pointed out that implementing a fall intervention program might have caused a Hawthorne effect, and altered the fall rate. As nurses become more aware of the fall-risk, they might conscientiously implement fall prevention interventions, causing the falls to decrease. Moreover, nurses who were previously cautious about reporting falls, might now methodically report every fall, causing the fall rate to increase as evidenced in the O’Connell and Myers study.\textsuperscript{20}

A review of the 16 studies illustrated that evidence on the effectiveness of fall prevention interventions in acute care inpatient hospitals is lacking in literature. In support of this review, systematic reviews of patient falls in hospital have also found no consistent evidence for prevention in falls.\textsuperscript{1, 2, 4}
Targeted Multiple Intervention Strategy

Targeted multiple intervention strategy refers to individualised interventions targeted at the risk factors of high-risk patients. Systematic reviews have shown that a targeted multiple intervention strategy can reduce the incidence of falls amongst elderly in the community.\textsuperscript{4, 32} This strategy has been demonstrated to reduce falls in both community and residential settings,\textsuperscript{4} and among patients in the Accident and Emergency department.\textsuperscript{10} However, this evidence on targeted multiple interventions was based on less frail, and clinically stable people living in residential facilities and the community. Oliver and colleagues\textsuperscript{33} noted that such evidence might not be able to translate to acute care populations who are medically unstable with a high incidence of cognitive impairment. Stronger evidence on targeted multiple interventions in acute care inpatient hospitals has been reported recently in three studies; one quasi-experimental\textsuperscript{34} and two large randomised controlled trials\textsuperscript{5, 6}.

The first study was a quasi-experimental study conducted by Schwendimann et al.,\textsuperscript{34} which compared the effect of 15 selected multiple interventions targeted at reducing falls in high-risk patients. The study was conducted over a four-month period in two wards of a 300-bed acute care hospital in Switzerland. It used a quasi-experimental design, involving 211 patients in an intervention group, and 198 patients in a control group. The mean age of patients in the intervention and control groups was 73 years and 69 years respectively. Patients in the intervention group who were identified as high-risk for falls with the Morse Fall Scale (score
of ≥ 55) received the appropriate interventions, which were orientated towards modifying the hospital environment and supporting the patients’ activities. Patients in the control group received the usual care. The results revealed a 38% reduction in falls in the intervention group, compared to 62% in the control group. The preventive interventions showed a statistical difference ($p=0.009$) in preventing multiple falls, but no statistical difference ($p=0.34$) in preventing the first fall.

The second study was a randomised controlled trial study conducted by Haines and colleagues$^5$ that evaluated a multi-targeted intervention program of 626 patients in three sub-acute wards in Melbourne, Australia. The 626 patients were randomised using a random table in the intervention (N=310), or control group (N=316). The intervention group received multi-targeted interventions: a fall-risk card with an information leaflet, exercise, an education program, and hip protectors, in addition to the usual care. Each intervention intentionally addressed one or more risk factors for falls. The control group received the usual care, comprising of weekly medical assessments, one-hour sessions of physiotherapy and occupational therapy each weekday, and 24-hour nursing assistance, and other allied health services when required. The results showed that participants in the intervention group had a 28% reduction in the number of fall-related injuries, and a 22% reduction in fall rates over a nine-month period. The difference in the fall rates was significant (Peto log rank test $p=0.05$), and was most obvious after 45 days of observation.
The third study was a large randomised controlled trial reported by Healey and colleagues,\(^6\) which evaluated the effect of targeted risk factor reduction to prevent falls in older inpatients using a large (N=3,386) controlled trial (clustered randomised by ward). The study took place in eight aged wards and associated community units of a district general hospital in Northern England. In the intervention wards, staff used pre-printed care plans for patients identified at risk of falling, with targeted interventions addressing medication, vision, blood pressure, mobility, urine test results, footwear, bedrail risk/benefit assessments, bed height, simple environmental factors, patient’s position in the ward, and the accessibility of the nurse call-bell. The study lasted 12 months, with the intervention applied to four wards for the latter 6 months of the study. There was a reduction of falls on the intervention wards but not in the control wards, with a significant difference between groups (relative risk = 0.71, 95% CI = 0.55 –0.90).

Strength and Limitations

There are five strengths to these three studies. First, the two large randomised controlled trials conducted by Haines et al.\(^5\) and Healey et al.\(^6\) demonstrated a significant reduction in the incidence of hospital falls. Second, the Schwendimann et al.\(^34\) and Healey et al.\(^6\) studies were nurse-led interventions that took place within a normal ward environment, delivered within existing practices, and resources incurred no additional cost. Third, the validity and reliability of the Morse Fall Scale was established prior to the study.\(^34\) Evaluating the tool in one’s own setting is essential as the ‘ability of the tool tends to diminish the more
dissimilar the population from the one used in the original validation cohort, especially in hospital patient where risk changes as quickly as clinical status, mobility, or cognition. Fourth, targeting interventions means that fall prevention strategies are tailored to individual patients, and the patient is only required to remember information that is relevant to them, enabling them to remember the information better. Finally, the three studies provided valuable information for nurses to reduce falls in the hospitals. Moreover, it reassures nurses that falls can be reduced.

There are five limitations to the three studies. First, the Haines and colleagues study was carried out in a sub-acute rehabilitation environment. In addition, the Healey and colleagues study took place in the rehabilitation, respite, and terminal care, stroke, and joint psycho geriatric assessment wards with stable staff and no rotational schemes, and low use of temporary staff. Thus, it is difficult to generalise the results of these studies to wards in acute care hospitals when patients admitted are of varying age with different levels of acuity and activity, with nurses who are of different skills-mix, coupled with high employment rate due to high turnover, and the potential for nurses being deployed daily across wards.

Second, the results of the Healey et al. and Schwendimann et al. studies could have been contaminated by an exchange of information related to the intervention
protocol between the nurses of the different wards. Moreover, enhancing the knowledge and skills of nurses on fall prevention, coupled with nurses implementing the protocol might cause the Hawthorne effect, and produce a positive or negative recording bias that could influence the outcome data outcome.\textsuperscript{31}

Third, Healey et al.\textsuperscript{6} adopted a cluster randomisation of wards within one hospital. This method of sampling could contaminate the results of the study through communication between nurses, and the practice of interventions being implemented in the intervention group spreading and contaminating the results of the control group.\textsuperscript{35}

Fourth, the reduction in fall rates in the Haines et al. study\textsuperscript{5} occurred only after 45 days, a period when only a few patients would still be in acute care hospitals. Hence, caution is required before drawing conclusions for other settings.\textsuperscript{36} However, Oliver noted that this study forms a useful generalisable and operational framework that could be subjected to replication in other settings.\textsuperscript{35}

Finally, Haines et al.\textsuperscript{5} reported that the ward nurses used clinical judgment to determine the need and appropriateness of each of the interventions, and recommended the interventions to the research nurses. This approach could have introduced a bias and influenced the results. In addition, placing the fall-risk alert card above the participant’s bed made the participants visible to other hospital
staff although the authors reported that they did a staff survey and confirmed that the hospital staff were not aware of which group the participants had been allocated.\textsuperscript{37}

**Conclusion**

A review of the literature on fall prevention in acute care inpatient hospitals revealed that there is an extensive volume of literature available, however, most of it consists of expert opinion, consensus practice guidelines, quality improvement summaries or studies that were conducted as part of quality improvement projects, implementation of clinical practice guidelines, and small to large scale descriptive research. Some researchers implemented universal fall prevention interventions to all patients based on the notion that all patients are at some risk of falling, while others implemented predetermined interventions for each level of risk. The multiple interventions utilised revealed four features important to fall prevention, which included: assessment of fall-risks, communication of risks within and across departments, education of patients, their families and health care professionals, and implementation of environmental safety interventions. Although, there were studies on multiple interventions that had demonstrated fairly impressive and encouraging results, the evidence base supporting these interventions is weak.

The use of a targeted multiple intervention strategy has been shown to reduce falls in both the community and residential settings. However, this evidence was
derived from studies on less frail, and clinically stable people living in the community and residential facilities. Such evidence might not translate to acute care populations who are medically unstable with a high incidence of cognitive impairment.33

From the evaluation of two large randomised controlled trials, it would appear that the use of a targeted multiple intervention strategy can reduce fall rates in sub-acute hospitals. There is no information in the literature relating to their evaluation in acute care inpatient hospitals, and in different international communities, although many studies have supported the need to prioritise interventions based on individualised assessments of risk factors. Given the evidence that the use of a targeted multiple intervention strategy could reduce fall rates significantly, it forms a useful generalisable and operational model that could be replicated in other hospitals.35 It has also been suggested that, although much effort has been invested in implementing complex interventions in hospitals, it may be just one or two components that could be equally effective or more cost efficient.35 Moreover, two researchers have supported the need to prioritise interventions based on individualised assessments of risk factors.38 39 Thus, the purpose of this study was to address the gap in evidence.
Method

Aim of the Study

The aim of the study was to determine the effectiveness of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital, and to contribute to the international body of evidence on fall prevention in acute care inpatient hospitals. As this study is one of the few large randomised controlled trials in an acute care inpatient hospital, the results of this study provide a benchmark, against which subsequent results can be compared and further studies can be based.

Research Question

The research question was:

- What is the effectiveness of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital?

Description of Research Design

Randomised Controlled Trial

This study utilised a double blind randomised controlled trial design whereby 1,822 subjects who met the inclusion and exclusion criteria were randomly assigned to either the control (n=912, n=50.1% or intervention group (n=910, 49.9%). The intervention group received the hospital’s usual universal multiple interventions as well as targeted multiple interventions, while the control group
only received the hospital’s usual universal multiple interventions (refer Appendix 1).

This study aimed to test the cause-and-effect relationship between a new intervention (targeted multiple intervention strategy) and an outcome (fall), thus a randomised controlled trial is the ‘gold standard’ for an interventional clinical study. 40

Double Blind Study

Double Blind is a process whereby neither the subjects nor investigators are aware of the identity of the groups until all the data has been collected.28 In this study, the subjects had no knowledge that they were research subjects, and the ward nurses were not aware that a targeted multiple intervention strategy study is taking place. The ward nurses were only aware of their involvement in the fall risk assessment, and that the research nurses will be collecting the fall-risk assessment forms daily. Moreover, the two research nurses who conducted the targeted multiple intervention strategy study were not involved in the care of patients. A double blind design was chosen because there is a potential risk of bias through observations in experimental study. The subjects’ and nurses’ knowledge of the intervention can consciously or unconsciously influence the performance or the recording and reporting of the outcome. 28
Assessment of Fall Risk

All new admissions into the study wards during the recruitment period had a routine fall-risk assessment performed by the ward’s registered nurses. The fall-risk assessment was performed within 4 hours of admission using the Hendrich II Fall Risk Model 2004 tool. The registered nurses placed the completed forms into a designated box placed within the wards. Patients who had a score of $\geq 5$ on the Hendrich II Fall Risk Model, and met the other inclusion and exclusion criteria became the subjects.

All registered nurses working in the study wards had a two-hour training session on the use of the Hendrich II fall-risk assessment tool, wherein they learnt to process fall-risk assessments and documentation. The registered nurses performed the fall-risk assessments on a sample of the population. Further training and evaluation on processing fall-risk assessments and documentation was provided when necessary before the commencement of the study.

Interventions

This study utilised a randomised controlled trial design whereby subjects who met the inclusion and exclusion criteria were randomly assigned to either the control or intervention group.

Control Group: Subjects in the control group received the usual universal multiple interventions comprising of: fall-risk assessments, placing the call-bell within
reach, providing instructions on the use of the call-bell and pressing of call-bell for assistance, raising of bed rails, keeping bed at the lowest position at all times, and applying body vest on confused patients if family members are unable to take care of the patient at the bed side. The ward nurses carried out these interventions as part of their usual nursing care to the patients on fall prevention.

**Intervention Group:** Subjects in the intervention group received the usual universal multiple interventions as well as education on specific interventions based on individual risk factors. A 30-minute information session at the bedside was provided to raise the subjects’ awareness of the risk of falling during hospitalisation, and to provide strategies to minimise the risk. The aim of this intervention was to reduce the subjects’ risk of falling by targeting specific risk factors. For example, if increased urinary elimination is identified as a risk factor for a particular subject, then risk factor reduction intervention would be educating patient to empty his/her bladder at regular intervals, and to call for assistance with toileting. The targeted multiple intervention strategy was developed based on the Singapore Ministry of Health nursing clinical practice guidelines on the prevention of falls in hospitals.41 (refer Appendix 2)

**Research Nurse Training**

Two research nurses who had no direct involvement with the patients in the study wards were employed to recruit patients into the study, and provide information on targeted multiple interventions to subjects assigned to the treatment group. The
research nurses were provided with a booklet containing detailed information on the aim and purpose of the study, the Hendrich II fall-risk assessment tool, fall prevention interventions, and specific instructions relating to the administration of data collection instruments.

A one-day training session was conducted to ensure that data was collected in a standardised, accurate, and consistent manner throughout the study. In addition, training is important for the collection of high quality data.\textsuperscript{42} The training provided outlined the content of the booklet, and provided demonstrations by the principal investigator on fictitious data collection episodes that were performed on two patients. The training also entailed having the research nurses perform trial runs of data collection in front of the principal investigator to aid in understanding the data collection process.\textsuperscript{42} The research nurses had the opportunity to access 20 patients and an evaluation of their educational sessions on the intervention processes. Further training was provided before the data collection commenced if the research nurses were not confident and competent in the process of data collection. It took approximately five days for the research nurses to familiarise themselves on the process of implementing the new interventions and completing documentation.
Setting

This study was conducted at the National University Hospital in Singapore, the nation’s only university hospital, and the only acute care tertiary hospital located in the western part of the country, serving a population of three million people. The hospital has 946 inpatient beds, and offers a wide range of comprehensive health care services. This hospital was considered appropriate for this study for three reasons. First, it provided access to a large number of subjects, thus increasing the possibility of obtaining a significant number. Second, all patients admitted to the hospital were assessed for their fall-risk within four hours of their admission. Lastly, the subjects were easily accessible as this was the hospital where the principal investigator was working.

The study took place in eight medical wards of the hospital. The size of the eight medical wards ranged from 17 to 46 beds, and admitted patients with medical conditions, that included cardiac, respiratory, renal, oncology, gastro-enterology, and endocrine conditions. All the wards had a daily average occupancy of over 90% throughout the year. These wards were chosen because they form the majority of the patient population in the study hospital, and the findings of this study provided a basis for changing or supporting current fall prevention interventions. Moreover, about 73% of patient falls in acute care hospitals occur within the medical discipline. 43
Subjects

The subjects were newly admitted patients from eight medical wards who met the inclusion criteria and exclusion criteria.

Inclusion Criteria

Patients with the following criteria were eligible for inclusion into the study:

- Admitted into a study ward during the period of the study
- Had a score of $\geq 5$ on the Hendrich II Fall Risk Model.

Exclusion Criteria

Patients with the following criteria were excluded from the study:

- Were already in a study ward before the study commenced
- Unable to communicate and understand English, Mandarin, or Malay, and therefore unable to understand the education session on targeted multiple interventions; it was beyond the resources of the study to engage the services of professional translators
- Had a score of $\leq 5$ on the Hendrich II Fall Risk Model.

Recruitment of Subjects

A total of 6,488 patients were admitted to the eight medical wards during the six-month data collection period. All patients had the routine fall-risk assessment performed by a ward Registered Nurse within four hours of admission, using the
Hendrich II Fall Risk Model tool. The ward’s Registered Nurses placed the completed assessment forms into the designated place within the wards.

The two research nurses visited the study wards, on a daily basis, and evaluated the completed assessment forms. Of the 6,488 patients who underwent the routine fall-risk assessment on admission, 1,822 patients had a score of ≥ 5 on the Hendrich II Fall Risk Model and met the inclusion criteria and exclusion criteria to become the study sample.

The research nurses assigned all subjects a trial number by writing the number at the top right hand corner of the subjects’ completed fall-risk assessment forms. For example, the research nurse would write the number ‘001’ at the top right hand corner of subject ‘A’’s completed form, number ‘002’ at the top right hand corner of subject ‘B’’s completed form, and so forth until all the subjects had a serial number.

The completed forms were then tagged by the research nurses to match a subject’s completed forms with its relevant envelope through a corresponding serial number. For instance, a research nurse would tag an envelope with the serial number ‘001’ with the completed form marked ‘001’ of patient ‘A’, and the envelope with the serial number ‘002’ with the completed form marked ‘002’ of patient ‘B’ and so forth until all the completed forms were tagged with their
corresponding envelopes. The research nurses then opened the envelope to identify the patients’ allocated group, that is, control group or intervention group.

The recruitment of subjects was carried out daily on Monday to Friday, and on the next working day for Saturday, Sunday, and public holidays because of budget constraints in employing more research nurses. However, there were very few admissions to the hospital on weekends and public holidays.

**Randomisation Procedure**

Randomisation is a process ‘whereby different treatments are allocated to subjects in a trial by chance mechanism’\(^\text{40}\) (p.61). Random allocation can be achieved using table of random numbers, sealed envelopes, telephone or internet.\(^\text{42, 44}\)

A biostatistician assisted in the randomisation process. Subjects were randomly assigned into either the treatment or control study group. A computer program was used to perform the randomisation, with the ward as a stratification factor to ensure an even mix in the ward. Stratification ensures that the number of subjects receiving each intervention is balanced with each group.\(^\text{45}\) A randomisation list with the ward as the stratification factor was prepared and given to an independent administrative assistant (refer Appendix 3). The list also contained the trial numbers for the allocated group. A trial number in sequential order was allocated to every subject, and the subject was randomly assigned to the intervention and control group. This design involved equal allocation of subjects
to two groups. For example, subject ‘001’ into the intervention group, subject ‘002’ into the intervention group, and subject ‘003’ into the control group. One student from the polytechnic college under the supervision of an independent administrative assistant placed each set of trial numbers with an allocated group in a brown envelope. The envelope was then sealed, and the trial number written on the front top left hand corner of the envelope. The completed envelope was filed neatly in a box in sequential order of the trial number. It took two people working full-time for four weeks to prepare 2,000 envelopes.

**Advantages of Randomisation**

Randomisation offers four advantages. First, randomisation eliminates bias in the assignment of treatment, which can affect the variable under study.\(^{46}\) Second, it blinds the investigators, subjects and evaluators to the types of interventions. Third, randomisation ‘permits the use of probability theory that any difference in outcome between the treatment groups merely indicates chance’\(^{45}\) (p.516). Finally, randomisation helps to meet the requirement of all the statistical tests used to compare the two groups.\(^{47}\)

**Disadvantages of Randomisation**

The main disadvantage of using randomisation is that it does not guarantee that the groups will be equal.\(^{42}\) Moreover, randomisation is an expensive and laborious process using a tremendous amount of resources.\(^{42,46}\)
Sample Size

Using a double blind randomised controlled trial design, 1,822 subjects, who met the inclusion and exclusion criteria, were recruited and randomly assigned to either the control ($n=912$, $n=50.1\%$) or intervention group ($n=910$, $n=49.9\%$). A biostatistician attached to the Clinical Trial and Epidemiology Research Unit (CTERU) assisted in the sample size calculation. The results of the first study revealed that the fall incidence rate during hospitalisation was 2\% for subjects who were at risk of falling when the score of the Hendrich II fall Risk Model was at $\geq 5$. To estimate a fall incidence with a 95\% Confidence Interval (CI) of 0.8\% to 2.5\%, 900 patients were required for the control group, and another 900 patients for the treatment group.\textsuperscript{48}

Duration of Study

The study was conducted over a nine-month period, from April 2006 to December 2006.

Ethical Considerations

The research proposal was submitted for approval to the Research Higher Degrees Sub-committee of the Discipline of Nursing at the School of Population Health and Clinical Practice of the University of Adelaide, and the National Healthcare Group (NHG) Domain Specific Review Board (DSRB) (refer Appendix 4). The DSRB comprises of representatives from all NHG institutions, who provide an
independent and timely review of the ethical and scientific merit of research studies.

The ethical issues related to this research were for the protection of human rights, which includes the right to self-determination, full disclosure of information, the right to privacy, and protection from harm and discomfort.\textsuperscript{42} In this study, the subjects’ right to self-determination and full disclosure of information had been violated. The DSRB had given approval for waivers of informed consent for three reasons. First, this study involved educational sessions on targeted multiple intervention strategy to reduce patient falls, posing only a minimal risk to subjects. Minimal risk refers to the probability and magnitude of discomfort or harm anticipated in the proposed research that is no greater than those encountered in daily life.\textsuperscript{42, 49} Second, this study involved interventions that did not require written consent when it was performed outside of the research setting.\textsuperscript{49} Lastly, this study was essential to determine the effectiveness of interventions in reducing patient falls. However, it may not be possible to conduct the study without waivers of informed consent. Disclosure of information related to the study may cause a Hawthorne effect on the subjects that could influence the outcome of the study.\textsuperscript{42} Hawthorne effects means that the ‘effect on the dependent variable resulting from the subjects awareness that they are participants under study’\textsuperscript{42} (p.703).
Although, the subjects had no knowledge that they were research subjects, their right to privacy and right to protection from harm and discomfort had been observed.

The Right to Privacy

The principle of privacy means that the subjects have the right to expect their privacy is maintained through the study, and that the data collected from the study will be kept in strictest confidence. This can be facilitated through anonymity or other confidentiality procedures.  

An identification code was used in lieu of the patient’s name to protect his or her identification when information related to the study needed to be disclosed. The data collected was kept in a filing cabinet inside a locked office, and only authorised personnel; principal investigator, co-investigators and the biostatistician had access to the data. The data will be kept secured in a locked cabinet for 3 years following the completion of the study in line with the DSRB policy. The Principal Investigator will destroy the data after 3 years with a shredding machine.

The Right to Protect from Harm and Discomfort

The principle of protection from harm and discomfort means that the subjects will be protected from physical and psychological harm, and that the subjects will not be exploited. The principal investigator carefully weighed the risk/benefit ratio for
Data Gathering Instruments

Two instruments were used for data collection, which included the demographic data form, and the Hendrich II Fall Risk Model tool.

Demographic Data Form

The principal investigator developed a form, based on a review of available literature, to collect demographic data on subjects, and the circumstances of their falls. Demographic data, such as age, gender, race, and diagnostic categories of the subjects, was collected to provide an overview of the study sample (refer Appendix 5). Additionally, data, such as time of fall, location of fall, activity performed at time of fall, injury sustained, and the management of the injury, was collected to provide an overview of the circumstances of falls.

Hendrich II Fall Risk Model

The Hendrich II Fall Risk Model is a newly revised fall-risk tool developed for an acute care population. The tool is comprised of the following risk factors: confusion/disorientation/impulsivity, symptomatic depression, altered elimination, dizziness or vertigo, gender (male), any prescribed anti-epileptics or Benzodiazepines, and the ‘get up and go’ test. Each risk factor on the instrument was allocated a score depending on the calculated relative risk. The subject was
assessed for the presence or absence of a risk factor, and a score was written in the space provided when there was a risk factor present. A total score of $\geq 5$ or higher indicates a high risk of fall.\(^{39}\) (refer Appendix 6)

**Validity of Hendrich II Fall Risk Model**

Validity of an instrument refers to the ability of the instrument to collect and measure data that is designed to measure.\(^{28}\) The sensitivity and specificity of the Hendrich II Fall Risk Model in the setting in which the tool was developed was 75% and 74% respectively.\(^{39}\) This tool had been validated in the first stage of this research, and found to have a sensitivity of 70%, and specificity of 62%.

A work group comprising of nurse managers and nurse clinicians from the eight study wards of the hospital reviewed the contents of the Hendrich II Fall Risk Model instrument. A review of the instrument by the work group was considered appropriate given their connection to the wards, and knowledge in medical nursing. The work group was consulted in order to acquire constructive feedback from them regarding the content of the instrument, and the feasibility of using the instrument in the study hospital upon completion of the study.

**Inter-rater Reliability of Hendrich II Fall Risk Model**

Inter-rater reliability refers to the degree of consistency between scores that are obtained by two independent assessors.\(^{52}\) The inter-rater reliability of the tool in
the setting in which the tool was developed was 100%, while the inter-rater reliability in the study hospital was 87%.

**Pilot Study**

A pilot study was undertaken in the study wards to test the feasibility of the data collection procedures. The aim of the pilot was to perform fall-risk assessments and implement targeted multiple interventions to a small group of patients similar to those who would be asked to participate in the study. The sample group used for this process met the same specified inclusion and exclusion criteria as for this study. The pilot study took place over a two-week period. All patients who were admitted to the medical wards during the nominated two-week period were invited to participate in the pilot study. Fifty patients who met the inclusion and exclusion criteria participated in the pilot study.

**Advantages of a Pilot Study**

The objective of piloting the data collection procedures before commencing the actual study was to ensure that the items on the instruments, and targeted multiple interventions were easy for subjects to understand. It also ensured that subjects understood the principal investigator’s interpretation of the terms on the use of instruments and interventions, and what the overall implications were, and that registered nurses were familiar with the process of completing fall-risk assessments, and understood what was required of them. It was also used to gauge how long the process of data collection would take for the research nurses...
to complete. This is beneficial because if the data collection process prove to be time-consuming and confusing, modification to the process could be made before the study commenced, thus reducing the potential for subjects drop out, research nurses collecting incomplete data, or registered nurses not entirely completing fall-risk assessments on patients. Furthermore, a pilot study can reveal any ambiguities or misunderstandings the research nurses or registered nurses might have, resulting in less stress for them, and improving the conduct of the study.\footnote{53}

In addition, the pilot study allowed ‘real’ data to be entered into the database to determine any issues with coding or/and analysis.\footnote{46}

**Disadvantages of a Pilot Study**

Although, there are benefits in conducting a pilot study to test the feasibility of the data collection procedures before commencing an actual study, there are also disadvantages, such as, recruiting additional manpower, the extra time required to conduct the pilot study, and reviewing the outcomes of the study.

**Data Collection Procedure**

Data collection comprised of: data collection form preparation, assessing for fall-risk, implementing the fall prevention interventions, monitoring for falls, and fall injuries.
Preparation of Data Collection Forms

The data collection form was outsourced to a printer for formatting into Optical Mark Recognition (OMR); optimal for computer scanning. OMR provides a fast, accurate way to collect and input data into the computer, thereby reducing the time required to manually enter huge amounts of data into the computer. Furthermore, it minimises the potential of data being entered incorrectly as a result of fatigue.54

Assessing of Fall Risk

A total of 6,488 patients were admitted to the eight medical wards during the six-month data collection period. All the patients had the routine fall-risk assessments performed by the ward’s Registered Nurses within four hours of admission, using the Hendrich II Fall Risk Model instrument. The Registered Nurse then placed the completed assessment forms into a designated place within the wards.

The two research nurses visited the study wards on a daily basis, and evaluated the completed assessment forms. Of the 6,488 patients who underwent the routine fall-risk assessment, 1,822 patients had a score of ≥ 5 on the Hendrich II Fall Risk Model and met the inclusion criteria and exclusion criteria to become study samples.

The research nurses assigned all the subjects a trial number by writing the number at the top right hand corner of the subjects’ completed fall-risk assessment forms.
For example, the research nurse wrote the number ‘001’ at the top right hand corner of subject ‘A’’s completed form, and number ‘002’ at the top right hand corner of subject ‘B’’s completed form and so forth until all the subjects were assigned a serial number.

The completed forms were then tagged by the research nurses to match a subject’s completed forms with its relevant envelope through a corresponding serial number. For instance, a research nurse would tag an envelope with the serial number ‘001’ with the completed form marked ‘001’ of patient ‘A’, and the envelope with the serial number ‘002’ with the completed form marked ‘002’ of patient ‘B’ and so forth until all the completed forms were tagged with their corresponding envelopes. The research nurses then opened the envelope to identify the patients’ allocated group, that is, control group or intervention group.

**Implementing the Interventions**

Using a double blind randomised controlled trial design, 1,822 subjects, who met the inclusion and exclusion criteria, were randomly assigned to either the control (\(n=912, n=50.1\%\)) or intervention group (\(n=910, n=49.9\%\)).

*Control group:* The research nurses reviewed the subjects’ medical record to gather information about their medical history and treatment, and at the same time documented the demographic data on a form. Subjects in the control group
continued to receive the hospital’s usual universal multiple interventions by the ward nurses.

*Intervention group:* The research nurses reviewed subjects’ medical records to gather information about their medical history and treatment, and at the same time documented the demographic data on a form. This was followed by an information session in a language the subject could comprehend; English, Malay or Mandarin. The aim of the information session was to raise the subjects’ awareness of their risk of falling during hospitalisation and to provide strategies to minimise the risk. The information session was also provided to the relatives of subjects who were confused and/or delirious. The information session on targeted multiple intervention strategy was based on the individual subject’s risk factors. For example, Subject A had increased urinary elimination identified as a risk factor, and thus received education on the importance of toileting at regular intervals, and to call for assistance when needed. Each information session lasted approximately 30 minutes. The contents of the information session were recorded on a data collection sheet (see Appendix 7). Subjects in the intervention group continued to receive the hospital’s usual universal multiple interventions by the ward nurses.

The intervention was carried out daily, and within 24 hours of a fall-risk assessment performed by the ward’s registered nurses from Monday to Friday, and on the next working day if admission was on a Saturday, Sunday, or public
holiday; this was due to budget constraints in employing additional research nurses. However, there were very few admissions on over the weekend or on public holidays, and would not have been cost effective to roster research nurses on duty.

Following entry into the study and the provision of fall prevention intervention for the intervention group, subjects in both the control and intervention groups were then monitored for falls and fall injuries.

**Monitoring for Falls**

One nurse educator, who was not involved in implementing the interventions, was assigned to visit the study wards daily, and monitor the subjects in both groups until the time of their first fall, discharge or death, whichever occurred first. For those subjects who fell, data was collected on: time of fall, location of fall, and activity at time of fall, and injuries sustained. The data was collected by reviewing the subjects’ medical record and from interviews with the subjects, and ward nurses using a data collection form (refer Appendix 5), which was developed based on a review of the literature. Subjects exited from the study after their first fall, discharge or death.
Monitoring for Falls Injury

The nurse educator visited the study wards daily to follow-up those subjects who had sustained injuries following their falls. The outcome measures included subjects that required dressings, surgery, repairs to fractures, died, or received pain relief as a result of an injury. Data collected (refer Appendix 5) on the outcomes of sustained injuries was gathered by reviewing a subject’s medical records or from interviews with the subject and ward nurses. The injuries sustained by the subjects were followed-up until the day of discharge from hospital or death.

Outcomes

This study was a randomised controlled trial in which a total of 1,822 subjects were randomly assigned to two different groups: the intervention group and the control group. The objective of the study was to determine the effectiveness of the targeted multiple interventions, with measures that included: a mean risk of falling score, the number of falls and fall injuries, and the severity of fall injuries in each group.

In this study, fall was defined as ‘an unexpected event in which the participants come to rest on the ground, floor, or lower level’⁵⁵ (p.1619). The severity of injury was classified based on the study hospital’s occurrence reporting system: no injury; minor injury, included contusions, abrasions, small skin tears and lacerations; moderate injury, included sprains or deep lacerations, skin tears and
minor contusions with medical and or nursing intervention, lacerations requiring suturing; severe injury, included fractures, loss of consciousness, changes in mental or physical status requiring medical intervention or consultation.

**Statistical Analysis**

**Data Coding**

On collection of a completed data form, each form was assigned a code number: 001, 002, 003 and so on. This process helped to preserve the anonymity and confidentiality of the subjects. In addition, it enabled the number to be recorded in the data file together with the data for reference if it was ever necessary to access the completed form from the data file.\(^{46}\)

The quantifiable data from the completed data collection forms were coded. Coding is the process of providing the data with a number that can be entered into the database in a form that can be easily analysed.\(^{46}\) The coding corresponded to the question/item number, with responses numbered also. For example, gender was listed as item 2 on the data collection form; the response to a male was coded as ‘1’, and female as ‘2’. Actual numbers such as the subject’s age did not need to be coded. These codes were used to reference the data prior to entering it into the statistical software package.\(^{46}\)
Data Entry

The principal investigator discussed the database set-up with a biostatistician before data entry. This was to ensure that the biostatistician could assist with data analysis without too much difficulty. Once all the questions/items had been coded, the data entry assistant (employed full-time for this study) scanned the OMR forms with an image scanner at the end of each day using Remark Office software. The Remark Office is a software package designed to collect data from bubble marks on plain paper forms. The software works in conjunction with the image scanner to collect and export the data into the SPSS. Data cleaning was performed once the data had been scanned into the SPSS data editor. Data cleaning is a process whereby the entered data was checked against the raw data, and any coding errors or discrepancies that were identified were rectified at once. This was important in ensuring the accuracy of numbers that the computer would process, and the validity of data analysis.

Data Analysis

Upon completion of data cleaning, statistical analyses of the data were performed using the Statistical Package for Social Science (SPSS) (SPSS Inc, Chicago, IL, and USA) version 14. Descriptive statistics, such as, frequency distribution (percentages), measure of central tendency (mean, median), measures of dispersion (range, standard deviation) and, where appropriate, inferential statistics such as chi-square, and relative risk estimates and survival analyses were undertaken.
**Chi-square**

Chi-square was used in this study to examine the relationship between two categorical variables, with two or more categories in each, for example, fall incidence (yes/no) and study groups (intervention/control). When completing the statistical analysis, the results were checked to ensure that one of the assumptions concerning the chi-square value was not violated. The validity of the chi-square test is violated when there are ‘small frequencies’ in the cells. The lowest expected frequency in any cell should be 5 or greater (or at least 80% of the cells with expected frequencies of 5 or more). For example, if none of the cells have an expected count of less than 5, the assumption has not been violated. Fisher’s Exact Probability Test will be used if the assumption has been violated.

**Mann-Whitney U Test**

A Mann-Whitney U test was used in this study to test the difference between two independent groups on a continuous measure. For example, age of subjects and study groups (intervention/control).

**Relative Risk**

Relative Risk (RR) is the risk of an event relative to exposure. Relative risk is the ratio of the probability of the event (fall) occurring in the treatment group versus the control group. In this study, the relative risk of falling between the two groups was examined by creating a 2 x 2 contingency table on the number of falls in the intervention and control groups, and a cross tabulation was carried out.
A relative risk of 1 means that there is no difference in risk between the two groups. A relative risk greater than 1 means the event is more likely to occur in the experimental group than in the control group. A relative risk less than 1 means that the event is less likely to occur in the experimental group than in the control group. 57

Kaplan-Meier Statistics

Kaplan-Meier is a non-parametric technique for estimating time-related events, comprising of a horizontal line (x axis) to represent days until the first fall, and a vertical line (y axis) to represent cumulative survival with value that runs from 0 at the bottom to 1 at the top. A survival curve always starts out at 100% surviving at time 0, the beginning. From there it can descend each time there is a fall, or flatten to a level plateau, suggesting that patients are not falling anymore, or it can descend all the way down to 0, implying that all patients fell, but the curve can never increase. It also takes into account censored observations (those subjects who did not fall), which are represented with a small vertical tick. 59

In this study, Kaplan Meier statistics were used to analyse the mean time of first fall of subjects of the intervention and control groups. The Log Rank test and the Cox proportional hazards test were used to compare the differences in Kaplan-Meier curves of the intervention and control groups. 56 A p-value of less than p<0.05 based on log rank test indicated a difference between two survival curves. A value of Hazard Ratio (HR) 1 means there was no difference between the two
groups in the shortest time until the first fall. A HR>1 means that the experimental group is more likely to have a shorter time until the first fall than the control group. A HR < 1 means that the experimental group is less likely to have a shorter time until the first fall than the control group.\textsuperscript{56}

**Statistical Significance**

Once the data has been analysed, and the values are approximately calculated, the results were interpreted for statistical significance. This measurement verifies if the results obtained have occurred by chance at some specified level of probability. The level of confidence should be set before data collection and not after.\textsuperscript{46} The $p$ value ranges from 0 to 1. At $p=0.0001$, there is no probability that the result could have occurred by chance, while at $p=1$, the probability that the result could have occurred by chance is at its highest.\textsuperscript{46} In this study, statistical significance was considered when the probability was equal to or less than 0.05. This means that there is less than a 5% probability that the results would have happened by chance alone.
Results

This section presents the results of the prospective double blind randomised controlled trial in which a total of 1,822 subjects who met the inclusion and exclusion criteria were randomly assigned to either the intervention (49.9%, \(n=910\)) and control (50.1%, \(n=912\)) group. Data was collected on the subjects’ baseline characteristics, their fall-risk score identified with the Hendrich II Fall Risk Model, and the outcomes of falls, which included: the incidence of fall, time and location of fall, activity at time of fall, fall injury, relative risk of falling, and time until first fall.

Subjects’ Recruitment

A total of 6,498 patients were admitted into the eight medical wards during the nine-month data collection period. Out of the 6,498 patients, 1822 (28%) patients met the inclusion and exclusion criteria and were eligible for the study, the remaining 4,676 (72%) were excluded from the study. The most common reasons for exclusion from the study were the following: 92.9% \((n=4344/4676)\) of patients did not meet the inclusion criteria, 0.1% \((n=8/4676)\) of patients died, 3.3% \((154/4676)\) of patients were discharged from hospital, and 1.5% \((n=71/4676)\) of patients were transferred to surgical wards.

The 1,822 (28%) patients that met the inclusion and exclusion criteria were randomly assigned to either the intervention group or control group and became the subjects. Of the 1,822 subjects, 910 (49.9%) subjects were randomised into
the intervention group and 912 (50.1%) subjects to the control group. There was no significant difference in the baseline demographics of gender, age, race, and diagnostic category between the intervention and control groups. No subject withdrew from either the control or intervention groups during the study period, and thus intention to treat is not reported.

**Subjects’ Baseline Characteristics**

The characteristics of subjects examined in this study were gender, age, race, and diagnostic category to provide an overview of the study sample.

**Gender of Subjects**

Of the 1,822 subjects recruited, 49.7% \((n=905/1822)\) were male and 50.3% \((n=917/1822)\) were female. Of the 905 subjects who were male, 47.6% \((n=433/910)\) were from the intervention group, and 51.8% \((n=472/912)\) from the control group. Of the 917 subjects who were female, 52.4% \((n=477/910)\) were from the intervention group and 47.6% \((n=433/910)\) from the control group. There were slightly more males in the control group (51.8%) compared to the intervention group (47.6%). Conversely, there were slightly more females in the intervention group (52.4%) when compared to the control group (47.6%). The proportion of males was not significantly different from the proportion of females across the intervention and control groups \((p=0.083)\). The gender of subjects for both groups is summarised in Table 1.
Table 1: Gender of Subjects in Intervention and Control Groups

<table>
<thead>
<tr>
<th>Gender</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Total Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>433 (47.6%)</td>
<td>472 (51.8%)</td>
<td>905 (49.7%)</td>
<td>*P=0.083</td>
</tr>
<tr>
<td>Female</td>
<td>477 (52.4%)</td>
<td>440 (48.2%)</td>
<td>917 (50.3%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>910 (100%)</td>
<td>912 (100%)</td>
<td>1822 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

*Chi-square

Age of Subjects

The age of the 1,822 subjects ranged from 21 years to 101 years with a mean age of 70 years (SD\(\pm\)14.43). The age of subjects in the intervention group ranged from 22 years to 100 years with a mean age of 70.3 years (SD\(\pm\)14.19). The age of subjects in the control group ranged from 21 years and 101 years with a mean age of 69.7 years (SD\(\pm\)14.66). The standard deviation was more than 10% of the mean ages. In a conversation with a biostatistician from the Clinical Trial and Epidemiology Research Unit (Dr Edwin Chan, oral communication, 10 May 2007), it was suggested that in a standard deviation of more than 10% of the means, the age of the subjects was not normally distributed. There was no statistically significant difference in the ages between the intervention and control groups \(p=0.339\). The age of subjects for both groups is summarised in Table 2.
Table 2: Age of Subjects in Intervention and Control Groups

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group (n=912)</th>
<th>Control Group (n=910)</th>
<th>Total Group (n=1822)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (±SD) (years)</td>
<td>69.70 ± 14.66</td>
<td>70.33 ± 14.19</td>
<td>70.01 ± 14.43</td>
<td>P=0.339 *</td>
</tr>
</tbody>
</table>

* Mann-Whitney

Race of Subjects

Of the 1,822 subjects who participated in the study, the majority (72%, n=1312/1822) of the subjects were Chinese, with 49.4% (n=648/1312) in the intervention group and 50.6% (n=664/1312) in the control group. This was followed by the Malays, which constituted 18.3% (n=334/1822) of the subjects with 54.2% (n=181/334) in the intervention group, and 45.8% (n=153/334) in the control group. The Indians constituted 7.8% (n=142/1822) of the subjects with 46.5% (n=66/142) in the intervention group, and 53.5% (n=76/142) in the control group. The category ‘others’ constituted 1.9% and included subjects from ethnic minority groups such as the Eurasians and Sikhs, and subjects on working permits from Asian countries such as the Philippines, Pakistan, Bangladesh, and Thailand. The race of the subjects is summarised in Table 3.
Table 3: Race of Subjects in Intervention and Control Groups

<table>
<thead>
<tr>
<th>Race</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Total Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>648 (49.4%)</td>
<td>664 (50.6%)</td>
<td>1312 (72%)</td>
<td>*P=0.420</td>
</tr>
<tr>
<td>Malay</td>
<td>181 (54.2%)</td>
<td>153 (45.8%)</td>
<td>334 (18.3%)</td>
<td></td>
</tr>
<tr>
<td>Indian</td>
<td>66 (46.5%)</td>
<td>76 (8.3%)</td>
<td>142 (7.8%)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>15 (44.1%)</td>
<td>19 (55.8%)</td>
<td>34 (19%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>910 (100%)</td>
<td>912 (100%)</td>
<td>1822 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

*Chi-square

Diagnostic Categories

Of the 1,822 subjects who participated in the study, the majority of subjects (35.9%, n=655/1822) were from general medicine with 49.9% (n=327/655) in the intervention group, and 50.1% (n=328/655) in the control group. Subjects with renal conditions made up the second highest proportion of subjects (12%, n=219/1822) recruited, with 45.2% (n=99/219) in the intervention group, and 54.8% (n=120/219) in the control group. Cardiac conditions constituted 11.6% (n=212/1822) of the subjects with 52.8% (n=112/212) in the intervention group, and 47.2% (n=100/212) in the control group. Subjects with neurology conditions (11.4%, n=208/1822) followed this, with 49% (n=102/208) in the intervention group, and 51% (n=106/208) in the control group. Subjects with oncology/haematology conditions constituted 10.8% (n=197/1822) of the
recruitment with 52.3% (n=103/197) in the intervention group, and 47.7% (n=94/197) in the control group. Subjects with gastro-enterology conditions constituted 8.7% (n=159/1822) with 52.2% (n=83/159) in the intervention group, and 47.8% (n=76/159) in the control group. Respiratory conditions constituted 4.2% (n=77/1822) of the subjects recruited with 48.1% (n=37/77) and 51.9% (n=40/77) in the intervention and control groups respectively. Endocrine conditions constituted 4.1% (n=75/1822) of the subjects with 49.3% (n=37/75) and 50.7% (n=38/75) in the intervention and control groups respectively. Subjects from geriatric medicine constituted 0.7% (n=14/1822) of the recruitment with 57.1% (n=8/14) and 42% (n=6/14) in the intervention and control groups respectively. The category ‘others’ included subjects with infectious disease, and rheumatoid conditions, and constituted the smallest proportion (0.3%, n=6/1822) with 33.3% (n=2/6) and 66.7% (n=4/6) in the intervention and control groups respectively. The diagnostic categories of the subjects are summarised in Table 4.
Table 4: Diagnostic Categories of Subjects in Intervention and Control Groups

<table>
<thead>
<tr>
<th>Diagnostic Categories</th>
<th>Intervention</th>
<th>Control</th>
<th>Total</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Medicine</td>
<td>327 (49.9%)</td>
<td>328 (50.1%)</td>
<td>655 (35.9%)</td>
<td>$*P=0.872$</td>
</tr>
<tr>
<td>Renal</td>
<td>99 (45.2%)</td>
<td>120 (54.8%)</td>
<td>219 (12%)</td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>112 (52.8%)</td>
<td>100 (47.2%)</td>
<td>212 (11.6%)</td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>102 (49.0%)</td>
<td>106 (51.0%)</td>
<td>208 (11.4%)</td>
<td></td>
</tr>
<tr>
<td>Oncology/ Haematology</td>
<td>103 (52.3%)</td>
<td>94 (47.7%)</td>
<td>197 (10.8%)</td>
<td></td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>83 (52.2%)</td>
<td>76 (47.8%)</td>
<td>159 (8.7%)</td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>37 (48.1%)</td>
<td>40 (51.9%)</td>
<td>77 (0.4%)</td>
<td></td>
</tr>
<tr>
<td>Endocrine</td>
<td>37 (49.3%)</td>
<td>38 (50.7%)</td>
<td>75 (4.1%)</td>
<td></td>
</tr>
<tr>
<td>Geriatric Medicine</td>
<td>8 (57.1%)</td>
<td>6 (42.9%)</td>
<td>14 (0.8%)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>2 (33.3%)</td>
<td>4 (66.7%)</td>
<td>6 (0.3%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>910 (49.9%)</td>
<td>912 (50.1%)</td>
<td>1822 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

*Chi-square
Subjects’ Fall Risk Score on Hendrich II Fall Risk Model

A total of 6,166 subjects were assessed for their fall-risk, of these, 29.5\% (n=1822/6166) were identified to be at high-risk for fall by the Hendrich II Fall Risk Model tool, while the remaining 70.5\% (4344/6166) were identified to be at low-risk for falls. The fall-risk score for subjects ranged from 5 to 15 with a mean score of 7.57 (SD $\pm$ 2). The fall-risk score for subjects using the Hendrich II Fall Risk Model tool is summarised in Table 5.

Table 5: Subjects’ Fall Risk Score in the Intervention and Control Groups

<table>
<thead>
<tr>
<th></th>
<th>Control Group (n=912)</th>
<th>Intervention Group (n=910)</th>
<th>Total Group (n=1822)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Score (+ SD)</td>
<td>7.63 (+ 2.3)</td>
<td>7.51 (+ 2.2)</td>
<td>7.57 (+ 2.2)</td>
</tr>
</tbody>
</table>

Outcome of Falls

Incidence of Falls

Of the 1,822 subjects recruited during the nine-month data collection period, a total of 18 high-risk subjects (1\%, n=18/1822) fell at least once during hospitalisation. Of the high-risk subjects who fell, four subjects (0.4\%, n=4/906) were from the intervention group, and 14 subjects (1.5\%, n=14/912) were from the control group. The chi-square test result was significant at $p=0.018$. This implies that the proportion of high-risk subjects who fell in the intervention group (0.4\%, CI: 0.2 to 1.1) was significantly lower compared with the control group (1.5\%, CI: 0.9 to 2.6). The incidence of falls for both groups is summarised in Table 6.
Table 6: Incidence of Falls in Intervention and Control Groups

<table>
<thead>
<tr>
<th>Incidence of Falls</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Total Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>4 (0.4%)</td>
<td>14 (1.5%)</td>
<td>18 (1%)</td>
<td>$P=0.018^*$</td>
</tr>
<tr>
<td>No</td>
<td>906 (99.6%)</td>
<td>898 (98.5%)</td>
<td>1804 (99%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>910</td>
<td>912</td>
<td>1822</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-square

Time of Falls

The largest proportion of falls occurred during night shifts (38.9%), followed by morning shifts (33.3%). Twenty-eight per cent of the falls occurred during afternoon shifts. The times of falls are summarised in Table 7.

Table 7: Time of Falls in Intervention and Control Groups

<table>
<thead>
<tr>
<th>Time of the Day</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Total Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>7am to 2pm</td>
<td>1 (25%)</td>
<td>5 (35.7%)</td>
<td>6 (33.3%)</td>
</tr>
<tr>
<td>2pm to 9pm</td>
<td>1 (25%)</td>
<td>4 (28.6%)</td>
<td>5 (27.8%)</td>
</tr>
<tr>
<td>9pm to 7am</td>
<td>2 (50%)</td>
<td>5 (35.7%)</td>
<td>7 (38.9%)</td>
</tr>
<tr>
<td>Total</td>
<td>4 (100%)</td>
<td>14 (100%)</td>
<td>18 (100%)</td>
</tr>
</tbody>
</table>
Location of Falls

Sixty-seven per cent of falls occurred next to the bed, with 11.1% of these in the patient cubicle. The toilet was the location for 11.1% of falls, while 5.5% occurred when walking along the ward corridor, and 1% of falls were in the lift lobby. The location of falls for both groups is summarised in Table 8.

Table 8: Location of Falls in Intervention and Control Groups

<table>
<thead>
<tr>
<th>Location</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 (100%)</td>
<td>8 (57.1%)</td>
<td>12 (66.7%)</td>
</tr>
<tr>
<td>Beside</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient cubicle</td>
<td>0</td>
<td>2 (14.3%)</td>
<td>2 (11.1%)</td>
</tr>
<tr>
<td>Toilet</td>
<td>0</td>
<td>2 (14.3%)</td>
<td>2 (11.1%)</td>
</tr>
<tr>
<td>Ward corridor</td>
<td>0</td>
<td>1 (7.1%)</td>
<td>1 (5.5%)</td>
</tr>
<tr>
<td>Others: Lift lobby</td>
<td>0</td>
<td>1 (7.1%)</td>
<td>1 (5.5%)</td>
</tr>
<tr>
<td>Total</td>
<td>4 (100%)</td>
<td>14 (100%)</td>
<td>18 (100%)</td>
</tr>
</tbody>
</table>

Activity at Time of Falls

Fifty per cent of falls occurred while the subject was attempting to get out of bed, with 27.8% occurring in areas categorised as ‘other’. This category included: ambulating, attempting to rise from a commode, and dragging a chair. Eleven per cent of falls occurred while getting off the toilet seat, 5.6% while dressing, and
5.6% occurred while getting into a chair. The activity at the time of falls is summarised in Table 9.

Table 9: Activity at Time of Falls in Intervention and Control Groups

<table>
<thead>
<tr>
<th>Activity</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attempting to get out of bed</td>
<td>2 (50%)</td>
<td>7 (50%)</td>
<td>9 (50%)</td>
</tr>
<tr>
<td>Dressing</td>
<td>1 (25%)</td>
<td>0</td>
<td>1 (5.6%)</td>
</tr>
<tr>
<td>Getting off toilet seat</td>
<td>0</td>
<td>2 (14.3%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>Getting into chair</td>
<td>1 (25%)</td>
<td>0</td>
<td>1 (5.6%)</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
<td>5 (35.7%)</td>
<td>5 (27.8%)</td>
</tr>
<tr>
<td>Total</td>
<td>4 (100%)</td>
<td>14 (100%)</td>
<td>18 (100%)</td>
</tr>
</tbody>
</table>

Fall Injury

Of the 1,822 subjects recruited for the study, a total of 18 subjects (1%, $n=18/1822$) fell once. Of the 18 subjects who fell, 10 subjects (55.6%, $n=10/18$) sustained no injury, while 8 subjects (44.4%, $n=8/18$) sustained minor injuries of contusions and small skin tears. Of the 10 subjects who sustained no injury, 1 subject (10%, $n=1/10$) was from the intervention group, while 9 subjects (90%, $n=9/10$) were from the control group. Of the 8 subjects who sustained minor injuries, 3 subjects (37.5%, $n=3/8$) were from the intervention group, and 5
subjects (62.5%, n=5/8) were from the control group. The severity of falls for both groups is summarised in Table 10.

**Table 10: Fall Injury in the Intervention and Control Groups.**

<table>
<thead>
<tr>
<th>Fall Injury</th>
<th>Intervention Group (n=4)</th>
<th>Control Group (n=14)</th>
<th>Total Group (n=18)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No injury</td>
<td>1 (10%)</td>
<td>9 (90%)</td>
<td>10 (100%)</td>
<td>$p=0.275^*$</td>
</tr>
<tr>
<td>Minor injury</td>
<td>3 (37.5%)</td>
<td>5 (62.5%)</td>
<td>8 (100%)</td>
<td></td>
</tr>
<tr>
<td>Moderate injury</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Severe injury</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4 (22.2%)</td>
<td>14 (77.8%)</td>
<td>18 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

* Fisher exact test

**Relative Risk Estimate**

The estimated relative risk in the intervention group was 29% of that in the control group. The results remained the same after accounting for age and gender. The risk ratio was less than 1, which implies a difference. The use of targeted multiple interventions reduced the risk of falling to about 29% of the usual fall prevention interventions. The risk ratio of the intervention group versus control group is summarised in Table 11.
Table 11: Risk Ratio of Intervention versus Control Group

<table>
<thead>
<tr>
<th></th>
<th>Risk ratio</th>
<th>95% Confidence Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention versus</td>
<td>0.29</td>
<td>0.10 –0.87</td>
</tr>
<tr>
<td>control group</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Time until First Fall during Hospitalisation

The Kaplan Meier survival analysis showed statistically significant differences ($p=0.046$) between the fallers in the intervention and control group for the time until the first fall following recruitment into the study. The intervention group had four subjects who fell within Day 1 to Day 24, while the control group had 14 subjects who fell within Day 1 to Day 17 after recruitment into the study.

Analysis of these fallers reveals a significance difference in the mean time until the first fall, of 14 days in the intervention group compared with 6 days in the control group. The time until first fall for both groups is summarised in Table 12 and Figure 1.

Table 12: Time to First Fall during Hospitalisation

<table>
<thead>
<tr>
<th>Intervention Group</th>
<th>CI 95%</th>
<th>Control Group</th>
<th>CI 95%</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>1.2 to 16.8</td>
<td>6</td>
<td>2.8 to 5.2</td>
<td>$P=.046$</td>
</tr>
</tbody>
</table>


Hazard Ratio Estimate

The estimated hazard ratio was 0.29% (95% CI: 0.11 to 0.73, \(p=0.019\), Log rank test). The results remained the same after accounting for age and gender (HR: 0.30, 95% CI:0.10 to 0.91, \(p=0.0033\)). The hazard ratio was less than 1; this implies that subjects in the intervention group were less likely to fall in a short period of time.

Summary of the Findings

There were 1,822 subjects who met the inclusion and exclusion criteria out of 6,498 eligible subjects admitted into the eight medical wards; 910 (49.9%) were randomised to the intervention group and 912 (50.1%) to the control group. Data were collected on the baseline characteristics of subjects, their score on the
Hendrich II Fall Risk Model, and the outcome of falls, which included the incidence of fall, characteristics of the fallers, relative risk estimate, and time until first fall.

Subjects’ Baseline Characteristics
Of the 1,822 subjects recruited, 49.7% (n=905/1822) were male and 50.3% (n=917/1822) were female, and their ages ranged from 21 years to 101 years with a mean age of 70 years old (SD ± 14.43). Majority of the subjects were Chinese (72%; n=1312/1822) followed by Malays (54.2%, n=334/1822), and Indians (7.8%, n=142/1822). Subjects from general medicine (35.9%, n=655/1822) constituted the majority of subjects, followed by renal (12%, n=219/1822), cardiology (11.6%, n=212/1822), neurology (11.4%, n=208/1822), and oncology and haematology (10.8%, n=197/1822). No difference in baseline characteristics was found between the intervention and control groups.

Subjects’ score on the Hendrich II Fall Risk Model
A total of 6,166 subjects were screened for their fall-risk using the Hendrich II Fall Risk Model. Of these, 29.5% (n=1822/6166) of the subjects were identified to be at high-risk (score ≥ 5) for falls, the remainder 70.5% (n= 4344/6166) at low-risk for falls. The mean score of the subjects’ fall-risk was 7.57 (SD ± 2).
Incidence of Falls

Of the 1,822 high-risk subjects recruited during the nine-month data collection period, 1% \((n=18/1822)\) of the subjects fell once during hospitalisation. Only 0.4% \((95\% \text{ CI: } 0.2 \text{ to } 1.1, n=4/910)\) of the intervention group fell once, compared with 1.5% \((95\% \text{ CI: } 0.9 \text{ to } 2.6, n=4/912)\) of the control group. The proportion of subjects who fell in the intervention group was significantly lower compared to the control group \((p=0.018)\).

Location and Time of Falls

Most falls occurred next to the bed \((67\%)\), with 11.1% of in the patient cubicle, 11.1% of falls occurred in the toilet, 5.5% while walking along the ward corridor, and 1% in the lift lobby. The largest proportion of falls occurred during the night shift \((33.3\%)\) followed by the morning shift \((33.3\%)\). The least amount of falls occurred during the afternoon shift \((28\%)\).

Activity at Time of Falls

Half the falls occurred while attempting to get out of bed \((50\%)\), with 27.8% occurring in areas categorised as ‘other’. This category included: ambulating, attempting to get off the commode, and dragging a chair. In following, 11% of falls occurred while getting off the toilet, 5.6% while dressing, and 5.6% occurred while getting into a chair.
Fall Injury

The majority of subjects (56%, \( n=10/18 \)) sustained no injury at all, while 44.4% \( (n=8/18) \) sustained minor injuries consisting of contusions and small tears. Although no significant difference was found between the two groups, five minor injuries were seen in the control group whereas three were seen in the intervention group. No subjects required any treatment for sustained injuries, except for one subject, who required normal saline dressing for a small tear.

Relative Risk Estimate and Time to First Fall

The relative risk estimate was 0.29 (95% CI: 0.10 to 0.87). The result remained the same after accounting for age and gender (OR: 0.9, 95% CI: 0.10 to 0.89, \( p=0.03 \)). The use of targeted multiple intervention strategy reduced the risk of falling by about 29% of the usual fall prevention interventions. In addition, an analysis of fallers revealed that subjects in the intervention group experienced a significant longer mean time until the first fall compared to subjects in the control group (14 days, CI: 1.2 to 16.8 compared to 6 days, CI: 2.8 to 5.2).
Discussion

This discussion section will restate the research question and summarise the design on study before highlighting the major findings of the study and their significance to clinical practice. Lastly, this section will provide an insight into the study limitations, and provide recommendations for further research.

Restatement of the Problem

The purpose of this study was to determine the effectiveness of a targeted multiple intervention strategy in an acute care inpatient hospital. This study was designed to answer the following research question:

- What is the effectiveness of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital?

Summary Description of Procedures

The study was conducted in a large tertiary acute care inpatient hospital in Singapore. It was a suitable setting for the study for three reasons. First, it provided access to a large number of subjects, thus increasing the possibility of obtaining a significant number. Second, all patients admitted to the hospital were assessed for their fall-risk within four hours of their admission. Lastly, the subjects were easily accessible as the principal investigator was working at the hospital.
This study utilised a double blind randomised controlled trial design. The subjects were newly admitted patients from the eight medical wards. The inclusion criteria demanded that all adult patients be admitted into the study wards during the period of the study, and have a score of $\geq 5$ on the Hendrich II Fall Risk Model. Patients were excluded from the study on the basis that they were already in the study wards before the start of the study, and were unable to communicate and understand English, Mandarin, or Malay and, therefore could not understand the information session on targeted multiple interventions. It was beyond the resources of the study to engage the services of professional translators. Patients, who had a score of $\leq 5$ on the Hendrich II Fall Risk Model were also excluded.

All subjects admitted to the study wards had their fall-risk assessment completed by ward nurses using the Hendrich II Fall Risk Model instrument. A total of 1,822 met the inclusion and exclusion criteria and were randomly assigned to either the control group ($n=912, n=50.1\%$ or the intervention group ($n=910, 49.9\%$). The intervention group received the hospital’s routine fall prevention interventions as well as a targeted multiple intervention strategy, while the control group received only the hospital’s routine fall prevention interventions.41

The control group received the usual universal multiple interventions comprising of: fall-risk assessments, accessibility of the call-bell, and instructions on using the call-bell and pressing it for assistance, raising the bed rails, keeping the bed at the lowest level at all times, and applying body vest on confused patients who has
no family members at the bed side. The ward nurses carried out these interventions as part of their routine nursing care to patients as part of fall prevention interventions.

The intervention group received the usual universal multiple interventions as well as education on specific interventions based on individual risk factors. A 30-minute information session was provided at the bed side to raise the subjects’ awareness of the risk of falling during hospitalisation, and to provide strategies to minimise the risk. The aim of this intervention was to reduce the subjects’ risk of falling by targeting specific risk factors. The targeted multiple interventions were developed based the Singapore Ministry of Health nursing clinical practice guidelines on prevention of falls in hospitals.41

On entry into the study, subjects in the intervention and control groups were being followed-up until the time of their first fall, discharge or death whichever occurred first. Similarly, subjects who sustained injuries as a result of a fall were followed-up until the time of discharge or death whichever occurred first.
Major Findings and their Significance to Clinical Practice

To the researcher’s knowledge, this was the first large randomised controlled trial to examine the effectiveness of targeted multiple interventions in an acute care inpatient hospital. The findings in this study appear to indicate that the targeted multiple fall prevention strategy may have played an important role in the overall prevention of falls. However, it is not possible to isolate which component(s) used in the targeted multiple intervention strategy are the most effective in preventing falls. The risk of falling is directly related to the number of risk factors present. Thus, interventions that decrease the magnitude of risk should be effective in preventing falls. It may not be possible to select which specific component(s) are effective, because the component(s) that are important will vary depending on the individual.

Estimated Relative Risk

The use of targeted multiple interventions reduced the risk of falling to about 29% of the risk in usual fall prevention interventions. This favourable result could be attributed to several factors. First, the fall-risk assessment and targeted multiple interventions components of the study were well planned and implemented systematically. In addition, the ward nurses and the two research nurses received training on conducting fall-risk assessments and implementation of targeted multiple interventions respectively, so there was consistency in the approach. Second, this study used two nurses who were not involved in the care of patients, thus there was time for them to take an individualised approach to fall prevention.
Third, this study focused on subjects with a high-risk (with a cut-off score of $\geq 5$ on the Hendrich II Fall Risk Model) for falls, which constituted 20% of the subjects. Thus, allowing scarce resources to be distributed to the group that needed the most attention. Finally, the results appear to indicate that targeting interventions to the specific risk factors of individuals can be effective.

The finding of this study appears to contradict previous studies by Healey et al. and Haines et al, who reported a high estimated relative risk of 0.79 and 0.78 respectively. The high estimated relative risk in previous studies could be attributed to differences in population and between interventions offered, which makes comparison extremely difficult. This study selected adult patients with a mean age of 70 years admitted for acute medical conditions and with interventions focused on modifying individual risk factors. Haines and colleagues selected older adults with a mean age of 80 years from a sub-acute hospital, and with interventions focused on exercise and education. The study by Healey and colleagues selected elderly patients from acute and sub-acute hospitals, with the mean age of 81 years, and with interventions focused around management of vision, medication use and postural hypotension identified from a health screening checklist.

A reduction in the risk of falling of this magnitude has important clinical implications because falls lead to physical and psychological discomfort for the patient. Second, it provides patients and their relatives with confidence in the health care system; that it has the ability to provide safe care and services. Third,
a significant reduction in fall rates would be less draining for ward nursing managers and administrators having to deal with the additional care and cost involved as a result of falls. Moreover, it could help in changing the perceptions of nurses; that it is possible to reduce or prevent falls in hospitals.

In this study, the number of subjects (37.5%, \( n=3/8 \)) in the intervention group who sustained minor injury was lower than the control group (62.5%, \( n=5/8 \)), although statistically this is not significant. The interventions used might be effective in preventing minor falls that are less likely to result in injury. This could have contributed to the low injury rate.

The insignificant injury rate could be attributed to the sample size not being adequately powered to detect a difference in injury rate, resulting in a Type II error. The sample size was calculated primarily to detect a difference in fall rates. It was based on the results of the first study, which revealed the fall incidence rate of subjects who were at risk of falling during hospitalisation when the score of the Hendrich II Fall Risk Model at \( \geq 5 \) was 2%.

The findings of this study are consistent with other studies, which reported that 60%-70% of falls resulted in no injuries at all, and 30%-40% resulted in minor and moderate injuries. Healey and colleagues also reported no significant reduction in the incidence of fall-related injuries, but differences in statistical
analysis made reporting their results and drawing comparisons between studies difficult.

**Low Injury Rate**

Low injury rate has important clinical implications for it provides the patients and their relatives, and nurses with confidence that targeted multiple interventions are effective not only in reducing the number of falls but in also preventing injuries. It also dispels the myth that not all falls result in injuries. In addition, low injury rates help to reduce a patient’s fear of falling, build their confidence in maintaining independence, and enable mobility. Restricting opportunities for movement related to fear of falling could result in physical deconditioning, which, in turn, will contribute to an increased risk of falling. Moreover, nurses would be less inclined to use restrictive measures to prevent patients from falling.

**Longer Mean Time to First Fall**

In this study, subjects in the intervention group (14 days, CI: 6.3 to 21.2) experienced a significantly longer mean time until their first fall compared to the subjects in the control group (6 days, CI: 3.2 to 8.1). This result appears to indicate that a targeted multiple intervention strategy was successful in preventing patients from falling during the first 14 days of recruitment into the study. This period appears to be sufficient as a patient’s average length of stay in the study hospital was 9 days.
This finding is consistent with the work of Schwendimann et al.\textsuperscript{34} who found a longer mean time until the first fall of 12 days in the intervention group. This study selected adult patients with a mean age of 70 years admitted for an acute medical condition. The study by Schwendimann et al. selected adult patients with a mean age of 73 years admitted for acute medical conditions. Similar patient profiles, such as medical condition and mean age, could account for the consistent result.

The clinical implications of a longer mean time until the first fall is important for patients and their relatives, as it helps to confirm the effectiveness of the individualised targeted fall interventions, and ensure that the ward is a safe environment for recuperation. Furthermore, it helps to raise the morale of the nurses; that their efforts to prevent patients’ falls have contributed toward a positive outcome.

**Study Limitations**

There are six limitations in this study. First, the study was conducted within one (medical) discipline of the study hospital. These findings cannot then be applied generally to other disciplines. Second, the targeted multiple intervention strategy was conducted in a tightly controlled efficacy study. Interventions shown to be effective in tightly controlled efficacy studies do not necessarily yield similar results when implemented on a large scale in clinical settings.\textsuperscript{67} Third, this study did not address the estimated cost of implementing the targeted multiple
intervention strategy, and thus the cost effectiveness of implementing the program in a clinical setting cannot be determined. Fourth, this study was unable to confirm that the reduction in falls was a direct result of the interventions that were implemented, and not due to the subjects’ increased awareness of fall prevention. Fifth, the sample size was not adequately powered to detect a difference in fall injury rate. Lastly, the constant presence of the research nurses at the patients’ bedside, and increased buzzing for toileting assistance by the patients might alert nurses as to who was in the intervention arm of the study.

**Recommendations For Further Research**

This study has revealed four recommendations for further research. First, a replication of this study is necessary to affirm its results by using two hospitals, with one hospital serving as an ‘intervention’ site, while the other hospital serves as a ‘control’ site. Second, this study could be expanded to include other disciplines. Third, an adequate sample size to detect injury rate, and economic evaluation should be built into the outcome assessment protocol. Fourth, this study was unable to identify which of the targeted multiple interventions are most effective in reducing the fall rate, and so further research is required to identify which of these interventions is effective.
Conclusion

This study has provided an insight into the effectiveness of targeted multiple interventions reducing the number of falls in acute care inpatient hospitals. The results have demonstrated that the use of a targeted multiple intervention strategy was linked to a reduction in the number of falls, a reduction in the estimated relative risk of falls, and a longer mean time until the first fall in the intervention group. However, the use of a targeted multiple intervention strategy did not significantly reduce the incidence of fall-related injuries.
REFERENCES


8 Stetler C. Integration of evidence into practice and the change process: fall prevention program as a model. Outcomes Management for Nursing Practice 1999;3(3):102-111.


37. Altman D. Study to predict which elderly will falls will show difficulty in deriving and validating a model. British Medical Journal 1997;315(7118):1309.
Appendix 1

STUDY PROTOCOL

Admissions into the study wards during the recruitment period

Patient Assessment (Routine fall risk assessment done by ward RNs within 4 hours of admission)

Randomization

Inclusion Criteria
- Adult patients ≥ 21 years old
- Risk identification
  - Hendrich score ≥ 5
- Written informed consent given

Exclusion Criteria
- Unable to speak and understand English, Mandarin, Malay

Intervention Group
Educate patient and family members on targeted risk factor reduction (refer to appendix 4) in addition to the usual care
Reinforcement of educational session will be carried when required.

Control Group (Routine Care)
- Place green tag on patient’s wrist
- Place green alert card on head board
- Place call bell within reach
- Instruct patient to call for assistance by pressing the call bed
- Raise both cot sides
- Keep bed at its lowest position
- Reassess patient every shift

Follow-up till discharge or death
### Appendix 2

**TARGETED MULTIPLE INTERVENTIONS**

<table>
<thead>
<tr>
<th>Individual Risk Factors</th>
<th>Targeted Interventions</th>
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</table>
| **1** Confusion Disorientation Impulsivity | • Involve family members to sit with patient, and educate safety needs  
• Obtain permission from family members regarding use of body vest as outlines in the hospital policy if family members unable to sit in  
• Reinforce activity limit to patient and family members  
*Others (please specify)* |
| **2** Symptomatic Depression | • Refer to doctor |
| **3** Altered Elimination (bowel or urinary) | • Check whether patient is receiving laxative or diuretics  
• Educate patient on the effect of laxative or diuretics: increased frequency of elimination, muscle weakness due to increased elimination  
• Instruct patient to call for assistance to use the toilet every two hourly  
• Instruct patient family members to call for assistance with toileting and mobility  
*Others (please specify)* |
| **4** Dizziness /vertigo | • Review recent Hb and biochemistry result  
• Check for lying and standing blood pressure for postural hypotension. Report  
• Report any deficit to physician  
• Educate patient on the effect of dizziness  
• Advise patient on changing position slowly  
*Others (please specify)* |
| **5** Review medication related to fall risk  
• antiepileptics  
• benzodiazepines  
• diuretics | • Explain to patient that medication increases his/her risk of falling dizziness  
• Instruct patient to call for assistance for toileting, bathing and mobility  
*Others (please specify)* |
| **6** Difficulty with mobility | • Review recent biochemistry results  
• Instruct patient to mobilize with assistance  
• Escalate to doctor for referral to physiotherapist for exercise programme and/or for walking aids if necessary |
### Randomization List

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Dear Ang,

Re: Randomized controlled trial evaluating the use of targeted risk factor reduction nursing interventions to prevent falls in acute care hospital (DSRB-A/06/103)

Thank you for your DSRE Application. Please refer to the application as above. DSRB has reviewed the study and has the following preliminary comments.

1. DSRB Application Form

P/s amend the foll sections in the Application Form as suggested below (if applicable).
1. Patient Information Sheet and written Informed Consent Form:
   Please consider applying for waiver of consent/verbal consent as otherwise the subjects might be biased with the knowledge that they are research subjects.
2. Recruitment Process:
   Please specify which are the study wards, refer to pg 15 of the Application Form.

3. Data Safety Monitoring Plan:
   P/s add this info under this section which should be followed:

   Adverse Events
   All study related adverse events will be recorded and reported to the DSRB. For serious adverse events, the investigator will inform the PI within 24 hours of the event. For non-serious adverse events, all events will be recorded, tabulated in a final report and sent to DSRB within 2 months of the completion of the study.

II. Patient Information Sheet (PIS)
   a. If you decide to take written consent, please delete the guiding lines as well as the sections which are not applicable (instead of indicating as nil/NA) and re-number the rest of the sections. P/s rephrase the sentence under section II. "You are invited because...” you have a higher chance of falling…” so it might be misunderstood by the patient.
   b. If you decide not to obtain pt's consent/verbal consent, you have to apply for waiver of consent, and fill up Annex E attached.
DSRB Ref: **DSRB-A/06/103**

23 March 2006

Ms Emily Ang
Department of TCI
NUH

Dear Ms Ang

Randomized controlled trial evaluating the use of targeted risk factor reduction nursing interventions to prevent falls in acute care hospital

We are pleased to inform you that the NHG Domain Specific Review Board has approved the above research project to be conducted in NUH.

Documents reviewed are:

- a. IRB / DSRB Application Form: Randomized controlled trial evaluating the use of targeted risk factor reduction nursing interventions to prevent falls in acute care hospital: Version 1.0 dated 21 March 2006
- b. Appendix 1 & Appendix 2: Version 1.0 dated 21 March 2006
- c. Data Collection Form: Version 1.0 dated 21 March 2006

The approval period is from **23 March 2006** to **22 March 2007**. Your study number is **DSRB-A/06/103**. Please use this code for all future correspondence.

Continued approval is conditional upon your compliance with the following requirements:

1. No deviation from, or changes of the protocol should be implemented without documented approval from the NHG DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change of monitor or telephone number).
2. Any deviation from, or a change of, the protocol to eliminate an immediate hazard should be promptly reported to the NHG DSRB within seven calendar days.

3. Please submit the following to the NHG DSRB:

a. Report on any new information that may adversely affect the safety of the subject or the conduct of the study.

b. NHG DSRB Bi-annual Status/Report Form — this is to be submitted 4 to 6 weeks prior to expiry of the approval period. The study cannot continue beyond the expiry date until re-approved by the NHG DSRB.

c. Study completion or termination report, if applicable

With best regards,

A/Prof Glenn Yoke Chan
Deputy Chairman
NHG Domain-Specific Review Board A

Cc: Director of Research, NHG (via fax only)
(05) OFFICE OF BIOLOGICAL RESEARCH, NHG
Chief, Department of TCI, NHG

Page 2 of 4

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Appendix 5

Study Title: Randomised controlled trial evaluating the use of targeted risk factor reduction nursing interventions to prevent falls in acute care

Section A: Demographic (To be completed when Hendrich score ≥ 5)

Instruction: Pls shade the correct code no.

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Instruction: Please shade the correct number in the bubble provided. Pls shade only one item for each section.

1. Study Group: 1 Control  2 Intervention

2. Discipline: 1 Medical  2 Oncology

3. Age:

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4. Sex: 1 Male  2 Female

5. Race: 1 Chinese  2 Malay  3 Indian  4 Eurasian
   5 Others (please specify)

6. Current Condition:

   1 Cardiology  6 Oncology/Haematology
   2 Respiratory  7 Neurology
   3 Gastro-enterology  8 Geriatric medicine
   4 Renal  9 Others (please specify)
   5 Endocrine

Name of Assessor: 1 2 3 4  Date of Assessment: __________

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Study Title: Randomised controlled trial evaluating the use of targeted risk factor reduction nursing interventions to prevent falls in acute care

Section B: (to be completed only when patient fall)

Instruction: Pls shade the correct code no.

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Pt's Name: ________________
Reg no: ________________
Date of Admission: __________

1. When did the patient fall?

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Date:

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</tbody>
</table>

Time:

2. Where did the patient fall?

1. Bathroom
2. Bedside
3. Patient cubicle
4. Toilet
5. Ward corridor
6. Others:
   (please specify)

3. What was the patient doing at the time of fall?

1. Attempting to get into bed
2. Attempting to get out of bed
3. Bathing
4. Dressing up
5. Reaching for things
6. Toileting
7. Transfer self/assisted
8. Others:
   (please specify)
Study Title: Randomised controlled trial evaluating the use of targeted risk factor reduction nursing interventions to prevent falls in acute care

4. How did the patient fall?
   ① Climbed over bed rails
   ② Dropped/mishandled patient
   ③ Fall from bed/bed trolley/table
   ④ Fall from chair/commode/shower/wheelchair
   ⑤ Found on floor
   ⑥ Lost balance/unsteady gait/fainted
   ⑦ Removed restraint(s)
   ⑧ Slipped or tripped
   ⑨ Others
   (please specify)

5. What was the outcome of the fall? *

<table>
<thead>
<tr>
<th>Severity</th>
<th>Outcome of the fall</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>contusion</td>
</tr>
<tr>
<td>②</td>
<td>abrasion</td>
</tr>
<tr>
<td>③</td>
<td>small skin tear or laceration</td>
</tr>
<tr>
<td>④</td>
<td>little or no tear</td>
</tr>
<tr>
<td>⑤</td>
<td>sprain or deep laceration</td>
</tr>
<tr>
<td>⑥</td>
<td>skin tear or minor contusion with medical and/or nursing intervention</td>
</tr>
<tr>
<td>⑦</td>
<td>forms of intervention include suturing/pressure bandage/ice bag</td>
</tr>
<tr>
<td>⑧</td>
<td>fracture</td>
</tr>
<tr>
<td>⑨</td>
<td>loss of consciousness</td>
</tr>
<tr>
<td>⑩</td>
<td>change in mental or physical status requiring medical intervention or consultation</td>
</tr>
</tbody>
</table>

6. State Medical / Nursing management given:
   ① Observation
   ② Pressure dressing
   ③ Surgery
   ④ Pain Relief
   ⑤ Dressing to wound
   ⑥ Application of back slab
   ⑦ Application of traction
   ⑧ Repair of fracture
   ⑨ Others: Pls specify

Name of Assessor: ① ② ③ ④
Date of Assessment: __________
### Hendrich II Fall Risk Model © 2004

**Appendix 6**

**Name of Assessor:**

**Date of Assessment:**

**Ward no.:**

**Instruction:** Please shade the only one bubble in each row i.e. present / absent

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Definition</th>
<th>Present</th>
<th>Absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confusion Disorientation Impulsivity</td>
<td>Patient is disoriented to time, place, and/or person. Patient is unable to retain or receive instructions or displays impaired judgment. This may be a progressive neurological state, drug induced, or behavioral in origin. Stroke patients (left hemi) may exhibit impulsive, unpredictable behavior as a result of the cerebral insult.</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Symptomatic Depression</td>
<td>Medical diagnosis or nursing assessment finds the patient appears depressed, is not interacting appropriately, is tearful, withdrawn, or the patient states they are depressed. If the depression is managed with drugs and/or therapies in need NOT be scored if the depression is therapeutically in control.</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Altered Elimination</td>
<td>Altered elimination from the clinical norm, such as incontinence, nocturia, frequency, urgency or stress incontinence, diaries, or related to use of catheters. This does NOT include a Foley or indwelling catheter UNLESS it causes symptoms referenced above while in use with the patient. When the catheter is removed, it can be a high-risk time until normal elimination is established.</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness Vertigo</td>
<td>Medical diagnosis of vertigo or the patient reports they feel like they are spinning or the room is spinning. Sway path may be present when the patient stands (circular motion upon arising). This is often seen in the aging adult with poor gait and balance and can occur as a result of some drug side effects.</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Any Prescribed Antiepileptics</td>
<td>Carbamazepine, Divalproex Sodium, Ethotoin, Ethosuximide, Felbamate, Fosphenytoin, Gabapentin, Lamotrigine, Mephenytoin, Methsuximide, Phenobarbital, Phenytoin, Primidone, Topiramate, Trimethadione, Valproic Acid</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Any Prescribed Benzodiazepines</td>
<td>Alprazolam, Buspirone, Chloridepoxide, Clonazepam, Clozapetine Dipotassium, Diazepam, Flurazepam, Halazepam, Lorazepam, Midazolam, Oxazepam, Temazepam, Triazolam</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

#### Get Up & Go Test

With patient sitting in a chair (preferred) or on the side of the bed, place palm of hands flat on thighs and ask the patient to stand without assistance. Score the patient according to the guidelines below.

**Instruction:** Pls shade only one bubble

| Ability to rise in a single movement | 6 |
| Pushes up, successful in one attempt | 3 |
| Multiple attempts, but successful | 3 |
| Unable to rise without assistance during test (OR if a medical order states the same and/or complete bed rest is ordered or ADL dependent) | 4 |

**TOTAL SCORE**

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**Note:**

1. To be completed for all new admissions when performing nursing assessment.
2. Place completed forms into prepared box ASAP.
TARGETED RISK REDUCTION NURSING INTERVENTIONS

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Targeted Interventions</th>
<th>Remarks (if any)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Confusion</td>
<td>• Check if nurse has informed family members to sit with patient. If not, contact the family.</td>
<td></td>
</tr>
<tr>
<td>Disorientation</td>
<td>• Involve family members to sit with patient, and educate safety needs:</td>
<td></td>
</tr>
<tr>
<td>Impulsivity</td>
<td>- not to put cot sides down if the nurse has done so</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- not to leave patient alone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- inform nurse when leaving</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Obtain permission from family members regarding use of body vest as outlines in the hospital policy if family members unable to sit in</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reinforce activity limit to patient and family members</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- call the nurse if patient wants to get out of bed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inform ward staff to monitor patient closely</td>
<td></td>
</tr>
<tr>
<td>2 Symptomatic Depression</td>
<td>• Check for referral to doctor. Inform nurse to follow up if not done.</td>
<td></td>
</tr>
<tr>
<td>3 Dizziness /vertigo</td>
<td>• Review recent Hb and biochemistry result</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check for lying and standing blood pressure for postural hypotension</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check that any deficit is noted by physician</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Educate patient on the effect of dizziness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Advise patient on changing position slowly</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Others (please specify)</td>
<td></td>
</tr>
<tr>
<td>Risk Factors</td>
<td>Targeted Interventions</td>
<td>Remarks (if any)</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>4  Review medication related to fall risk</td>
<td>• Explain to patient that medication effect/side effect increases his/her risk of falling</td>
<td></td>
</tr>
<tr>
<td>• antiepileptics</td>
<td>• Instruct patient to call for assistance for toileting, bathing and mobility</td>
<td></td>
</tr>
<tr>
<td>• benzodiazepines</td>
<td>Others (please specify)</td>
<td></td>
</tr>
<tr>
<td>• diuretics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5  Difficulty with mobility</td>
<td>• Review recent biochemistry results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For score 3 &amp; above, instruct patient to mobilize with assistance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Escalate to doctor for referral to physiotherapist for exercise programme and/or for walking aids if necessary</td>
<td></td>
</tr>
</tbody>
</table>

Any Other Comments:
Section 4: Conclusion
<table>
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<th>Page</th>
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<td>Implications to Practices</td>
<td>253</td>
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<td>Future Directions in Fall Research</td>
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<td>Translation of Research Evidence</td>
<td>261</td>
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<tr>
<td>Conclusion</td>
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<tr>
<td>References</td>
<td>264</td>
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</tbody>
</table>
Section 4

This section of the portfolio presents a summary of the two pieces of research, their implications for nursing practices, and future directions for nursing research in the area of fall prevention in acute care inpatient hospitals. It also presents strategies for translating the research evidence.

Introduction

As was previously asserted in Section 1, falls are the most common and serious injuries that nurses must deal with in acute care inpatient hospitals. This problem is likely to be exacerbated by an aging population, as most inpatients now are elderly people. Many inpatients have physical and cognitive limitations, frailty and dementia, and are unfamiliar with the hazardous surroundings of the hospital. The best practice would be the use of fall-risk assessment tools to identify patients at risk of falling, and institutionalise appropriate interventions to minimise those risks. The research presented here aimed to identify the fall-risk assessment tools that have the best predictive validity and reliability, as well as determining the effectiveness of a targeted multiple intervention strategy to reduce the number of falls of inpatients. The results provided a broad insight into the topic and highlighted the implications for clinical practice. Further research to improve fall prevention practices is needed, as is discussed below.
Summary of the Two Studies

The literature review presented in Section 1 highlighted the need for further evaluation of fall-risk assessment tools in acute care inpatient hospitals. The purpose of the first study was to evaluate the validity and reliability of three pre-selected fall-risk assessment tools: the Morse Fall Scale, STRATIFY and the Hendrich II Fall Risk Model. By evaluating these three tools, it was intended for the findings to assist the researcher in identifying one specific tool that had the best predictive validity and reliability, and that could then be used for the second study. Moreover, it was hoped that the findings would provide information that would help nurses select an assessment tool for use in clinical practice.

As a result, a prospective descriptive study was conducted over a five-month period divided in two stages where different subjects volunteered for each stage. Stage I was the inter-rater reliability component in which 144 observations were carried out independently by two research nurses using three fall-risk assessment tools. Stage II was the validity component in which two research nurses assessed a total of 5,489 subjects using the three fall-risk assessment tools.

The findings of this study demonstrated that the inter-rater reliability of the three tools were good with kappa values all higher than 0.80. STRATIFY, (with a cut-off score of ≥ 2 and ≥ 3), had the lowest sensitivity values at 25% and 55%, respectively. The Morse Fall Scale, (with a cut-off score of ≥ 25), and the Hendrich II Fall Risk Model, (with a cut-off score of ≥ 5), had both strong
sensitivity values of 88% and 70%, respectively. The specificity of all tools was more than 60%, except that of the Morse Fall Scale with a cut-off score of ≥ 25. However, only the Hendrich II Fall Risk Model had an acceptable specificity of 61% compared to that of the Morse Fall Scale (specificity = 48.3%). Thus, the Hendrich II Fall Risk Model provided a better balance in terms of sensitivity and specificity values.

The second part of research was directed towards fall prevention interventions. The objective was to determine the effectiveness of a targeted multiple intervention strategy in reducing the number of falls in an acute care inpatient hospital. By evaluating these interventions through research, it was intended for the findings to assist nurses formulate evidence-based protocol(s) that would inform and instruct them with regards to effective fall prevention intervention strategy.

As the randomised controlled trial enabled the outcomes of a particular clinical intervention to be reliably measured, and because the evidence provided was considered valid and reliable in guiding clinical practice decision-making, this particular research method was used in the second part of this work. The randomised controlled trial was designed to compare the effectiveness of a targeted multiple intervention strategy, which involved 1,822 patients who met the inclusion and exclusion criteria and were randomly assigned to either the intervention or control group. The intervention group received the hospital’s
routine fall prevention interventions, as well as targeted multiple interventions, while the control group received only the hospital’s routine fall prevention interventions.

The findings of this study indicated that the use of a targeted multiple intervention strategy was linked to reductions in the mean number of falls, the relative risk of recorded falls, the number of injuries, as well as being associated with a longer mean time until the first fall in the intervention group.

**Implications to Practices**

The results of the two studies highlighted eight factors that have implications in clinical practice: patient population and the choice of cut-off scores, fall-risk scoring, reliability of the tool, nurses’ time and training, the use of targeted multiple fall interventions, and infrequent fall-risk assessment.

**Patient Population and Cut-off Score**

The results clearly showed that the patient population and the choice of cut-off scores influenced the sensitivity and specificity values of the tools.

**Patient Population**

The results corroborate Oliver’s notion that the efficacy of the tools in classifying fallers and non-fallers ‘tends to diminish the more the population is not similar to the original validation cohort.’ For example, STRATIFY was originally developed for an adult population over the age of 80 years that were admitted into
three district general hospitals for medical conditions. Evaluating the STRATIFY tool in an acute care population had resulted in the lowest predictive values. This result has important implications for choosing an appropriate tool in clinical practice. As it is useful to perform an audit to determine the patients’ fall-risk profile first, it is, therefore, necessary to choose a tool that reflects similar patient populations and fall-risk profiles in order to follow the evaluation of a patient’s profile.  

Cut-off Score

The results showed that cut-off scores were influenced by the sensitivity and specificity values of the tools. This has implications for clinical practice as nurses have traditionally been tempted to develop homemade tools, or import a fall-risk assessment tool into clinical practice without first validating it.  

This practice must change, and nurses need to realise the importance of determining the sensitivity and specificity values of tools at the optimal cut-off score before implementing them into clinical practice. Moreover, the patients’ risk of falling varies across specialties, hospitals and countries, which poses a problem when determining an optimal high-risk score. For example, if a score is set low enough to detect all possible falls in a surgical unit, then almost all the patients in that medical unit will be at high-risk for falls. Thus, the optimal score indicating a high-risk for falls must be determined by each specialty, and not hospital-wide.
Reliability of Tool

The results showed that a tool with good inter-rater reliability is important in clinical practice, as many nurses will use the tool to perform fall-risk assessments. The tool needs to yield similar results, irrespective of who is using the tool. Thus, it is essential to formulate a structured training program, and to conduct training before implementing any new tool into clinical practice. The contents of the program should include the importance of performing fall-risk assessments correctly, a demonstration on how to conduct a fall-risk assessment, and practice sessions.

Fall Risk Scoring

The results clearly demonstrated that tools such as STRATIFY, the Morse Fall Scale, and the Hendrich II Fall Risk Model under or over predicted falls, even when these tools were developed using rigorous research designs and validated in settings where they were being used. These results have important clinical implications in terms of ‘misdirecting resources when tools incorrectly identify patients as high risk, and through missing patients who are identified as low risk but go on to fall’\(^7\) (p.36).

Oliver argued that fall-risk scores are designed to predict falls, which is not the same as preventing falls. Moreover, fall-risk scores do not always include risk factors that could be modified. If a risk score is used, a further assessment is still required that identifies and treats the risk factors, and that can be modified.\(^3\) Thus,
Oliver\textsuperscript{8} recommended looking out for common treatable risk factors for falls that have been consistently identified in literature for all patients admitted to hospitals. These treatable risk factors are: recent falls, delirium, agitation or behavioural disturbance, gait instability and lower limb weakness, postural hypotension or faint urinary frequency/incontinence, and prescription of ‘culprit’ drugs\textsuperscript{8}. It is then recommended to formulate a care plan for each one of these factors instead of relying on a fall-risk assessment tool to categorise patients being at low or high risk of falling. Perhaps it would be worthwhile exploring the possibility of implementing this recommendation in clinical practice.\textsuperscript{1,8}

\textbf{Nurses’ Time and Training}

The second study clearly demonstrated that a planned, systematic and individualised approach is necessary to create effective interventions. In order to achieve this, time and training to implement targeted multiple fall interventions is required. Thus, two experienced registered nurses were employed for the study through additional funding. As highlighted by Morse,\textsuperscript{9} this has an implication in clinical practice as nursing directors and hospital administrators need to realise that a fall prevention program is not something that can simply be added on to a nurse’s workload without incurring extra costs. In order for effective interventions to take place and for falls to be prevented, support and commitment to funding for the recruitment of extra nurses for the program is required.\textsuperscript{9}
Use of Targeted Multiple Intervention Strategy

The results provided reasonable evidence that interventions to prevent falls must be individualised, as each patient is affected differently by the interplay of different risk factors. This can be achieved through the use of checklists or care plans that provide a list of treatable risk factors linked to suggested interventions that emphasise the patient’s individuality. Nurses need to be appropriately trained to gain in-depth knowledge and experience in evidence-based fall prevention strategies, as well as targeted multiple intervention strategy that can be tailored to address different risk factors. This is important as the findings of this study proved that targeted multiple intervention strategy were better in reducing the number of falls in an acute care inpatient hospital than universal multiple interventions. As a patient condition and circumstances that lead up to hospitalisation varies, so too must fall prevention strategies. A conservative attitude that advocates predetermined universal multiple intervention programs are suitable for all patients, or patients with certain scores, is no longer appropriate in an environment with patients of varying acuity.

Infrequent Fall-risk Assessment

The results showed that performing a fall-risk assessment only at admission prevented the time until first fall from extending beyond 14 days. The clinical implications of this result are that patients’ conditions in acute care inpatient hospitals are relatively unstable, and that their conditions and risk factors changes. Thus, nurses need to recognise the importance of performing fall-risk assessments
upon admission of the patient and thereafter if their condition changes,\textsuperscript{5} so that interventions can be adjusted to target any new fall-risk factors.

**Future Directions in Fall Research**

The data from the two studies provided reasonable evidence that using a tool that had been validated in the setting in which it was intended to be used, and that using targeted multiple interventions are effective in reducing the number of falls in an acute inpatient hospital. However, these interventions must not be used separately, but in conjunction with other factors that are crucial to an effective fall prevention program. This important issue warrants further examination and research. Some of these other factors include the patients’ view on fall prevention interventions, patients’ education, nurses’ knowledge, skills and attitudes, and the financial costs.

**Patients’ Views on Fall Prevention Interventions**

The interventions tested in this study did not include the patients’ input and thus, the factors that motivate them to accept and comply with the interventions are unclear. Whitehead and colleagues\textsuperscript{10} noted that interventions used in clinical trials may not be attractive to the general population of patients. The benefits of involving the patients and their families require further review. Perhaps the patients’ view and acceptability of the interventions in acute care in-patient hospitals should be considered, as it is essential in ensuring patient compliance
with fall prevention strategies whilst preserving the individual’s right to dignity, independence, and choice on the risks that they are prepared to accept.  

**Patients’ Education**

The second study incorporated an educational component for patients to assist with producing an encouraging result through the use of targeted multiple interventions. However, the study did not include the individual effectiveness of the educational component as a contributor in the targeted multiple fall prevention interventions program. Further research is, therefore, required to explore an educational model of providing an effective targeted multiple fall interventions program to patients within the resource constraints of a contemporary acute care inpatient environment.

**Nurses’ Knowledge and Skills**

The labour-intensive fall-risk assessments and subsequent targeted multiple fall prevention interventions were conducted using external funding, which was used to employ two experienced registered nurses dedicated to the study. Although this approach was appropriate for a proof-of-concept study, it is unlikely to be economically viable given the present resource constraints in the acute care inpatient environment. Future study could explore whether a program that expands the knowledge and skills of nurses in targeted multiple interventions fall prevention program, can reduce the number of falls in acute care inpatient hospitals.
Nurses’ Attitude

It is unclear in this study if a reduction of fall rate can be contributed to the positive attitude of the two registered nurses who implemented the fall prevention program. Morse\textsuperscript{11} identified that the successful reduction of patient falls lay in the attitude of the nurses. Semin-Goossens and colleagues\textsuperscript{12} reported a failed attempt to implement an evidence-based guideline for fall prevention because in their study, the nurses expressed believed it was impossible to prevent patients from falling, and patient falls were seen as an unavoidable event rather than something predictable and preventable. Similar beliefs were also shared by the nurses in Dempsey’s research.\textsuperscript{13} Semin-Goossens et al.\textsuperscript{12} recognised that the most successful strategy in fall prevention appeared to changing the nurses’ attitudes, but no clear strategy on how best to achieve this was provided. A strategy such as academic detailing may help change the nurses’ attitude. Academic detailing is a technique/teaching and learning strategy originally used as a marketing strategy to improve sales, which has been adapted by the health care industry to improve professional health practice and health care outcomes.\textsuperscript{14} It has been found to be effective in changing the behaviour of physicians’ prescribing practice, in preventive service, and in improving health outcomes.\textsuperscript{15} It would be useful to summarise and evaluate the research already conducted on this topic.
Financial Costs

Although, this study illustrated that using targeted multiple interventions is an effective way to reduce the number of falls in an acute care inpatient hospital, the financial costs of implementing such a program are not known. Further work is needed to determine the cost benefits in applying this evidence to clinical practice. Economic analysis is becoming increasingly important, as the cost-effectiveness of targeted multiple interventions comes under close scrutiny, especially with the current diminishing health care resources.

Translation of Research Evidence

The results from this portfolio have promoted awareness for the need to review current practices on fall prevention in the study hospital. Tinetti noted that ‘the clinical and public health integration of fall prevention programs has lagged, and continues to lag, far behind the research findings’ (p.676). Thus, the principal investigator of this portfolio has an obligation to clearly articulate the relevant findings of these studies to all health care professionals and the community. That is, to draw their attention, and to work towards translating the research findings into better clinical and public health practices. These findings will be promoted through the publication of this portfolio in peer-reviewed journals as well as through presentations at national and international levels, including patient and public forums. More importantly, strategic planning and policy development is required to translate the evidence from this work and apply it to the relevant ‘at-
risk’ population in the study hospital. This will require cooperation and support from patients, nurses, ward managers, and nursing directors.

Conclusion

This portfolio of research has investigated nursing practices in two major areas of fall prevention: 1) the evaluation of fall-risk assessment tools, and 2) the effectiveness of targeted multiple interventions in an acute care inpatient hospital. Several areas have been highlighted where nursing practice can be improved. These include selecting a fall-risk assessment tool that is suited to the patient population, and establishing the optimal fall-risk score and reliability before adopting the tool into practice. It also raises awareness that even tools that were developed using rigorous research designs and validated in a particular patient population, ended up under or over predicting falls. Thus, the focus should shift toward directly identifying and treating those reversible risk factors. Moreover, this work revealed that a targeted multiple interventions approach was better than the hospital’s existing universal intervention approach.

Further research in several areas is necessary to enhance the effectiveness of the fall prevention program. These areas include: the patient’s views on fall prevention, exploring an education model for patients, an educational program that will enhance the knowledge and skills of nurses in fall prevention, providing a strategy for changing the attitudes of nurses on fall prevention, and determining 262
the financial costs of implementing targeted multiple fall interventions in clinical practice.

From the results obtained in this portfolio, strategies have been recommended for the translation of research evidence, which include: reviewing the current fall prevention practices in the study hospital, disseminating this evidence through publications in peer-reviewed journals, presenting at national and international conferences, and performing strategic planning and policy to applying these findings to the relevant ‘at-risk’ population in the study hospital.
REFERENCES

Section 5: Publication

NOTE: This publication is included in the print copy of the thesis held in the University of Adelaide Library.

It is also available online to authorised users at:

http://dx.doi.org/10.1111/j.1365-2648.2007.04419.x