A. Study Purpose and Rationale

The increased life expectancy of the population and rising rate of age-related illnesses have led to an increased incidence of acute conditions requiring hospitalization. [1] The Centers for Disease Control (CDC) state that falls are the third most common cause of unintentional injury or death across all age groups and the leading cause among people aged 65 years and older. These data, however, do not differentiate between falls that happen at home and those that occur in hospitals. [2] Inpatient falls consistently compose the largest single category of reported incidents in hospitals, affecting from between 2% to 10% of annual hospital admissions. [3] Among adults over 65 years old, most falls occur in hospitals and nursing homes, where the rate of falls reaches 1.5 per bed annually, almost three times the rate for community dwelling elderly persons. [4] This is an area of great importance, as patients who fall incur physical injuries and adverse psychological effects and have greater lengths of stay in the hospital. [5] It is estimated that the total cost of fall injuries for older people was $20.2 billion per year in the United States in 1994, and that it would reach $32.4 billion in 2020, while others put the 2020 costs at $43.8 billion. [6] It has been estimated that 30% of inpatient falls result in injury, with 4% to 6% resulting in serious injury. [7]

A large body of literature examines the causes and risk factors involved in patient falls in hospitals. Fall risk is generally considered to be multimodal, with a combination of factors most often leading to a fall. [8] These risks are articulated in terms of intrinsic and extrinsic factors. Intervention studies typically focus on moderating intrinsic (ie: poor balance, weakness, drug effects) and extrinsic (ie: reducing barriers, eliminating hazards, adding external reminder cues) conditions. The occurrence of falls in the hospital setting is largely determined by patient traits, one being age which has been closely associated with the risk of falling. The literature documents that the majority of hospital adult falls are related to intrinsic causes, with fewer than 10% to 15% caused by the environment alone. [9]

Although the role of the environment in causing or preventing patient falls is widely accepted such that the American Institute of Architects (AIA) has recommended private rooms become the industry standard in all new construction of acute care hospitals, [10] there is no conclusive evidence linking environmental interventions with reduced falls. Studies have sought to identify the design issues that might have contributed to falls (such as the placement of doorways, handrails, and toilets), but no studies have determined the independent impact of a single design factor on the incidence of falls. [6] Previous studies have examined the locations of fall incidents retrospectively with several studies indicating the majority of falls occur in patient rooms when patients are alone and attempting to reach the bathroom, [6,3] or are within the bathroom. One study reported transfers to and from bed as the cause of 42.2% of inpatient falls. [5] In another study, a group of researchers analyzed 1-year fall data (267 falls), and reported that 38% of the falls occurred during transfers to and from bed and 16.1% during toileting. [11] Although fall-
prevention strategies that include environmental modification have worked in the past, it is not clear how much the effectiveness of such strategies can be attributed to environmental factors alone. [6]

Furthermore, many existing hospitals have a significant number of semi-private rooms which are likely to remain in use for the foreseeable future secondary to space and financial constraints. Given the hospital building boom to meet an increased demand and the costs of healthcare construction, it is becoming the industry standard to employ principles of Evidence-Based Design (EBD), defined by The Center for Health Design as “the process of basing decisions about the built environment on credible research to achieve the best possible outcomes.”[12] While the EBD literature has been growing since being officially defined in 2003, [13] there have been limited studies to determine which type of room may have the best outcomes for a specific patient population.

Besides the lack of literature addressing the room type related to patient falls, there is no evidence to date which documents bed location and falls within a shared room. Anecdotal evidence has suggested that the rate of patient falls may be reduced in private rooms that have space to accommodate family members. [8] A large coronary critical care unit (with limited visiting times) with centralized nurse stations was renovated from two-bed rooms to single rooms designed to support family presence and localized nurse stations having direct visual access to patients. The combination of single rooms designed for family presence, and localized nurse stations with good visual access to patients, cut falls by more than two-thirds. [14,15] The researchers proposed that the greater presence of family helped prevent falls by reducing the risk that patients would get out of bed unassisted or unobserved. However, the rate of falls has also been found to be significantly higher for rooms with direct visibility to commonly occupied workstations than to infrequently used workstations or rooms with no direct visibility, attributed to policies that place patients with high fall risk in rooms closest to the nursing stations. [8] Therefore, data on increased patient supervision and monitoring to prevent falls have been inconclusive.

Although the hospital environment and more specifically the design of the hospital room appears to have an effect on the prevention of falls and the safe care of patients, there is little conclusive evidence to support a specific design or type of hospital room where falls occur less frequently. A recent retrospective case comparative study determined that room type may play a role in the occurrence of falls in hospitalized older adults. [1] Another cross-sectional analysis of multiple sites using archival fall data identified a number of design characteristics that were associated with greater or fewer falls, including visibility to staff work spaces, presence of a dedicated family space in the room, bathroom layout and various supportive features. [8]

In summary, the existing literature is relatively weak in identifying the impact which the designed and built environment might have on falls. While a number of features have been identified to potentially impact falls or fall risk, virtually no studies have actually linked these factors with differences in fall rates. Thus, the goal of the proposed retrospective study is to identify whether the bed location within a semi-private room is associated with fall risk.
B. Study Design and Statistical Analysis

Study Design
The proposed study design will be a retrospective cohort study of geriatric patients (age > 65 years) hospitalized at NYPH/CUMC. Designing experiments to study fall prevention is challenging since randomized controlled trials cannot be performed because once risk status is established, it would be unethical to withhold measures to prevent falls, that is, to place the patient in a no-treatment/control group. [16]

The aim of the study will be to examine data for an association between patient falls and bed location within the semi-private room design. The semi-private room is defined as a patient room containing two beds, one located adjacent to the exterior wall containing a window (window bed) and the other one located closer to the entry of the room and further from the window (non-window bed) with a shared toilet room located on the corridor side in close proximity to the non-window bed (See Figure I).

![Figure I](image.png)

**Figure I.** Example of a semi-private patient room layout at NYPH/CUMC with two bed locations: (1) window bed and (2) non-window bed. Net area in square feet is provided for the room and the toilet room separately.

It is hypothesized that the proportion of falls from the window bed location will be significantly different and fewer than what is assumed to be the proportion of falls expected if there is no falling risk (set at 0.5 or 50%). It is postulated that although the window bed may be farther from the toilet room, patients are closer to the beneficial effects of natural light from the window which may improve circadian rhythms, maintain normal sleep-wake cycles, and limit the effect of poor sleep on outcomes such as delirium. [6] Regarding design, there is some evidence that sensory deprivation from environmental design (ie: lack of windows) can be associated with higher rates of delirium. However, it is recognized that these studies were conducted in ICUs with comparison groups which may not have been well-controlled for certain other factors. [17,18]

For the current study proposal, a fall will be defined in accordance with the World Health
Organization’s (WHO) definition: “an event which results in a person coming to rest inadvertently on the ground or floor or other lower level.” [19] Because of the use of retrospective data, only falls that result in an incident report being filed within NYPH’s electronic system will be included. It is recognized that due to the retrospective nature of the study design, there may be an element of under-reporting of falls.

The recruitment strategy to determine the sample size involved a single group chi-square test needed for the cohort, yielding $N = 420$. This was increased upwards and therefore 500 fallers will be studied. This sample size will need to be made up of falls within semi-private rooms so all falls within private rooms will be excluded prior to reaching the final $N$ value. In order to obtain the sample size, data collection will go back in time until the maximum $N$ is reached, without a particular time period defined in advance.

The objective of the proposed study is to demonstrate that environmental factors are independently associated with falls. Therefore, intrinsic factors will be taken into consideration and several key confounders will be collected during chart review: age, gender, medical history, medications, baseline function prior to admission, gait, balance, cognition including a history of dementia, delirium while in hospital or prior to admission, home versus assisted living versus skilled nursing facility (SNF), a history of falls, use of assistive device(s), home health aide or caregiver, vision, and hearing. In addition to intrinsic confounders, architectural or extrinsic confounders will also be recorded to include the distance of the patient room to the central nursing station, sight lines to the nursing station, and distance to the toilet room from each bed location for a typical semi-private room design. Time of day or night when falls occurred will also be noted.

The outcome measure will be proportion of falls in the window bed compared to the proportion of falls in the non-window bed. Of note, all semi-private rooms within the hospital have the same basic architectural layout. All semi-private rooms have the two beds configured in the same way, allowing one bed window access while the other one is parallel to the window bed and closer to the toilet room (See Figure I). The sample will consist of fallers. Due to the randomized nature of bed allocation within the semi-private rooms, a control group is not required in trying to determine an association.

Statistical Procedures
Data will be accessed using MERS-TH (Medical Event Reporting System- Total Healthcare), which records all falls in the hospital. Information will be extracted from the MERS database including demographics such as age > 65 which is an important variable when studying fall risk and other health outcomes in older adults. Because location of a fall is not recorded within the MERS database, the data collection will not be fully de-identified as medical record numbers (MRN) will be used to perform a more detailed chart review in order to determine room and bed location at the time of the fall.

Within the semi-private room model, it is presumed that allocation of patients to bed location (ie: window bed versus non-window bed) is done randomly. This would imply a 0.5 (50%) chance of being admitted to either bed type and yields an inherent randomization to the study sample. This acts to minimize confounders between window and non-window subjects. Of note, actual hospital utilization records will be obtained prior to the study in order to confirm this assumption.
of randomly assigning bed locations. If, for example, it is found that patients are initially admitted to window beds until those are at full capacity and then non-window bed are filled next, the proportion of 0.5 (50%) will need to be updated and the calculations for power and sample size readjusted.

**Power Calculations**

A 25% risk reduction was determined as the proportion needed to compare to 0.5 (proportion of falls expected if no falling risk) in order to find significance. This was determined by taking an example of 1000 patients and the assumption that 100 may experience a fall in a non-window bed (this estimate is based on numbers found in the literature which state that the vast majority of elderly individuals who were recorded to fall actually fell at home, and 10% fell in health care settings [20]), while 75 may experience a fall in a window-bed. Using the proportion of window fallers to total fallers (75/175), a rate of 0.43 (43%) was determined. The effect size in this case would be $0.5 - 0.43 = 0.07$ (7%). A single group chi-square test was performed to determine the sample size needed for the cohort, in other words, the number of fallers needed to find a difference from 0.43. The calculation yielded an $N=420$. This was increased upwards and therefore 500 falls will be studied. This sample size will need to be made up of falls within semi-private rooms so all falls within private rooms will be excluded prior to reaching the final N value. In order to obtain the sample size, data collection will go back in time until the maximum N is reached, without a particular time period defined in advance.

In summary, it is hypothesized that fewer patients will fall in a window bed, so the study will be powered ($p<.05$, 80% power) to detect a 25% risk reduction (absolute decrease in falls of at least 7%) for the window group. The study will include 500 patients with documented falls, validated by using the Chi-square test to approximate the size of the cohort. [21]

**C. Study Procedure**

There are no procedures to be performed in this study. Specifics of the study design are described above.

**D. Study Drugs**

There are no drugs or devices involved in this study.

**E. Medical Device**

Not applicable

**F. Study Questionnaires**

This study involves secondary data analysis, so there are no primary questionnaires.

**G. Study Subjects**

Chart reviews of patients aged > 65 years who have had a documented fall while in hospital and within a semi-private room on a medical-surgical unit. There will be no active recruitment of patients for this study.
**Inclusion Criteria:**
- Patients over the age of 65
- Patients who were admitted to the hospital on a general medical-surgical unit
- Patients with at least one documented fall while hospitalized

**Exclusion Criteria:**
- Patients admitted to the Intensive Care Units (ICU) and Cardiac Care Unit (CCU)
- Patients who have fallen while admitted within a private room
- Of note, we will not exclude patients with cognitive impairment as these patients are more likely to fall

*The challenge will be to determine a patient's cognitive status since most charts will not have MMSE or the CAM provided. However, proxy measures could be used such as documentation of orientation, IADL/ADL functioning or the nursing admission form recording prior level of function, etc.*

**H. Recruitment of Subjects**
No recruitment required since this is a retrospective study.

**I. Confidentiality of Study Data**
All the data taken from this project will be stored in safe and secure locations only accessible to the research team members assigned to this project. All study files will be stored in password protected files on Columbia University Medical Center computers. Only project staff will be able to access them. Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the Columbia University Medical Center will take steps allowable by law to protect the privacy of personal information. In some cases, participants' information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

**J. Potential Conflict of Interest**
The principal investigator is currently involved in the Milstein building’s redevelopment project on the NYPH/CUMC campus looking at the re-design of the medical-surgical bed units.

**K. Location of Study**
Charts will be reviewed from the medical-surgical patient units at NYPH/CUMC.

**L. Potential Risks**
The potential risks are minimal and are related to breach of confidentiality. Information collected may be accidentally disclosed to a person not involved in the study. The potential risks for disclosure of private health information will be minimal, as measures listed above will be taken to ensure patient confidentiality. These include a code assigned to identify the participant, locked files, password protected files, and destruction of the participant list after study completion. We have used the same procedures for other projects with success and it is expected that they will continue to be effective.
M. Potential Benefits
Research is designed to benefit society by gaining new knowledge. Participants may not benefit personally from being in this research study. However, future hospitalized elderly patients may benefit because this information can be used as preliminary data to develop future evidence-based design studies looking to reduce health outcomes such as falls, and subsequent disability.

The New York-Presbyterian Hospital is currently undertaking an architectural project to renovate the existing Milstein building’s acute care inpatient bed units. This redevelopment project would benefit from this data set in order to inform all parties moving forward including the architects and medical planners who are developing the redesign, as well as administrators with an interest in hospital admitting protocols related to room type, falls incidence during hospitalization and length of stay.

N. Alternative Therapies
Not applicable

O. Compensation of Subjects
Not applicable

P. Costs to Subjects
Not applicable

Q. Minors as Research Subjects
Not applicable

R. Radiation or Radioactive Substances
Not applicable

S. Future Directions
If significance is found with this study, the research could then be taken to the next level of looking at room type in terms of private room versus semi-private room and fall risk. The aim with this next research question could be to examine the relationship between falls within two different room types in a geriatric population within acute care medical units. It could be hypothesized that there would be more falls occurring within private versus semi-private patient rooms. This is based on the notion that patients are not easily observed in these spaces, despite anecdotal evidence that private rooms promote family presence which encourages increased observation.

The challenge with this research question is to consider the bed allocation practices within the hospital where private rooms are used for isolation purposes. This implies a number of confounders, both intrinsic in terms of differences in medical diagnoses, as well as extrinsic architectural variables such as room layout and room door being open versus closed (ie: in the case of infection control). Information on these factors would need to be collected and adjusted for (or taken into consideration) as much as possible to maintain the objective of demonstrating that environmental factors are independently associated with falls.
References


