

Balancing the Complexity of Patient Falls:

**Implementing Quality Improvement and Human Factors/Ergonomics and
Systems Engineering Strategies in Healthcare**

by

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TABLE OF CONTENTS

Table of Contents	ii
List of Figures	vii
List of Tables.....	x
Dedication	xi
Acknowledgements.....	xii
Abstract	xiii
List of Publications Linked to Thesis	xv
1 Chapter 1 introduction	1
1.1 Purpose of the Research	1
1.2 Research Aims:.....	1
1.3 My perspective.....	2
1.4 Three Studies	4
1.5 Assumptions & Limitations.....	6
1.6 Definitions	7
1.7 Significance of the Research.....	7
1.8 Outline of Chapters.....	8
2 Chapter 2: Literature review	11
2.1 Search Strategy	12
2.2 Quality Improvement methods to reduce patient falls.....	14
2.2.1 Duration of Post Intervention Period	15
2.2.2 Interventions	16
2.2.3 Critical thinking.....	17
2.2.4 Fall rates and fall with injury rates	18
2.2.5 Sustainment	19
2.2.6 Phase 2 QI Literature	21
2.2.7 Summary of QI Literature.....	22
2.3 Patient Adherence	22
2.3.1 Patient expectations	25
2.3.2 Link between patient satisfaction and falls	25
2.3.3 Methods to discover what patients want	26
2.3.4 Environmental recommendations	27
2.3.5 Patient and family education suggestions	28
2.3.6 Phase 2 Patient Adherence Literature	30
2.3.7 Summary of Patient Adherence Literature.....	32
2.4 Participatory Ergonomics	32
2.4.1 Definition of PE.....	34
2.4.2 PE Framework	35

2.4.3	Roles and participation in PE.....	37
2.4.4	Success of PE.....	38
2.4.5	Phase 2 PE Literature.....	38
2.4.6	Summary of PE Literature	40
2.5	Discussion from Literature Review	41
2.5.1	Methodology.....	41
2.5.2	Metrics	41
2.5.3	QI and HFE can be complementary.....	41
2.5.4	Know the Patient	42
2.5.5	Mutually beneficial environment.....	42
2.5.6	Participatory Ergonomics and patients	42
3	Chapter 3 QI and HFE FramEworks	43
3.1	Methodologies Investigated in Thesis	43
3.1.1	Lean	43
3.1.2	Six Sigma.....	45
3.1.3	Human Factors Engineering	46
3.2	Comparison of Methodologies.....	47
3.3	Application to Fall Prevention	51
4	Chapter 4: Study #1: Lean: Standard Work	53
4.1	Introduction for Lean	53
4.1.1	Lean	54
4.1.2	Aim.....	54
4.2	Method for Lean.....	54
4.2.1	Preparation for the Rapid Improvement Event	55
4.2.2	Rapid Improvement Event	56
4.2.3	Post Rapid Improvement Event Activities.....	60
4.2.4	Sustainment	60
4.3	Interventions for Lean	61
4.3.1	Overcoming Barriers for Interventions	62
4.4	Results for Lean	63
4.4.1	Fall and Injury Rate from Lean: Standard Work (Study #1)	63
4.4.2	Qualitative Results from Lean: Standard Work (Study #1)	66
4.5	Model after Study #1.....	68
4.6	Discussion for Lean.....	70
4.6.1	Rates for Falls and Severity of Injury	70
4.6.2	Cost of falls: Return on Investment	70
4.6.3	Facilitator Insights	71
4.7	Limitations and Strengths of Study #1	72
4.7.1	Limitations of Study #1	72
4.7.2	Strengths of Study #1.....	72

4.8	Conclusions for Lean	73
5	Chapter 5: Study #2: six sigma: Patient Partnering	74
5.1	Introduction for Six Sigma	74
5.1.1	Six Sigma.....	75
5.1.2	Aim	75
5.2	Method for Six Sigma	75
5.2.1	Define Phase	76
5.2.2	Measure Phase	77
5.2.3	Analyze Phase.....	82
5.2.4	Improve Phase	85
5.2.5	Control Phase.....	87
5.3	Interventions for Six Sigma	90
5.3.1	Convince the patient to partner	92
5.3.2	Critical Thinking and Customized Interventions	93
5.4	Results for Six Sigma	94
5.4.1	Fall and Injury Rate: Lean/Six Sigma/Post Intervention	95
5.4.2	Comparing reasons for falls with injury and without	99
5.4.3	APN and Patient Partnering	102
5.4.4	Qualitative Results from Six Sigma (Study #2).....	104
5.5	Model for Study #2.....	109
5.6	Discussion for Six Sigma.....	111
5.6.1	Patient Partnering.....	112
5.6.2	Comparisons of fall rates for Six Sigma and Lean Studies	113
5.6.3	Statistical verses Clinical Significance	113
5.6.4	Cost of falls: Return on Investment	114
5.6.5	Facilitator Insights	115
5.7	Limitations and Strengths of Study #2.....	115
5.7.1	Limitations of Study #2	115
5.7.2	Strengths of Study #2.....	117
5.8	Conclusions for Six Sigma	117
5.8.1	Generalizability	118
6	Chapter 6: Study #3: Patient interview	120
6.1	Introduction for Patient Interview	120
6.1.1	Aim	120
6.1.2	Participatory Ergonomics Framework	120
6.2	Method for Patient Interview.....	121
6.2.1	Setting and Sampling Strategy	122
6.2.2	Ethics	122
6.2.3	Recruitment	123
6.2.4	Data Collection and Analysis	124

6.3	Results for Patient Interview	126
6.3.1	Patient Quotes from Interviews	126
6.3.2	Patient Perception of Fall Risk	131
6.3.3	Patient Suggestions for Fall Prevention.....	132
6.3.4	Thematic Categories	133
6.3.5	Theoretical Structure	150
6.4	Discussion for Patient Interview	155
6.4.1	Environmental Suggestions	156
6.4.2	Patient Background.....	157
6.4.3	Patient Partnering.....	158
6.5	Model for Study #3.....	159
6.6	Limitations and Strengths of Study #3.....	162
6.6.1	Limitations of Study #3	162
6.6.2	Strengths of Study #3.....	163
6.7	Conclusion for Patient Interview	164
7	Chapter 7: Temporal analysis of fall incidence throughout the duration of the research.....	166
7.1	Introduction.....	166
7.1.1	Aim	166
7.2	Time line Phases	166
7.2.1	Baseline	167
7.2.2	Advanced Practice Nurse 100% Focus on Falls: Best Practice	167
7.2.3	Study #1: Lean: Standard Work.....	167
7.2.4	Study #2 Six Sigma: Patient Partnering.....	168
7.2.5	Post Intervention.....	168
7.3	Results	168
7.3.1	Combining Lean and Six Sigma as a QI Phase.....	169
7.3.2	Number of Days between Falls with Serious Injury	171
7.3.3	Combined Qualitative Results from QI	173
7.4	Advantages and Limitations of Temporal Analysis	178
8	Chapter 8 Discussion	180
8.1	Introduction.....	180
8.2	Overview Summary of Three Studies.....	180
8.2.1	Impact on Society	182
8.3	Systems Approach: Combining methods and balancing components	184
8.3.1	Combining Methodology	185
8.3.2	Systems Approach: Bundle vs. Single Best intervention.....	187
8.3.3	Balancing System Components	188
8.4	Continuous Improvement and Complexity.....	188
8.4.1	Intrinsic/Extrinsic factors.....	189

8.4.2	Risk perception	191
8.4.3	Severity of Consequence & Balance of Safety vs. Autonomy & Priorities	192
8.5	Critically Re-thinking Falls	193
8.5.1	Comparison to Non-healthcare Industries	193
8.5.2	Employee Fall Prevention Programs and Environmental Interventions	196
8.5.3	Comparison of falls and other never events	199
8.5.4	Conflicting Benefits and Limited Resources Create Trade-offs	201
8.6	Models	203
8.7	Limitations of study	207
8.8	Strengths of study.....	208
9	Chapter 9 Conclusion.....	210
9.1	Background	210
9.2	Restated Purpose and Aims of Research.....	210
9.3	Summary of Results	211
9.4	Conclusions	212
9.4.1	Systems Approach: Combining Methods & Balancing Components	212
9.4.2	Complexity and Continuous Improvement	214
9.4.3	Critically Re-thinking Falls	214
9.4.4	Model of Systems Approach.....	215
9.5	Recommendations	215
9.6	Impact on society.....	217
9.7	Future Research Recommendations.....	217
9.8	Closing Statement	218
9.8.1	Key Message.....	218
10	References.....	219

LIST OF FIGURES

Figure 2-1 Exclusion/Inclusion Consensus session with Fall Expert	13
Figure 2-2 QI fall literature review exclusion and inclusion criteria	15
Figure 2-3 Patient adherence exclusion and inclusion criteria.....	24
Figure 2-4 Participatory Ergonomics exclusion and inclusion criteria	34
Figure 4-1 Algorithm for Linking Fall Risk Assessment to Appropriate Interventions	58
Figure 4-2 Fall Tracker Board for Posting Information after Fall Occurred	59
Figure 4-3 Monthly Fall Rates and Project Milestones.....	64
Figure 4-4 Model After Study #1: Extending the SEIPS Model for Fall Risk Factors	69
Figure 5-1 Team working on fishbone diagrams	79
Figure 5-2 Team Compliance Fishbone Diagram	81
Figure 5-3 Reasons patients push call light.....	83
Figure 5-4 Reasons patients get out of bed	84
Figure 5-5 Reenactment of Patient Partnering	86
Figure 5-6 New combination of FMEA and Impact Matrix Technique.	87
Figure 5-7 Example of Preventable Harm report printed daily by the APN.....	89
Figure 5-8 Photographs of IV poles	91
Figure 5-9 Checklist used by nurses during patient partnering.....	93
Figure 5-10 Photos representing interventions in Study 2	94
Figure 5-11 Fall and Fall with Serious Injury Rates for the oncology division implementing Six Sigma	96
Figure 5-12 Fall Tracker Board.....	100
Figure 5-13 Model After Study #2: Patient and Staff Centered.....	110
Figure 6-1 Average rating of Likert scale question shows patients do not perceive risk of falling or injury (n=30)	131
Figure 6-2 Patients perceive they are slightly more likely to fall at home than in hospital (n=20)	132
Figure 6-3 Model of Categories from Participants 1-10 before Fall Panel Review	135
Figure 6-4 Model of Categories from Participants 1-10 after Fall Panel Review – Part 1	137

Figure 6-5 Model of Categories from Participants 1-10 After Fall Panel Review – Part 2	138
Figure 6-6 NVivo-10 Coding from Participants 1-30 used during the Second Fall Panel Review.....	140
Figure 6-7 New coding structure for “Belief of Denial” of fall risk after Fall Panel review #2.....	141
Figure 6-8 New coding structure for “Reasons for Denial” of fall risk after Fall Panel review #2	142
Figure 6-9 New coding structure for “Education” of fall risk after Fall Panel review #2.....	143
Figure 6-10 New coding structure for “Environment” after Fall Panel review #2 .	144
Figure 6-11 New coding structure for “Equipment and Support” after Fall Panel review #2.....	144
Figure 6-12 New coding structure for “Interventions” for fall prevention after Fall Panel review #2	146
Figure 6-13 New coding structure for “Type of Injury” after Fall Panel review #2	146
Figure 6-14 New coding structure for “Patient Partnering” after Fall Panel review #2	147
Figure 6-15 New coding structure for “Fall Risks” after Fall Panel review #2	148
Figure 6-16 Suggestions for care team to prevent falls.....	148
Figure 6-17 Categories from Studies #1 and #2 unused by participants in Study #3	149
Figure 6-18 Word Cloud Visualization for Participants 1-10 on left and Participants 1-30 on right.....	150
Figure 6-19 Flip charts to guide discussion during selective coding session.....	151
Figure 6-20 Photograph of confusing call lights and telephone.....	153
Figure 6-21 SEIPS 2.0 Model of Human Factors Framework for Healthcare	156
Figure 6-22 Model After Study #3: Disconnect Between Nurse and Patient	161
Figure 7-1 Timeline for Phases of Research 2009-2015.....	167
Figure 7-2 Fall and Fall with Injury Rates 2009-2015.....	169
Figure 7-3 G-Chart falls with serious injury 2009-2015.....	172
Figure 7-4 G-Chart falls with serious injury excluding patient partnering	173
Figure 7-5 Categories of Insights.	174

Figure 8-1 Environmental design solutions from employee safety programs	197
Figure 8-2 Model of Systems Approach Balances Components with Continuous Improvement Driven by Critical Evaluation.....	206

LIST OF TABLES

Table 1-1 Study Methods and Interventions	6
Table 2-1 Phase 2 Literature Review Update.....	14
Table 2-2 Features of PE Framework	35
Table 3-1 Comparison of Lean and Six Sigma Methodologies	48
Table 3-2 Comparison of QI and HFE	49
Table 4-1 Lean Interventions linked to contributing factors and falls	62
Table 4-2 Fall Results Combined from Three Oncology Divisions.....	65
Table 4-3 Insights from Lean Study #1	68
Table 5-1 Tools used during Define Phase	77
Table 5-2 Cause and Effect Matrix for Patient Fall Prevention	78
Table 5-3 Interventions linked to contributing factors and falls	90
Table 5-4 Fall data from Lean, Six Sigma and Post Intervention	97
Table 5-5 Location of falls and falls with injuries during 2013	99
Table 5-6 Unassisted patients more likely to be injured from a fall than assisted patients.	101
Table 5-7 Insights from Six Sigma Study #2	107
Table 6-1 Participant Characteristics (n=30)	124
Table 6-2 Activity time line for Study #3	126
Table 7-1 Fall Data from 2009 - 2015.....	170
Table 8-1 Advantages and Disadvantages of HFE & QI in fall prevention.....	185
Table 8-2 Cross over table of sub theme topics	204

DEDICATION

I would like to dedicate this thesis to the
Oncology patients and the staff that care for them at
Barnes-Jewish Hospital.

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ABSTRACT

Introduction:

Falls are the leading cause of death due to injury among the elderly. Every 24 minutes an older adult dies from a fall related injury. Studies using 3 different methods were performed at a large urban, academic medical center in the US.

- Aim #1: Understand the advantages and disadvantages of QI methodologies (Lean and Six Sigma) and HFE when applied to fall prevention in the acute care setting:
 - Evaluate the contribution of QI and HFE to fall prevention with a focus on reducing falls with serious injury.
 - Use studies with different methodologies (Lean, Six Sigma) to develop and implement an intervention with the goal of decreasing total falls and falls with injury.
 - Compare methodologies (Lean, Six Sigma and HFE) to understand their benefits and limitations.
- Aim #2: Develop recommendations for fall prevention:
 - Investigate interventions and assess success of fall prevention.
 - Develop an understanding of interventions that prevent falls resulting in injury.

Methodology and Results:

Study #1 (Method = Lean, Intervention = Standard Work): Study #1 used Lean techniques such as standard work to improve fall risk assessment and intervention selection. Total falls decreased by 22%. At first glance this appears successful but a deeper evaluation of the serious injuries revealed more improvement is needed. There were still 15 falls with serious injuries that occurred among the three oncology divisions. These rare but serious injuries result in a longer hospital stay and increased cost of treatment that is not reimbursed. Due to a climate of increasing financial pressure further reduction of serious injury was desired.

Study #2 (Method = Six Sigma, Intervention = Patient Partnering): Study #2 used Six Sigma tools to investigate root causes of falls. An intervention called “Patient Partnering” was developed to encourage patients to call for help and participate in preventing their own falls. There were no falls with serious injury for over 14 consecutive months. However, the intervention was difficult to sustain due

to resistance from nurses and patients. Falls with injuries resumed as the intervention ceased.

Study #3 (Method = Qualitative HFE, Intervention = Patient Interview): Study #3 was a qualitative study based on Human Factors principles to understand patient's perception of fall risk. It was found that patients did not think they would fall and felt particularly safe and protected while in hospital. They found it difficult to get around with IV tubes and crowded spaces. They wanted information and assistance when they need it, in the format they prefer (customized for each individual patient).

Impact on society:

Falls prevention interventions need to be designed for all the stakeholders (patients and staff). Patients think nurses will keep them safe and are willing to participate with fall prevention if they feel it is tailored to their needs. Until all perspectives are taken into account it is unlikely that there will be sustained and embedded improvements.

Key message:

Falls with injury are rare events with complex root causes that require agile solutions with constant revision to align with rapidly changing conditions and interactions. Reducing injury will take a balance between safe environment, organization, processes, tasks and behaviors from staff and patients.

LIST OF PUBLICATIONS LINKED TO THESIS

Chapter 4: Study #1: Lean: Standard Work

- Wolf, L., Costantinou, E., Limbaugh, C., Rensing, K., Gabbart, P. & Matt, P. 2013a. Fall prevention for inpatient oncology using lean and rapid improvement event techniques. *HERD: Health Environments Research and Design Journal*, 7, 85-101.
- Wolf, L., Costantinou, E., Matt, P. & Schulte, L. 2013b. Rapid Improvement Event to Prevent Patient Falls. In: Duffy, V. G. (ed.) *Advances in human aspects of healthcare*. Boca Raton: CRC Press.

Chapter 5: Study #2: Six Sigma: Patient Partnering

- Wolf, L., Hignett, S. & Costantinou, E. 2014. Ending the Vicious Cycle of Patient Falls. *Proceedings of the HFES 2014 International Symposium on Human Factors and Ergonomics in Health Care*. , 9-11 March 2014.
- Wolf, L. 2015a. Using Lean, Six Sigma and Human Factors to prevent patients from falling. In: ASQ, M. C. O. (ed.) *American Society of Quality St. Louis MO Section 1304*.

Chapter 6: Study #3: Patient Interview

- Wolf, L., Hignett, S. 2015b. Are patients at risk of falling? Not if you ask them! *Proceedings of the 19th Triennial Conferene of the Interational Ergonomics Association, Melbourne, Australia*.

Chapter 8: Discussion

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- Hignett, S., Wolf, L., Taylor, E. & Griffiths, P. 2015 c. Firefighting to Innovation: Using Human Factors and Ergonomics to Tackle Slip, Trip, and Fall Risks in Hospitals. *Human Factors*.
- Wolf, L., Matt, P., Aycock, J., Sona, C. 2010. Pressure Ulcer Prevention. Presentation at Barnes-Jewish Hospital Operational Excellence Briefing.

1 CHAPTER 1 INTRODUCTION

This research aims to contribute to patient safety by reducing the number and severity of inpatient falls. Three studies using Quality Improvement (QI) and Human Factors Engineering (HFE) were performed to understand the advantages and disadvantages of each method and develop (and test in Studies #1 and #2) recommendations for fall prevention.

Background

Patient falls in the acute care setting is an ongoing problem that continues to cause physical, psychological and financial problems for hospitals, staff, patients and families. Falls are the leading cause of death due to injury among the elderly; every 24 minutes an older adult dies from a fall related injury (Centers for Disease Control and Prevention CDC, 2015) Falls with injury can cause additional tests and treatments and prolong hospital stays (Wong et al., 2011a). Six Sigma methodologies are among the latest approaches used to reduce falls with injury in the acute care setting (Christopher et al., 2014, DuPree et al., 2014).

1.1 Purpose of the Research

There is a need to understand the benefits and limitations of QI and HFE and their contributions to fall prevention. Fall prevention was selected as the focus for this research because it continues to be a persistent problem in the acute care setting with potentially disturbing impact on patients and staff. Lean was the QI method selected for Study #1 because it had been successful in a previous project reducing pressure ulcers. Six Sigma methodologies were chosen for Study #2 because they are used in Barnes-Jewish Hospital (BJH) for complex problems and it coincided with an opportunity to collaborate with The Joint Commission. Qualitative interview was selected for Study #3 to provide a deep understanding of the patient perspective using qualitative analyses.

1.2 Research Aims:

The overall research goal was to develop an understanding of contributions of QI and HFE to the prevention of inpatient falls.

- Aim #1: Understand the advantages and disadvantages of QI (Lean and Six Sigma) methodologies and HFE when applied to fall prevention in the acute care setting:
 - Evaluate the contribution of QI and HFE to fall prevention with a focus on reducing falls with serious injury.
 - Use studies with different methodologies (Lean and Six Sigma) to develop and implement an intervention with the goal of decreasing total falls and falls with injury.
 - Compare methodologies (Lean, Six Sigma and HFE) to understand their benefits and limitations.
- Aim #2: Develop recommendations for fall prevention:
 - Investigate interventions and assess success of fall prevention.
 - Develop an understanding of interventions that prevent falls resulting in injury.

1.3 My perspective

My name is Laurie Wolf. I have a master degree in Human Factors Engineering (HFE) from Virginia Tech and am a Certified Professional Ergonomist (Board of Certification in Professional Ergonomics) and Certified Six Sigma Black Belt from the American Society of Quality. I work for BJH, a 1,200 bed academic Medical Center affiliated with Washington University School of Medicine. In the Operational Excellence Department my role is Lead Performance Improvement Engineer. My typical assignments involve conducting quality improvement (QI) projects for Medicine Divisions. In addition to QI projects, I also provide HFE input to projects throughout BJC as requested and train physicians, nurses and ancillary staff on the principles of HFE.

My master degree training focused on the importance of designing a system for human capabilities and limitations so workers could achieve their tasks safely and efficiently. I was able to stay true to this focus in my first two jobs with General Motors in Advanced Vehicle Engineering and Emerson Electric where my mission was to design products (control panels and displays) that were functional, aesthetically appealing, and feasible to manufacture and that allowed the user to perform their tasks efficiently without error. HFE input was part of contractual

requirements in these projects which allowed time and resources for mock ups and experimentation to determine the options that yielded the highest usability performance. However, when I started working in a hospital there were no contractual obligations or regulations that required HFE, my work focused on processes and behaviors to work around inadequate equipment and environments. Built environments were inflexible and new construction projects perceived HFE as slowing down the timeline and increasing cost with minimal benefit. In my experience, projects that focus on processes and policies targeting behavior and culture change are much more common in healthcare than projects that change environmental or equipment design to achieve error proofing.

Although HFE research in healthcare is increasing, I struggle to find studies that apply to my specific projects. I am often requested to make decisions quickly with no time to conduct usability simulations to test alternatives. My career-long struggle with finding academic applications to my work environment inspired me to pursue a PhD to understand the rigors of academic research and the benefits it can bring to the applied healthcare world. I understand the need to establish a research based foundation that would provide better support when fast paced decisions are demanded. I continue to seek evidence to know when to stop the process and demand that more research is needed to make an appropriate decision. Examples of these kinds of decisions have recently included, approval of a door handle for the patient rooms in a new hospital based on a photograph (not to scale) in one hour and a request to design a new layout for armbands that would improve readability and decrease errors with results expected to be completed in four hours!

During my training in Lean and Six Sigma methodologies I was intrigued with the techniques and integrated them with my HFE expertise whenever possible. This thesis provided the opportunity to systematically explore various different methods while applying them to our experience with persistent fall prevention issues.

All research in this thesis was conducted at Barnes-Jewish Hospital (BJH), the largest hospital in Missouri and the largest private employer in the St. Louis region. An affiliated teaching hospital of Washington University School of Medicine, BJH has a 1,800 member medical staff. They are supported by a staff of 9,500 health-care

professionals. Barnes-Jewish Hospital is a member of BJC HealthCare, one of the nation's largest health-care organizations.

1.4 Three Studies

My work offered a unique position to conduct this research with easy access to physicians, nurses and ancillary staff as they care for patients. My access to data supports selection of improvement projects based on data and trend analyses. Requests also come from the hospital and medical school. My role and involvement in each project varies according to what is needed (facilitator, project manager, HFE trainer and investigator, data collector and analyzer). The following is a brief description of my role in the three studies described in future chapters.

- Study #1 (Method = Lean, Intervention = Standard Work): The BJC corporate Patient Safety & Quality department asked me to facilitate this project using Lean methodology for three oncology divisions at BJH because they were among the highest divisions in falls with injury. I had previous success using a similar process for a pressure ulcer reduction project the previous year. Phase 1 involved a team including representation from all 13 BJC hospitals to help develop a guideline of what was needed (fall assessment, interventions and post fall investigation). I participated as a team member. In phase two my role switched to facilitator and focused on the divisions with the three highest fall-with-injury rates. The goal was to figure out how to consistently provide fall interventions based on individual patient risk and to develop a thorough post-fall investigation process. Lean methods were used to develop standard work processes. I facilitated representatives from the three oncology divisions through a Rapid Improvement Event (RIE) and helped them implement the improved processes. Although facilitating the RIE process was typical for my role, working with the oncology division was new for me. I also began a journal prior to the event to track insights and experiences since I planned to use it as part of my PhD work. My role in this study was to prepare and facilitate the event and provide support to the team during implementation. I collaborated with our Fall Expert from BJH to develop algorithms to assist with selecting interventions. I assisted in training sessions for the nurses and staff. I had frequent meetings with the

Advance Practice Nurses (APN) from each of the three divisions to review progress and modify interventions as needed. I collected and analyzed data for all divisions. I prepared and facilitated “reunion” meetings as needed to check progress and sustain momentum (see Chapter 4).

- Study #2 (Method = Six Sigma, Intervention = Patient Partnering): As we were discovering that we still needed improvement with fall injury; The Joint Commission was looking for seven hospitals to collaborate using Six Sigma methodology to prevent falls with injury. BJH volunteered to participate and I was selected as project facilitator. My role was to prepare, facilitate and coordinate all leadership and team meetings, provide training as needed throughout the process, collect and analyze data, prepare presentations for toll-gate reviews, provide program management guidance for all aspects of the project and provide updates to BJC Healthcare and BJH executives and staff throughout the project. The Six Sigma methods lead to the development of an intervention called Patient Partnering. (see Chapter 5).
- Study #3 (Method = Qualitative Patient Interview, Intervention = Understanding Patient Perception): This qualitative patient interview study was not a performance improvement project, so I began by getting Ethics and Protocol committee approvals under the guidance of our nurse research team. I was responsible for all work conducted in this study. I selected all eligible patients at risk for falling, with nurses giving the final approval to approach patients with an invitation to participate. I conducted all interviews and analyzed results under the guidance of my Thesis Advisor (Sue Hignett). I conducted coding sessions with the BJH Fall Expert and APN periodically during data collection to validate coding structure and framework for analysis (see Chapter 6).

Study Number	Methodology	Intervention
Study #1	Lean	Standard Work
Study #2	Six Sigma	Patient Partnering
Study #3	Qualitative Human Factors – Patient Interview	Understanding Patient Perception

Table 1-1 Study Methods and Interventions

I facilitated Study #1 and #2 as part of my QI role, however; I provided more extensive analysis and much more rigor surrounding insight compilation and ongoing support due to my PhD work. Study #3 was entirely beyond the scope of my QI work and was driven by the need identified in Study #1 and #2 so was conducted as a research study specifically for my PhD work. I was fortunate to have access to the oncology patient population as part of my role at BJH to allow continuity for 5 ½ years of study. Table 1-1 shows the type of method that I used for each study and the intervention that emerged from the process. Study #3 was a qualitative study where I conducted patient interviews so there was no intervention to be implemented but the goal was to understand patient perceptions.

My dual certification in HFE and Six Sigma combined with my hospital's need to reduce falls aligned to provide the opportunity for this research. Since the request for Study #1 came as a directive from BJC and Study #2 from BJH, gaining permission to conduct these studies was not a barrier. As I facilitated both Study #1 and #2 I got to know management and staff, making it a natural progression for me to request patients to interview during Study #3. The staff trusted my intentions to help their patients. To gain support for Study #3, I attended a few staff meetings to keep everyone informed of my progress. At the end of Study #3, I presented each nurse, tech and unit secretary a written summary of findings so they could see the success of their contributions.

From this point forward the thesis will be written in 3rd person and I will refer to myself as "Thesis Author".

1.5 Assumptions & Limitations

The intent of this applied research was for it to be conducted in a hospital with all interventions to be incorporated into patient care activities. Interventions developed during in this research were to be realistic, simple and affordable. All activities had to be mutually beneficial to staff and patients. One limitation of this applied approach was the presence of confounding variables that could not be controlled (such as turnover rates and hospital-wide mandated safety interventions).

Limitations of each individual study are discussed in their respective chapters.

1.6 Definitions

A glossary of definitions and acronyms can be found in Appendix A.

Throughout this research the definition of a fall was aligned with the Agency for Healthcare Research and Quality (AHRQ) source from the National Database of Nursing Quality Indicators (NDNQI). A paraphrase of the March 2012 fall definition is as follows (Quality, 2013):

“A patient fall is an unplanned descent to the floor with or without injury to the patient. Include falls when a patient lands on a surface where you wouldn't expect to find a patient. All unassisted and assisted falls are to be included whether they result from physiological reasons (fainting) or environmental reasons (slippery floor). Also report patients that roll off a low bed onto a mat as a fall.”

The Barnes-Jewish Hospital Center for Patient Excellence has a long standing adherence to this definition and was confirmed again during The Joint Commission project that will be discussed in Study #2.

1.7 Significance of the Research

At the completion of the first phase of the literature review, very few studies had used QI or HFE to prevent falls in the acute inpatient care setting. Participatory Ergonomics (PE) programs primarily were conducted in manufacturing environments. The few PE studies that were conducted in hospitals did not include patients as team members. PE studies typically involve non-healthcare workers over a long period of time to address workers' compensation issues such as musculoskeletal risks. QI methods had been conducted in healthcare to address fall prevention but none of these studies compared Lean and Six Sigma methods. No articles were found that involved qualitative interviews of patients during admission to an acute hospital.

The literature review update performed in the final year of research revealed a few very relevant articles that had not yet been published in the first phase. Dupree (2014) published an article with results from Study #2 combined with six other hospitals that participated in the study along with BJH. A study by Christopher used Six Sigma methodology and tools that resulted in similar interventions to Study #2. A team conducted “proactive rounding” to assess risk and ensure universal

precautions were in place. In addition they would identify and promote individualized plan of care with customized interventions (Christopher et al., 2014). One study that used a participatory program involving education of patients found it was an effective method to increase knowledge about falls which in turn increased awareness of the potential of falling (Huang et al., 2015). A study that interviewed patients at bedside (like Study #3) states that a patient's perception of fall risk does not match their clinical risk and they overestimate the ability of their care team to prevent falls (Sonnad et al., 2014).

This research will provide insight helpful to QI experts showing where and when Lean and Six Sigma methods are most successful and to create new techniques that combine approaches. The combination will help to invent new strategies that assemble the strengths of each tool to develop the most powerful tools. An equally significant component of this research is to contribute an innovative approach to fall with injury preventions.

1.8 Outline of Chapters

Chapters 4-6 contain results, discussions and conclusions applicable that chapter's respective study methodology. These data are then combined and discussed in chapters 7 (Temporal analysis of fall incidence throughout the duration of the research), 8 (Discussion) and 9 (Conclusion).

The research described in the following chapters will investigate advantages and disadvantages of QI methods and discusses an innovative approach to continuous improvement of fall prevention by understanding and integrating the patients' perspective.

- Chapter 1: Introduction
 - This chapter introduces the thesis and provides a context for the research (personal perspective and role in each study and research site) and a general background introduction for the topic and selection of methodologies.
 - Aim #1: Understand the benefits of QI & HFE methodologies
 - Aim #2: Develop innovative recommendations for fall prevention

- Chapter 2: Literature Review
 - Three areas of literature were investigated
 - QI methods to reduce patient falls
 - Patient Adherence
 - Participatory Ergonomics in Healthcare
- Chapter 3: QI and HFE Frameworks
 - This chapter provides a general understanding of Lean, Six Sigma, QI and HFE to provide the framework for the chapters that describe individual studies that used each of the selected methods.
 - A general description and history of Lean, Six Sigma and HFE leads to an explanation of QI and comparison of each methodology. A discussion of the contribution of these methods to fall prevention is included.
- Chapter 4: Study #1 (Lean Methodology: Standard Work intervention)
 - Lean techniques such as Standard Work were used to improve fall risk assessment, intervention selection and post fall investigation processes. Total falls decreased by 22% but reduction of serious injury was desired.
- Chapter 5: Study #2 (Six Sigma Methodology: Patient Partnering intervention)
 - Six Sigma tools were used to investigate root causes of falls. An intervention called “Patient Partnering” was developed to encourage patients to call for help and participate in preventing their own falls. There were no falls with injury for 14 months. The intervention was difficult to sustain due to resistance from both nurses and patients. Falls with injuries resumed as the intervention ceased.
- Chapter 6: Study #3 (Patient Interview)
 - A qualitative study based on Human Factors principles was conducted to understand patient’s perception of fall risk. It was found that patients did not think they would fall and felt particularly safe and protected while in hospital. They found it difficult to get around with IV tubes and crowded spaces. They wanted information and

assistance when they need it, in the format they prefer (customized for each individual patient).

- Chapter 7: Temporal Analysis of Fall Incidence Throughout the Duration of the Research
 - Results in this chapter look at over five years of data to allow comparison of both Lean and Six Sigma to a baseline prior to either project. Discoveries of long term trends are revealed.
- Chapter 8: Discussion
 - Nine insights are discussed that were compiled based on all three studies and investigations into literature. Discussion includes how the work in this research fits in with previous studies found in the literature.
- Chapter 9: Conclusion
 - This chapter celebrates insights and conclusions. The aims of understanding the benefit of QI methods and developing recommendations for fall prevention were met. Findings support three insights: A systems approach is practical (combining methods and balancing components), Continuous improvement is needed for address complex issues, and Critically Re-thinking falls is necessary.

2 CHAPTER 2: LITERATURE REVIEW

Although numerous initiatives have been focused on fall prevention, there is surprisingly few randomized control trials that indicate success from a single intervention (Cameron et al., 2010). Even Cochrane systematic literature reviews indicate that multiple interventions supported by a multi-disciplinary team of coordinated healthcare workers is needed to reduce rates of falls (Cameron et al., 2012, Gillespie et al., 2003, Robertson and Gillespie, 2013, Goldsack et al., 2014). Exercise interventions results have been inconsistent and vitamin D supplements have an indication of decreasing falls but not the risk of falling (Cameron et al., 2012). Muscle strengthening and balance exercise such as Tai Chi have been successful in sub-acute settings (Cameron et al., 2012, Robertson and Gillespie, 2013) but may not be as impactful during the short length of stay of an inpatient, acute care hospital setting. Even less is known about preventing fall related injury (Gillespie et al., 2003). A recent survey of nurses was conducted to determine the top ten interventions to prevent an injury during a patient fall revealed a large variation of opinion across ten different specialty areas. The only common intervention that was mentioned by all ten specialty areas was to keep bed brakes locked (Huey-Ming, 2015). The fact that so many gaps remain after years of dedicated effort to reduce falls indicate that the issue is complex with no easy “silver bullet” solution (Goldsack et al., 2014). There is an opportunity to explore the benefits that QI and HFE can contribute to the problem of fall and injury prevention.

As the research pathway for the thesis evolved so did the need to conduct literature reviews on relevant topics. This chapter will introduce literature in three stages starting with a review of research on Quality Improvement (QI) methods with respect to interventions to reduce the risk of patient falls (discussed in Chapter 4 Study #1: Lean and Standard Work). Study #1 revealed patient involvement in fall prevention was important so the literature review was extended to explore patient adherence to falls interventions this knowledge was considered during the second study (discussed in Chapter 5 Study #2: Six Sigma and Patient Partnering).

Although some success was achieved in Study #2, sustainment in patient engagement was limited so a literature review was carried out to explore how participatory ergonomics has been used to facilitate involvement in risk management

interventions – this was further explored in the qualitative interviews conducted for the third study (discussed in Chapter 6 Study #3: Patient Interview).

The intent for these literature reviews was not to conduct a comprehensive review or meta-analysis but to take a systematic, replicable approach to provide insight into the scope of previous research. All literature searches were conducted at Washington University Library with guidance for index terminology, search strategies and data base selection.

2.1 Search Strategy

Three searches of the published literature were conducted using strategies created by a medical librarian for the concepts of 1) Quality Improvement (QI) and fall prevention, 2) patient adherence and fall prevention and 3) Participatory Ergonomics (PE). Search strategies were established using a combination of standardized terms and key words, and were implemented in PubMed, Embase, Scopus and the Cumulative index for Nursing and Allied health Literature 1937. Key words were checked for standardized index terms (MESH terms) and then combined with natural language terms to narrow and/or broaden the search depending on the search results. Root words were expanded as needed, such as the word “prevent” could be expanded to “prevention”, “prevented”, “preventing”, “preventable”, “preventative”, “preventive”, “preventability”. All results were exported to EndNote. Full search strategies for each literature review are provided in Appendix B. The automatic duplicate finder in EndNote was used and duplicates were assumed to be accurately identified and removed. The few remaining duplicates were removed during detailed review of article titles for inclusion in the abstract review. After initial screen of titles for exclusions, a consensus session was held with a Fall Expert to review abstracts and further refine the inclusion and exclusion criteria. The purpose of the consensus session was to secure engagement from subject matter experts and embed the project in the hospital.

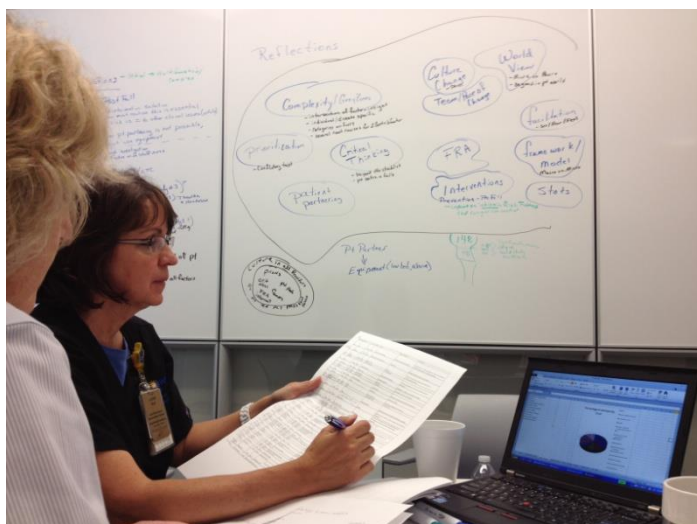


Figure 2-1 Exclusion/Inclusion Consensus session with Fall Expert

Due to the extended timeframe of this part time research, literature searches were conducted in two phases. Phase 1 was conducted in 2012 (for QI and patient adherence) and 2013 (for PE). Phase 2 occurred in June 2015 and updated all three topics. The inclusion and exclusion criteria for selecting relevant articles remained the same for both phases and are specifically described for each topic in each respective section.

Phase 1 involved a critical appraisal of the included papers to provide an in-depth understanding of current methods used for patient fall prevention. This understanding helped to identify gaps that guided the direction of research described in each section of the thesis.

Phase 2 updated the literature review including articles from 2012 to June 2015. A narrative review was compiled for the newer articles for awareness of new research contributions and did not include a critical appraisal. New articles considered during Phase 2 are tallied in Table 2-1. Articles from the total run were screened by title according to Phase 1 inclusion and exclusion criteria. Abstracts from the most relevant titles were reviewed and the top picks were included in the narrative review. A summary of Phase 2 top articles will be included in a separate section at the end of each topic.

Phase 2: Topic	Total run 2012-2015	Selected for abstract review	Top Picks
QI	3,415	67	18

Patient Adherence	794	42	12
PE	821	29	8

Table 2-1 Phase 2 Literature Review Update

2.2 Quality Improvement methods to reduce patient falls

Phase 1 of the QI literature review results are discussed in 2.2.1 through section 2.2.5 while Phase 2 is discussed in 2.2.6. The summary of both phases can be found in 2.2.7. The initial search strategy on implementing Lean and Six Sigma methodologies for patient fall prevention yielded very few articles. Since these searches resulted in a limited number of articles the next search was broadened to Quality Improvement Methodology. By using the search terms “quality improvement”, “accidental fall”, “prevention”, 236 abstracts were identified. The abstracts were reviewed for relevancy and 47 were progressed for further evaluation. Figure 2-2 illustrates the number of abstracts that were selected according to the inclusion and exclusion criteria for QI.

The original exclusion categories of this phase include: “nursing homes and diagnoses – Parkinson’s, stroke, bone health, hip fractures”, “ancillary departments such as radiology”, “nursing practice – care models – nursing education”, “legislation”, “no abstract available”, “dashboard”, “restraints”, “children’s falls”, “community”, “exercise interventions”, “nursing education”.

The remaining 47 articles were further reviewed in a consensus session (with the Fall Expert from BJH) where each abstract was discussed. During this session additional inclusion and exclusion criteria were developed based on knowledge of previous success and failures of QI initiatives in healthcare and falls prevention.

Exclusion does not necessarily mean the abstract was not valuable but simply was not applicable to the QI methodology of the fall prevention program. Additional exclusion criteria: “benchmarking/quality indicators”, “clinical and post fall care”, “assessment tools”, “staffing levels”, “falls from heights”, “intrinsic factors”, “organizational factors”, “descriptive type of fall” “environmental factors”, “reporting systems”.

Inclusion criteria: “best practice”, “standard work”, capability to roll out across several hospital divisions and a systematic data-driven process of fall prevention.

Fourteen articles were selected that met the following inclusion criteria: “QI program/tools”, “rollout/sustainment”, “multi-disciplinary teams”, “change management”, “patient partnering”, “continuous QI through patient safety”.

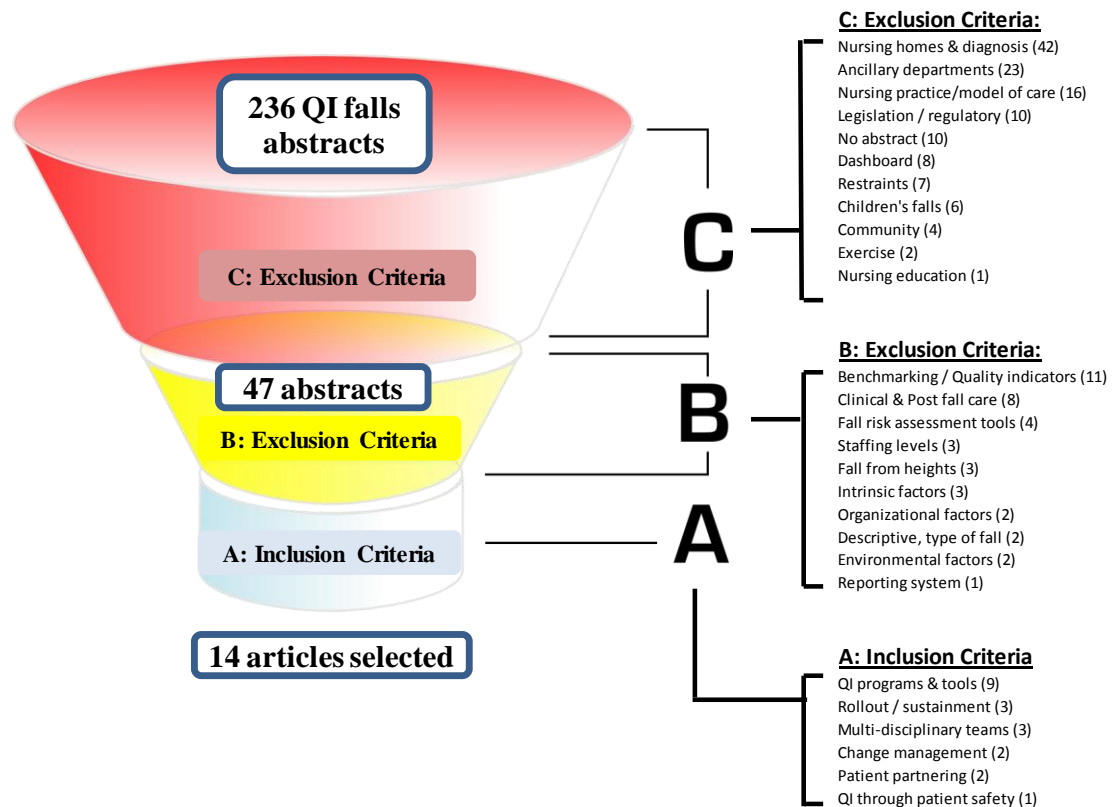


Figure 2-2 QI fall literature review exclusion and inclusion criteria

During Phase 1 of the literature review the earliest publication from 14 selected QI articles was published in 2005 and the most recent study was published in 2011. (Phase 2 included QI articles from 2012-2015 discussed in section 2.2.6). Appendix C includes a tabular summary of factors considered in the critical appraisal.

2.2.1 Duration of Post Intervention Period

Frequently studies are published before an adequate amount of time has elapsed to evaluate if an intervention is actually successful. Research that had no timeline information or insufficient time to understand sustainment received a lower critical appraisal score. Duration of studies in the literature review ranged from three months (Veluswamy and Price, 2010) to five years (Barker et al., 2009a) to continuous improvement projects over seven years (Sulla and McMyler, 2007). Sometimes it's difficult to tell if the time frame included the baseline measures or

were just post intervention or even worse, if a time frame is not mentioned. In a study by Anderson it is difficult to understand the true impact of the project since the period of time for baseline or post intervention was not reported (Anderson et al., 2009).

Alternatively other projects very clearly delineate a timeline. A three year project at Caulfield General Medical Center in Melbourne (four wards with between 96 and 120 beds) took one year for baseline measurement, three months to implement the intervention and had a two year follow up period (Fonda et al., 2006).

2.2.2 Interventions

The type(s) of interventions implemented in QI studies vary widely from a single intervention to bundled-multifaceted solutions (several interventions standard for all patients) to multi-factorial interventions (multiple interventions selected by risk factor and customized to patient needs). In addition, the literature search revealed interventions ranging from unique solutions such as glow in the dark toilet seats (Fonda et al., 2006) to traditional hourly rounding interventions (ECRI, 2009) and visual cues (yellow socks and fall signs posted on the door and in the chart), safety meetings at change of shift to highlight patients at risk for falls and post fall debriefings (Anderson et al., 2009).

Some solutions may be successful but are costly and difficult to sustain such as the addition of two nurse assistants to each shift to assist with hourly rounds and support nursing care on a 39-bed medical surgical unit (Veluswamy and Price, 2010). This involves large staffing commitments and is difficult to sustain. If extra staffing was removed, perhaps the success of these interventions would diminish. Other studies developed low cost solutions such as customized fall prevention signs designed by patient families. These showed short term success but are questionable for sustainment (Jeske et al., 2006).

Some studies focused on aspects other than interventions. The study conducted by Hunderfund was focused on the assessment of the patient more than the prevention measures. The unique twist in this study was to add a physician's rating of a patient's fall risk to the electronic admission order set. Only 4.6% of the patients were identified at risk by the physician and not the nurses. The real benefit of

requiring physician involvement was to increase awareness of fall risk upon admission and may influence other fall prevention measures by the physician like care in prescribing fall risk medications (Hunderfund et al., 2011).

Studies that did focus on interventions took a multi-faceted approach that included work practice, environmental and equipment changes along with staff education (Fonda et al., 2006). This study along with Sulla & McMyler, (2007) are encouraging because they both used continuous improvement strategies to implement real-life interventions that were multi-faceted and identified by staff to improve adherence.

2.2.3 Critical thinking.

A thorough four year study conducted by Weinberg (2011) included reflection about the critical thinking that must be involved when selecting the most patient appropriate fall interventions. The first year was spent assessing the existing fall prevention processes at Staten Island University Hospital (714 beds) and collecting baseline metrics. During their assessment phase, they found the protocol for interventions was based on best practice however, compliance was not adequate due to low priority given to fall prevention. This failure to adhere to fall interventions resulted in missed opportunities for prevention. They also found that staff was not using critical thinking skills when applying the fall protocols to an individual patient. One technique used to improve critical thinking was monthly fall reviews for management and staff providing patient care. During the meeting, root causes of past falls were reviewed to identify best practice. Role playing techniques were used to illustrate some situations (Weinberg et al., 2011).

Another interesting approach to encourage critical thinking in the Weinberg study was the daily fall prevention rounds performed by management. They audited fall risk assessments for all newly admitted patients to check for accuracy and ensured appropriate prevention measures were implemented. Management and staff were held accountable with a review of cases of noncompliance in a monthly meeting. Other attempts to reinforce falls as a high priority included daily contests for the best record of consecutive fall free days. Fall outcome data were presented at unit, departmental and institutional level meetings. Fall prevention in-services were held for all physician, therapists, housekeepers and transporters. These techniques helped

illustrate to staff the high priority of fall prevention and reinforce the partnership of management and staff by sharing accountability. In order to evolve their culture of safety and continuous QI they embedded accountability into all levels of the hospital. The duration of this study is useful as an example of the evolution of improvement over time (Weinberg et al., 2011).

2.2.4 Fall rates and fall with injury rates

The study by Williams et al. (2007) on three medical wards (72 beds) and on a geriatric ward (17 beds) used a similar methodology as Barker (2009) and Hunderford (2011) with targeted interventions for individual patient needs but with a conflicting outcome. Williams et al found that total falls decreased but falls with injury remained the same. The authors suggest that the change may have been due to increased awareness of fall prevention by the staff more than a specific intervention (Williams et al., 2007). Since falls with injuries are such a rare occurrence just one or two can skew results of a short time frame. It would have been interesting to see the trends for an additional six months. Neily et al (2005) found more team momentum improvement at one year than at six months due to culture change through multi-disciplinary teamwork. This study found no statistical improvement in total falls but falls with injuries were zero.

The most common outcome was a large decrease in injury and smaller decrease or no change in total falls (Sulla and McMyler, 2007, Barker et al., 2009a, Fonda et al., 2006, Anderson et al., 2009) Anderson found overall fall rates decreased by 18% and falls with injury by 30% (Anderson et al., 2009) but the time period is unknown. A quality study by Barker (2009) showed no significant change in fall rate comparing pre to post intervention periods. However the fall with injury rate did show significant improvement that was sustained throughout the post intervention period. Several possible reasons for the lack of change in total falls were given; an increase in reporting non-injurious falls, implementation of computer based reporting, and increased staff awareness of the definition of a fall (Barker et al., 2009a). Fonda et al (2006) conducted a three year study that used a multi-strategy program to achieve a 19% reduction in total falls and a 77% reduction in falls with serious injury.

In another study, implementation of interventions had to be tailored to each different hospital ward over 14 months. Ten hospitals and ten nursing homes were selected with five intervention units and five usual care units as control groups (van Gaal et al., 2009). Data were collected from September 2006 to November 2008. Although the experimental design is intriguing, no results were reported in the initial article. Part 2 of this study was published in 2011 and although the number of adverse events decreased, preventive care given to patients in the high risk category for falls remained unchanged (van Gaal et al., 2011). Another benefit of this study was the use of both outcome (number of falls) and process measures (assessment with written plan and multi factorial interventions). Unfortunately, it is difficult to monitor all the continuously changing preventive care tasks even for one topic and this study attempted three different safety topics. The study also had a rigid definition of “correct” process metric where a patient had to have a fall risk assessment and multi-disciplinary plan with multiple factorial preventive interventions. If any part of the process metric was missing it was categorized as not being correct (van Gaal et al., 2011). One possible explanation of the improvement in falls but no change in process metric was that the partial implementation of the assessments and interventions is enough to help reduce adverse events even though the implementation may not be done perfectly every single time.

Considerations in planning the intervention in Study #2 (discussed in Chapter 5) that were informed by this section of the literature review included: 1) reducing the number of interventions for high risk patients (simplify to individualize to a patient’s needs) and 2) understanding that a program can be effective over time if falls with injuries continue to decline even if the overall total fall rate remains unchanged.

2.2.5 Sustainment

The study by Veluswamy and Price in a 392 bed hospital in Wilkes Barre, Pennsylvania illustrated that Lean Six Sigma processes can be applied to fall prevention but the three month time period after intervention was too short to establish sustained success. Many QI programs experience a short term improvement period when the true proof of culture change is in the sustainment. Veluswamy and Price implemented popular interventions such as hourly rounding, therapy evaluations, alarm systems and education programs. These interventions are

unlikely to maintain unless staff culture is shifted to accommodate these changes (Veluswamy and Price, 2010).

The study by Barker et al. (2009) conducted in a 323 bed hospital in Melbourne Australia implemented popular interventions (fall alert sign, supervised toileting, low bed, two or four hour toileting rounds, walking aides within reach and bed alarms) with a post intervention period of five years. This follow up period was long enough to show stable fall rates for three years, a slight worsening for the fourth year but recovery to better than baseline for the fifth year.

A fall prevention program with long duration was conducted at Mayo Clinic in Rochester Minnesota (Sulla and McMyler, 2007). The seven year program began with changes in fall risk assessment, patient and staff education with a collaborative, multi-disciplinary approach in 2000. Rehabilitation began using a falling star symbol as a visual cue to identify patients deemed to be at high risk for falling. In 2003 a fall prevention team enhanced existing processes for reducing falls in the following five areas: fall risk assessment, communication, culture and delegation, education and facilities/design. Over the next two years they continued to improve and enhance their program. Similarly to Barker and Anderson (2009), Sulla & McMyler, (2007) found the total number of falls remained unchanged but serious falls decreased with an increase in the time between serious falls.

Neily, et al (2005) found that using QI to achieve collaboration was the key to achieving sustained improvement. Their program built momentum over time by achieving a better improvement spread after one year than they had at six months (Neily et al., 2005). It has been indicated that comprehensive multi-faceted programs can achieve sustained results but often seem to achieve a greater decrease in falls with injury than total falls. (Fonda et al., 2006, Sulla and McMyler, 2007).

Many different types of interventions can achieve short term reduction in falls. However sustained success must be realized over a long duration. It's even more critical to observe trends in falls with serious injuries over several years due to the infrequency of occurrence. Although patience is required to track long term success, several studies were able to show fall trends for three to five years after interventions (Barker et al., 2009a, Sulla and McMyler, 2007).

2.2.6 *Phase 2 QI Literature*

The same inclusion and exclusion criteria were used during Phase 2 as shown in Figure 2-2. The search strategy shown in Appendix B.1.1 resulted in 3,415 articles from 2012-2015. Reviewing the titles using the exclusion criteria reduced the possible articles to 67. These abstracts were reviewed for more detail resulting in 18 top picks selected for inclusion in this section.

The literature indicates using QI to develop a fall program is effective in reducing falls and falls with injury (Ohde et al., 2012, Lohse et al., 2012, Ortiz, 2012). Tools such as Lean, Six Sigma and Change Management are well suited to deal with complex quality challenges (Chassin, 2013). Six Sigma methodology has been successfully used to verify compliance to fall programs, identify barriers to compliance (Goldsack et al., 2014) and decrease fall rates (Christopher et al., 2014). It has also been helpful to develop post fall investigation processes to provide critical information for learning and planning for future fall prevention (Healey, 2012).

In order for a fall prevention program to be most successful it must achieve a system approach encompassing many components. Organizational culture changes that include leadership promote reporting errors and suppress intimidating behaviors that may inhibit this open philosophy (Chassin, 2013, Miake-Lye et al., 2013). All staff (including providers) must hold each other accountable for fall prevention and promoting a culture of performance improvement (Goldsack et al., 2014). Hospital policies must continually be updated to reflect best practice (Healey, 2012). Environmental safety interventions are an essential consideration that must be optimized to enable safe behaviors (Ohde et al., 2012, Olvera-Arreola et al., 2013).

Patients must also be engaged as active partners in their fall interventions (Goldsack et al., 2014). Engagement requires additional time from the patient's nurse that's already constrained with numerous tasks. Technology must help and not hinder these time constraints for nurses (Grant, 2013). The fall prevention process must be simple and efficient in order to gain staff acceptance (Ireland, 2013). A higher skill mix of registered nurses with higher nursing hours per patient day resulted in lower fall rates (He et al., 2012). Another method to gain staff compliance with a fall

prevention program is to customize the interventions to each unit by listening to nurses opinion on the best solutions for their patients (Huey-Ming, 2015).

Since fall risks are multi-factorial, interventions must involve multiple components carried out by a multidisciplinary team (Healey, 2012). Common components included in a multifactorial interventions include: fall risk assessment, staff compliance to intervention protocols, staff and patient education, information technology, leadership support and staff engagement (Ohde et al., 2012, Miake-Lye et al., 2013). Multi-component programs have decreased falls by 20-30% (Noel, 2013, Healey, 2012).

QI and multi-factorial approaches to fall prevention is a promising approach but better reporting on study specifics are needed to combine and synthesize results so interventions can be compared to establish evidence needed to select the most efficient fall prevention strategies (Hempel et al., 2013). Studies that have implemented QI methods lack consistent framework and outcome measures making it difficult to identify the optimal intervention or bundle (Miake-Lye et al., 2013).

2.2.7 Summary of QI Literature

Fall prevention is a complex multi-faceted problem requiring multiple interventions customized through critically thinking about the risk factors to develop an agile intervention plan in response to changing conditions (Weinberg et al., 2011, Healey, 2012, Ohde et al., 2012). QI is an appropriate methodology to assist a multidisciplinary team through the continuous improvement process needed to sustain success (Ortiz, 2012, Lohse et al., 2012). The post intervention period needs to be a duration long enough to ensure sustainment. Falls with injury are a rare occurrence and it is impossible to prevent every fall so trends must be observed over one to three years (Lohse et al., 2012, Sulla and McMyler, 2007, Fonda et al., 2006). There is a wide variation of reported improvement in fall rates which may be due to variation in the application of QI methods and outcome measures (Hempel et al., 2013).

2.3 Patient Adherence

Phase 1 of the Patient Adherence literature review results are discussed in 2.3.1 through section 2.3.5 while Phase 2 is discussed in section 2.3.6 . The summary of

both phases can be found in 2.3.7. After reviewing unassisted falls during Study #1, it became evident patients were not using the call light to ask for assistance. The direction of this literature review section was influenced by the results from Study #1 and the reflective development of a fall prevention model where patient intrinsic factors have been observed to have a large influence on the care process.

To investigate patient adherence literature, the search terms were used: “inpatient”, “accidental falls”, “non-compliance”, “cooperation”, “behavior” and “non-adherence”. This search identified 107 potential abstracts. These abstracts were reviewed for relevancy and 16 were progressed for further assessment.

The original exclusion categories used to reduce 107 abstracts to 16 include: “nursing homes and diagnosis”, “dashboard”, “exercise”, “ancillary departments”, “nursing practice / model of care / staffing”, “hip protectors”, “interviews / barriers”, “electronic fall detectors”, “no abstract”, “restraints”, “efficiency”, “vision” and “medications” (see Figure 2-3).

The remaining 16 articles were further reviewed in a consensus session (with the Fall Expert from BJH) where each abstract was discussed. During this session, additional inclusion and exclusion criteria were developed to seek opportunity to gain insight to new opportunities and techniques.

Exclusion does not necessarily mean the abstract was not valuable rather it simply was not applicable to advancing patient compliance with intervention recommendations. Additional exclusion criteria included: “Patient satisfaction”, “Bedside shift report”, “Pressure ulcers”, “Output” and “Sitters”.

Inclusion criteria which left ten remaining articles included: “Patient satisfaction and call light usage”, “Patient and family education”, “Participation with interventions”, “Patient / caregiver agreement” and “Patient perception of stay with fall risk”.

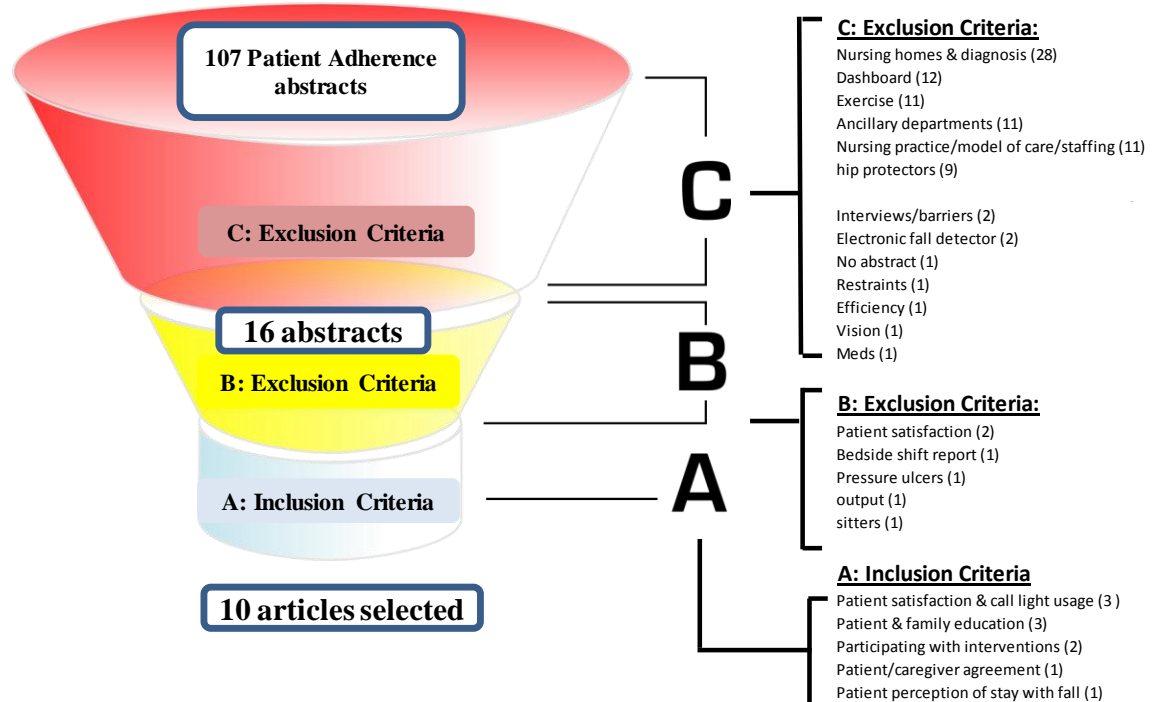


Figure 2-3 Patient adherence exclusion and inclusion criteria

During Phase 1 of the Patient Adherence literature review the earliest publication from the ten selected articles was published in 2004 and the most recent study was published in 2011. (Phase 2 included patient adherence articles from 2012-2015 discussed in section 2.3.6). Appendix D gives a tabular summary of factors considered in the critical appraisal.

A Cochrane systematic review of randomized control trials of fall prevention literature offers an understanding of patient adherence with fall prevention interventions (Cameron et al., 2010). A unique focus was to include only single intervention studies. Due to the complexity of fall prevention, typically studies include multifaceted (bundled) interventions applied to all patients in a standard way making it difficult to determine which part of the intervention was effective. Forty papers were included that were published between 1990 and 2008 but only 21 of those addressed adherence and included the following interventions: “exercise”, “medication” and “multifactorial”. The review suggested half of the patients that are approached in institutions are likely to participate in fall prevention interventions. A researcher should plan for ten percent attrition rate plus an additional six percent mortality rate (in a geriatric population) for a 12 month study. Adherence rates were

best for an individualized approach for exercise, while a group approach had better adherence for medication interventions (Nyman and Victor, 2011).

2.3.1 Patient expectations

One of the insights from the patient adherence literature review was the component of understanding what a patient wanted and anticipated before expecting them to comply with an intervention that healthcare workers thought best for them. For example, if the call light is within easy reach of the patient, the care team expects them to use it. Tzeng et al (2011) found that more calls resulted in less falls. Increasing call light usage requires a partnership between patient and hospital staff. Patients expected a call light to be answered in 2.5 minutes but 80% of the patients thought average response time was three minutes. A suggestion was made that patients should be able to prioritize the urgency of their call light requests.

2.3.2 Link between patient satisfaction and falls

The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) is a standardized survey of patients' perspective of hospital care. It began in 2006 and is intended to increase hospital accountability for QI across the United States. This is an objective and meaningful way for hospitals to make comparisons of patient experiences. The goal for fair comparisons is for each hospital to complete at least 300 surveys annually with results adjusted for patient mix and ongoing 12 month rolling reporting periods. Rating scales on the core questions are based on how frequently the patient perceived the measured action to take place; never, sometimes, usually, or always (Owens, 2011).

Some articles explored the idea of linking patient satisfaction to fall reduction (Tzeng et al., 2011, Tzeng and Yin, 2009b, Tzeng and Yin, 2009a). Seven of the 22 core questions on the HCAHPS survey were included in correlational analyses including: 1) communication with nurse, 2) communication with physicians, 3) responsiveness of staff, 4) pain management, 5) communication about medications, 6) cleanliness of hospital environment and 7) quietness of hospital environment. These seven questions were selected because an earlier exploratory study had found them to be potential contributors to fall occurrence. The purpose of this article was to determine if there is an association between a patient's perception of these satisfaction measures and their fall rate during their hospital visit. They stratified

data according to four different age groups. Injury rates were calculated four different ways according to the age groups: 1) all ages, 2) 65 years and older, 3) 18 years and older and 4) 0-17 year olds. Generally they found the higher the satisfaction levels were for responsiveness of staff, cleanliness and quietness of hospital environment, the lower were the injurious fall rates. This article stopped short of saying HCAHPS measures and injurious fall rates have an impact on each other but simply investigated an association. They did find that teaching hospitals had higher injurious fall rates, lower satisfaction measures and higher acuity than nonteaching hospitals. In other words, the higher the acuity level, the higher the fall rate. This indicates the importance of reporting the hospital type, acuity and teaching status of the environment in which a study is conducted (Tzeng et al., 2011).

2.3.3 Methods to discover what patients want

A few studies attempted to get patient opinions about fall prevention. Techniques ranged from asking patients what interventions are important to them (Haines and McPhail, 2011) to visiting their home after a hospital stay or going to a patients home after a hospital stay for interview and assessment of home environment (Tzeng and Yin, 2009b). Others involved completing a patient satisfaction survey after returning home as discussed previously (Tzeng et al., 2011). The innovative approach by Haines & McPhail, 2011 was to understand how much a patient is willing to pay for six different fall prevention approaches. This cross-sectional survey of 125 patients during their first week on a geriatric rehabilitation unit in Queensland, Australia were asked to rate the value of the following six interventions: 1) a falls consultation, 2) an exercise program, 3) a face-to-face education program, 4) a booklet and video education program, 5) hip protectors and 6) a targeted, multifactorial intervention program. The intervention perceived as most valuable was the targeted-multifactorial intervention program with the falls consultation program second. The face to face education was not valued as highly as the exercise intervention with the booklet and video education valued less than both. Researchers created a sense of urgency by providing patient with information; statistics like one in four patients are at risk for falling and the risk of injury is one in every three falls. They used a Latin square design to make sure there was no bias in the order of intervention presentation. Linear regression analysis was used to assess the impact that cost had on a patient's consideration of value for a specific

intervention. Results indicated, tailoring many choices is important to patients. One limitation of this study is that the sample was only taken from a geriatric rehabilitation population and caution may be needed when extrapolating results to a broader application.

2.3.4 Environmental recommendations

At first glance the environment may appear to be excluded from adherence. However if the environment becomes a barrier, as a patient is attempting to comply with fall interventions, it can become an important feature to consider. An exploratory study by Tzeng et al (2009) discussed some unique environmental features such as motion sensors for lighting in the patient room and bathroom and a bed height position of lower than 15 inches to match 80 percent of the lower leg lengths measured during data collection. Adjusting the bed height to correspond to a patient's lower leg length was inspirational since a large percentage of falls occur at the bedside as a patient attempts to exit the bed. Patients in the survey stated they had to "leap off" their hospital beds during a recent stay. They surveyed 91 patients over 65 years of age in their homes within 30 days of being discharged from a hospital stay that may or may not have included a fall. The survey was conducted at the former patient's home and took approximately 15 minutes. Simultaneously, data collectors were responsible for taking measurements such as height, weight, lower leg length and height of bed. Quantitative and qualitative data were collected and divided into three dimensions developed by Tzeng: 1) patient room setting, 2) presence of hospital equipment and 3) workforce concerns. Participant suggestions for better fall prevention included lower beds, dry bathroom floors, better lighting, wider doorways, clear pathways, pull bars on walls, access to walkers or canes and bedside commodes. Patients also expressed the need for nurses to repeat fall prevention education as often as possible and not to leave a brochure without explanation (Tzeng and Yin, 2009b). One limitation of this study is that it was conducted within 30 days of a patient's discharge so they may have had difficulty recalling details of their stay. This drawback must be balanced with the benefit that patients were free to make comments without fear of offending a healthcare provider while under their care.

2.3.5 Patient and family education suggestions

Several sources agreed an unsuccessful method of achieving patient adherence to fall interventions was using a brochure or flyer to convey information (Haines and McPhail, 2011, Tzeng and Yin, 2009a, Tzeng and Yin, 2009b). This study discussed previously by Haines & McPhail found that patients were least likely to pay for a booklet or video on fall prevention. It was perceived to have less value than face to face education. In patient surveys they expressed a preference for nurses to repeat fall prevention education as often as possible and not leave a brochure without explanation (Tzeng and Yin, 2009b). However in a relevant but not very rigorous study by Ryu et al (2009) they found it beneficial to mount the flyer on the wall and discuss it with the patient. The lack of rigor mentioned above involved the short duration span of the intervention and lack of sustainability. The purpose of the study on a neuroscience unit was to evaluate patient and family education on fall prevention via a pamphlet and education. It involved 91 sessions with 67 patients over a six-week period. Each five to twenty minute session was conducted by a student from the Clinical Nurse Leader program covering the content of the pamphlet (fall risk factors, common location of falls, consequences of a fall, how to prevent falls and what to do if a fall occurs). The content of the pamphlet had been developed by a fall team from the hospital. It was left with the patient and family after the session was complete. The length of the session could vary depending on the patient's physical condition and level of interaction. The student was at the hospital three or four days a week for six weeks and saw all high risk patients that were available on the days she was present. Some patients asked for the pamphlet to be posted on the wall as a reminder. This prompted the student to develop a poster that could be seen from across the room to remind patients to use the call light to get assistance getting out of bed. During the six-week program, none of the patients who received the education session fell. The two patients that did fall had not attended a session (Ryu et al., 2009). The lack of rigor in this study is evident in the results and conclusions of the article. The QI methodology of Plan-Do-Study-Act (PDSA) was used to implement the study, but the duration of the intervention was not adequate to evaluate success. The sessions between the student and family only occurred a few days a week and were not sustained by bedside nurses after her departure. The reduction in fall rate is shown together for a three month period even though the

intervention was only conducted for a six week period. The additional assistance of the student's time to conduct education session cannot be maintained so the intervention was not sustainable.

Another interesting survey (not analyzing metrics of fall interventions) was conducted by Vassallo et al. (2004) to compare the opinions of patients and relatives (n=100) to those of nurses and doctors, physiotherapists and occupational therapists (n=100) for fall prevention. The survey involved attitudinal statements followed by a five point Likert scale to assess degree of agreement. Almost everyone interviewed (99%) thought fall prevention was important and that prevention measures should be taken for patients at risk for falling. Only 17% thought falls should be ignored to concentrate on higher priorities. Non-healthcare professionals were more accepting of interventions such as bed rails, lap belts, "at risk" labels by the bed, identification bracelets, recliner chairs and bed alarms. They found a difference in opinion on acceptability of restraint measures among patient/relative and health care professionals. Patient adherence was also found to be most successful if patient and family were included in fall intervention planning (Vassallo et al., 2004).

A randomized control trial was conducted using behaviour modification through education by an Occupational Therapist as the intervention for 226 patients in a metropolitan hospital in Melbourne Australia specializing in aged care. The 111 patients in control group did not receive education. One hundred fifteen patients received the education program. Each education session ranged between 15 and 35 minutes and was conducted two times a week. The sessions were intended to facilitate discussion between the patient and therapist so barriers with compliance to recommended interventions could be discovered. The content of the program was intended to be delivered over four sessions and aligned with the following concepts: 1. Threat appraisal, 2. Protection motivation and 3. Goal setting. Outcomes were the number of patient falls and a patient survey with five point Likert scale response. Results of the study revealed that one-on-one education with the appropriate content discussed in a series of sessions can result in modified behavior. They could not, however, state a specific activity they modified and credited a more general increase in awareness of falls (Haines et al., 2006).

To encourage patient adherence, research suggests it is important to have face to face communication (Haines et al., 2006) and not to rely on pamphlets to convey information (Tzeng and Yin, 2009b, Ryu et al., 2009) . Family inclusion (Vassallo et al., 2004) with multi-factorial methods of interventions (Haines and McPhail, 2011) customized to patient needs were the most effective, but there also may be incongruence between goals of patients, family and healthcare workers (Vassallo et al., 2004).

2.3.6 Phase 2 Patient Adherence Literature

The same inclusion and exclusion criteria were used during Phase 2 as shown in Figure 2-3. The search string shown in Appendix B.1.2 resulted in 794 articles from 2012-2015. Reviewing the titles using the exclusion criteria reduced the possible articles to 42. These abstracts were reviewed for more detail resulting in 12 top picks selected for inclusion in this section.

The first theme from patient adherence literature is the importance of multi-disciplinary team work to achieve a common goal of fall prevention. Team members should include physicians, nurses, housekeeping, nutrition, labs, therapies and anyone walking in or near the patient's room (Stempniak, 2015). An article that was also included in the QI literature stressed the importance of patient engagement as an active partner (Goldsack et al., 2014). Multidisciplinary team work and cooperation is also a critical component in successful QI projects so it makes sense that patients would be a critical team member. A project in a health network in Southeastern US used an intervention strategy called Mobility/Activity circles to improve communication about falls. The focus was to improve timely communication about fall risk during patient handoffs. Information included activity levels, mobility challenges and determining the best way to transport patients including recommended handling equipment if needed (Murphy, 2013). Kullberg discovered that a lack of information exchange between patient and their health care professional has a negative impact on patient safety risk (Kullberg et al., 2015).

Systems need to encourage patients to report problems and create opportunities for communication. This is necessary because patients may hesitate to formally report concerns. When patients who believed something had “gone wrong” during their care were interviewed, 47% thought the problem was a lack of communication, 28

% thought the problem was with medical care and 24% thought both communication and medical care was responsible (Mazor et al., 2012).

Many of the articles resulting from the patient adherence literature review involved the topic of hourly rounding. This intervention creates intentional interactions with patients and allows nurses more time to address care needs (Sherrod et al., 2012). Hourly rounding was found to show “moderate – strength” evidence to reduce patient falls and improve call light usage (Mitchell et al., 2014). A four week pilot study by Petras implemented hourly rounding resulting in improvement in patient complaints and call light usage due to the opportunity for communication between nurse and patient but the increase in number of falls during the pilot study may have been due to the short duration of this study period (Petras et al., 2013). Although not a statistically significant finding, a study by Sherrod showed an improvement in falls with serious injury three months after implementing the rounding intervention (Sherrod et al., 2012).

It is important for patients to perceive the need to participate in fall interventions while still maintaining control and independence. To achieve this understanding the nurse must convey a positive message about the benefits of fall prevention. Interventions must be simple and tailored to each individual need (Hawley-Hague et al., 2014). Greenberg found that health fair participants were more willing to discuss fall risk and interventions than patients visiting their family practice physicians. This suggests the certain settings may be a more meaningful opportunity to discuss fall risk prevention (Greenberg et al., 2015).

Interventions are best received if they are simple and customized for an individual patient. Even simple fall kits were only used by patients if their provider discussed the kit and its application to their individual fall risks (Keuter et al., 2015). Technology may be another way to increase adherence to fall prevention interventions. “Smart grab bars” with auditory and visual cues to encourage participants to use the grab bars as they entered and exited the shower were found to increase usage. Participants preferred visual cues (a lighted panel that illuminated when approached) instead of the auditory cue (a male voice with a reminder message to use the grab bar). The auditory cue, however, was the most effective in promoting use of the grab bar.

2.3.7 Summary of Patient Adherence Literature

It requires multiple interventions to reduce fall risk but they must be simple and customized for each patient (Keuter et al., 2015, Hawley-Hague et al., 2014, Haines and McPhail, 2011, Tzeng and Yin, 2009b). Environmental and equipment interventions e.g. dry bathroom floors, lighting, wide doorways, clear pathways, pull bars on walls, access to walkers or canes and bedside commodes are important so as not to become a barrier to patient adherence (Tzeng and Yin, 2009b). A multi-disciplinary team approach involving physicians, nurses, therapists, housekeepers, dieticians etc. is important for successful fall interventions (Stempniak, 2015). A critical member of this team is the patient and family and an understanding of their expectations (Murphy, 2013). Communication is critical for the entire multi-disciplinary team (Petrus et al., 2013). Staff must communicate fall status and patient risks to their colleagues at change of shift (Murphy, 2013). Communication with patient and family is critical for involvement with customizing interventions and education on fall risk (Vassallo et al., 2004, Mazor et al., 2012, Sherrod et al., 2012).

2.4 Participatory Ergonomics

Phase 1 of the Participatory Ergonomics (PE) literature review results are discussed in 2.4.1 through section 2.4.4 while Phase 2 is discussed in section 2.4.5. The summary of both phases can be found in 2.4.6. The third literature review focus on Participatory Ergonomics (PE) was needed to explore the use of this technique in healthcare and other industries to consider stakeholder involvement (patients) from an ergonomics perspective rather than from a QI perspective. The purpose was to learn more about theories for patient engagement from an HFE perspective. PE is a HFE technique used to understand the human in the system and influence behavior.

Although PE programs have been conducted in hospitals they had not included patients as team members until the literature search conducted in Phase 2 (see 2.4.5). This was a tempting direction for further research but before this thesis applied another methodology, it was important to pause to understand the patient perspective on falls. Elements of PE were used as a foundation to develop the data collection proforma. The difficulty with acceptance of Patient Partnering in Study #2 revealed

the need to close the gap in understanding between nurse and patient to achieve the collaboration required for an effective partnership.

Search term words for the PE literature review included “participatory”, “ergonomics” and “HFE” and yielded a total of 144 abstracts that were considered with 44 progressing for further assessment. Figure 2-4 illustrates the number of abstracts selected according to the inclusion and exclusion criteria for PE.

The original exclusion criteria included: “traditional musculoskeletal disorders”, “heavy manufacturing”, “construction/agriculture”, “general”, “office”, “healthcare”, “return on investment”, “design only”, and “shiftwork”. Excluding all studies that did not involve patients and falls was not practical because it would not leave an adequate number of articles for review.

The remaining 44 articles were further reviewed in a consensus session (with the Fall Expert from BJH) where each abstract was discussed.

Exclusion does not necessarily mean the abstract was not valuable, but simply that it was not unique in advancing knowledge of PE in a healthcare setting. Additional exclusion criteria included: Abstracts older than 2009 if there was another more recent article with a similar theme, studies “applicable to only one population”, “exclusively involving manufacturing”, “exclusively involving a musculoskeletal disorder” and articles that were “theoretical only with no applied basis”.

Inclusion criteria resulting in 12 remaining articles included: “PE techniques”, “support of participatory techniques that improved the workplace”, a “credible journal source”, “recent or ground breaking articles”, “systematic reviews”, those involving “acute healthcare settings” and “applied studies that used PE approach”.

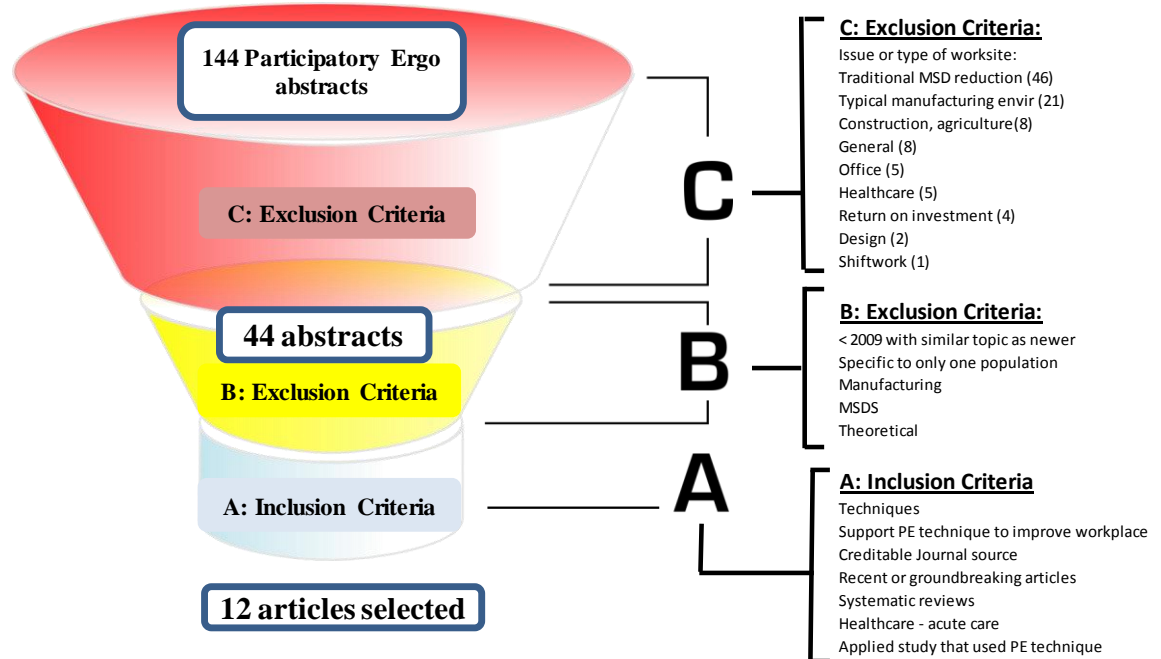


Figure 2-4 Participatory Ergonomics exclusion and inclusion criteria

During Phase 1 of the PE literature review the earliest publication from 12 selected articles was published in 1997 and the most recent study was published in 2013. (Phase 2 included PE articles from 2012-2015 discussed in section 2.4.5). Appendix E gives a tabular summary of factors considered in the critical appraisal.

2.4.1 Definition of PE

PE is described as an umbrella term for different approaches (Vink et al., 2006). PE adapts the environment to the human by getting the "proper people's" input. Wilson (1995) (Wilson and Corlett, 2005) states that successful PE includes involvement of people in planning and controlling their work activities combined with the knowledge and power to influence process and outcomes. (Matthews et al., 2011) defines PE as a macro-ergonomic intervention to improve the fit between worker and environment. Projects can be on an individual (workstation) level or organizational (redesigning organizational structures). A common theme in all definitions is that PE is a systematic approach involving worker, manager, ergonomist and other appropriate staff depending on the focus of the project. Decisions can be made by the workers or ergonomist or management and then changes are tested with the workers. Literature reveals both success and failures with each PE approach.

2.4.2 PE Framework

The Participatory Ergonomics Framework (PEF) was developed using a systematic, peer validation process with retrospective description of seven independent studies to classify the 9 dimensions Table 2-2 (Haines et al., 2002). The validation process began with an interview of the ergonomics leads/facilitators of each of the seven studies to classify the project according to the nine PEF dimensions. These classifications were then verified with the original project team who voted for the importance of dimensions through ranking.

PE Framework: (Haines et al, 2002)	PE Framework (Morag, 2013)
Permanence (ongoing, temporary)	Workforce Involvement
Involvement (full direct, partial direct, representative)	Analysis Duration
Level of Influence (entire organization, department/workgroup)	Reporter Role
Decision Making (group delegation, group consult, individual consult)	Scope
Mix of Participants (operator, supervisor, middle & senior management, union, specialist)	IS Analysis/Management
Requirement (compulsory, voluntary)	
Focus (design equipment, tasks, jobs, work organizations, formulate policies)	
Remit (process development, problem identification, solution development/evaluation)	
Role of Ergonomic Specialist (initiate process, team member, training, consult)	

Table 2-2 Features of PE Framework

Two case studies by (Dixon and Theberge, 2011) were conducted according to the framework developed by Haines et al in a courier and furniture manufacturing company. The purpose was to see how the roles and participation of the team members changed as throughout the process improvement cycle. One problem encountered during the furniture manufacturing project was that the solutions were

complex with consequences for division of labor. The workers lacked authority and expertise to be involved in the implementation so they found their role in the PE team diminished during this phase of the project. The right mix of PE members depends on organizational structure, production processes and hierarchy of authority in a company to implement solutions. The role and amount of participation can vary according to where the team is in the improvement process (Dixon and Theberge, 2011).

Morag (2013) used a less objective method than Haines to develop a PE Framework with five dimensions shown in Table 2-2. Researchers reviewed 20 studies and categorized them into a framework to use during a workplace analysis. The summary was done by independent researchers without consulting the authors of the original studies (unlike Haines, 2002). The authors assumed if overall participation of workforce was not mentioned that it was not considered, however without checking, it might be that the information was not published and the assumption could be misleading. The dimensions were defined with three categories (low <25%, medium 25%-75%, high >75%).

A systematic process was conducted to develop a quick survey to evaluate the effectiveness of a PE team (Matthews et al., 2011). During Phase 1 a literature review of 20 articles and subject matter expert reviewed combined to develop 42 common items to evaluate psychometric properties of PE. These items were tested in a survey (written and verbal option) and answered by 63 line workers from a manufacturing plant in New England. Factor analysis was used to explore the contribution of each factor related to the corresponding dimension. Five dimensions emerged as most promising and can be assessed reliably with 17 items in an eight minute survey. 1. Self-involvement, 2. Ergo Knowledge Base, 3. Managerial Support, 4. Employee Supportiveness, 5. Strain related to ergonomic changes

A survey with these five components could be given to members of the PE team in an effort to improve their own PE process. Survey results are more immediate than overall outcomes so can be used periodically to understand engagement level of a team and adjust activities according to issues that arise from survey results.

A systematic review by Rivilis of 12 articles revealed moderate evidence that PE has positive impact on musculoskeletal disorders, reducing injury, workers'

compensation claims and lost work days; although the magnitude of improvement is not precise.

Rivilis et al (2007) defines PE as an approach that encourages workers to be involved in controlling their own work activities and consequently decreasing their risk factors. If the PE framework was done with the patient as one of the team members, it may empower them with knowledge of their risks and give them control over their plan of care to decrease their risk factors. Loss of independence and control is often a reason cited by patients for not cooperating with fall prevention interventions. Using the PE approach may help return some of the power to the patient making them an active participant in their own safety.

Further suggestions by Rivilis to improve experimental rigor of future studies include: use of a control or comparison group, recording pre and post intervention time periods, documentation of participation (including percentage of population) and description any confounding factors. The strength of the PE approach is that a variety of ergonomic changes that can be implemented as changes are directed to specific situations. This approach aligns with the fall prevention where each patient is different and assessment/intervention must be customized for each individual resulting in a solution that will continuously change. Rivilis gave a very thorough summary and description of the 12 selected projects that was very helpful in understanding the context of the findings.

2.4.3 Roles and participation in PE

Participants and the amount of their involvement with PE projects evolve over time according stages of the project. A facilitation insight from (Vink et al., 2006) is to teach a PE team the "optimal" way (as an ideal state) to help them create a better future state and understanding why the improvement will be beneficial. The stages of PE change are hazard identification, assessment and implementation of solutions. Expertise of members can be helpful at different stages, however, in Patient Partnering the intervention is completely within the control of the nurse to at least attempt the effort to patient partner. Involvement of staff and patients during intervention selection is critical. Although nurses have the power to do Patient Partnering, they perceive it as another task and do not have time. Patients also have

the power, but they may feel by calling for help, they are giving up their power and loss of independence.

2.4.4 Success of PE

A creative article by Vink 2006 went beyond the framework by Haines 2005 to identify factors that make PE a success. First they defined PE as a discipline that studies how different parties are involved in a design process. This is a contrast to Haines where the framework implies PE is an improvement methodology.

Vink conducted a literature search of successful and unsuccessful PE case studies to identify the following success factors: 1. direct worker participation, 2. management support, 3. good inventory, 4. step-by-step approach, 5. steering group to guide process, 6. check effects & side effects, 7. focus on more than health issues and 8. develop cost/benefit ratios. Based on a review of four PE case studies the following additional insights were added: 9. effect of improvement (let worker experience the new change) and 10. effect of empowerment of employees (direct involvement – allow worker to experiment with new interventions).

In a large company it's difficult to impact a high percentage of employees by an intervention from a single PE project. An organization-wide transformation initiative would be required to reach a majority of employees. A transformation journey like this can take several years to achieve the necessary culture change to influence behavior of all employees. Numerous interventions and customized solutions would be required to achieve an optimal workload design where physical and mental stress would not be under or overloaded for each employee. A paramount effort such as this must be a priority for the entire organization with complete executive support (Morag and Luria, 2013) .

2.4.5 Phase 2 PE Literature

The same inclusion and exclusion criteria were used during Phase 2 as shown in Figure 2-4. The search string shown in Appendix B.1.3 resulted in 821 articles from 2012-2015. Reviewing the titles using the exclusion criteria reduced the possible articles to 29. These abstracts were reviewed for more detail resulting in eight top picks selected for inclusion in this section.

The user centric nature of Lean complements PE principles. These complementary methods provide an opportunity for redesign of facilities and processes and change management (Reijula, 2014). Since the QI literature review in section 2.2 included Lean and Six Sigma methodologies, this section will focus on the PE framework and possible applications to healthcare. A revision of the Systems Engineering Initiative for Patient Safety (SEIPS) model adds three new components to create a model more suitable to healthcare (Configuration, Engagement, and Adaption).

Configuration represents the dynamic and interactive nature of technology, tasks and social factors that network and interact simultaneously. The configuration concept focuses on specific interactions making it possible to look at performance at one moment in time. The engagement component can include anyone actively or indirectly contributing to an activity (e.g. healthcare worker, patient, family, community). The adaption component accounts for feedback loops. Overall and process outcomes are both required for a dynamic system to evolve according to planned and unplanned circumstances (Holden et al., 2013).

Recent PE literature involves interviews conducted at children's hospitals with family members participating to represent the patient voice. A study by Baekager held focus groups to interview families to understand a patient's customized needs. The environment in the patient's room was altered according to suggestions (e.g. lighting and room decor). These changes led to a further study to investigate patient satisfaction and stress (Baekager, 2014). The goal of another study by Pernet was to understand the role patients can have in managing patient safety. Conclusions included two ways for a patient to participate in the safety of their treatment.: 1) active participation to help develop an intervention plan and 2) complying to this recommended behavior (Pernet, 2012).

Patient/family centered rounding is a technique being used to improve family engagement. PE promotes HFE principles when redesigning a system to achieve family centered rounding (Xie, 2015). A technique called simulated situations was also used to identify barriers and facilitators of family centered rounds. This technique had patients/families and their healthcare team watch video-recordings of their own rounding sessions (Carayon et al., 2014). Rounding is the daily meeting at bedside where the healthcare team and patient/family discuss care plans, treatments,

procedures and discharge plans. As they watched videos researchers asked questions to get feedback from families and their healthcare team.

Similar to patient adherence literature, multi-disciplinary teams were also included in this body of PE literature. Soares conducted structured interviews and work observations in an actual medical setting. The multi-disciplinary team participated to design workflow software in radiation therapy to promote cooperation among the team and achieve patient safety (Soares, 2012). Another study conducted in a radiology setting observed 100 patients in order to identify potential adverse events. A participatory method called “Active Research” requires active participation between researchers and subjects. A multi-disciplinary team developed interventions involving environmental, work procedures, training and managerial interventions. Cooperation between the front-line medical team, HFE and patients was achieved to promote safety (Tourgeman-Bashkin et al., 2013).

2.4.6 Summary of PE Literature

HFE provides the systems approach needed to address the complex multifactorial problem of patient falls (Holden et al., 2013). One technique of HFE is PE involving multidisciplinary teams to identify problems and develop solutions. It has commonly been used in manufacturing environments to reduce risk of musculoskeletal injuries (Haines et al., 2002, Matthews et al., 2011, Rivilis et al., 2008). The flexible format of PE has been demonstrated in recent PE work with patient and families in the healthcare setting (Xie, 2015, Carayon et al., 2014).

It is critical to assemble the correct mix of team members to resolve difficult issues (Dixon and Theberge, 2011). Input from a multi-disciplinary team is essential to successfully identify the multiple dimensions of complex problems (Soares, 2012, Tourgeman-Bashkin et al., 2013). A multidisciplinary team in healthcare can include physicians, nurses, therapists, ancillary staff, patients and families (Xie, 2015, Carayon et al., 2014). Customizing interventions to the needs of the multi-disciplinary team creates a culture of patient centered care to achieve safety for patient and workers (Vink et al., 2006, Pernet, 2012). The topic of multi-disciplinary teams also emerged in the patient adherence literature.

2.5 Discussion from Literature Review

2.5.1 Methodology

One important implication of the literature review was the benefits of QI methodology for a complex multi-faceted problem like patient fall prevention. Multiple interventions selected by risk factors that are customized to an individual patient's needs seem to be the most appropriate approach. Single interventions or even standardized multiple interventions that are identical for all patients do not appear to prevent falls.

2.5.2 Metrics

The rate of total falls seems to be independent of the number of falls with injury. It is possible to achieve a decrease in falls with injury and have no change in the total number of falls (and vice versa).

The duration of post intervention is critical to acclaim success of a project. The time frame for falls with injury is especially long because of the rare occurrence of injury. Sustainment must be achieved for several years before a statistically significant impact can be proved. This is another reason that fall prevention must be a continuous improvement project with never-ending momentum. Since fall prevention interventions are very difficult to hardwire, it is important to achieve a safety culture that continually searches for new ways to maintain safe patient and staff behavior.

2.5.3 *QI and HFE can be complementary*

QI and HFE processes may be different but they complement each other. QI can be top down while Lean is bottom-up. HFE typically uses an expert to solve a problem with input from users & management. PE uses the best of both processes (top down – with management participation and executive support and bottom up with workers as team members as well as an ergonomic expert to facilitate, guide and education the team).

Eklund's article provides a link between worker benefit and improved quality with fewer errors. That is, what is good for the worker is good for quality (this can be extended to benefit to the patient in the healthcare setting). A process or design with

worker benefit will result in improved quality. Deficiencies in quality are often caused by insufficient design of work, workplace or environment or product.

2.5.4 Know the Patient

Patients clearly want hospital staff to talk to them about their fall issues. If they think their nurse understands their needs and has time for them they will call for help when it's needed. If they call for help they are less likely to fall. Another benefit of being understood by their nurse is that patient satisfaction will also improve.

2.5.5 Mutually beneficial environment

By understanding tasks required to care for patients, a functional environment can be achieved to enhance job performance and improve patient experience. Environments, tasks and procedures that are beneficial to the staff are also good for the patient.

2.5.6 Participatory Ergonomics and patients

While QI, Lean, Six Sigma have been used for fall prevention, very few projects have used PE with patients in healthcare. When PE has been used in healthcare it more often includes ancillary staff (e.g. transporters, laboratory) and rarely involves clinical staff. One reason may be because patients are typically temporary with average length of stay being three to four days. They do not stay long enough to become part of a team in the traditional sense. However there is enough time for a partnership to be formed between nurse and patient. This partnership is crucial to reach an understanding of patient's unique needs and to customize the best interventions. A nurse must also use critical thinking to sort out the complexity of risk factors and available interventions to be agile enough to meet the requirements of the dynamic healthcare environment.

3 CHAPTER 3 QI AND HFE FRAMEWORKS

One of the aims of this thesis is to evaluate the contributions of Lean, Six Sigma and Human Factors Engineering (HFE) principles to fall prevention programs. The literature review (Chapter 2) revealed that very little has been published to bring together these methods and apply them in this arena. In this thesis, each of these three methodologies was used in a separate study to provide an understanding of its contribution to fall prevention. Subsequent chapters describe each study in detail: Lean is described in Chapter 4, Six Sigma is described in Chapter 5 and HFE is presented through Patient Interviews in Chapter 6. The purpose of the current chapter is to provide a general overview of each methodology.

3.1 Methodologies Investigated in Thesis

Lean and Six Sigma are considered Quality Improvement (QI) methodologies and are two of the most recent methodologies being used in hospitals to reduce the occurrence of adverse safety events. Other QI methodologies have been used in the past (e.g. Plan Do Check Act and Total Quality Management) to make incremental improvements involving continual change. Lean and Six Sigma were selected for this investigation because they are institutionally supported by BJC Healthcare as being most promising to achieve sustained improvement in clinical measures such as patient fall prevention.

HFE is a discipline that includes a body of knowledge (i.e., a collection of data and principles related to human capabilities and limitations), as well as process design and development (i.e., design of equipment, processes, and work methods to achieve safety, comfort and productivity): it is also a profession and a multi-disciplinary science (Wilson and Corlett, 2005). For the purposes of the current chapter, HFE will be discussed in a broad sense. In Chapter 6 it will be discussed more narrowly and illustrated through patient interviews.

3.1.1 Lean

The term *Lean* is shorthand used to refer to a lean manufacturing system. Lean originated in Japanese industry and developed over the last 100 years. It is also known as the *Toyota Production System* (TPS) because the Toyota Motor Corporation is the foremost example of Lean in action and has a continual goal of

achieving a process with minimum waste and maximum flow of value-added tasks (Junewick, 2002). Lean was recognized by the automotive industry during the early 1970s but not disseminated in America until the 1980s; it was further accepted in the 1990s as a result of Toyota's success in a declining American automotive market (Stone, 2012).

Fundamental concepts of Lean include the following principles: (Liker et al., 2008)

- A Lean process proposes the right process will produce right results. It includes but is not limited to process flow, pull systems, workload leveling, standardized work tasks and visual controls.
- The long-term philosophy of Lean bases decisions on future objectives not short term financial goals.
- Lean challenges people through long term relationships. This includes growing leaders, developing exceptional people and respecting suppliers and all multidisciplinary team members.
- Problem solving and continuous improvement maintains going to the workplace to understand a situation, making decisions by consensus and becoming a learning organization through reflection and continuous improvement.

Lean has a focus on quick turn-around and it is a good fit with the fast pace and constant change of the healthcare environment. Fairly simple projects that need a quick resolution can be addressed with Lean's Kaizen method. A Kaizen is an improvement technique involving a multidisciplinary team event lasting four days or less including short experiments to prove the success of an idea and to create a standard work process for the best method to achieve the task at hand. A few other techniques that are often associated with Lean projects include the following:

- Visual factory (e.g. locations for equipment are clearly marked, signage is visible, current information is displayed, enables detection of errors at a glance).
- Kanban system (e.g. simplified resupply procedure with clear visual cues)
- Poka-yoke (means mistake proofing where the process emphasizes design to prevent errors).

- Standard work (documentation of a standardized method to perform activities of value added tasks).
- Fishbone diagram (systematic method to explore possible causes of a specific problem).
- Gemba walks (investigative method that involves going to the source of work and observing all tasks).

Lean methods can lead to successful improvements and yield a foundation that will make defects visible when standard work is not being followed. However, Lean methods can lack the robust flexibility that is needed in complex environments. The Six Sigma methodology can yield a more in-depth understanding of the interaction of several variables at once and can be an ideal complement to a healthcare project in which defects or errors are unacceptable.

3.1.2 Six Sigma

Six Sigma is a QI methodology that uses a collection of techniques to increase business performance by reducing defects (unexpected outcomes) and process variation (inconsistent methods resulting in unpredictable results). Six Sigma is a method of improvement that focuses on strong leadership tools and emphasizes bottom-line financial results (Benbow and Kubiak, 2005).

The fundamental principles of Six Sigma include the following:

- The framework encompasses five processes components: Define, Measure, Analyze, Improve and Control (DMAIC).
- All processes have inputs that are required to achieve an output or result.
- Techniques include a variety of qualitative and quantitative tools such as process mapping and statistical process control charts to drive process improvement.
- The name Six Sigma comes from the goal to achieve performance within six standard deviations from the mean. This means to strive for 3.4 defects per million opportunities for success or to be 99.9996% “correct” (Benbow and Kubiak, 2005). For example, if an airline was trying to measure lost luggage as a defect, the goal would be to lose no more than 3.4 suitcases per 1 million suitcases handled: this would mean that 99.9996% of the suitcases arrived at

the correct destination without “defect”. This outcome would achieve Six Sigma (or be six standard deviations from the mean).

A few methods or tools that are often associated with each process phase of Six Sigma’s DMAIC components include the following: (Benbow and Kubiak, 2005)

- Define: Identify project scope, metrics and problem statement.
- Measure: Process analysis, statistics, collect and summarize data, measurement systems, analysis process capability.
- Analyze: Data analysis, hypothesis testing.
- Improve: Design of experiments, evolutionary operations.
- Control: Statistical process control, measurement system re-analysis.

Six Sigma projects may take more time for analysis but the intervention will be correlated to the root cause of the problem. A simultaneous drawback and benefit to the use of Six Sigma in healthcare is that it is not a quick fix but rather a new way of thinking that requires a culture change. Healthcare workers are accustomed to frequent shifts in initiatives (i.e. the “flavor-of-the-month”). For example, working on hand hygiene one month and infection rates the next makes the staff shift focus to the next topic and does not provide the mechanisms that are necessary to embed and sustain change. A culture change involves every employee and sustains.

3.1.3 Human Factors Engineering

HFE which is also called *Ergonomics* or *Human Factors* is a field that conducts research regarding human psychological, social, physical, and biological characteristics and that works to apply findings to the design, operation and use of products or systems to optimize human performance, health, safety, and habitability (Stramler, 1993). HFE began as a formal discipline after World War II primarily in the military aerospace arena, and it began to be applied to industry during the 1970s (Cafazzo and St-Cyr, 2012, Wilson and Corlett, 2005, McCormick and Sanders, 1982). HFE has been slow to enter the healthcare field but its benefits include the support of the cognitive and physical work of staff to achieve high quality and safe care for patients (Russ et al., 2013).

The following concepts form the foundation of HFE. These concepts are inclusive and cover all of the capabilities and limitations of humans who are performing a task (Carayon, 2007):

- Cognitive Ergonomics: Perception, attention, memory
- Physical Ergonomics: Anthropometrics, physical capabilities, layout
- Physical Environment: Sound, lighting, glare, vibration
- Job Design and Workload: Efficiency, errors, performance
- Systems Analysis and Design: Productivity, usability, quality

Usability testing is one technique used to determine if a product, process or system satisfies the previous concepts. The term usability refers to the capability of a human to perform a task easily and effectively with a range of users in a specified time and environment. Usability testing is an HFE technique that provides insight into things like performance measures (e.g. time, errors, and efficiency) as well as qualitative feedback that can be achieved with a satisfaction survey. Usability studies are needed to understand user input during design improvements. Other measurement techniques such as surveys, interviews and testing of experts/users are essential in understanding their perspective and suggestions for improvements. The systems approach is the foundation of HFE, and it provides a flexible method to pull information from many sources to compile a complete understanding of an issue from an overall systems perspective.

3.2 Comparison of Methodologies

It is helpful to compare Lean and Six Sigma since they are both QI methodologies. Table 3-1 provides a comparison between Lean and Six Sigma for the following dimensions that aligned from a combination of Graban (2009) and Benbow & Kubiak (2005). These dimensions provide a list of examples to illustrate the differences in QI methods.

Dimensions	Lean Methodology	Six Sigma Methodology
Definition	“Lean is a toolset and management system, a method for continuous improvement and employee engagement, and problem solving	“The Six Sigma method is a quality philosophy, a collection of techniques and tools for use in reducing variation; a program of improvement that

	approach” (Graban, 2009).	focuses on strong leadership tools and an emphasis on bottom-line financial results (Benbow and Kubiak, 2005).”
Philosophy	Eliminate waste by continuously striving for adding value to the customer	Decrease variation, using a systematic data driven process – Define-Measure-Analyze-Improve-Control (DMAIC)
Data Collection & Analysis Strategies	Continuous improvement based on short-term snapshots – may not realize long term trending, simplistic graphs, pareto and control charts to show trends, customer preference, efficiency focus (throughput, decrease in wasted motions)	Examples include: statistical tools such as Chi square, ANOVA, Gauge Repeatability & Reproducibility (a technique used to understand inter and intra rater reliability), benchmarking, financial benefit focus (net present value, return on investment)
Methods & Improvement Tools	Rapid Improvement - Kaizen events (focused problem solving event), value stream mapping, workplace observation, customer driven performance requirements, standard work, 5S (sort, straighten, shine, standardize, sustain), Kanban (managing inventory), visual management, error proofing	Multi-disciplinary teams working to decrease variation, control charts, SIPOC (Supplier, Input, Process, Output, Customer), Design of Experiment, Voice of Customer, culture change methods, stakeholder assessment, statistics, process mapping, process capability evaluation, measurement systems

Table 3-1 Comparison of Lean and Six Sigma Methodologies

Lean practitioners define waste as unnecessary steps that do not add value to the finished product while pure Six Sigma proponents believe that waste results from variation in the process. In service environments like healthcare; there may be necessary waste (i.e. a step that is required for regulatory compliance) as well as complex, constantly changing conditions (i.e. patient’s reaction to medication) with inherent variation. Consequently Lean and Six Sigma are used together so frequently that the term Lean Sigma is being adopted by many QI initiatives. They use different but complimentary approaches to achieve an efficient system with minimal waste. A missing component to this combination is the consideration of capabilities and limitations of the humans involved in this efficient system. Hence; the need to include HFE in QI initiatives to achieve success that is mutually beneficial to patient and staff.

Table 3-2 combines Lean and Six Sigma into a QI category to compare differences with HFE (Hignett et al., 2015 a, Hignett, 2015 b).

Characteristics	QI	HFE
Also known as...	Quality Circles, Total Quality Management (TQM), Lean, Six Sigma, Statistical Process Control (SPC), Quality Management	Human Factors, Ergonomics, Human Factors Engineering, Human Factors Science
History	<p>1920s Production quality control</p> <p>1940s Value Engineering (manufacturing)</p> <p>1950s Total Quality Control / Management (Feigenbaum)</p> <p>1960s Kaizen (Ishikawa)</p> <p>1980s Continuous Quality Improvement (Deming)</p> <p>1984: Formation of International Society for Quality in Healthcare (ISQua)</p> <p>1991: Institute for Health Improvement (IHI, USA)</p> <p>1984: 1st international conference on QI in Healthcare</p>	<p>1700s Ramazzini (Occupational Health)</p> <p>1857 Jastrzebowski: 'An Essay on Ergonomy'</p> <p>1910s: Taylor & Gilbreth: Scientific Management</p> <p>1930 Dobrovorsky: Human factors analysis of aircraft cockpit</p> <p>1950 Formation of Ergonomics Research Society (UK)</p> <p>1961 International Ergonomics Association (IEA). Federated Societies from over 50 countries include:</p> <ul style="list-style-type: none"> • UK: Institute of Ergonomics and Human Factors (IEHF)/Chartered Member • US: Human Factors and Ergonomics Society (HFES)/Board of Certified Professional Ergonomics (CPE) <p>1991: 1st international conference on HFE in Healthcare</p>
Education	<p>1980s: Degree level qualification (B.Sc. and M.Sc. courses)</p> <p>1990s: Lean / Six Sigma qualifications</p> <p>2010s Academic discipline of Improvement Science</p>	1960s: Degree level qualification (B.Sc. and M.Sc. accredited courses based on IEA core competencies)
Academic Journals	<ul style="list-style-type: none"> • BMJ Quality & Safety (IF=3.281) • International Journal for Quality in Healthcare (IF=1.584) • Joint Commission Journal on Quality Improvement • International Journal of Quality & Reliability Management 	<ul style="list-style-type: none"> • Ergonomics (IF=1.608) • Applied Ergonomics (IF=1.332) • Human Factors (IF=1.29) • International Journal of Industrial Ergonomics (IF=1.214)
Role of HFE/QI Expert	Expert in improvement methodology, facilitation and coaching skills, recognition and reworking of barriers to workflow and pace	Expert knowledge about problem, propose intervention/improvement based on analysis of problem, facilitation (change agent)

Table 3-2 Comparison of QI and HFE

QI and HFE each offer a systematic approach to the complex problem solving process of fall prevention (Hignett, 2015 b). Each approach has a unique philosophy but with the common purpose of improving the conditions for the user. The goal of QI is to make incremental improvements for a defined scope while HFE uses a system approach to achieve an efficient and safe environment for all humans involved in the process. The user for each approach has a different name (supplier/customer for QI, and user/operator/human for HFE) but the goal is to develop a process that matches the needs of the person that will use or benefit from the output of the process.

Techniques used to implement the approaches can vary based on the time required to implement a project. Lean is typically the shortest time frame because it condenses change into a Rapid Improvement Event that is typically less than four days. Outcomes can be tracked over time in a control chart that will show progress trends.

Each approach has “borrowed” tools from one another with frequent overlap between Lean and Six Sigma (e.g. value stream mapping, standard work and voice of the customer). “Design of Experiments” in Six Sigma and “Experimental Design” in HFE also have very similar concepts. Techniques for understanding tasks and workflow are also similar but each has a different complexity level. For example, a Lean spaghetti diagram will simply illustrate where a worker travels along a floor plan by linking one location to the next for a worker to complete a task. In Human Factors, a link analysis can be used to address more complex issues by adding meaning/importance (or beta weights) to each link that would represent the value of that link.

Lean typically uses very simple, visual charts that can easily be updated throughout the day to provide timely feedback about the process. Six Sigma and HFE tend to use more complex data analysis and statistics while Lean tends to be more simplistic with control charts and workload leveling.

The skill with applying these tools to projects in healthcare is to know when to use which tool and to be flexible with the strategy to meet the intent of the process. Tools and techniques must also be modified to meet the needs and skills of team members.

3.3 Application to Fall Prevention

A common theme throughout literature regarding falls is that prevention requires individualized (Haines et al., 2006, Wong et al., 2011b) multiple interventions to match a timely, accurate assessment. It is also important that reassessment be completed upon any change in a patient's condition or circumstance (Williams et al., 2007, Hunderfund et al., 2011). This intervention strategy provides justification to match multiple interventions to specific assessment issues of each individual patient (like a bed alarm and bedside commode for a confused patient with altered elimination). Combining quality improvement methodologies such as Lean and Six Sigma with the information about human capabilities provides the flexibility necessary to achieve a systems approach to address the complex and dynamic environment of healthcare (Cafazzo and St-Cyr, 2012).

As previously mentioned, the aim of Six Sigma is to achieve a defect rate of no more than 3.4 defects per million opportunities (Junewick, 2002). One problem in applying this metric to patient falls is defining the terms. The number of falls for the numerator is possible with clear definition of a fall. At first glance this seems straightforward, but agreement must be reached on "assisted falls" and falls that land on something other than the floor, like bed, wall or furniture in the room. An even more difficult challenge is to define the denominator that would be an "opportunity" for a fall. Typically fall rates are calculated per 1,000 patient days because falls are rare and a rate like 3.4 (3.4 falls per 1,000 days patients are in the hospital) is easier to understand than 0.034 falls per day (0.034 falls occur each day a patient is in the hospital). The problem with using one patient day as one opportunity for falling is that there can be several opportunities to fall in a single day.

HFE research typically combines qualitative and quantitative methodologies with a systems approach to understand a problem. A qualitative research interview technique is appropriate in order to focus on the patient perspective of falls. A semi-structured interview is an ideal way to identify the range of experiences and perceptions about a specific issue (Robson, 2011). This will be discussed in more detail with Study #3 in Chapter 6.

This complex topic is ideal to leverage the benefits of the qualitative and quantitative research methods from both QI and HFE. Numerous fall prevention

initiatives have been implemented in the past where sustainment is a challenge. To investigate the contribution of each method in fall prevention, the Thesis Author conducted studies to prevent oncology patients from falling during their hospital stay. Study #1 (described in Chapter 4) used Lean methodology during a Rapid Improvement Event to develop standard work to assess patients and implement appropriate interventions. Study #2 (described in Chapter 5) used Six Sigma methodology to develop and implement a fall prevention strategy that created a partnership between patient and nurse in attempt to customize interventions to specific patient needs. Study #3 (described in Chapter 6) was a qualitative study to understand the patient's perspective on their risk of falling and prevention strategies. In addition to understanding the contributions and limitation of QI and HFE approaches, information will also be compiled on fall prevention strategies.

4 CHAPTER 4: STUDY #1: LEAN: STANDARD WORK

4.1 Introduction for Lean

Preventing patients from being injured due to a fall during their hospitalization has been a concern in healthcare for many years. Organizations around the world such as Institute of Medicine, The Joint Commission, National Institute for Health and Clinical Excellence, National Australian Patient Safety Foundation and the World Health Organization have been conducting research and publishing guidelines to identify evidence based interventions for fall prevention (Ulrich et al., 2008, Di Pilla and Di Pilla, 2010). Patient falls continue to be the most frequently reported adverse event in hospitals and the leading cause of injury and death in adults 65 years and older. Falls in the adult inpatient setting range from 0.86 to 9.2 falls per 1,000 patient bed days; with geriatric areas as high as 10.7 (Hignett et al., 2011). Falls are the most common cause of non-fatal injury and hospital admission for trauma. The consequence of a fall can include an injury such as laceration, fracture, or head injury. A serious injury can result in an extended hospitalization or even death. There has been increasing financial pressure to improve patient safety and quality. In 2002, the National Quality Forum labeled hospital falls resulting in death or serious injury as a serious reportable event. In 2008, the Centers for Medicare and Medicaid Services (CMS) stopped reimbursement for inpatient hospital falls resulting in trauma (Spetz, 2015).

This chapter will discuss the implementation of the Lean approach to falls prevention applied in Barnes-Jewish Hospital (BJH) and the use of research to identify strengths and limitations of the methodology for preventing falls in the context of inpatient adult oncology care. Lean methodology was conducted as part of a preventable harm initiative in collaboration with BJC Healthcare. A Rapid Improvement Event (RIE) was conducted with a multidisciplinary team to develop a standard process for nurses to conduct a fall risk screen on every patient and to assign appropriate fall interventions along with a post fall investigation strategy after every fall.

4.1.1 Lean

Lean has a focus on quick turn around and is a good fit with the fast pace and constant change of the healthcare environment. Study #3 used a technique called a Rapid Improvement Event (RIE) with a focus on Standard Work to address fall prevention. A multi-disciplinary team participated in the three day event that included short experiments to prove success of ideas. Fundamental principles and concepts of Lean are discussed in Chapter 3.

4.1.2 Aim

The aim of Study #1 was to use Lean methodology to reduce patient falls and falls with injury on three oncology divisions at BJH. A gap analysis identified fall risk assessments were not being conducted in a consistent manner. It also revealed that if a fall risk assessment indicated a specific intervention (such as a bed alarm or low bed), that the intervention may not be implemented until after the patient had fallen. By standardizing assessment, intervention, and post-fall investigation processes the goal was to decrease patient falls and falls with injury rate by 50% and 30% respectively. This aligns with aims of the entire thesis to (1) understand the advantages and disadvantages of QI methodologies and (2) develop innovative recommendations for fall prevention.

4.2 Method for Lean

The RIE technique was selected to implement the fall prevention initiative because it aligned with the hospital's Lean transformation initiative (Wolf et al., 2013b). Lean transformation is a journey toward improving efficiency and quality by eliminating wasted motion and promoting consistent processes. Leadership support for this project was obtained from the Clinical Nurse Executive and Director of Oncology at the hospital level as well as unit level management. Leadership supported the allocation of resources which allowed front-line nursing staff to attend the three-day RIE. The multidisciplinary team included representation from Physical and Occupational Therapy, pharmacy, physicians, information systems, a low bed equipment vendor and clinical operations. Leadership attended the event and enabled meeting and project work preparation activities. The oncology director also demonstrated support for this project by requesting to be called 24/7 whenever a patient fell.

4.2.1 Preparation for the Rapid Improvement Event

As part of a system-wide Preventable Harm Initiative, a consortium of fall prevention experts and front line staff from BJC Healthcare was assembled to develop a fall prevention bundle. The bundle reflected best practice and evidence-based methods to assess patients and to select appropriate interventions. The fall prevention bundle had three components: 1) fall risk assessment, 2) intervention recommendation and 3) post fall investigation with data transparency. In preparation for the consortium, a system level team reviewed data and conducted a literature review to understand the three components and best practice interventions. The National Database of Nursing Quality Indicators (NDNQI) was used to benchmark fall and fall with injury rates and to help set goals for the program. The consortium also established the goal to decrease patient falls and falls with injury rate by 50% and 30% respectively.

A review of patient falls, combined with observation of current processes and feedback from front-line nursing staff indicated that improvement was needed in assessment of patient gait and mental status. For the gait assessment component, the consortium evaluated several gait assessment tests against selected criteria and selected the Get Up and Go (GUG) tool. The first part of the GUG evaluates the ability to stand up from a seated position. If the patient passes, then they walk for approximately ten feet and the nurse scores their ability to ambulate. The GUG tool was selected because it was quick to administer and did not require the nurse to have any extra tools like a stop watch. For the mental status assessment, the Short Portable Mental Status Questionnaire (SPMSQ) was selected. The SPMSQ is a validated 10 item questionnaire used to screen older adults for cognitive impairment. It tests orientation, memory and the ability to count backwards by threes. This screening test was later eliminated by the oncology divisions due to problems encountered during repetitive administration that were identified by both patients and staff. It was replaced with a set of standard questions: having the patient state their name, location, date of birth and current year in addition to determining if the patient overestimates/forgets their limitations and/or lacks understanding of their physical and cognitive limitations (Erkinjuntti et al., 1987).

Three oncology divisions from BJH were selected to participate in the RIE because they had the highest number of falls with injury in BJC Healthcare. The goal for the RIE was to determine how the recommended bundle of assessments, interventions and post fall investigations would be incorporated into the nurses' daily work flow process.

Hospital leadership performed a SIPOC (Supplier/Input/Process/Output/Customer) to select which roles would be represented in the RIE (George, 2005). Specific team members selected for those roles were chosen according to availability and expertise. A key stakeholder assessment was conducted initially to identify potential areas of support and resistance. Key stakeholders identified were front-line nurses, division leadership, and the director of oncology.

4.2.2 Rapid Improvement Event

Lean methodology provided structure for this project with a focus on developing standard work for assessment, intervention and data transparency. In order to implement the fall prevention bundle, the three-day RIE established how the bundle would be implemented on the oncology divisions. Lean and QI tools were used throughout the event (e.g. fist to five, silent voting, affinity diagramming, rotating techniques of brainstorming). The tools were used to ensure input from all team members (Benbow & Kubiak, 2005).

Current State: Current state was documented in a process map with swim lanes for each of the three oncology divisions (Benbow & Kubiak, 2005). Nursing process maps were verified by direct observation on all three oncology divisions. Multi-disciplinary input from key stakeholders was represented in each swim lane and solicitation of input and feedback continued throughout the project during frequent reunion meetings following the RIE.

Future State: A future state map was developed with the following goals:

- A Fall Risk Assessment will be completed every shift (and when patient condition changes) that reflects a clinical assessment of gait and mental status.
- Appropriate fall prevention interventions will be selected and implemented based on the results of the fall risk assessment.

- A thorough, systematic post fall investigation will be conducted within 60 minutes after a fall has occurred followed by a more detailed investigation by the unit Advanced Practice Nurse (APN) using a four page post fall form.
- Transparent information about falls will be available to all staff displayed on a fall tracking board with information collected during the post fall investigation.

The following outcomes for the falls and falls with injury were established by BJC Healthcare and adopted by the RIE team for the three oncology divisions:

- a. Goal for reduction in falls rate was 50%
- b. Goal for reduction in falls with injury rate was 30%

The remaining activities performed during the RIE addressed the gap between the current and the desired future state. These activities included: 1. Fall Risk Assessment, 2. Intervention Recommendation and 3. Post fall investigation with data transparency.

Fall Risk Assessment: Since a new system-wide Fall Risk Assessment tool was scheduled for implementation a few months after the RIE, the team decided to enhance screenings for gait and mental impairments to supplement any fall risk assessment. Subgroups were established to develop standard work for use of the Get-Up and Go (GUG) gait screening and the Short Portable Mental Status Questionnaire (SPMSQ) screening (Currie, 2008). A laminated reminder card was developed to highlight steps involved with the nursing assessments. Standard work was also developed for how to easily document results of the assessments in the Electronic Medical Record (EMR).

Intervention Algorithm: Another subgroup worked on developing an algorithm to ensure the appropriate interventions were selected and implemented by the nurse based on assessment and clinical expertise. The algorithm developed by this subgroup is shown in Figure 4-1; it was based on deficits identified during the patient assessment in an attempt to mitigate risk associated with individual risk factors and common combination of risk factors. Algorithm guidelines are based on best-practices interventions according to the BJH Fall Expert and fall prevention literature (ECRI, 2009).

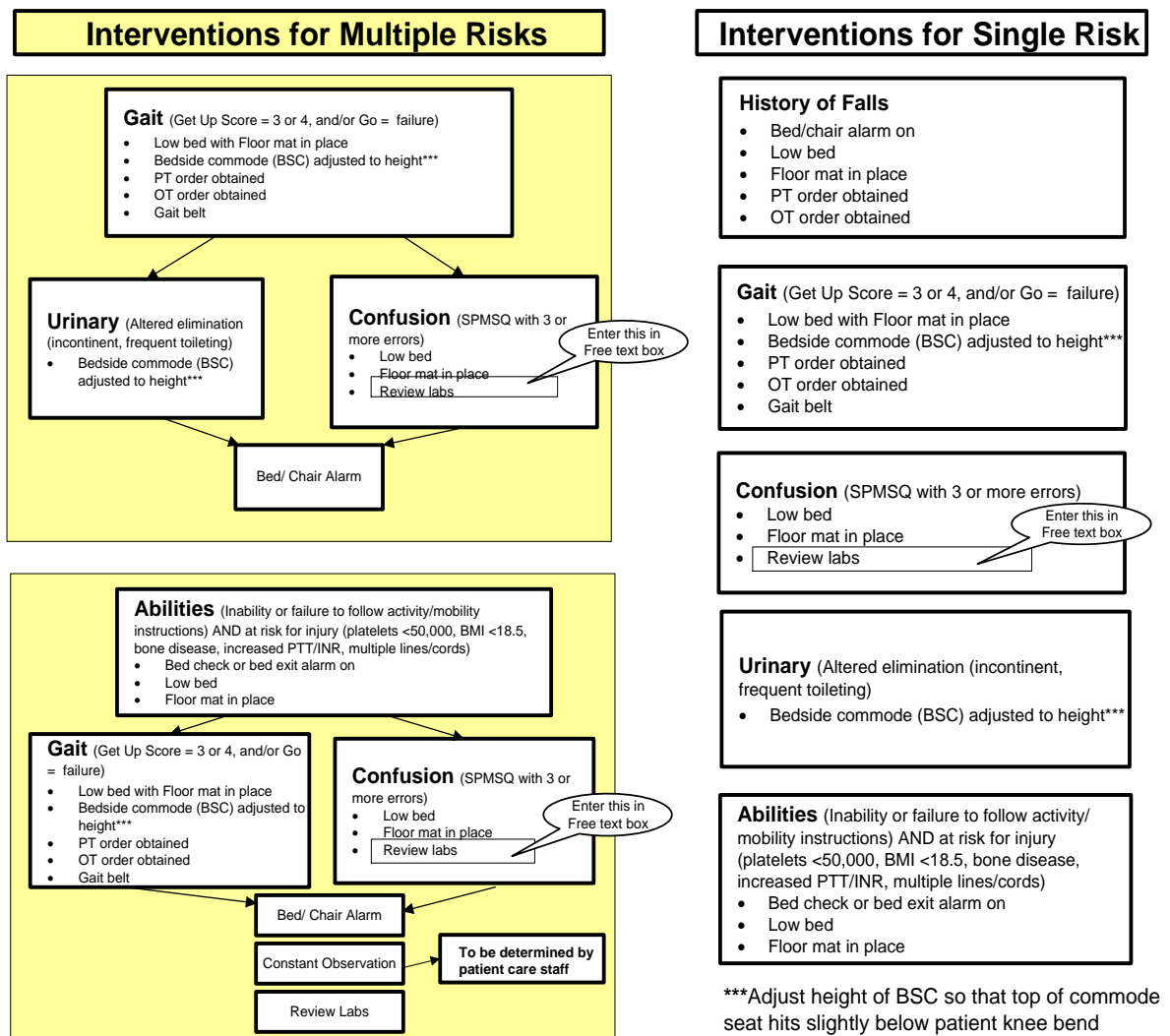


Figure 4-1 Algorithm for Linking Fall Risk Assessment to Appropriate Interventions

The box in the upper left corner of Figure 4-1 shows that if a patient has an “altered gait” (that is they failed the GUG test) then the recommended interventions would be to use a low bed and floor mat with a bedside commode along with a gait belt and to request an order for Physical and Occupational Therapy. If the same patient also had altered elimination (required frequent toileting) no additional intervention would be required because the patient already had a bedside commode. If this same patient also became confused (they missed three or more questions on the SPMSQ test), in addition to a low bed and floor mat the nurse would also review the patient’s lab results. If the patient had all three risk factors (gait, urinary and confusion) simultaneously the algorithm also recommended a bed/chair alarm.

Post Fall Investigation: The third subgroup established the processes required after a patient fell. Each division was already conducting post fall investigations but was

Fall Frequency

	Jan	Feb	Mar	Apr	May	June
U 1:25:15						
A 05:10						
U 1:20:15						
A 1:30:0						
A 1:10:15						
A 1:10:15						
A 06:15						

Action Plan

What	Who	When	Completion

Fall Details

Assessment	Interventions	Expected intervention implemented
<div style="display: flex; justify-content: space-between;"> <div> <div style="width: 15px; height: 15px; background-color: red; border: 1px solid black;"></div> Applicable intervention not implemented </div> <div> <div style="width: 15px; height: 15px; background-color: lightblue; border: 1px solid black;"></div> Intervention not applicable </div> <div> <div style="width: 15px; height: 15px; background-color: green; border: 1px solid black;"></div> Expected intervention implemented </div> </div>		

PR	Reason for Getting Up	Location of Fall	Contributing Factor	Staffing	Transparency
1	unknown	bedside	tangled in bedding (lost balance?)	1:35 1:19	Yes NO
2	in shower	shower	slipped	1:37 1:20	NO NO
3	getting out of chair pt/family lounge	pt/family lounge	cracks	1:33 1:16.5	NO NO
4	go to bathroom (BSC)	bedside	weakness	1:32 1:16	Yes NO
5					
6					
7					

Executive reviews were held at the end of each of the three days of the RIE to engage leadership and key stakeholders in assisting the team with setting goals and outcomes for the project. If ancillary team members were unable to attend during the event they were encouraged to join the discussions at the end of the day to understand activities and decisions completed.

4.2.3 Post Rapid Improvement Event Activities

Setting a go-live date established the deadline for achieving all activities that needed to be completed after the RIE (e.g. training and staff demonstration of competencies). Action plans were compiled with the W-W-W methodology (What action is needed? –When must it be completed? – Who is responsible?). Action item lists from the RIE structured the schedule for implementation. Approximately four weeks were required to finalize preparation materials. For example, photographs and standard work processes had to be completed before the educational materials could be developed for the training sessions. Weekly meetings were held by a core team to monitor progress of action items. Additional work sessions were required to integrate standard work from the assessment and intervention subgroups. Another four weeks were needed to allow time for nurse training and communication to all multi-disciplinary partners.

The entire multi-disciplinary team committed to changes in their work to achieve project outcomes. Physical and Occupational Therapy posted an activity communication form in each patient room. Heightened awareness of medications and their link to falls was addressed by Pharmacy staff during daily rounds with physicians. Risk Management incorporated the post fall investigation documents in their fall event files. Issues with availability and quality of low beds were identified and resolved; this impacted all inpatient units within the hospital. Multiple ideas for enhancements to the EMR were generated during the project (e.g. a fall note indicating the patient fell and short summary note). Tip sheets, developed by the hospital Fall Team, were utilized for ancillary departments to elicit their help in making fall prevention the responsibility of every hospital staff member. Physician engagement in knowing the patient fall risk level was evident by writing activity orders when needed (e.g. “Up with assistance only.” and requests for Physical Therapy and Occupational Therapy).

4.2.4 Sustainment

Fall prevention issues were integrated into existing leadership frameworks to increase executive awareness and sustain success. Progress and results were discussed as a regular agenda item at Oncology Leadership and unit staff meetings. These meetings provided a forum for discussing issues and providing answers to

questions. Progress was shared during Executive Out-briefs. Guidance was provided during 1:1 meetings between the oncology director and APNs. The Joint Unit Practice Committee (UPC) met bi-monthly to discuss implementation of the processes. Adjustments were made as needed during reunion meetings held monthly to identify barriers and revise interventions. Original team members from the RIE were invited to attend the reunion meetings to achieve coherence and sustainability. Each reunion meeting was scheduled four weeks ahead to ensure all members could attend.

The APNs wrote articles for newsletters, sharing patient's stories and best practices related to fall prevention. Posters and bulletin boards were maintained for staff, patients and families. The BJH Fall Expert shared results during monthly hospital fall team meetings and as needed to the Clinical Practice Council and Patient Care Leadership. In addition to the Fall Tracker board, reports were accessible from the EMR and provided the APNs and unit leadership with a real time display of fall risk assessment and intervention documentation for each patient. The APN and management ownership of the project was critical to sustain the momentum. Based upon the heightened engagement that was experienced during and after the RIE, one of the divisions was selected to participate in a collaborative project with The Joint Commission (see Chapter 5 Six Sigma: Patient Partnering).

4.3 Interventions for Lean

Lean methods during the RIE culminated in the interventions shown in Table 4-1 with a focus on standard work. All nurses were trained on the standard work process with official implementation on all three divisions in August 2011.

Intervention	Link to Contributing Factor	Impact
1. Standard Work for Patient Assessment	Inconsistent methods of evaluating fall risk	Clarification of roles and responsibilities for assessment
2. Standard Work for Intervention: Algorithm	Confusion deciding which interventions are most appropriate for fall risks	Provides guidance to aide decision making to match risks to interventions
3. Standard Work for Post Fall Investigation	Lack of thorough information about fall events	Provides consistent time frame and information that is required for

		investigation
4. Fall Tracker Board: Data Transparency	Lack of transparency when a fall occurs and the cause	Standardized board for presentation of fall information, same on all divisions

Table 4-1 Lean Interventions linked to contributing factors and falls

Standard work was used to establish a uniform method for fall risk assessments and selection of appropriate interventions. Nurse Managers and an APN educated every nurse utilizing a competency validation checklist. A return demonstration was required to ensure understanding was achieved. Approximately 150 nurses received individual education and signed the competency checklist validating their commitment. Training for ancillary disciplines was achieved in staff meetings and individual communication. Vendors from bed alarm and low bed manufacturers provided education during staff meetings and skills day training sessions to ensure consistency.

4.3.1 Overcoming Barriers for Interventions

Various problems and barriers were encountered as interventions were implemented across all three departments. The following list describes how some of the barriers were resolved.

1. It was difficult to educate so many nurses in a short amount of time. This challenge was overcome by the Joint Oncology Unit Practice Committee identifying nurse champions to assist with training.
2. Results of a staff survey post implementation identified problems with staff acceptance of the cognitive assessment (SPMSQ). Nurses expressed their patients thought the questionnaire was redundant and staff was dissatisfied due to the time required to complete the assessment. Based on this feedback the SPMSQ was eliminated and education was conducted on a standardized version of the current mental status assessment questions.
3. Lack of utilization of low beds was overcome by consistent education and coaching by the APN with the staff. A collaboration with the low bed vendor also improved availability of low beds which decreased time from order to delivery. A culture change was evidenced by a 50% increase in low bed usage post implementation.

4. No parameter existed in the EMR to document results of the gait and cognitive assessment (GUG and SPMSQ) so modifications were programmed. Nurses were trained to document these assessments according to a standard method.
5. Lack of knowledge and consistent utilization of existing bed alarms was addressed by having the vendor participate in training competency sessions.

4.4 Results for Lean

Data in this chapter combine results for all three oncology divisions that participated in the Lean project to develop standard work for addressing patient falls. The baseline time period was the 16 months prior to RIE and post intervention data collection began at “go live” on August 1, 2011. The two months after RIE and before go live date were not included in data collection to reduce any confounding impact training may have had on awareness as preparations were made for the kick off in August.

The results of this Lean methodology are divided into the following sections.

1. Fall and Injury Rate from Lean: Standard Work (Study #1)
2. Qualitative results from Lean: Standard Work (Study #1)

4.4.1 Fall and Injury Rate from Lean: Standard Work (Study #1)

Inpatient falls were categorized according to American Nurses Association-National Database of Nursing Quality Indicators (ANA-NDNQI): (1) None indicates that the patient did not sustain an injury secondary to the fall. (2) Minor indicates those injuries requiring a simple intervention. (3) Moderate indicates injuries requiring sutures or splints. (4) Major injuries are those that require surgery, casting, further examination (e.g., for a neurological injury). (5) Deaths refer to those that result from injuries sustained from the fall (Currie, 2008). This research further categorized falls with serious injury by including categories of Moderate, Major and Death. The same fall categorization strategy is used in Chapter 5 Study #2 (Six Sigma: Patient Partnering).

The duration of baseline was 16 months and post-intervention period was 17 months with different number of patient days so results are reported as a rate. Total fall rates are calculated by the number of falls divided by the number of patient days

multiplied by 1,000. The Total Falls Rate includes all falls with and without injury. The graph in Figure 4-3 illustrates major project milestones in Study #1 with the corresponding fall rates by month. The top line represents the rate of total falls that occurred on the oncology divisions. The middle dashed line represents the rate for falls with any type of injury (minor, moderate, major and death). The bottom dotted line represents the rate for falls with serious injury (moderate, major and death). The baseline was determined by BJC Healthcare and ranged from January 2010 to April 2011 but is represented as a single point in time for graphic simplification.

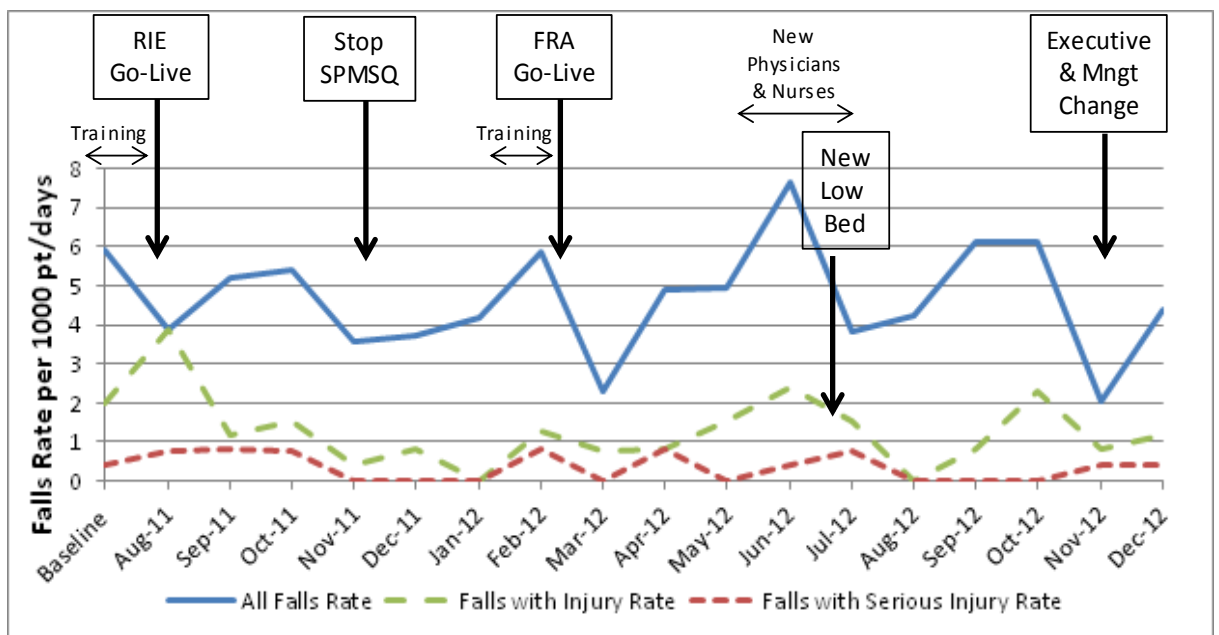


Figure 4-3 Monthly Fall Rates and Project Milestones

As shown in Figure 4-3, falls with injury and serious injury trends improved the first six months after the RIE. Then a rise in rates occurred in February 2012 during training for the new Fall Risk Assessment that was incorporated into the EMR. Other peaks were seen in April and June/July. While increased rates in the summer could be explained by new physician and nursing staff, the peak in April is puzzling. The increase in falls in April 2012 shows how much one or two falls with serious injury can impact the trend. Falls are typically a rare occurrence. One of the falls in April resulted in death and occurred with a patient that was terminally ill and had numerous co-morbidities before the fall. She fell trying to grab her IV pole as it tipped over while she was pushing it over the power cord. Another fall in July occurred due to the patient's fatal heart attack and subsequent fall.

During the study, there was large staff and executive turnover with all management (Clinical Nurse Manager and Lead Charge Nurses) gone by end of 2012. By the fall of 2012, one division only had one original team member remaining (the APN).

Three Oncology Divisions: Combined Results	Jan 2010 - April 2011 (Baseline 16 mo.)	Aug 2011 - Dec 2012 (Post RIE 17 mo.) Lean: Standard Work	% Improvement		Significance Level
			Goal	Actual	Z Distrib.
All Falls (number)	227	197			
Falls with Minor Injury (FWMI) (number)	62	39			
Falls with Serious Injury (FWSI) (number) = falls in moderate and major categories	15	15			
Total Falls with Total Injury (FWI) (number) = (FWMI)+ (FWSI)	77	54			
Patient days (number)	38,296	42,771			
All Falls Rate = ((all falls/patient days)*(1,000))	5.93	4.61	50%	22.3%*	Z=2.60 p=0.009
Falls with Total Injury Rate = ((FWI)/patient days)*(1,000))	2.01	1.26	30%	37.3%*	Z=2.65 p=0.008
Falls with Serious Injury Rate = ((FWSI)/patient days)*(1,000))	0.39	0.35	no goal	10.30%	Z=0.30 p=0.764
*statistically significant Z test = compare two incidence density rates. An alpha level of 0.05 was designated as statistically significant. % change = (baseline rate - intervention rate)/baseline rate					

Table 4-2 Fall Results Combined from Three Oncology Divisions

Table 4-2 shows that a 22% decrease in total fall rate and a 37% decrease in falls with injury rate were achieved in the 17 month post intervention period. Although a 22 % decrease in total falls did not meet the goal of 50% decrease, the total falls with injury decrease of 37% exceeded the goal of 30%. Differences in rates were assessed for statistical significance by using the two-tailed Z distribution (proportion of falls to patient days at baseline compared to Post RIE). The Z test was conducted to compare the rate for all falls at baseline of 5.93 to the 4.61 rate that occurred post RIE (Z=2.60, p=0.009). An alpha level of 0.05 designated this was statistically significant. For falls with any injury (minor and serious), the difference from baseline to post-RIE (2.01 versus 1.26 respectively) was also statistically significant (Z=2.647, p=0.008). There was no statistically significant difference between falls with serious injury rate from baseline to post-RIE (0.39 versus 0.35 respectively) for the combined divisions (Z=0.303, p=0.764).

For results on the single oncology division that also participated in the Six Sigma intervention see Chapter 5 for Study #2 that used Six Sigma methodology. Chapter 7 also includes results from the same single oncology division but spans 5.5 years with a two year baseline period prior to any fall prevention initiatives.

4.4.2 Qualitative Results from Lean: Standard Work (Study #1)

In addition to applying Lean methodology to fall prevention, one aim is to gain insight on successes and failures with the approach. This section focuses on the results of insights that were understood during Study #1. Qualitative insights from Six Sigma methodology learned from Study #2 are discussed in Chapter 5. Results and insights from all methodologies combined are discussed in Chapter 7 with overall results from all three studies.

Notes were documented in a journal throughout the Lean project to gain an understanding of fall issues. The following comments summarize highlights from the insights listed in Table 4-3.

- **Communication Challenges:** Nurses, physicians and therapists find communication difficult and charting information cumbersome to share. Physicians commented fall prevention is a “nurse responsibility”.
- **Training Difficulty:** Achieving competency with train-the-trainer model is difficult. There was variability in the thoroughness of trainers. A special team of trainers dedicated to fall prevention were found to be more effective. This special team was comprised of fall champions that were passionate about making standard work processes a success. As a result, they achieved greater competency scores than the train-the-trainer method.
- **RIE Process:** The prep time for the RIE was adequate but if the RIE had been one more day, the post RIE work before implementation could have been reduced by a couple weeks.
- **Environmental/Equipment issues:** Lack of acceptance of bed alarms by patients makes it difficult for nurses. The call light pendant slides onto the floor or out of sight and is easily misplaced. The process to acquire a low bed requires several extra steps and is a barrier for implementation.

Barrier/Problem Identified	Insight/Understanding
Difficult to get PT/OT consults	Physician must order PT/OT consult... WHY?
Lack of communication	Rehab communication form needs new name because nurses don't read it thinking it is for Rehab only
A&O x 4 is inconsistent	Lack of standard method to inquire about Alert & Oriented
Patient satisfaction (nurses wanting to please patients) may be in conflict with patients best safety interests	Do HCAHPS and PRC scores relate to falls?
High risk meds	High risk meds were not addressed in RIE (plan to include for six sigma)
What components are required in a minimum standard bundle for fall prevention	1. Assessment (GUG-gait, SPMSQ-mental), 2. Intervention (algorithm, document and order intervention), 3. Transparency (SBAR -post fall huddle, MDI - fall tracker board)
Difficult to train all staff	include fall prevention in skills day, also conducted focus groups to see how RIE process was going
Competency from training all staff is difficult	One root cause of falls (like cognition impairment) can have several interventions (like bed alarm, BSC, up with assist)
Competency from training all staff is difficult	A special team passionate about fall prevention were more effective than "train-the-trainer"
Ran out of time in RIE to combine subgroups	We could have used a 4th day in the RIE to combine the standard work created by each subgroup. This was done afterward to create the training material and competency checklists
Time pressure on RN	If team members do not voice concern about lack of time, the RNs could sabotage the intervention
Prep for RIE is critical	3 weeks prep for RIE was enough to get core team prepared and collaborate on goals
Lack of acceptance of bed alarms	Frequent bed alarms bother patients, increase complaints, decrease patient satisfaction, decreases "quiet at night" perceptions
Pendant with call light slides onto floor	Need cup holder to hold pendant and grip-pad to put on arm of chair to prevent pendant from sliding
Lack of compliance with SPMSQ	Nurses said patient complained about the repetition of the short portable mental status questionnaire
Patients refuse bed alarms	Nurses present bed alarm as a threat if patient doesn't cooperate
Nurses resist low beds	Low beds are extra work to order, get in room, change linen and patients don't like them - redesign low bed with manufacturer

Barrier/Problem Identified	Insight/Understanding
Safety vs privacy dilemma	Safety Tops Privacy vs. Patient Rights and Dignity - patient broke nose from a fall but still cried when the "cage" bed was ordered - she strongly refused the bed alarm
Lack of low bed availability	Try low bed study with all rooms having low bed
38 interventions, too complex, too much time	Interventions must be easy and quick
Conflicting interventions	Patient must be sitter free for 24 hours before placement into next facility - yet may need sitter to prevent fall
Lack of importance to physician	Fall priority to oncology physician is not high, just like pressure ulcer was not high priority to ICU physician

Table 4-3 Insights from Lean Study #1

4.5 Model after Study #1

The model developed throughout Study #1 began with the Systems Engineering Initiative for Patient Safety (SEIPS) developed at the University of Wisconsin. The SEIPS model describes five components in the interdependent nature of a work system where the care provider (1) is performing various tasks (2) using tools and technology (3) in a given environment (4) with in an established organization (5) is the people factor. Next this work system performs the process of patient care to achieve patient and hospital outcomes (Carayon, 2007).

Intrinsic and extrinsic risk factors for falls were incorporated to extend the SEIPS model to include dimensions identified during Study #1 and literature reviews (shown in Figure 4-4). Risk factors were aligned to the most appropriate section of the SEIPS model (represented in the yellow boxes). The “Person” component inside the work system represents staff and patient. For this analysis, patient intrinsic factors were placed outside the work system box as they are associated with the patient and are relevant during the patient assessment in the care process. There are additional factors that align with the care giver such as: capabilities, limitations, and mental workload, stress, perception and communication issues. These care giver characteristics were aligned inside the work system box.

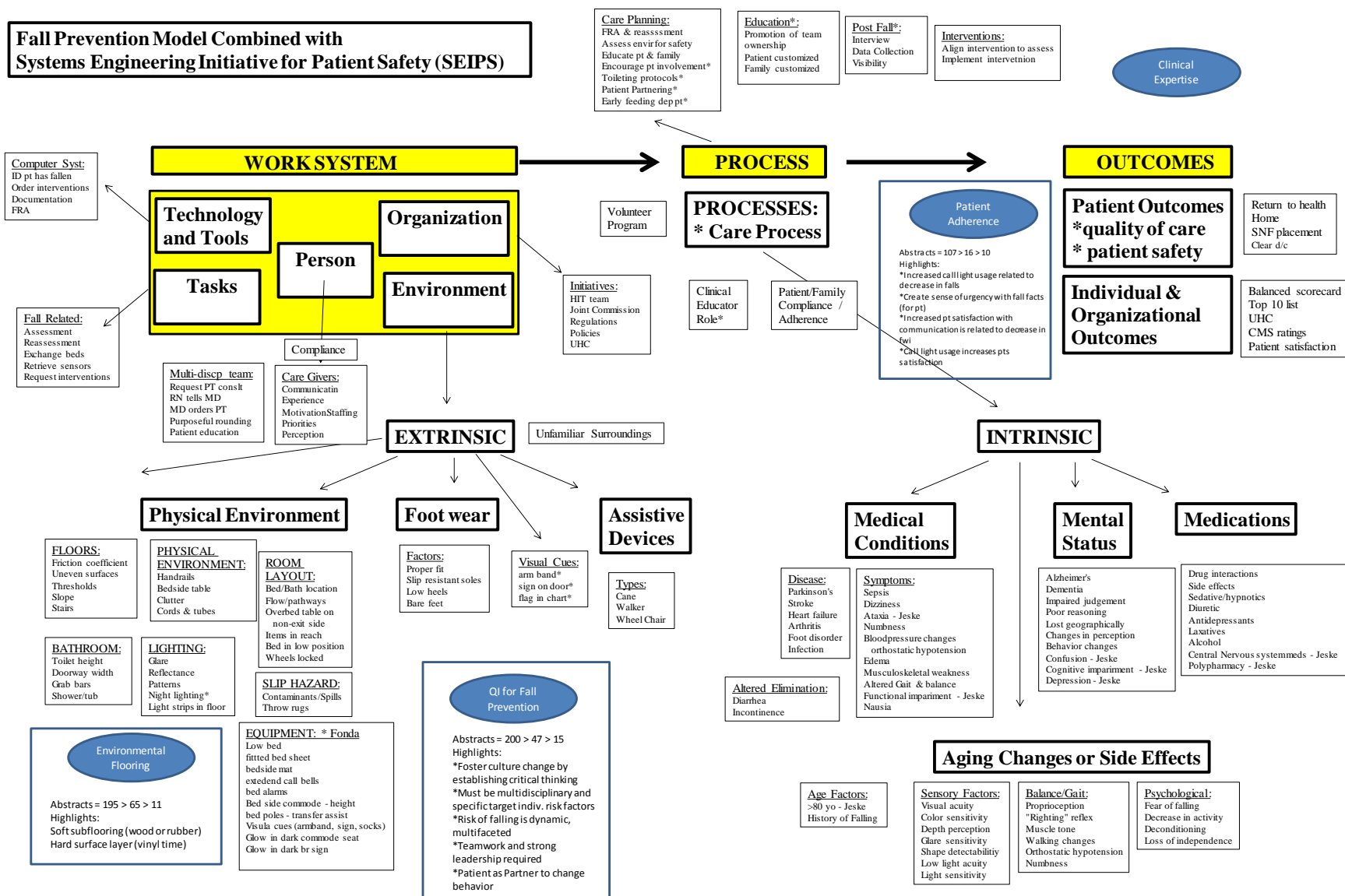


Figure 4-4 Model After Study #1: Extending the SEIPS Model for Fall Risk Factors

4.6 Discussion for Lean

The standard work that evolved from the Lean methodology in Study #1 provided a consistent foundation for further fall prevention work conducted in Study #2 (discussed in Chapter 5: Six Sigma). The standard work processes helped to achieve consistency in the way patient risk is assessed and in how interventions are selected across all three oncology divisions.

4.6.1 *Rates for Falls and Severity of Injury*

Fall rates decreased by 22% (5.93 to 4.61). Falls with injury and serious injury did not experience a statistically significant improvement. A learning point here was that changing the overall number of falls doesn't necessarily correlate with changes to falls with injury and serious injury. Other researchers have found variations with decreased injuries and not in total falls or vice versa (Sulla and McMyler, 2007, Barker et al., 2009a, Fonda et al., 2006, Anderson et al., 2009). Fonda et al (2006) conducted a three year study that used a multi-strategy program to achieve a 19% reduction in total falls and a 77% reduction in falls with serious injury.

The advantage of a standard work study is that fall reporting and documentation will be accurate and consistent with process compliance. Further investigation into the reasons for falls with injury is evident and forms the foundation for Study #2 (Chapter 5).

4.6.2 *Cost of falls: Return on Investment*

A previous study of falls at Barnes-Jewish Hospital conducted by Washington University revealed a patient experiencing a severe injury from a fall has increased operational costs of \$13,316 and stayed for 6.3 days longer (Wong et al., 2011a). The Center for Medicaid and Medicare Services has identified 'Falls and Trauma' on its current list of Hospital-Acquired Conditions (HAC) for which reimbursement will be limited contributing even more urgency for fall prevention programs (Center for Medicare & Medicaid Services, 2007). Unfortunately the number of falls with serious injury was 15 during both baseline and post intervention. This makes cost justification particularly difficult.

It is still important to understand the cost of conducting the project. The three-day RIE was 7.5 hours with 25 people attending (562.5 hours) plus three reunion

meetings lasting 2 hours with 20 people attending (120 hours) plus training time of 30 minutes for 150 nurses and 30 minutes for the trainers (150 hours) for a total of 832.5 hours. This time estimate multiplied by \$35.00 per hour as an average salary brings the cost of manpower for the project to approximately \$30,000.

Cost justification may not be evident in this study but it doesn't mean establishing consistent work processes is not valuable. Perhaps it indicates fall prevention interventions need additional customization that goes beyond basic standardization to reach the root cause of falls with injury. This premise is explored using Six Sigma methodology in Study #2 (Chapter 5).

4.6.3 Facilitator Insights

System wide initiatives are often standardized in order to be scalable (or capable of being spread) throughout a large hospital system. The nature of standardization limits individualization that may be needed to resolve unique patient specific problems. Standard work is a useful tool to gain consistency in behaviour and to achieve compliance to regulatory issues (e.g. documentation). RIEs are an effective way to increase awareness and build momentum for behaviour change. Likewise, a well validated screening tool performed thoroughly and accurately may also increase staff awareness; but risk assessment alone does not prevent falls.

A benefit of standard work is to clarify roles and expectations of the multidisciplinary team that must work together to achieve fall prevention. Role confusion leads to a lack of accountability for fall safety. Prior to the RIE, physicians thought falls was a nursing responsibility; nurses thought therapists were responsible for patient mobility; therapists thought nurses should convince physicians to write orders for therapy. Lack of communication also adds to confusion making it easy to see how details can be overlooked and opportunities for interventions can be missed. Standard work allows each role to understand what is expected and the team can hold each other accountable. It also enables consistent training for new employees to quickly achieve competency.

Standard work is necessary to develop a consistent, safe basis for fall prevention. At the same time, to reduce falls with injury preventions must be customized for an individual patient. It is difficult to simplify numerous fall interventions into a simple

algorithm. Standard checklists do not address the complexity needed to understand falls with injuries; however, standard work is a good first step that provides a foundation of consistency and opportunity for further investigation.

4.7 Limitations and Strengths of Study #1

4.7.1 Limitations of Study #1

As with any applied research, the issue of confounding impact from different interventions is a concern with this project. It is difficult to isolate the impact of one specific factor when interventions are implemented at different times and so many variables are uncontrolled. Outside contributing factors we observed during our project included: management changes, staff turnover, a new fall risk assessment tool dictated by the hospital system, construction projects, new staff arrivals, mentor training and executive leadership changes bringing new direction and focus.

Another limitation is that the results were combined from three divisions, masking contributions of each individual division. Deeper investigation that went beyond the scope of Lean revealed that two divisions went several months without a fall with serious injury while one division was responsible for almost half of the serious injuries.

There was no control group in this study because the hospital wanted to implement improvements as fast as possible to all the divisions with high injury rates. It's not in the patient's best interest to withhold best practice interventions. This is why randomized control trials are so difficult in applied, real world research.

All falls are self-reported by staff so it is possible that a patient may fall and staff is not aware of the incident.

4.7.2 Strengths of Study #1

The strength of an applied QI project like Study #1 is that it was conducted on an actual oncology division with no interruption to patient care. Staff maintained full patient workloads and the patient admission process was unchanged. Environmental changes were minimal so they should not have been a primary influencing factor.

Another benefit of a standard work project is that if staff complies with protocol, process performance and documentation will be consistent and reliable.

4.8 Conclusions for Lean

Standard work can bring consistency to a process but may not provide enough flexibility to address complex issues like falls with serious injuries. Falls are a multi-faceted, complex problem requiring constant vigilance and continuous improvement to sustain patient safety.

Any patient's risk for fall is subject to change at any time. While well validated screening tools performed thoroughly and accurately can help hospital staff identify patient specific fall risk factors, risk assessment alone does not prevent falls. Anticipating and assessing risk is only part of the puzzle. Implementing appropriate interventions before the fall is critical to prevention.

Communication with a multidisciplinary team is also critical. Standard work can provide clear roles and expectations that are important to achieve good communication. If the prevention of patient falls is identified as important by leadership and staff at the division level and all are invested in achieving established goals, success can be achieved and sustained

5 CHAPTER 5: STUDY #2: SIX SIGMA: PATIENT PARTNERING

5.1 Introduction for Six Sigma

Despite ongoing efforts and the wealth of knowledge devoted to reducing patient falls the problem still remains a daunting challenge to inpatient care (Christopher et al., 2014). In 2011, Barnes-Jewish Hospital had the opportunity to collaborate with The Joint Commission's Center for Transforming Healthcare (CTH) and six other hospitals in the US to use Six Sigma methodology to prevent falls with injury. Collective results of this collaboration found 62% improvement in falls with injury (falls with injury per 1000 patient days pre rate of 1.31 vs. post rate of 0.503) and 35% (falls per 1000 patient days pre-rate of 4.001 to post-rate of 2.613) reduction in overall falls pre verses post intervention (DuPree et al., 2014). This chapter will discuss the implementation of the Six Sigma approach to falls prevention applied in Barnes-Jewish Hospital and using the research findings to identify strengths and limitations of the methodology for preventing falls in the context of inpatient adult oncology care.

The intensive nature of the Six Sigma process dictated the selection of only one division to participate in this study. The oncology division selected to participate in this study had 38 beds with 26 single rooms. As the oncology division with the most semi-private rooms (2 patients in one small room); maneuvering was especially challenging due to lack of space and clutter from equipment, chairs and computers. Prior to Study #2, Lean methodology was conducted as part of a preventable harm initiative (see Chapter 4 for details of Study #1). A standard process was developed for nurses to conduct a fall risk screen on every patient and to assign appropriate fall interventions embedded within the EMR (Wolf et al., 2013a). A consistent reporting process was developed and a post fall investigation was implemented to understand the circumstances each time a fall occurred (Wolf et al., 2013a). Seventeen months after implementing the standard work process, a reduction in total falls was achieved but falls with serious injuries with serious injuries needed improvement (see Chapter 7). The challenge of Study #2 was to see if Six Sigma methodology could help reduce falls with serious injuries (Wolf et al., 2014). Falls that result in serious

injury are more impactful to everyone involved and can be life-changing for patients and families as well as caregivers. They also have potentially severe financial consequences.

5.1.1 Six Sigma

Six Sigma is a Quality Improvement (QI) methodology that uses a collection of techniques and tools to increase business performance by reducing defects (unexpected outcomes) and process variation (inconsistent methods and results) (Junewick, 2002). It focuses on strong leadership and emphasis on bottom-line financial results (Benbow and Kubiak, 2005). Fundamental principles and concepts of Six Sigma are discussed in Chapter 3.

5.1.2 Aim

The aim of Study #2 was to use Six Sigma methodology to develop and implement an intervention that would decrease total falls and falls with injury and gather comparisons with results from Study #1. The focus was on reducing falls with serious injury. An additional aim was to understand interventions that prevent injury from falls. This aligns with aims of the entire thesis to (1) understand the advantages and disadvantages of QI methodologies and (2) develop innovative recommendations for fall prevention.

5.2 Method for Six Sigma

Based upon the heightened engagement and management support experienced during Study #1 (Lean), one oncology division was selected to participate in Study #2 (Six Sigma). This division had worked for years to decrease falls with incremental but inconsistent improvements and had never gone through the Six Sigma process specifically for their individual division. This study began with a kick-off meeting on November 9, 2011 and continued with numerous Six Sigma tools to develop an intervention by investigating root causes using the DMAIC (Define, Measure, Analyze, Improve, and Control) approach. Both revealed critical contributing factors to falls such as unassisted toileting and continuously changing patient conditions including cognition and medications. The culmination of these assessments led to the development of an intervention called “Patient Partnering”

that was implemented in January 2013. Outcomes were measured during the 18 months after the intervention was implemented (Wolf et al., 2014).

The purpose of patient partnering is to apprise the patient of their fall and injury risk factors, discuss and agree on prevention measures and to emphasize the importance of calling for help. This allows the patient to become an active participant in preventing their own falls.

Fortnightly conference calls were conducted with CTH and representatives from the other six participating hospitals. In the interim week, a small core team met as a steering committee to plan and conduct analyses. A two-hour meeting was held once a month with the entire multi-disciplinary team. As each phase of the DMAIC process was completed, there was a tollgate review conference held at a designated location with all hospitals presenting their findings. The role of the thesis author in this project was as principal investigator and facilitator. Responsibilities included meetings preparation (coordinating agendas, prepping team members, and organizing project logistics), conducting data analyses, developing presentations for tollgates and providing neutral guidance during project progression.

5.2.1 Define Phase

During the Define Phase, customer needs were stated and processes in need of improvement were identified. Patient input was considered by including a patient representative in several of the initial meetings. However, this representation ceased after a few months due to schedule conflicts resulting in the focus of the “customer” becoming the nursing staff. Some of the following tools were used during the Define Phase:

- A charter was developed to align objectives, identify current state, and develop goals, metrics and deliverables. Approval was received from executive leadership.
- The Supplier-Input-Process-Output-Customer (SIPOC) method was used to select interdisciplinary team members.
- Voice-of-the-Customer and Strength-Weakness-Opportunity-Threat (SWOT) methods were used to create a sense of urgency among team members to increase engagement.

Trends in falls and falls with injury were reviewed and baseline measures were defined before any interventions were implemented. Even though improvement was experienced during previous Lean interventions, additional opportunity for further fall reduction was identified. Some of the tools used during the Define phase are shown in Table 5-1.

Tool	Components	Highlights
Charter	Problem Statement Business Case Project Scope Goal Statements Project Plan Project Team	Despite interventions, patients fall and are injured while under our care, Goals = falls decrease by 25%, falls with injury decrease by 50% from baseline in 2009-2010 Sponsors, Champions, Owners and team members defined
SWOT	Strengths Weaknesses Opportunity Threats	Collaboration opportunity Increased injury rate Team work, trust building Increased length of stay
Criteria for Selection	Fall rates Executive Support Advanced Practice Nurse (APN) engagement	Highest oncology fall and fall-with-injury rates Director and Manager support Excellent APN past success
Voice of Customer	Solution Tree	Equipment, Call Lights, Communication, Staffing, Education
SIPOC	Supplier Input Process Output Customer	Nurse, provider, housekeeping, dietary, unit secretary Fall risk assessment, signage, equipment delivery Patient admit to discharge Fall information, clean/safe room, video Patient, entire multi-disciplinary care team

Table 5-1 Tools used during Define Phase

5.2.2 Measure Phase

The purpose of the Measurement Phase was to determine the baseline and target measures of the process. Input and output variables of the process were defined and measurement systems were validated. A cause-effect matrix was used to determine which factors were most closely related to falls in oncology.

The Cause & Effect (C&E) Matrix began with consideration of the components from the SIPOC completed during the Design Phase. The matrix shown in Table 5-2 was developed by the team in attempt to understand the link between fall risk factors and outcome measures of falls. To complete the C&E matrix, the team must rank the outcomes on a scale of 1 to 10 according to customer priority (e.g. falls with injury

was rated the highest with a 10 and falling was rated as 8). Next, each process input (such as call light usage and toileting activity) must be rated for how much of an effect it has on each output. For example, the “input” of call light usage was thought to have a great impact on falls with injury and so was given a score of nine out of ten. Seventeen different process inputs were rated in the matrix. The top eight inputs that had the highest total priority score are included in Table 5-2.

		Total Falls	Falls with Injury	Acheivment, guilt, failure, remorse	
	Customer Priority	8	10	4	
Process Step	Process Input				Total
	Communication devices, call light - bed alarm- pagers	9	9	9	198
	barriers/ability to respond	9	9	9	198
	multi-disciplinary team compliance	9	9	9	198
Implement Intervention	Utilization of Availble equip (lowbeds, alarms, mats)	9	9	3	174
Implement Intervention	Toileting,	9	9	3	174
	lack of pt & family compliance	9	9	3	174
Assess Patient	Medication	9	9	1	166
Assess Patient	Dynamic risks	9	9	1	166

Table 5-2 Cause and Effect Matrix for Patient Fall Prevention

This tool was difficult and time consuming because the team struggled to associate each factor with a number. To ease the struggle, a common grouping strategy was used. The ten point scale was grouped into 0, 1, 3, 9 scale. Even this strategy proved difficult for the team.

The fishbone diagram technique was used to brainstorm root causes for the top eight topics from the Cause and Effect Matrix. The team developed problem statements to represent each of the eight topics. The team enjoyed the fishbone technique and the rich discussion that was generated. Team members completing diagrams are shown in Figure 5-1.



Figure 5-1 Team working on fishbone diagrams

The following list includes the eight problem statements and highlights from issues that were discussed during the development of each fishbone diagram.

1. Communication Devices: “How do problems with communication devices contribute to falls with injury?”
 - a. Staff become desensitized to bed alarms
 - b. Patient forget they are attached to tethers and forget their need to call for help
 - c. Call light is out of reach
 - d. Patients and families turn off bed alarms
2. Barriers to Respond: “What are the barriers that impede your ability to respond to a call for fall prevention?”
 - a. Long hallways, no visibility

- b. Competing priorities
 - c. Calls for help are typically emergencies
 - d. Staff fatigue surrounding fall issues – constant vigilance is difficult
- 3. Multidisciplinary Team Compliance: “Why are multidisciplinary team members non-compliant with fall prevention efforts?”
 - a. Medications administered by pharmacy have fall risk but are required to accomplish clinical treatments
 - b. Lack of multidisciplinary communication after a fall
 - c. Dietary places tray beyond reach of patient
 - d. Physical Therapy recommendations not visible or current
- 4. Equipment Utilization: “Why isn’t fall prevention equipment utilized?”
 - a. Unaware of available resources
 - b. Fall issues not incorporated into bedside shift report
 - c. Patient refuse equipment (bed alarm, low bed)
 - d. Switching beds requires additional work (order bed, change sheets)
- 5. Toileting: “How does toileting contribute to falls?”
 - a. Private nature of toileting
 - b. Bedside commode adds clutter to room and are not adjusted properly
 - c. Vasovagal response causes dizziness
 - d. Emergent need to toilet causes urgent action
- 6. Patient Compliance: “How does lack of patient and family compliance contribute to falls?”
 - a. Staff unaware of cultural barriers
 - b. Family and patient unaware of fall and injury risk
 - c. Patient feels guilty for asking for help
 - d. Desire to be independent
- 7. Medication: “How does medication contribute to falls?”
 - a. Medication changes are more frequent than fall risk assessments
 - b. Patients, nurses, physicians may not understand implications of medications (dosages, half-life, interactions)
 - c. Medication review may not include fall risk considerations
 - d. Medications that cause risk for fall are needed for treatment
- 8. Dynamic Risk: “How do changes in risk factors contribute to falls?”

- A photograph of the fishbone diagram with the topic of “Multidisciplinary Team Compliance” that addressed the question: “Why are multidisciplinary team members non-compliant with fall prevention efforts?” is shown in Figure 5-2.



A data plan was developed to investigate root causes that were identified in the eight fishbone diagrams. Smaller teams were assembled to investigate problems such as response to call lights, patient behavior, and dynamic change in condition, activity prior to fall, and medication management. Team members were selected with

expertise required to collect data according to the goals on the plan. For example a Medication Management team was formed with two pharmacists that investigated medications administered 24 hours prior to a patient's fall. In addition to chart review for data extraction it took an understanding of side effects and interactions of medications to determine the association with the fall. Graphical scorecards and control charts were some of the tools used by the special teams to visualize data collected for further analysis.

5.2.3 Analyze Phase

The Analyze Phase used data collected during the Measure Phase to identify key process inputs to guide and develop an appropriate intervention. Results of the analysis phase are shown at this point because this information was used to develop appropriate interventions. The results section (5.4) of this chapter is reserved for results of the time period after interventions were implemented. There were five mutually agreed upon measures and experimental protocols that were conducted by all participating hospitals in the national Joint Commission project:

1. Call light response time: Managers watched as 30 calls for help came to the nursing station then observed response time and noted the reason for the call and if the patient was attempting to mobilize before the care team could respond to the call.
2. Patient behavior (reason for getting out of bed): Over a two week period, 30 patients were randomly selected by the manager to answer seven interview questions about their call light usage and frequency and reason for getting out of bed during their hospital stay.
3. Medication management: In attempt to correlate medication with falls, 41 patients that experienced a fall were "matched" (age, diagnosis, fall risk score) with 30 control patients that did not fall. Pharmacists looked at medications given 24 hours prior to fall and compared the medications that were administered to patients that did not fall.
4. Changes in patient condition 24 hours prior to fall: A small team of nurses conducted a chart audit of 36 patients that experienced a fall to assess if any change in condition was experienced prior to the fall. A

change in condition was defined as: procedure with sedation, change in cognition, vitals, lab values, or altered elimination.

5. Patient activity at time of fall: The Thesis Author and a nursing Fall Expert reviewed post-fall investigation forms for 30 patients that experienced a fall in attempt to determine activity prior to the fall.

Investigation into these factors that were determined to contribute to falls yielded the following information: Call Light Response: The average time it took a care team member to respond to a call light was 5.41 minutes (median was 3 minutes). The longest response time observed was 37 minutes. The reasons that patients called for help are shown in Figure 5-3.

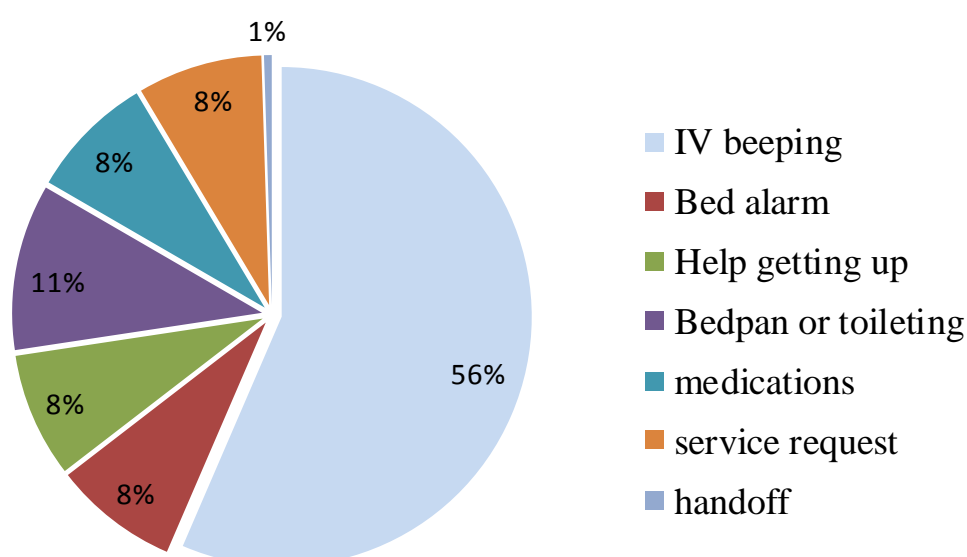


Figure 5-3 Reasons patients push call light

Out of 30 patients interviewed, 60% thought they did not need to use the call light before they got out of bed (63% of patients were evaluated to be able to move independently without calling for help). Patients estimated that they got out of bed a median of eight times per day (range 1-25). They estimated using the call light for help a median three times per day (range 0-20). Time estimated for someone to answer their call light was a median of 5.5 minutes. As mentioned previously, the observed response time was a median of three minutes so patients perceived that it took longer to get help when requested. These patients were asked to list the reasons

they got out of bed (see Figure 5-4). The most common response was toileting activities (42%).

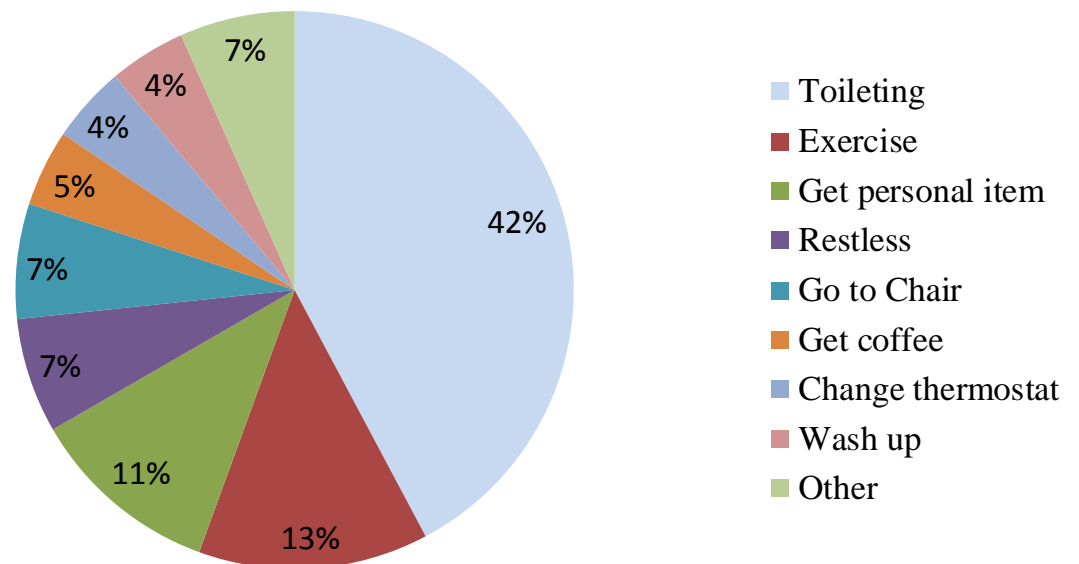


Figure 5-4 Reasons patients get out of bed

During the Analyze Phase medications administered 24 hour prior to a fall were investigated to determine possible contributors to falls:

- 68% of patients that fell were Bone Marrow Transplant (BMT) patients
- 80% were given three or more high risk medications within 24 hours prior to the fall
- Opioid dose stacking was identified as an issue (narcotic for pain relief) indicating a need for opioid administration training

A chart audit of 36 patients revealed to following changes in condition prior to their fall:

- 53% of patients had a change in condition 24 hours before they fell
- Many patients had more than one change in condition prior to falling. Cognition and lab values were the most common change in condition that a patient experienced prior to a fall.

- None of the patients that experienced a change in condition were reassessed for fall risk after the change in condition was recognized. This is contradictory to protocol.

Results from the investigation into these contributing factors lead to the formulation of interventions that were implemented during the Improve Phase.

5.2.4 Improve Phase

The Improve Phase identified improvements to optimize outputs and eliminate or reduce defects and variation, e.g. variables that increases the risk of a patient fall (DuPree et al., 2014). Results from the analysis revealed the most critical contributing factors were:

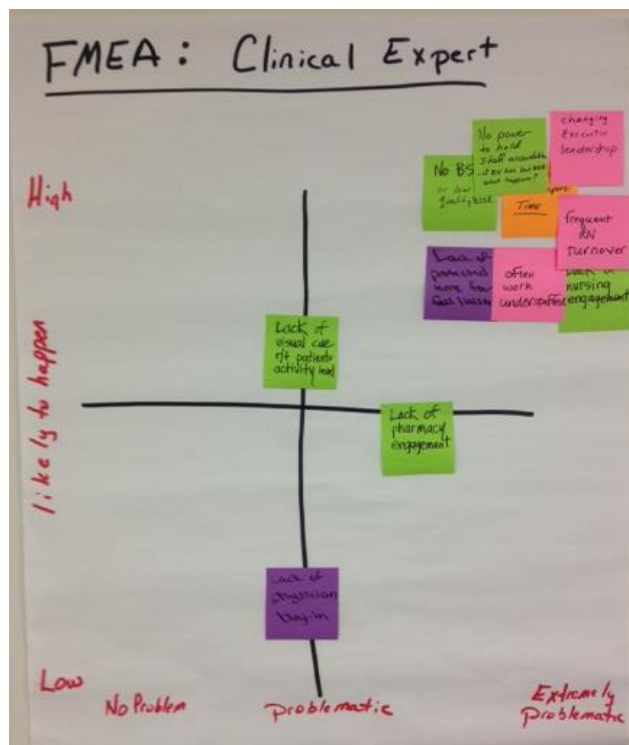
- a) Patients do not use the call light when they should: (60% of the 30 randomly interviewed patients did not feel they needed assistance)
- b) Patients get out of bed without assistance: (59% of the patients that fell were assessed as needing assistance to ambulate)
- c) Patient's overestimate their ability: (of the 53% of patients that experienced a change in condition prior to their fall; the reasons for the change in condition was due to cognitive impairment 79% of the time)
- d) Bathroom related or toileting activities (63% of the falls involved toileting)
- e) Unassisted falls (92% of patients were unassisted when a fall occurred)
- f) Medication management (80% of patients had 3 or more high risk medications within 24 hours prior to the fall)

Interventions were developed to link to these critical factors. Most of the contributing factors are patient driven so improvements focused on processes that promoted safe patient behavior. A process called Patient Partnering was developed to address each of these critical factors. The Patient Partnering process was developed with the intent to improve understanding between the nurse and patient. This clear understanding would provide opportunity to educate patients on risk for falling and injury and allow nurses to understand patient needs and resistance to suggestions. All nurses were trained on patient partnering techniques during staff meetings and individual coaching was performed as needed. A photo taken from the video that was used during training is shown in Figure 5-5.



Figure 5-5 Reenactment of Patient Partnering

A modified Failure Mode Effects Analysis (FMEA) was performed during a multidisciplinary meeting. The purpose was to understand where the patient partnering intervention might fail and identify actions that could be taken to minimize failure. The first step of an FMEA is to define possible barriers or failure that could occur if the intervention was implemented. Because the team responded well to brainstorming techniques in previous phases this step was not changed. In a traditional FMEA the next step is to quantify how Probable, Severe and Visible it would be if the failure did occur. Since the team struggled with quantifying factors during the Analyze phase, the facilitator created a technique to achieve the intent of an FMEA without using numbers. This was achieved by integrating the understanding of Probability and Severity from FMEA with the Impact Matrix technique by making one axis represent how likely it was that the barrier would occur, with the other axis representing how severe the problem would be if the barrier was to occur. Each barrier identified by the team in the brainstorming session was then placed onto the matrix in the position agreed upon by team consensus. Figure 5-6 is a photograph of the flexible technique that is a combination of FMEA and the impact matrix. The result was a list of issues most likely to occur and to be the most problematic if they did occur. Identifying these potential failures allowed discussion with management to reduce the risk of occurrence.



Most likely to happen & Problematic Issues:

- No power to hold staff accountable
- Low quality Bedside Shift Report - handoffs
- Turnover (staff & leadership)
- Lack of clinical expert time
- Understaffed
- Lack of nursing engagement

Figure 5-6 New combination of FMEA and Impact Matrix Technique.

Patient Partnering related to fall prevention was an innovative approach that empowers the patient to make an informed decision about their own safety. This technique is good nursing care and could be applicable throughout the hospital.

5.2.5 Control Phase

The Control Phase documented monitored and assigned accountability to sustain the gains from the process improvements. The APN played a prominent role with primary responsibility for sustainment of the Patient Partnering intervention by mentoring nurses throughout the 18 months after implementation. In addition the APN personally conducted the partnering process with the 87 highest risk patients. Each partnering episode was documented in a log and any falls recorded. The APN also shared best practices related to fall and injury prevention with the unit staff at regular intervals.

A tool that was developed to assist the APN with sustainment during the control phase was called the Preventable Harm Report. This was a report from the Electronic Medical Record (EMR) which included a real time display of fall risk assessment and intervention documentation for each patient. This report enabled the APN to target patients that had a mobility deficit and a high risk for injury (e.g.,

bone metastases). Based on this information, the APN assembled tailored education material and interviewed the patient utilizing a patient centered approach. The APN printed and shared the report daily to identify patients at highest risk and to ensure that nurses were appropriately matching interventions to a patient's risk assessment. An example of the Preventable Harm report (with all private health information removed) is shown in Figure 5-7.

Project status and success was shared regularly at unit staff meetings, Oncology Leadership meetings and the Oncology Joint Unit Practice Committee. Various posters and bulletin boards were maintained for staff, patients and families. Executives brought findings and results to monthly Fall Team meetings, and as needed to additional Shared Governance Councils.

Preventable Harm Monitoring - Fall Risk



Patient Info	Falls this Admission	Abnormal Labs	Fall Risk Assessment / Level	Fall Risk Assessment Details	Interventions	Additional Interventions	GUG/Activity/Assistance	Rehab Services
 Admit Date: 02/22/2013 Admit MD: Prelutsky, David Admit Diagnosis: viral encephalopathy Team: Gold South - Blue		Calc AHC: 4174 HCT: 39.8 L HGB: 13.5 L	6 entered by: Wall, Theresa A MODERATE entered by: Wall, Theresa A	Age: Less than 60 years old (0) Fall History: No fall within 6 months (0) Elimination: None of the above (0) Medications: On 2 or more high fall risk drugs (5) Patient Care Equipment: 1 present (1) Mobility: None of the above (0) Cognition: None of the above (0)	All Low All Moderate Interventions	Over-bed table on non-exit side	Activity As Tolerated	
 Admit Date: 02/24/2013 Admit MD: Otepka, Hannah Admit Diagnosis: sepsis Team: Med 1 - Red - Striped		PT: 12.6 H HR: 1.22 H Creatinine: 1.49 H Calc AHC: 2371 HCT: 26.6 L HGB: 8.7 L	10 entered by: Weber, Jason MODERATE entered by: Weber, Jason	Age: 80 or more years old (3) Fall History: No fall within 6 months (0) Elimination: Incontinence (2) Medications: None (0) Patient Care Equipment: 2 present (2) Mobility: Requires assistance or supervision for mobility (2) Cognition: Altered awareness of immediate physical environment (1)	All Low All Moderate Interventions	Over-bed table on non-exit side Exit bed on strong preferred side	Up with Assistance	PT Eval and Treat - completed 02/27/2013; OT Eval and Treat - completed 02/27/2013; Speech Eval and Treat - completed 02/27/2013; PT Eval and Treat; OT Eval and Treat

Figure 5-7 Example of Preventable Harm report printed daily by the APN

5.3 Interventions for Six Sigma

Six Sigma methods culminated in the interventions shown in Table 5-3. Patient Partnering was the intervention that encompassed the majority of contributing factors and consequently is the focus of this chapter. The detailed nature of Six Sigma resulted in additional interventions that were also implemented on January 2013 along with Patient Partnering.

Intervention	Link to Contributing Factor	Impact
1. Patient Partnering	Patients do not use call lights Patients out of bed for activity Overestimation of ability Toileting activity Unassisted falls	Increase safe, proactive behavior (patient & staff)
2. Real-Time Preventable Harm Report	Change in condition prior to fall	Improve efficiency in patient partnering, information & critical thinking
3. IV pole stability	76% of injuries from falling were caused by IV poles	Reduce environmental hazards without design changes
4. Opioid training: stagger administration of short & long acting opioids	Medication management & change in condition	Decrease patient confusion due to opioids

Table 5-3 Interventions linked to contributing factors and falls

1. Patient partnering and agreement: The APN and staff nurses use scripted words to encourage patients to adhere to a fall prevention program tailored to their needs throughout their hospital stay. Customized educational materials were provided during short but repeated discussions about fall prevention. An agreement was posted in a place visible to both staff and patients with responsibilities of the staff and patient.
2. Preventable Harm Report: See Figure 5-7 for an example of the preventable harm report that contains real-time information with factors important to fall

prevention for each patient. This report was originally designed to aid in sustainment for the patient partnering intervention during the Control Phase. However additional usage of this report was realized as it provided information needed during critical thinking to link various issues together and compile a complete picture of the patient's fall risk. The Discussion Chapter 8 discusses the role of technology in providing assistance with critical thinking required to compile a copious amount of information from several sources.

3. IV pole instability: A review of falls that occurred in 2012 showed that 75% of falls resulting in injury involved IV poles. One IV pole design had a high center of gravity causing it to tip easily (shown in Figure 5-8). The APN had to constantly monitor IV pumps to ensure that the unstable poles did not reappear on the division. Signs were placed in the storage areas to alert nurses of the danger of using the improper IV pole.

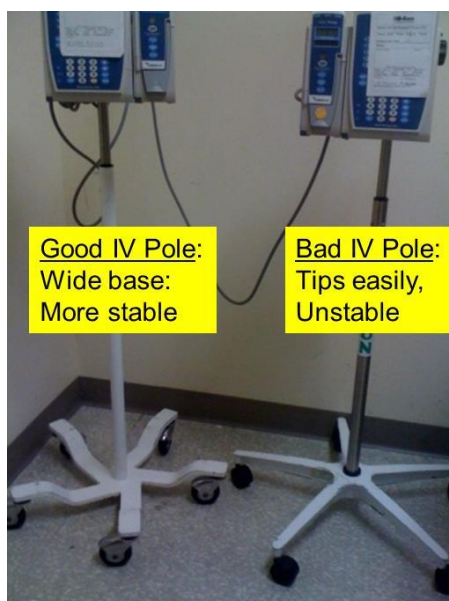


Figure 5-8 Photographs of IV poles

4. Opioid Training: As pharmacists investigated high risk medications administered within 24 hours prior to the fall they found opioid stacking was an issue. An opioid is a narcotic administered for pain relief. Opioid stacking occurs when long and short acting opioids are administered at the same time. Nurses did not realize that the long acting opioid included an initial dose along with the time delayed dose in the same pill. When taken at the same

time as a short acting opioid it caused a higher dosage than intended. Nurses were trained to stagger administration of these medications in attempt to reduce patient confusion and change in condition due to medication.

In spite of attempts to control as many variables as possible, there were some interventions that occurred during the Six Sigma period that were demanded by hospital-wide initiatives.

5. Shift Change Safety Report: At every change of shift the on-coming and off-going nurses gathered together (for less than 5 minutes) to review any safety issues that needed awareness by the on-coming shift. They discussed any falls that may have occurred during the last shift and any new interventions that were required. Discussions also included safety issues such as transfusions, Chemo, “do-not-resuscitate” status, and pressure ulcers.
6. Low bed study: A vendor supplied free low beds to be placed in every patient room on one side of the hallway. Patients on the other side of the hallway could still have a low bed if special-ordered by the nurse but the delivery process did not change from current practice. Comparisons were made of falls with injury from low beds to traditional hospital beds.
7. Call light response: A hospital wide initiative was implemented that required a staff member to enter a patient’s room within three minutes of the patient pressing the call light. If the call light remains unanswered past three minutes there is an alert escalation algorithm that ultimately goes to the nurse manager.

5.3.1 Convince the patient to partner

As mentioned previously, Patient Partnering was the primary intervention requiring the most focus of this project. A customized approach was taken to convince a patient to participate in fall prevention. The APN selected training materials to discuss with the patient that matched the issues identified from chart reviews and conversations with the patient and based on the checklist in Figure 5-9 . For example, if the patient’s medication causes numbness the APN would explain that the loss of sensation can interfere with the sense of touch. The APN would then ask the patient to demonstrate the use of the call light. If the numbness made it difficult to press the button they would discuss alternatives. After this first session, the APN

gave the patient time to absorb the conversation and returned about two hours later for a follow up conversation.

<ul style="list-style-type: none">✓ You are ____ years old✓ You have fallen in the past✓ You are weak✓ You have diarrhea✓ You have urinary urgency✓ You are not eating well✓ You are not drinking well✓ You are forgetful✓ You do not use our call light✓ You are connected to the following ____ (insert tether here) ____✓ You are receiving the following drugs ____ (insert medications here) ____✓ You have a platelet count of ____ or an INR of ____ or other ____✓ You are at risk for fracture because _____✓ You have peripheral neuropathy✓ You have cerebellar neuropathy✓ Your fall risk assessment score is _____
--

Figure 5-9 Checklist used by nurses during patient partnering

5.3.2 Critical Thinking and Customized Interventions

The final step in the “improve” phase was to train all staff nurses to use the best methods for Patient Partnering developed by the APN. There was a patient/caregiver agreement for each nurse to sign and post on the patient’s information board to remind them of the interventions recommended to keep the patient safe. A diagram representing the multi-disciplinary components of interventions from the Six Sigma process is shown in Figure 5-10. Patient Partnering training was completed in January 2013 and the project was moved into the “control” or sustain phase. The Patient Partnering intervention was active from January 2013 until June 2014 when the APN left the oncology division. Fall rate metrics were collected throughout the 18 month Patient Partnering intervention and from July 2014 through June 2015 to

track falls for 12 months post intervention to understand the trend in outcome metrics.

Multi-disciplinary Fall Prevention Team



Figure 5-10 Photos representing interventions in Study 2

5.4 Results for Six Sigma

Results discussed in Chapter 4 (Study #1) included three oncology divisions that participated in the Lean project to develop standard work for addressing patient falls. This chapter only includes data from the single oncology division that also participated in the Six Sigma intervention. (That is, the results shown in the Lean phase of this chapter will differ from Study #1 because data from the two divisions that did not participate in Study #2 are excluded from analyses in this chapter.) Chapter 7 also includes results from this single oncology division but spans 5.5 years with a two year baseline period prior to any fall prevention initiatives.

The results of this rigorous, data-driven methodology are divided into the following sections.

- Fall and Injury Rate: Lean/Six Sigma/Post Intervention
- Comparing reasons for falls with injury and without injury
- APN and Patient Partnering

- Qualitative results from Six Sigma (Study #2)

5.4.1 Fall and Injury Rate: Lean/Six Sigma/Post Intervention

Since the duration of intervention periods and number of patients vary; results are reported as a rate. Fall rates are calculated by the number of falls (and number of falls with serious injury) divided by the number of patient days multiplied by 1,000. Injuries were categorized in the same manner as Chapter 4 (4.4.1) according to American Nurses Association-National Database of Nursing Quality Indicators. “Total Falls Rate” includes all falls, with and without injury. “Serious Injury Rate” (falls with serious injury) includes falls resulting in a moderate injury (e.g. sutures or splints) or major injury (e.g. surgery, casting) or death.

The bar chart in Figure 5-11 represents rates from the one oncology division that was selected for the Six Sigma project from August 2011 through June 2015. The Lean intervention that began in August 2011 involved standard work to ensure that all nurses were assessing patients and assigning interventions in a similar fashion (Study #1 in Chapter 4). Since the Patient Partnering intervention from the Six Sigma project did not begin until January 2013, there was an opportunity to monitor sustainment of the Lean project for 17 months after the standard work intervention was implemented (Wolf et al., 2013a). The Patient Partnering intervention was active for 18 months. Patient Partnering ended when the APN left at the end of June 2014. Rates continued to be monitored for 12 months post interventions from July 2014 to June 2015.

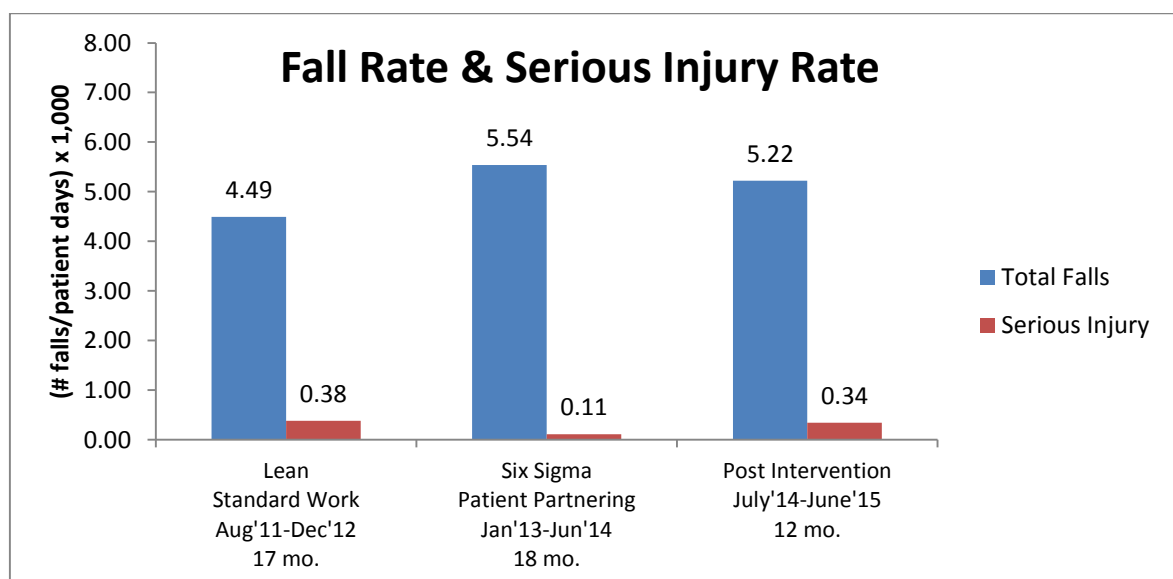


Figure 5-11 Fall and Fall with Serious Injury Rates for the oncology division implementing Six Sigma

Table 5-4 compares the rate of total falls, and falls with serious injury during Lean, Six Sigma and post intervention. Although the fall rate increased by 23% (4.49 to 5.54) during the Six Sigma phase, the falls with serious injury rate decreased by 71% (0.38 to 0.11). To determine if there was a statistical difference the two-tailed Z test was used (proportion of number of falls to number of patient days comparing two time periods). The Z test was conducted to compare the Lean fall rate of 4.49 to the increase of 5.54 rate that occurred during the Six Sigma phase ($Z = -1.35$, $p = 0.177$). An alpha level of 0.05 designated this was not a statistically significant difference. Another Z test was performed to determine to test the improvement of falls with serious injury rate (from 0.38 to 0.11) and again there was no statistical significance ($Z = 1.58$, $p = 0.114$). Although none of these differences were statistically significant using the Z test, it is still concerning to see the fall with serious injury rate increase by 68% (0.11 to 0.34) in the post 12 months after the Patient Partnering intervention ceased ($Z = -1.312$, $p = 0.190$). When considering falls with serious injury, it is of interest to note how much impact one or two falls with injury can impact the rate of a rare occurrence event. The issue of statistical verses practical (or clinical) significance is discussed in the discussion section of this chapter 5.6.3.

	STUDY #1	STUDY #2	POST INTERVENTION
Methodology	Lean	Six Sigma	
Intervention	Standard Work	Patient Partnering	
Time frame	Aug 2011 to Dec 2012	Jan 2013 to June 2014	July 2014 to June 2015
Number of months	17 mo	18 mo	12 mo
Metric - rates	rate during Lean phase	rate (% change from Lean)	rate (% change from Six Sigma)
Total Falls Rate	4.49	5.54 (-23.4%) Z=-1.35, p=0.117	5.22 (5.8%) Z=0.36, p=0.719
Falls with Injury Rate	1.54	1.66 (-7.8%)	1.77 (-6.6%)
Minor Injury Rate	1.15	1.54 (-33.9%)	1.43 (7.1%)
Serious Injury (mod+maj) Rate	0.38	0.11 (71.1%) Z=1.58, p=0.114	0.34 (-67.6) Z=-1.312, p=0.190
Number of Patient Days	15601	17519	11869
	#	#	#
Number of Falls	70	97	62
Number of FWI	24	29	21
Number of Minor injuries	18	27	17
Number of serious injury (moderate & major)	6	2	4
*statistically significant Z test = compare two incidence density rates. An alpha level of 0.05 was designated as statistically significant. % change = (baseline rate - intervention rate)/baseline rate			

Table 5-4 Fall data from Lean, Six Sigma and Post Intervention

One reason the number of falls were elevated during the Six Sigma project was due to “frequent fallers”. From Jan – Dec 2012 during the Lean project there were two patients that experienced repeat falls for a total of four falls. From Jan – Dec 2013 during the Six Sigma project there were 8 patients that experienced repeat falls. These eight patients accounted for 21 of the falls during the Six Sigma project. One very confused and ill patient fell five times during one admission. This was a particularly challenging patient who was combative and resistant to medical and nursing care. Repeated attempts were made to partner with this patient because of his high fall risk and tendency to walk outside of the hospital. One day during his hospitalization the APN happened to observed him outside the hospital in his wheelchair pulling his IV pole. He was on the verge of falling off the curb and tipping over! To avoid a confrontation, while a visitor was distracting him, the APN approached and supported the wheelchair from behind while hiding out of his line of sight. As he precariously balanced she assisted him and perhaps prevented a fall

without him ever realizing she was the one who helped. Although she knew the patient did not want her help, she continued to intervene for his safety during his stay.

However in this same comparison period, there were fewer falls with injury likely because more patients experienced an assisted fall. There were 14 consecutive months without a fall with serious injury during the Six Sigma project. The two falls with serious injury that did occur in the 18 month time period involved patients that were very ill and had numerous co-morbidities before the fall, making them more vulnerable to injury. The first fall occurred at 1:15 am by a 70 year old female with lymphoma and low platelet count making her susceptible to bleeding. The nurse had assisted her to the toilet and taught her how to use the call light. The nurse told her to call when she was finished (she left the patient alone on the toilet for privacy). The patient did not call for help and successfully walked back to bedside but fell when she bent over to remove her slippers. Her husband was in the room and then called for help after she fell. She had a fractured nose and a subdural hematoma (head bleed) probably due to low platelet count (categorized as a major injury). Prior to the fall the patient was classified as low risk for falling. This is a classic example of a fall that could have been prevented if the nurse had assisted her back to bed. It is hard to determine if the nose fracture was due to her medical condition but the head bleed may have been caused by her impaired blood clotting.

The second fall occurred at 2:20 am involving a 60 year old male with neuroblastoma that had brain surgery and was classified as high risk for falling and had experienced a previous fall during his hospital stay. The patient had mental confusion (alert and oriented times two, where four is considered normal) and was incontinent. A nurse found him on the floor by the bed with a cut on his ear that required stitches and antibiotics (categorized as a moderate injury). All high risk fall interventions were in place for this patient but the bed alarm did not go off (reason unknown). This is an example of a fall that is very difficult to prevent. The patient was not mentally able to understand to call for help. If a sitter had been assigned to watch the patient they may have alerted someone for help. An improved bed alarm technology would be helpful if it could predict when these types of patients are attempting to get out to bed.

From Jan – Dec 2012 during the Lean project there were 6 patients that experienced an assisted fall (12% of all falls were assisted). From Jan – Dec 2013 during the Six Sigma project there were 14 patients that experienced an assisted fall (19% of all falls were assisted).

5.4.2 Comparing reasons for falls with injury and without

Further investigation into the reason for improvement in the falls with injury verses no injury was warranted. The data rich fashion of six sigma methodology provided this opportunity by allowing contributing factors (reasons for falling) to be compared with fall information (injury verses no injury).

An evaluation of contributing factors was conducted by a team (fall team chairperson, two nurses with fall expertise, APN and the Thesis Author) to understand the circumstances of each fall and to determine which intervention would be likely to decrease the risk of injury. Post fall investigation reports, sentinel event records and medical records were reviewed to reach consensus on the background and details of 74 falls that occurred between Jan – Dec 2013 during the Patient Partnering intervention. Twenty-four resulted in minor injuries. There were no moderate or serious injuries during this time. Table 5-5 describes the location of each fall and indicates which fall resulted in an injury.

Location of Fall	Number of Falls	% falls	Number of Injuries (all were minor)	% injury
Bathroom	18	24%	8	33%
shower (2)	2	3%		0%
Ambulating	22			
to bathroom (6)		8%	4	17%
to BSC (11)		15%	1	4%
to/from chair (4)		5%		
from sink (1)		1%	1	4%
Bedside	18	24%	6	25%
fell out of bed (3)	3	4%	2	8%
Patient room	7	9%	2	8%
Wheelchair	2	3%		
Hallway	1	1%		
Outside	1	1%		
Total	74	100%	24	100%

Table 5-5 Location of falls and falls with injuries during 2013

A fall Tracker Board shown in Figure 5-12 was maintained with information about each patient that experienced a fall to visualize and identify trends. Information included risk factors and interventions that were in place (or lacking) at the time the fall occurred. For example when the first six months of fall information was posted on the board, it confirmed that unsupervised toileting was one of the primary contributions to patient falls. An unexpected revelation was that more than 80 percent of the falls were with patients categorized as “moderate risk for fall”.

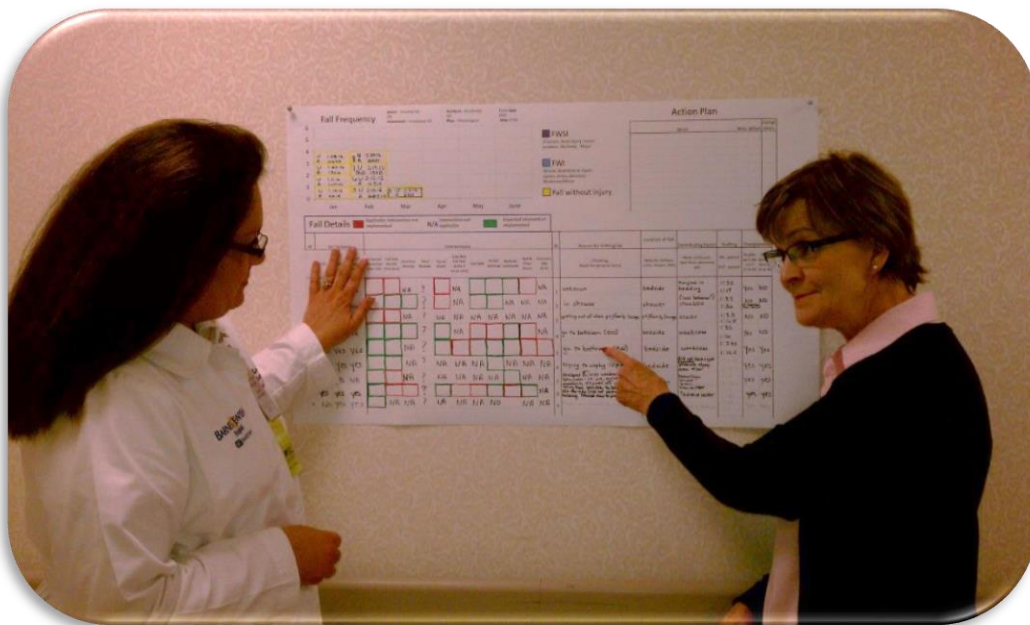


Figure 5-12 Fall Tracker Board

Contributing factors identified during the analysis phase (such as assistance, toileting, bed alarm and low bed) were investigated to compare falls that resulted in injury to those that did not. For example, the number of patients that had an assisted fall and had an injury was compared to the number of patients that had an injury from an unassisted fall. A Test of 2 proportions, Fisher exact test was performed to determine level of significance.

The only contributing factor found to be statistically significant was assisted falls. A patient who was assisted to the ground during a fall was less likely to have an injury (see Table 5-6). In 2013, 60 of the 74 of the falls were unassisted (81%) and 23 of these falls resulted in an injury while only one of the assisted patients was injured. This means that 38% of unassisted patients were injured while only 7% of assisted

patients were injured (p value = 0.028 using the Test of two proportions, Fishers' exact test).

	Injured	No Injury	Total
Assisted	1 (7% injured)*	13 (93% no injury)	14
Unassisted	23 (38% injured)*	37 (62% no injury)	60
Total	24	50	74
*statistically significant			

Table 5-6 Unassisted patients more likely to be injured from a fall than assisted patients.

Other contributing factors that were analyzed but not found to be statistically significant include: low beds, bed alarms and toileting related falls.

- Low beds: Out of the 74 falls in 2013, 22 of these falls were out of (or off of) the bed (11 falls from low beds and 11 from traditional hospital beds). There was no statistical difference between the injuries that resulted in falling from the low bed compared to the traditional bed. Falling from a low bed was not statistically different in the reduction of injuries (p = 1.0).

Low Bed		
Low Bed = 11	Injury = 5	5/11 = 45%
	No injury = 6	
No Low Bed = 11	Injury = 4	4/11 = 36%
	No injury = 7	

- Bed alarms: Out of the 74 falls in 2013, 37 patients fell that needed a bed alarm according to their fall risk assessment and 11 of them had alarms on their beds before their fall (26 did not have an alarm but should have). There was no statistical difference between the number of patients that were injured from a fall with a bed alarm vs. without (p=0.268)

Bed Alarm		
Alarm on = 11	Injury = 6	6/11 = 54.5%
	No injury = 5	
No Alarm = 26 But should have been	Injury = 8	8/26 = 31%
	No injury = 18	

- Toileting Related: Out of the 74 falls in 2013, 12 falls had undetermined activity. 42 falls occurred during toileting activity and 20 were not. There was no statistically significant difference between the injuries that occurred while toileting vs. patients that were injured in non-toileting activities ($p=0.78$).

Toileting related		
Toileting = 42	Injury = 17	17/42 = 40.5%
	No injury = 25	
Not toileting = 20	Injury = 7	7/20 = 35%
	No injury = 13	

5.4.3 APN and Patient Partnering

The APN personally partnered with 87 high fall risk patients during Study #2. Of these, 6% (5 patients) experienced a fall. Twenty-one of these 87 patients were found to be extremely probable to fall and two of these very vulnerable patients fell during their hospital stay.

One insight from the APN Patient Partnering revealed the importance of understanding the dynamic nature of clinical assessments (e.g. boluses, labs) with respect to falls risks. Interventions must be as dynamic as the changing conditions, for example, when an antibiotic is ineffective, it will be changed. Similarly, fall interventions should be based on information about fall risk, e.g. medications such as Lasix may cause frequent urination so a bedside commode may be a temporary solution to decrease risk of falling while walking to the bathroom.

The APN compiled educational flyers to give to the nursing staff based on stories from her Patient Partnering experience. The following story is an excerpt from one of her flyers:

- Teaching Vignette of a fall - patient, 57 years of age, Central Nervous System (CNS) Lymphoma, High dose MTX (chemotherapy medication)
 - “Before you know another thing about this patient, you should already be suspicious. He has disease in his CNS. CNS disease can cause neurological symptoms including an unsteady gait and confusion. He is getting hi-dose chemotherapy (MTX), which crosses

the blood brain barrier. In fact patients with this disease often have an already more highly permeable blood brain barrier than usual.

MTX also has the potential to impact renal and liver function.

Compromised renal/ liver function means the drug may not be as readily metabolized and excreted, thereby increasing the body's exposure to the drug leading to the exacerbation of side effects, including neurological side effects such as an unsteady gait and confusion. Stay alert to all of your patients' lab values."

- "This patient fell on July 12th, 2013. His assessed risk for fall was moderate. The nursing staff did not catch his history of fall. P.T. had written "difficulty standing within the last 2 weeks and difficulty walking". I am not sure how this was communicated and I am following up on this. Oddly, according to the documentation on the chart, he passed the Get-Up-Go test (even though on the Fall Risk Assessment he was noted to "require assistance or supervision for mobility"). Despite the apparent lapses in assessment noted in the EMR, the patient's nurse placed the patient on a bed alarm the night before he fell. So, she had a feeling about him and she was right...and did the right thing."
- "When I spoke with the patient I got the following responses:
 - I can't wait to go to the bathroom; when I have to go, I have to go...
 - When I put my call light on, no one comes; when the bed alarm goes off people come..."
- "The nurse asked me to see this patient, before he actually fell. I tried to see him but he was sleeping soundly. He later got up and fell, before I had a chance to get back in the room. I did visit him after that. "
- "Hourly rounding is very important. Offer toileting to this patient on every round. Gently, humbly and with the greatest respect, remind patients that this is the plan to keep them safe. Acknowledge how

difficult this is for otherwise independent adults. Maintain your composure. It works well.”

- “Prioritize toileting associated call lights. Thank the patient for calling and waiting.”

These types of vignettes and ongoing communication were an important contribution of the APN’s guidance and mentoring provided throughout Study #2.

5.4.4 Qualitative Results from Six Sigma (Study #2)

In addition to applying Six Sigma methodology to fall prevention, one aim is to gain insight on successes and failures with the approach. Qualitative insights from Lean methodology learned from Study #1 are discussed in Chapter 4. This section focuses on the results of insights that were understood during Study #2. Overall results and insights from all methodologies combined are discussed in Chapter 7.

Notes were documented in a journal throughout the Six Sigma project to gain an understanding of fall issues. The following comments summarize highlights from the insights that are listed in Table 5-7:

- Identifying the root cause of falls is multi-faceted and complex with no easy solution. The way the EMR was programmed created confusion. The sequence of scroll-down menu options influenced the documentation of risk factors and interventions (e.g. “no follow up needed” was the first option available in a scroll down list encouraging lack of follow through). Many of the patients that fell were confused about their abilities and surroundings but this deficiency was not assessed by traditional technique to determine a patient alertness and orientation.
- A checklist with tasks does not promote an understanding of interaction between factors that contribute to falls. A good assessment will consider the interactions of risk and match to the most appropriate and simple interventions.
- Quantifying reasons for falls and identifying appropriate solutions must use a combination of qualitative and statistical methods to demonstrate trends and success.

- A wide variety of interventions is needed to address the variability of risks and must be customized accordingly. Fall prevention efforts need constant rejuvenation to maintain a heightened culture.
- The Patient Partnering technique needs revision to reduce time required by integrating with other interventions and strategies.
- Falls are not perceived to be highest priority by staff or patients. Patients do not think they are at risk for falling. Patients and staff do not understand the difference between fall risk and injury risk. There can be conflicts between priorities that can make it difficult to align risk and intervention (e.g. privacy for toileting verses assistance with mobility).
- Long lasting projects are difficult to maintain momentum with high turnover of team members.

Barrier/Problem Identified	Insight/Understanding
Nurses think if patient is Alert and Oriented then they are not at risk for "fall confusion"	Idea: need to develop terminology for "fall confusion" (impulsive, does not understand limitations, unfamiliar with surroundings)
Electronic medical record barriers: 1. "Reinforce as needed" should be top selection of scroll list 2. Eliminate "no follow up needed" or move to bottom of scroll list 3. Make a hard-stop for "explanation" of exception 4. The free text box needs an example to display in hover box	Electronic Medical Record enhancements recommended
Three categories of fall risk is too complex	Idea: consider change to Low or Mod/High
No control over management changes, staff moves, Fall Risk Assessment (FRA) implemented by system, construction, new staff, executive leadership new focus, staffing levels	Lack of control over outside contributing factors
Fall risk assessment is time consuming and doesn't seem to add to appropriate interventions	Patient assessment should focus on determining best interventions (e.g. bed alarm or never walk alone)
Lack of opportunity to thoroughly understand the situation after a fall occurs	e.g. Toileting is reason they get up, but not why they fall...
Fall issues are difficult	Silver bullet, magic answer doesn't exist

Barrier/Problem Identified	Insight/Understanding
Hourly rounding focus is "care" not "clinical" critical thinking	Need to change mindset away from a to-do-list mentality to clinical critical thinking
Conflicting information in chart: patient charted as pass Get-Up-&-GO (GUG) but are "up with assist" or Fail GUG but rated as Low Risk	Fall Risk Assessment has inconsistencies in documentation
Fall prevention is viewed as tasks to be completed	Knowing the patient vs. task oriented (checklist)
Six sigma tools can be cumbersome	Develop creative ways to combine best feature of tools to achieve desired results: See/Hear/Feel work with Zero Injuries. Brainstorm how to mitigate risk discovered in FMEA
Definition of critical factor	A "critical factor" is either a cause of the problem (fall) statistically or "soft" cause where the team feels it is an issue (statistical vs. practical)
DMAIC Phases & Data Collection	Improve Phase looks at process metrics, Control Phase looks at impact on Big Y (that is the primary outcome measure = falls with injury)
Best way to achieve transparency of fall information is difficult	G-chart useful on an individual unit to see rare events, but not good for aggregate data
Inconsistent method of showing results	Idea: try using P charts to show progress for all Joint Commission hospitals
Patients get hurt when unassisted	Idea: if patient is assisted they won't get hurt, How can we make sure patient is always assisted? - no one walks alone
Inconsistent FRA and interventions (high risk interventions are more work)	Idea: Fall Friday: 1. print preventable harm report, 2. review FRA with nurse 3. brainstorm best solutions based on FRA 4. go to room to observe interventions in place compare to documentation
Patients don't call for help when toileting	Unassisted toileting was problem for all hospitals in Joint Commission project
"fall precaution" vs. "fall risk" Nurse can write an order "ORDER FOR FALL PRECAUTION"	"Fall risk" can vary from one day to the next or throughout the day, but "fall precaution" doesn't change, Nurse can order "ORDER FOR FALL PRECAUTION"

Barrier/Problem Identified	Insight/Understanding
Patients don't call for help when toileting	Partner with patient to increase usage: 1. Measure call light usage, 2. Measure if "Partner with Patient" is being used
Lack of incentive	"Zero Award" idea... if floor goes 12 months without injury (doesn't have to be consecutive)
Too many protocols and variables	Combine efforts with preventing pressure ulcers (in hourly rounds) and with patient handling assessments
Interventions are not adapted to specific population	Intervention must be adapted to specific patient, if mobility screen shows a problem, then assess the patients issues around mobility and figure out a specific intervention for that patient's mobility
Patient partnering takes too much time	Simplify, change culture
Nurse and patient can be non-receptive to fall information	Wait until nurse/patient is in a "more accepting mode" to approach with a fall suggestion, several short sessions may be required to reinforce an idea
Central Line Infection and Ventilator Associated Pneumonia (VAP) studies show a checklist will prevent the issue every time, falls are not perceived the same way	Nurses comply better with VAP and Central Line Infection, fall is not an easy checklist that works every time and falls not perceived to be as "important" as infections (or medical issues)
Staff/executive turnover is high and impacts momentum	Change must be quick
Transient team members - patient and staff	Idea: build in handoff for understanding of fall project with new employees
Very high turnover for long duration projects (> 1 year)	Interventions are hard to implement without continuity of team support
Detailed analysis takes a long time	Fall prevention is a Discovery and Journey (continuous effort required)
Why aren't patients calling for help?	Patients don't think they need help, don't understand their risk or stronger need for independence or privacy?

Table 5-7 Insights from Six Sigma Study #2

Patient Partnering. This interactive technique between caregivers and patients is an intervention that was developed and refined during Study #2 to enhance patient

engagement and encourage them to participate in their fall intervention process. Patient Partnering may empower a patient and return a sense of control and independence.

The Fall Tracker board developed during Study #1 continued to provide insight to causes of falls in Study #2. The information provided guidance in the Six Sigma process. Analysis conducted as part of the Six Sigma process showed how the interventions needed to be dynamic to match the changing needs of the patient. Assessments were not being conducted after the patient experienced a change in condition (e.g. medication or cognitive change).

Fall risk assessments encouraged “checklist thinking”. The assessment became a task that was completed without thinking through the interaction of each factor. For example, a patient might score 12 or 13 (which is in the moderate category) but they wouldn’t consider that the medication made them weak and that the patient had frequent urination needs and brittle bones. A patient with these factors would have been safer in the high risk category with interventions such as bedside mat and bedside commode.

The influence of the APN was also critical to the success of reducing falls with injury. The APN was the “fall prevention champion” for this project. She provided initial education that was needed to begin the project. She took teach-back to a whole new level by drafting a script for Patient Partnering and making it available to staff. She also provided ongoing mentoring to the nursing staff. For example when she reviewed the preventable harm report and noticed conflicting documentation she would go to the nurse responsible for that patient and resolve the discrepancy. The APN attended physician rounds in the morning to discuss patients at risk of falling and the need for an accurate activity order (e.g. up with assist). She also compiled educational messages for all nursing staff that discussed cases with interesting teaching opportunities. The APN provided guidance for individual nurses by accompanying them to approach a patient with particularly difficult fall risk issues.

The following scenario is an example of how the APN would interact with a patient as she responded to a call light request or bed alarm alert. When she entered a room she knocked on the door and introduced herself right away. She offered assistance to patients by using therapeutic language and thanked the patient for calling out. While

in the room she continually assessed the environment, minimized trip hazards and cleaned up clutter, all during a compassionate conversation about the patient's risk factors for falling. In caring for oncology patients she adapted her language to positively emphasize their capabilities, rather than their weaknesses. This included encouraging them to exercise, but to do it with company (their nurse!) for safety and prevention of harm. It was important to her to discover in the patient's own words what motivates or discourages them. She was honest about their diagnosis, their risk factors and their current state. "You may be weaker than you expect." would be an example of her simple, clear explanation of their abilities. Finally, when she had completed her work at the bedside, she returned to the primary nurse to disclose any findings and discuss patient needs. Understanding the workload, she offered to assist any nurse who was unable to attend to a patient due to conflicting responsibility.

Although momentum for Patient Partnering was maintained by the APN, the intervention was never fully adopted by the bedside nurses. Nurses cooperated with the APN in Patient Partnering, but at times hesitated to initiate the partnership themselves. The nurses did not universally adopt the technique due to time constraints and conflicting priorities. Although the additional partnership with the APN was successful in reducing serious injuries it was time intensive. The goal was to build this type of partnership into the work flow of all nurses to become a normal part of assessment and patient interactions.

5.5 Model for Study #2

After Study #2 the model in Figure 4-4 discussed in Chapter 4 was reviewed to consider the integration of Lean Six Sigma methodology. One shortcoming with the model was that the patient centered concept was not prominent. The model was enhanced by changing the format and moving the family and patient into the center of the model see Figure 5-13 . This format also provided a logical way of combining other methods such as PE and QI in the model.

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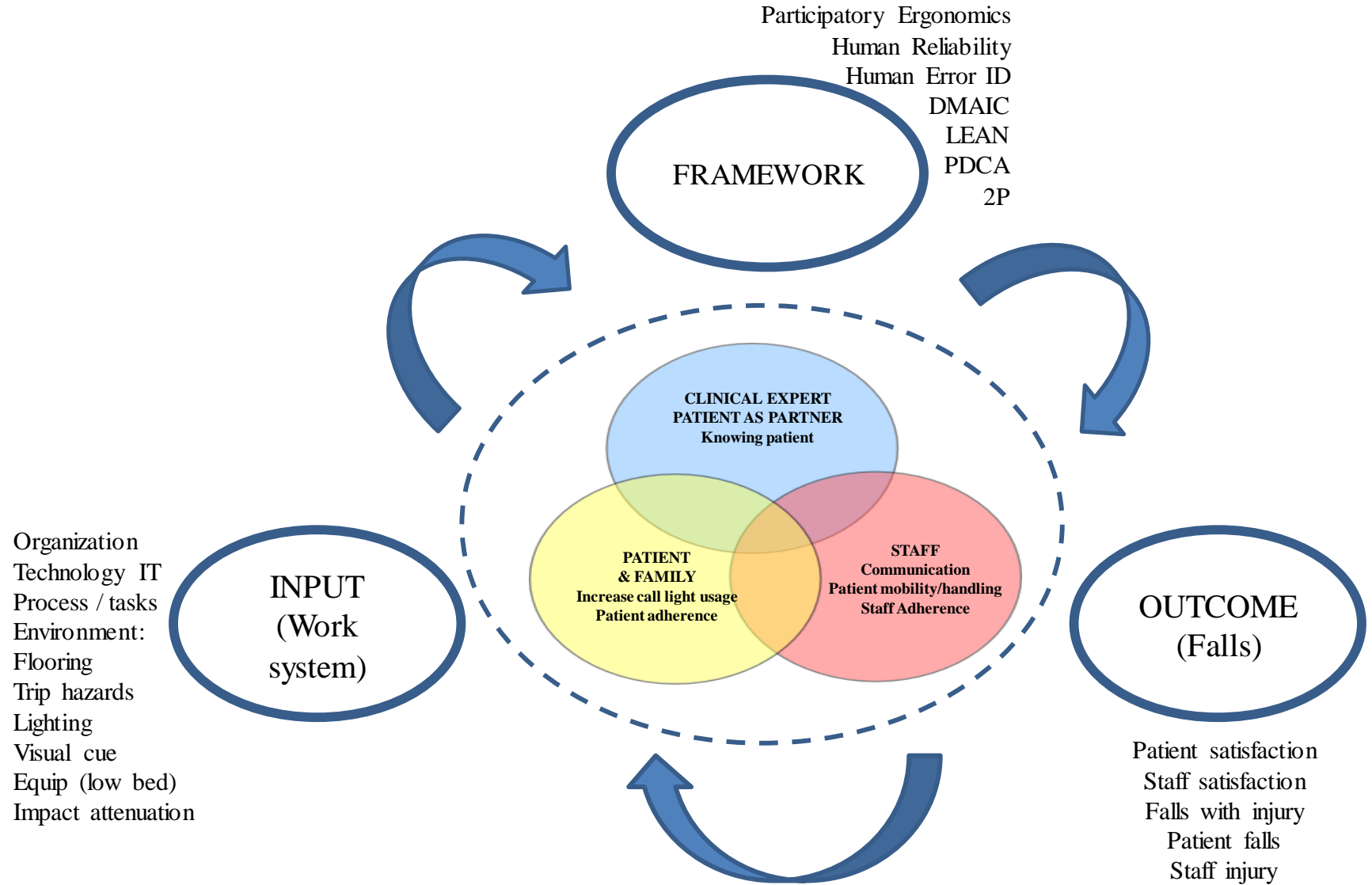


Figure 5-13 Model After Study #2: Patient and Staff Centered

5.6 Discussion for Six Sigma

The standard work that evolved from the Lean methodology in Study #1 provided a consistent foundation for further fall prevention work that was conducted in Study #2. The Six Sigma process involved more thorough analysis than was conducted with Lean. The detailed analysis provided insight into the complexity and interaction between numerous fall risk factors.

At the start of Study #2, studies using Six Sigma to prevent falls for inpatients were not evident in literature reviews (DuPree et al., 2014). The collaborative study with The Joint Commission found that robust Quality Improvement tool of Six Sigma was successfully used in seven hospitals to examine why processes fail and to implement targeted, long lasting solutions to prevent falls and injury.

A study published after the completion of Study #2 was conducted by Hospital of the University of Pennsylvania (HUP). They also used Six Sigma methodology during a QI project that resulted in an intervention called Proactive Rounding. This team approach focused on patient needs and recommended patient-specific interventions and an individualized plan of care that was unique for each patient. They also found that a standardized fall prevention program did not accommodate individualized needs and consequently was not as effective as expected. It is interesting that no mention was made of falls with injury even though interventions were customized to the specific needs of patients (Christopher et al., 2014).

Industries outside of healthcare have used the concept of collaborating with critical stakeholders to develop a safer process or environment. Rivlis et al (2007) defines Participatory Ergonomics (PE) as an approach that encourages workers to be involved in controlling their own work activities and consequently decreasing their risk factors. With the patient as a team member, it may empower them with knowledge of their risks and give them control over their plan of care to decrease their risk factors. Loss of independence and control is often a reason cited by patients for not cooperating with fall prevention interventions. Using a participatory approach may help return some of the power to the patient making them an active participant in their own safety.

5.6.1 Patient Partnering

Six Sigma tools were used to investigate root causes of the most critical factors such as unassisted toileting and continuously changing patient conditions (cognition, medications) during Study #2. Insights from these assessments lead to the intervention described previously as “Patient Partnering”.

Several sources agreed that an unsuccessful method of achieving patient adherence to fall interventions is using a brochure or flyer to convey information (Haines and McPhail, 2011, Tzeng and Yin, 2009a, Tzeng and Yin, 2009b). This further supports the insight of partnering with the patient to allow them to gain an understanding of their risk for falls and potential injury as integrated into their daily assessment and intervention plans. Patient adherence was also found to be most successful if patient and family together are included in fall intervention planning (Vassallo et al., 2004).

According to (Morag and Luria, 2013) an objective of PE is to involve the end user to improve safety of the workplace. First step is to conduct an analysis of the situation. To apply Morag’s framework from industry, an analogy can be made to a nursing assessment done with each patient upon admission and with every change of condition. An insight from this article is that as frameworks are being developed and validated, the application to each individual should be considered. One dimension of Morag’s framework (extent of workforce involvement) could be aligned with a patient’s willingness or ability to be actively involved in their plan of care. Another concept that was incorporated into the Patient Partnering intervention was where management effort must be continuous and not just a unique episode in order to become embedded in the plant’s operations. Sometimes a nurse may need to wait until the patient is in a "more accepting mode" to approach with a fall suggestion. Patients are asked to absorb many complex issues in a short amount of time during their hospitalization. Several short sessions may be required to reinforce an idea. Nurses must repeatedly return to re-enforce fall prevention concepts throughout all shifts in order to sustain fall awareness. In Study #2, the APN talked with high risk patients before leaving for the night and asked for their agreement to call for help as needed throughout the night so they will remain safe until she checks back with them the next morning. The combination of the team continuing to provide fall

prevention support to the patients along with management support of the activities come together to create the culture change that is needed to reduce falls.

5.6.2 Comparisons of fall rates for Six Sigma and Lean Studies

Although no statistically significant differences were achieved, the total fall rate increased from 4.49 to 5.54 during the Six Sigma phase, while falls with serious injury rate decreased from 0.38 to 0.11. This result is somewhat consistent with Quality Improvement literature in that reducing total falls does not guarantee a similar reduction in falls with injury. The most common outcome was a large decrease in injury and smaller or no change in total falls (Sulla and McMyler, 2007, Barker et al., 2009a, Fonda et al., 2006, Anderson et al., 2009). Although the results of Study #2 align with the study by Barker, 2009 that showed a small change in fall rate and a larger improvement in injury rate; the explanations given by Barker do not apply to Study #2. One explanation given for the lack of change in total falls was an increase in reporting non-injurious falls (Barker et al., 2009a). Due to the Fall Tracker board process that was implemented in Study #1 and continued during Study #2 (see Figure 5-12) reporting of non-injurious falls was accurate and consistent in both studies. Likewise computer based reporting remained unchanged in both studies. The definition of a fall and a risk assessment screening were set as a foundation in Study #1 and did not change over time in this research. Similar to the timeline of this research, Fonda et al (2006) conducted a three year study that used a multi-strategy program to achieve a 19% reduction in total falls and a 77% reduction in falls with serious injury.

In spite of the fact that the longest period of 14 months went without one fall with serious injury occurred during the patient partnering interventions it was not statistically significant. Likewise, no statistically significant change occurred during the 12 months after the APN left and the patient partnering intervention was no longer active in comparison during the Six Sigma phase.

5.6.3 Statistical versus Clinical Significance

The analysis of these data is challenging due to the infrequency of falls with serious injury and the requirement for a long duration of time to achieve adequate sample size and statistical power. For comparison of intervention to baseline in this analysis the Z test was used to assess the statistical significance of a change in rate between

two different time periods (baseline verses intervention verses post intervention). The number of falls proportional to the number of patient days during the 18 month intervention period can be compared to the 17 month period of the baseline (while standard work intervention was in place from the Lean methodology).

However a G-chart may be more appropriate for illustrating trends in falls because it is based on the geometric distribution and is designed specifically for monitoring rare events (Barker et al., 2009b). These results are not as commonly used as a Z test and are more complex to explain.

Ultimately the decision of “clinically important” must be decided by the healthcare professional (Buescher, 2008). Especially when assessing rare events (occurrences less than 20) statistics can be unreliable and prone to random error. When we observe a record-breaking 14 months without one fall resulting in serious injury it is clinically important. A clinician defined “clinically significant” as the impact to the patient that occurs after a fall e.g. any treatment or x-ray procedure. Even if no injury is experienced the patient can have a fear of falling that can limit their mobility creating other long term issues. When considering clinical significance, preventing every single fall is important and significant to the patient affected.

5.6.4 Cost of falls: Return on Investment

A previous study of falls at Barnes-Jewish Hospital conducted by Washington University revealed a patient experiencing a severe injury from a fall has increased operational costs of \$13,316 and stayed for 6.3 days longer (Wong et al., 2011a). The Center for Medicaid and Medicare Services has identified ‘Falls and Trauma’ on its current list of Hospital-Acquired Conditions (HAC) for which reimbursement will be limited contributing even more urgency for fall prevention programs (Center for Medicare & Medicaid Services, 2007).

There were four fewer serious (major and moderate) injuries during the Six Sigma than during Lean time period resulting in a cost avoidance of \$53,264 in 18 months ($4 \times \$13,316 = \$53,264$). The average salary of an APN is \$86,000 per year. The ideal situation would be for an APN to devote part of their attention to fall prevention while combining focus on preventing other adverse events. The APN fall

prevention initiative is clinically, emotionally and financially important to patients, staff and the hospital organization.

The cost impact and time of patient partnering can be shared if all nurses help promote partnering. However this study showed how valuable it is to have a role similar to the APN that can guide the intervention and keep momentum providing mentorship to staff.

5.6.5 Facilitator Insights

Part of the skill of a facilitator is to know when to adapt a tool according to the strengths and limitations of the team. Using tools from both Lean and Six Sigma together allows the facilitator to complement the simplicity of Lean tools with the more detailed analysis that can be used from Six Sigma when needed.

Team members and patients often have higher priorities than fall prevention. Priorities can change over time and will vary across a single hospital stay. Team work is essential to help align priorities and ensure an appropriate balance is achieved. The turnover of patients and staff is very high, making it important to accomplish short, simple, quick improvements. Six Sigma methodologies typically take several months and make it difficult to keep up team momentum for the entire length of the project.

To summarize the overall categories of interventions that addressed most of the contributing factors it would be:

- Behavioral: Staff and patient awareness and cooperation (Patient Partnering)
- Critical Thinking: Interconnection of factors (preventable harm report)
- Environmental: Select equipment to make fixed environment as safe as possible.

5.7 Limitations and Strengths of Study #2

5.7.1 Limitations of Study #2

A project of this duration has many unexpected changes that naturally occur in real-world research. Changes in staffing, hospital policy and even equipment changes are

beyond the control of the researchers (e.g. hospital wide initiative to answer calls lights in less than three minutes and requirement of a quick safety meeting at the beginning of every shift). The following list describes highlights of changes that occurred throughout the intervention period.

- 2011 August: Additional duties of APN diminished focus on fall prevention
- 2012 February: Johns Hopkins Fall Risk Assessment was implemented
- 2012 June: New low bed available upon request & free trial with vendor
- 2012 November: Executive and Management change (Director, Manager, Lead Charge Nurses)
- 2012: Forty-three percent turnover in nursing staff
- 2012 December: trial patient partnering (APN only)
- 2013 March patient partnering expectation for all nurse staff
- 2013 Late summer– Bone Marrow Transplant (BMT) patients moved to another division (population became mostly oncology patients, with some BMT patients)
- 2013 September - Zones were added in attempt to decentralize the nursing station
- 2014 June: APN resigned marking the end of her participation in Patient Partnering

One limitation with this study is the lack of control group. Study #1 was conducted on all three of the most similar oncology divisions. The manager of the fourth division that was not involved in the Lean event made sure to implement the standard work interventions in the same manner even though it was not required. This best practice adoption is common in hospitals because everyone wants to do their best for the patients as soon as possible.

Another limitation of this study is that all falls were self-reported by staff. After a fall the nurse must manually enter a fall report into a computerized adverse event reporting system. Although the nursing team is diligent about this process and it was consistent across the Lean and Six Sigma time period; it is possible that a patient could experience a fall and the staff is unaware of the occurrence.

5.7.2 Strengths of Study #2

The most obvious strength of this applied research study is that it was conducted on an actual oncology division with no interruption to patient care. Staff maintained full patient workloads and the patient admission process was unchanged. Environmental changes were minimal so they should not have been a primary influencing factor.

The duration of time to track the number of falls and observe the impact of the interventions was sufficient to understand successes and failures. Continuing to track fall rates after the APN was no longer on the division also helped to understand the lack of sustainment when the APN is not available for support. Conducting both studies on the same division provided as much consistency as possible given the high staff and management turnover rate.

Another strength of this study is that it was built on the foundation of Study #1 so many of the unknown factors that occur in other studies were previously addressed. Definition of falls and protocols were already developed and staff was trained and documenting events consistently.

5.8 Conclusions for Six Sigma

The most comprehensive methodology for improvement is the appropriate combination of Lean & Six Sigma and other problem solving methods. Standard work is necessary to develop a consistent, safe basis for fall prevention. At the same time, to reduce falls with injury, preventions must be customized for an individual patient. Although the Six Sigma period saw no statistically significant improvement in falls or falls with serious injury from the Lean period, the majority of falls were unwitnessed and data indicate a patient is more likely to be injured if their fall is unassisted. 38% of the patients that were unassisted were injured while only 7% of the patients that were assisted during their fall were injured.

Patient Partnering provides the opportunity for a nurse to understand the patient's needs and for patients to understand their roll in their own safety. A different strategy is needed to gain acceptance of Patient Partnering for all nursing staff. If fall risk assessment and interventions were incorporated into the plan of care, it might help overcome the nurses perception of increased time required to address fall issues.

Six Sigma methods provided a deep understanding of critical risk factors than was possible using Lean methods. Simply going through a checklist or even following an algorithm is not enough for the critical thinking that is needed. The APN commented, “It is the intersection of several factors simultaneously that provides the most insight.” Understanding the patient story and how the patient’s background influenced their comprehension of their disease process was critical. Paired with their preference for learning and daily changes like pain level and scheduled procedures all must be balanced to determine the most appropriate approach at each moment in time.

5.8.1 Generalizability

Although the APN was instrumental in implementing patient partnering in Study #2 and provided guidance in Study #1 this role could be performed by other staff that could act as a clinical partner. A study by Christopher successfully implemented an inter-professional team for this role. The team consisted of a nurse leader, pharmacist, therapist and provider that engaged patients and staff in fall prevention interventions (Christopher et al., 2014). The most critical characteristic of this person (or team) would be a passion or motivation to prevent falls. It is also important for this person to have enough clinical knowledge to understand medical charts in order to assemble and understand links between numerous fall and injury risks. The ability to critically think about the intersection of many risk factors is important to develop a fall prevention program that meets each individual patient’s needs. The final characteristic of this role is a patience to be a mentor and role model for staff. They must provide guidance and assistance as risk factors are identified and partner with patient and staff to achieve a safe hospital stay.

It is possible to prevent every fall? The two patients that were injured from a fall during the Patient Partnering intervention illustrate how difficult this problem is to completely eliminate. The fall resulting in a broken nose could have been prevented if someone was assisting the patient from the bathroom to get back into bed. The second injured patient was very confused and could not be expected to remember to call for help before getting out of bed. Both these cases illustrate that patients that move with intentions of their own, put themselves at risk.

Although not every fall may be prevented, it is important for organizations to use multifactorial programs and engage patients and staff buy-in to achieve a culture of accountability (Goldsack et al., 2014). Recent fall research brings encouragement by shifting focus from fall risk to injury prevention using a systems approach to align technology, environment, behaviors and tasks will make it possible to achieve the safest hospital stay possible (Quigley et al., 2016). The importance of reducing falls must be identified by leadership and all health care staff as a priority to achieve success. A division or service based champion that is passionate about preventing injury and that serves as a role model for nursing and other health care workers is critical to sustaining improvements.

Study #1 and #2 revealed the importance of the patient in the fall prevention process. To that end, a deep understanding of patient perception is needed to help to create solutions that can be hardwired and sustained. To gain an understanding of patients' perception of fall and injury risk a third study was needed. Study # 3 used a qualitative approach to interview patients during their hospital stay (see Chapter 6). It was important that patients were given the opportunity and time to voice perceptions while they were experiencing their hospitalization. Listening to patients during their hospital stay allowed feelings to be heard in the moment and perceptions noted as they were formed without time fading after patients had gone home.

6 CHAPTER 6: STUDY #3: PATIENT INTERVIEW

6.1 Introduction for Patient Interview

Chapter 5 discussed an intervention called Patient Partnering that required a nurse to get to know each patient and help them understand their fall and injury risk factors, discuss and agree on customized prevention measures and to emphasize the importance of calling for help. It was the intention that this intervention would empower the patient to seek assistance when moving about in the room, especially during toileting related activities. During one 14 month stretch during the Patient Partnering project, there were no falls with serious injury (serious injuries include categories of moderate, major and death).

Although this appears to be a successful approach to reduce serious injury from patient falls; sustainment of the intervention is challenging, with high staff and management turnover and patient resistance. Insights from Studies #1 and #2 reveal a difference between staff and patients in their approach to fall prevention (Wolf et al., 2014). To further investigate this issue, the methodology used in Study #3 was qualitative interview. Participatory Ergonomics (PE) was used as a framework for understanding components that could be included to encourage discussion about patient participation in the fall prevention process. It was important to understand the patient perspective on falls in order to achieve the collaboration required to have an effective partnership.

6.1.1 Aim

The aim of this study was to explore perceptions of patients on risk of falls and injury and fall prevention strategies. A deep understanding of patient perceptions will help to enhance relationships between patients and hospital staff to achieve fall prevention.

6.1.2 Participatory Ergonomics Framework

One benefit of the PE approach is the variety of ergonomic changes that can be implemented directed to many specific situations (Rivilis et al., 2008). Literature revealed that PE has been successfully implemented in healthcare and industrial environments to decrease worker injury. Unlike other industries, healthcare has the

added complexity of the key stakeholder (the patient) being critically ill with rapidly changing conditions causing the need for constant dynamic assessment and adjustment. PE concepts can be used to improve communication with stakeholders in healthcare (nurses and patient) (Hignett and Lu, 2010). The following nine components of the PE framework (Haines et al., 2002) were modified and considered in the patient interview structure of Study #3: Permanence, Involvement, Level of Influence, Decision Making, Mix of Participants, Requirement, Focus, Remit, Role of Ergonomic Specialist.

Questions from the EPPEQ (employee perceptions of participatory ergonomics questionnaire) (Matthews et al., 2011) were modified during the development of the interview proforma since the dimensions were originally designed for industrial workers. For example one dimension of the survey by Matthews that was helpful to understand effectiveness of PE, provided an understanding of an employee's engagement in the PE process. This question was modified to determine if patients felt involved in understanding interventions that had been put in place for them (Matthews et al., 2011). Study #2 already established how important it is to have individual interventions specific for each unique patient situation. Individual patient interview was needed to understand the patient perspective.

6.2 Method for Patient Interview

The qualitative study in Study #3 followed the structure and rigor of the grounded theory approach. Grounded theory procedures lead to the emergence of conceptual categories providing deep understanding of an issue. Procedures used during analysis of information gathered during patient interviews included open, axial and selective coding techniques. Open coding is the interpretation that occurs as information from interviews is broken down for further understanding. Axial coding is reining categories and subcategories and understanding their relationships. Selective coding involves unifying all categories around a core theme or theory (Corbin and Strauss, 1990).

Insights from Study #1 and #2 lead to the realization that there was a lack of understanding of the patient perspective of fall risk. Therefore the focus of Study #3 was formed around the patient. Since the perception of the patient was unknown, it was important to have a process structure that would allow flexibility for a theory to

evolve as information was collected and revised. The semi-structured interview format was an appropriate tool to provide guidance to get information, yet the flexibility to allow patients to reveal any opinions and suggestions they thought important (Robson, 2011).

6.2.1 Setting and Sampling Strategy

To avoid a limitation encountered by (Tzeng and Yin, 2009b) where patients were interviewed 30 days after discharge and may have had difficulty recalling details of their stay, patients in this study were interviewed while still in the hospital. Newly admitted inpatients on a 38 bed (26 single rooms) medical-oncology unit at Barnes-Jewish Hospital were recruited using purposive sampling from information contained in the daily Preventable Harm Report. This report displays the fall risk score for each patient as it was assigned by the nurse using the Johns Hopkins fall risk assessment (evaluating age, fall history, elimination, medication, equipment and mobility). Figure 5-7 has a sample Preventable Harm Report that is discussed in more detail in Chapter 5. Approximately four to six new patients are admitted daily on this division with an average length of stay of 5.38 days.

Original Inclusion Criteria for patients selected to participate in the interview included:

- English speaking
- Alert and Oriented x 4 (name, date, location and president)
- Johns Hopkins fall risk assessment score >5 (moderate and high fall risk)
- Newly admitted patients with estimated length of stay greater than 24 hours
- No restriction on gender, ethnicity, race and age

6.2.2 Ethics

All participants were recorded during the interview and signed an informed consent form approved by Loughborough University Ethics Committee (standing as approval for Human Research Protection Office at Washington University) and the Siteman Cancer Center Protocol Review and Monitoring Committee (PRMC) for trials involving patients with cancer. PRMC approved Research number 14-X113: “Exploring patient perception of risks of falls and injury and fall prevention strategies” at a meeting held on May 14, 2014.

All data were anonymized and only accessed by investigators working directly on the project. The principle investigator Thesis Author was assisted for coding reviews by a Fall Panel consisting of a fall prevention expert from the BJC HealthCare's Centre for Clinical Excellence and the Advanced Practice Nurse from the oncology division with expertise in falls. All investigators received scientific ethics training according to Washington University protocol. All notes and paperwork were kept in locked file cabinets while electronic files and recordings were kept on password protected computers.

6.2.3 Recruitment

Between May 23, 2014 and Sept 10, 2015, 159 patients were identified as eligible participants based on information from the Preventable Harm Report. Each eligible patient was discussed with the responsible nurse to determine if all inclusion criteria were met and if timing was appropriate to make contact with the patient. Examples of inappropriate timing included devastating (typically life altering) news received earlier that day, patient was groggy from earlier sedation during a procedure, or extreme pain levels. An early participant had a tracheotomy and could only communicate in writing. The interview was tedious and frustrating for the patient to convey a detailed answer. Tracheotomy patients that could not speak were therefore added to exclusion criteria during the study.

Nursing approval was obtained for 64 patients who were given an information sheet and 24 hours to consider their willingness to participate in the bed-side interview. Approval from the nurse was obtained again on the day of interview to determine if any changes overnight had occurred which may cause the interview to be inappropriate. This overnight change in status occurred frequently; indicating the dynamic conditions of this patient population. Ultimately a total of 31 patients were interviewed. Data were eliminated from one patient after she became ill after answering only two questions. The information sheet was read to all participants prior to consent and they did not receive reimbursement.

Participant Characteristics (N=30)	Value
Length of Interview, mean (range)	22 min (8 - 53 min)
Age, mean (range)	56 years (26 - 83 years)
Gender, n (%)	

Participant Characteristics (N=30)	Value
Male	13 (43%)
Female	17 (57%)
Length of Stay, mean (range)	7 days (2 - 43 days)
Fall Risk Score, mean (range)	7.7 (4 - 16)
Fall Risk Category, n (%)	
High Risk	3 (10%)
Moderate Risk	25 (83%)
Low Risk*	2 (7%)
Fall Risk Features - Johns Hopkins Assessment	
No Cognitive Impairment, n (%)	30 (100%)
No Altered Elimination Problems, n (%)	27 (90%)
No Fall History (past 6 months), n (%)	24 (80%)
Taking 2 or more high risk fall meds, n (%)	21 (70%)
No Mobility Problems, n (%)	18 (60%)
Require Assistance, n (%)	12 (40%)
Attached to one or more tethers, n (%)	22 (73%)
Passed Get-up-and-Go test, n (%)	19 (63%)
*Two participant's risk scores decreased from moderate risk (score = 5) on day prior to interview to low risk (score = 4) due to reduction of one high risk medication and tether at time of interview. Fall risk scores are reassessed every shift or at change of condition.	

Table 6-1 Participant Characteristics (n=30)

6.2.4 Data Collection and Analysis

Patients were interviewed at bedside during their hospital stay. The interview began with five Likert scale questions followed by fifteen semi-structured questions that lead to spontaneous conversation about perceptions of falls. Interviews were recorded with a Livescribe pen and then imported into NVivo-10 for analysis.

Interview proforma topics and wording were compiled as a combination from consultation with fall experts, modified from a perception of PE survey (Matthews et al., 2011), and adapted from a survey instrument to capture data on perceived risk of future falls and injury (Haines et al., 2014). Analysis of the first ten participants led to the addition of four questions for the final twenty participants to gain further depth of understanding. The full interview proforma is in Appendix F. Topics covered include:

- Perception of risk for fall & risk of injury
- Importance of fall issues

- Perception of fall interventions
- Ideas about various roles (e.g. nurse, physician, therapist) in fall prevention
- Perceptions and suggestions of fall prevention strategies

Data from each participant were coded thematically using a conceptual framework derived from the literature, previous Studies #1 and #2 and the interview proforma (coding down). Coding-down occurred when information was matched to existing codes. New codes also emerged from the data (coding-up). Coding-up occurred when data did not fit into an existing category and a new code or property (sub category) was created. Each interview was coded as part of the chronological process (after data collection).

After completion of the first ten interviews a coding meeting was held with the Fall Panel experts to discuss and reach consensus on any areas of discrepancy in coding and interpretation. This first phase used an open coding structure with NVivo-10 as the tool for organizing concepts into categories. The Fall Panel suggested some modifications to the categories. Twenty additional participants were interviewed with no changes to the interview proforma.

Timeline Study #3 2014	Data Collection	Data Analysis
May 14	Ethics and protocol review committees approval	Develop initial coding framework from insights
May 23-June 20	Participants 1-10 interviews	Ucode categories in NVivo-10 (open coding)
July 16	Fall Panel review #1	Recode categories in NVivo-10
July 16-23	Revise interview proforma	Advisor review and advise
July 23 – September 10	Participants 11-30 interviews	Ucode categories (axial coding)
October 3	Fall Panel review #2	Finalize categories
October 3-13	Revise categories	Down code all participants with final framework
October 13-17	Develop cross walk to bridge categories and theories	Theory development (selective coding), core theories emerged
November 19	Present research to oncology nurses	Develop one page summary
December 17	Present to Oncology Service Organization	Study #3 presentation preparation

	(Grand Rounds)	
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Table 6-2 Activity time line for Study #3

Theoretical saturation (no further codes emerging) was achieved by the 30th participant. Phase two involved an Axial Coding method to investigate links between the categories (Robson, 2011) and integrate the major categories into a larger theoretical scheme that considered interactive relationships between categories. The axial coding phase began by reassembling the Fall Panel to review all coding and analysis. Consensus was reached for the final coding structure and axis or linking of similar themes. A final down-coding process was completed for all responses to ensure that a consistent coding scheme was used for every participant. Queries were run to check for inclusive coding. The final Axial coding structure is shown in Appendix G.

Selective coding was conducted in a third phase by integrating and refining the theoretical saturation. All categories from previous coding sessions were assembled to unify around the core category of patient perception (Corbin and Strauss, 1990).

6.3 Results for Patient Interview

Thesis Author spent 92 hours identifying 159 potential candidates from their risk assessment and getting approval from their nurses to distribute information sheets to 64 patients and finally getting consent from 30 participants and conducting interviews. Each patient was interviewed two to three days after admission to the medical oncology division. The length of interviews ranged from eight to 53 minutes for a total of eleven hours of actual interview time.

6.3.1 Patient Quotes from Interviews

The following quotes were selected from patient interviews that discussed the definition of a fall:

“Anytime you are unable to control your body and you’re going in a direction that you don’t want to go to it is a fall. If you slowly lower yourself to the ground without force and you know you are going down it is not a fall it is called “being prepared”. (Participant 5)

“I didn’t fall, in my mind of craziness, I thought I was going home and I got out of bed and I made it 2 steps and I sat down on the floor, I was too weak to

go any further – it happened on my first day here in the ICU. I don't think I would call it a fall, I took 2 steps and I just sat down, I didn't really fall to the ground, but I sat down on the ground, I weigh 230 pounds, so I would say it was a little bit of force". (Participant 6)

"anytime you hit the floor, it has to have force to be a fall, you can't protect yourself and you hit the floor with force" (Participant 20)

"Unexpected physical altitude change – roll, pitch and yaw of the human body that results in a sudden stop – you have to hit the ground or wall or something. There has to be some type of force." (Participant 22)

"A fall is a stumble where I fall on one knee or it could be that I trip and fall all the way to the ground and hopefully if I did that I don't hit my head onto the sink walking by. A pass out fall is still a fall even with no force." (Participant 14)"

"A fall is an unplanned vertical decent when you hit ground. If you hit anything it is still a fall, even if you pass out slowly it is still a fall." (Participant 23)

The next quotes are from the discussion that occurred when patients were asked to describe a time when they have fallen in the past:

"When I fell in a semi-private room there was less space between the bed and the chair and the wardrobe the IV pole got tangled up in all that. It happened so fast, I was pulling the IV pole and all of a sudden I was tangled up in my feet and the tubing, there was not enough space to get through." (Participant 21)

"The silly thing I did a couple weeks ago and I was moving a friend into college. I wouldn't really call it a fall. I walked down the first flight of steps and I misjudged the step and I fell and one leg was out and hit the edge of two sept and I skid down the steps boom-boom-boom and hit my bottom on the steps. I was so embarrassed and I just had a little bruise. It wasn't that I was unsteady on my feet, but as I rounded the corner I misjudged the step. I was

just happy to be helping move and going quickly without paying attention. Also bifocal glasses make it difficult to go down steps.” (Participant 14)

“When I was in the rehab institute they put me in a class with elderly people I asked “why am I here?” and then I remembered oh yeah, I fell and broke my femor that is why I am here! I stepped out of the front door of my house without my brace on, it wasn’t a high step and I didn’t realize this leg was as weak as it was and started wobbling like a little toddler. A voice in my head told me if you don’t stand up you are going to break your leg. I couldn’t find anything to grab onto... next thing I know, if felt like I was falling down hill and I heard a POP and I fell over into my rock-bed and in a few seconds my leg swelled up. I fell into that rock-bed with my head inches from a retaining wall. Paramedics had to come get me.” (Participant 13)

These quotes were from patients that said they felt particularly safe and protected during their hospital stay:

“No I won’t fall here in the hospital, I have perfect balance. They are there to watch you, they keep an eye on you, if you do happen to get out of bed and have a little accident they are there to pick you up immediately, they are very quick” (Participant 6)

“I won’t fall here, it is too protected here”. “Staff is always on you watching you close; even when they are busy they are watching you close. My nurse is driving me crazy because she is always in here with me, except now because you are in here. I’m not going to fall, I’m sure I am not going to fall. The mat keeps me from breaking anything. I hate that bed alarm noise, if I step on it, it will ring like crazy, it makes me mad. I forget it is there and it rings real loud, it is irritating if you are me”. (Participant 2)

This quote was from a patient that felt particularly strong about the importance of teamwork to prevent falls:

“I am not aware of a whole lot recently I have been in a fog, that is the reason I have been staying in my bed and doing what the nurse asked me to. That’s the thing we are a team, the nurses the doctors and me were are a team I can’t get better unless I play with my team correctly. This is about me and if I want

to get better I have to work with them. Dietary and housekeeping always ask me if I need anything or if everything is out of the way. They suggested keeping my socks on the bedrail while you sleep so you will have them when you get out of bed. The team could explain more about my need to be patient and have the doctor give the speech about what the patient needs to do. Here is an example of a good speech that the team could give to patients: “We will help you, and we will be with you as much as possible, but you have to make us aware of what you need, we are not mind readers, don’t wait until the last minute, when you have a small pain or you think you may have to go the bathroom, don’t wait, hit the button and call for help. The nurse will relay any messages.” (Patient 5)

This quote was from a patient that discussed the prioritization of fall prevention:

“The last 2 years have not been kind to me. I went through Chemo and all that and then I had metastasized tumors and get all that taken care of and now this comes up and they think that is cancer again – all in 2 years, I am just having a ball, there is a point of diminishing returns that I am passing rapidly I think, my body did not tolerate the chemo and radiation well last time, I’m not looking forward to another go round, so falls is not high on my priority list, just getting by day to day, a fall certainly wouldn’t help anything. About the only interaction I have on Chemo is with the techs I only see doctors every 6 weeks as an outpatient – they do not discuss falls as outpatient I don’t think falls is very high on their list either. If it needed prioritizing I am sure doctors would make it higher, but it just wasn’t too high with my type of cancer”.

(Participant 23)

The next quotes are representative of comments made about patients feeling confident that they will know when they need help and will call for assistance at that time:

“I do not need to call for help. I do not feel weak, I am trying to be extremely careful, I will know when I need to call for help. When you get up you feel a little weak or light headed, you can just tell if you are not as strong one day as the next, right now it is not a big concern, but when I was having chemo I sat on the edge of the bed before I got up and did not get up too quickly, if I got up

and felt weak I would call for help, I don't need to do this now because I feel good now. It has to do with how you are feeling that particular day, if appetite is bad or you don't sleep well you might be feeling a little weak, you can tell the difference between when you feel really good today and I don't feel so well the next day." (Participant 21)

"Take your time, remember to slowly get up and make sure feet are solid and test out a walk along-side the bed to see if you need to call and get assistance, someone like me (used to being in hospital) just needs to slow down and take time." (Participant 15)

This quote is from a patient that described a preference for timing and method of fall prevention education:

"When I am calm I would rather be talked to, I really don't like pamphlets shoved in my face, the frequency depends on the day big time (most definitely), you have to catch people in the right mood, if they have an angry look on their face you have to keep away from them. I am willing to listen at the right time since only have one leg and I might lose my balance." (Participant number 4)

These quotes are from patients that were describing their difficulty in reaching a call light when they needed to request assistance:

"There were two times when I was not able to reach my emergency light and had to get up on my own to try and get to the bathroom. The call light on the bed does not work; the only call light button is on a pendant that keeps falling off the bed and is difficult to reach." (Participant 12)

"There is no way to call for help other than the one call light button, so when I fell near the wardrobe (across the room) I had to crawl up onto the bed to push the call for help button – some people are too weak to do that. I wasn't weak so I was strong enough to call for help. There was just too much stuff in the corner and I couldn't get the IV pole around the corner around the edge of bed between the chair and wardrobe. I fell 3 feet from the bed but call light was draped over the edge of the far end of the bed." (Participant 21)

6.3.2 Patient Perception of Fall Risk

Results from the Likert scale questions revealed that the patients did not think they were at risk for falling or injury (Figure 6-1). The topic of falls was not extremely important to them.

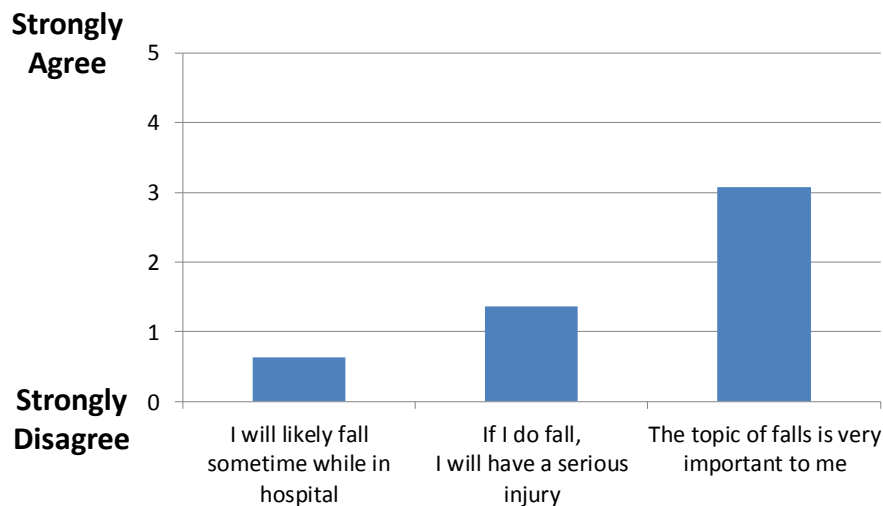


Figure 6-1 Average rating of Likert scale question shows patients do not perceive risk of falling or injury (n=30)

Review of comments from the first ten participants indicated they felt less likely to fall while in the hospital than they did at home. Both the Fall Panel and supervisor reviews indicated this topic needed more exploration. Since it was mentioned so often that patients felt more protected in the hospital, additional Likert scale questions were added to determine how much safer they felt at in the hospital or at home. Hence, the following two additional Likert scale questions were added to the interview proforma with 0=extremely unlikely and 10=extremely likely (there were only 20 participants responding to these new questions) (Figure 6-2):

1. Based on how you feel right now, rate your risk of falling in the hospital.
(average = 1.3)
2. Based on how you feel right now, if you were at home, rate your risk of falling at home. (average = 2.3)

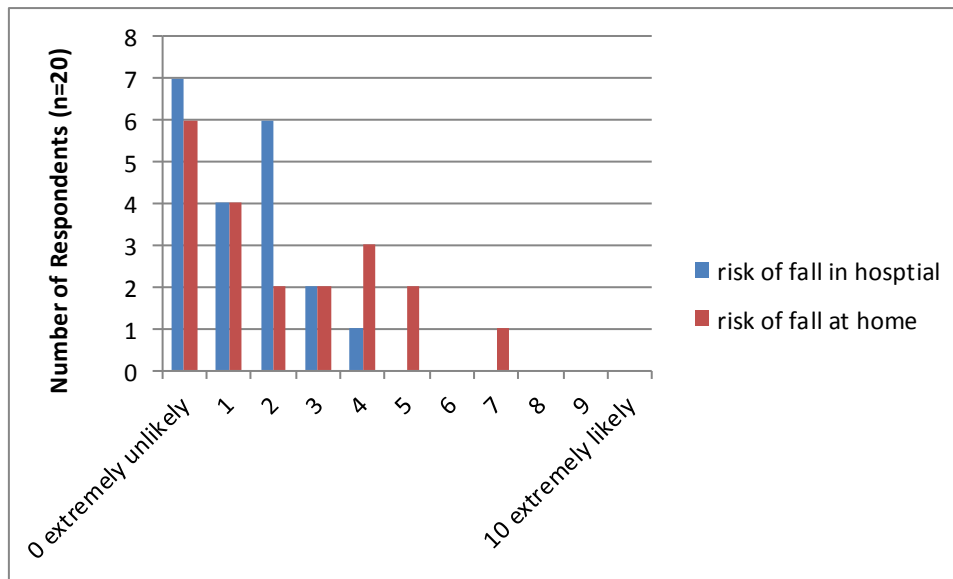


Figure 6-2 Patients perceive they are slightly more likely to fall at home than in hospital (n=20)

Almost all patients strongly disagreed that they were at risk for falling sometime in their hospital stay. Many felt protected and safe in the hospital saying “My nurse will not let me fall.”, even though they often got up without calling for a nurse to be present. Even patients who had fallen within the last six months thought their fall was a chance occurrence and they would not be likely to fall again.

Some of the common reasons that patients gave for not being likely to fall included:

- Having awareness of surroundings
- Using caution when walking around
- Desiring independence and denying need for help
- Feeling strong and stable while standing and walking
- Feeling protected and safe in the hospital

6.3.3 Patient Suggestions for Fall Prevention

Some of the patients had some specific ideas to help reduce risk of falling and improving their hospital experience.

- Put IV fluid in a back pack to enable walking without the IV pole
- Wheel of the IV pole interfered with walking so adding a Weed Eater handle on the IV pole extends the handle to allow foot clearance without tripping
- Add wireless technology for the telemetry machine

- Leave the IV pole outside the bathroom while using the toilet to avoid the threshold

6.3.4 *Thematic Categories*

Participants 1-10. Information was categorized in an open coding fashion as participants one to eleven were interviewed. One incomplete survey was eliminated, due to patient illness. A model was developed based on codes that emerged. The initial categories from insights of Study #1 and #2 are indicated by a square in the model in Figure 6-3. Four of the original categories contained responses from the first ten participants (interventions and environment, patient partnering, priority & culture change).

The codes were grouped into similar themes to prepare for the first Fall Panel review. A name for each grouping was initially assigned to assist in discussion.

- **Interventions:** From the first ten participants the interventions primarily came from the Preventable Harm report and included equipment such as armband, fall sign on the door, magnet on the white board, gait belt and bed/chair alarms. The only exception noted was one occasion where a patient was not placed near the nurse station due to a lack of room availability. When patients were asked “Have any fall prevention activities been implemented?” very few of them could describe an intervention. The most frequently mentioned intervention was the “Call Don’t Fall” Magnet that was attached to the patient information board in every room regardless of their fall risk.
- **Risks:** Initially, separate categories were made for risk of falling, risk of injury and cause of falling. Additional comments that potentially might be appropriate for this category include: patients think they are cautious, they have been active prior to being in the hospital and they feel protected and safe while in the hospital. Denial and belief in fall risk were combined under the fall risk category.
- **Environment:** The environmental category included issues like clutter in the room, unfamiliar surroundings, thresholds and toilet heights. Wet floors were initially kept separate because it was mentioned by participants during suggestions/ideas for prevention.

- Support: This category was made of a combination of Equipment and Support Methods. Equipment included walking aides such as walker, cane or wheel chair. Support method included support from another person as well as grab bars or furniture.
- Types of Injury: Patients most often described a body part that might be injured such as head, wrist or bottom more than the type of injury that could occur like broken bone or scrape.
- Role: Many participants had no idea of what a doctor or technician could do to reduce risk of falling. They typically thought of this as a nurse role. Many understood the connection between Physical or Occupational Therapy and building strength to prevent falls.
- Ideas: Most of the ideas were in the educational category. Perhaps this was driven by a question that directly addressed “How do you prefer to learn about your risk of falling?” If a participant had no ideas for prevention this was noted in a category called “Stumped”.

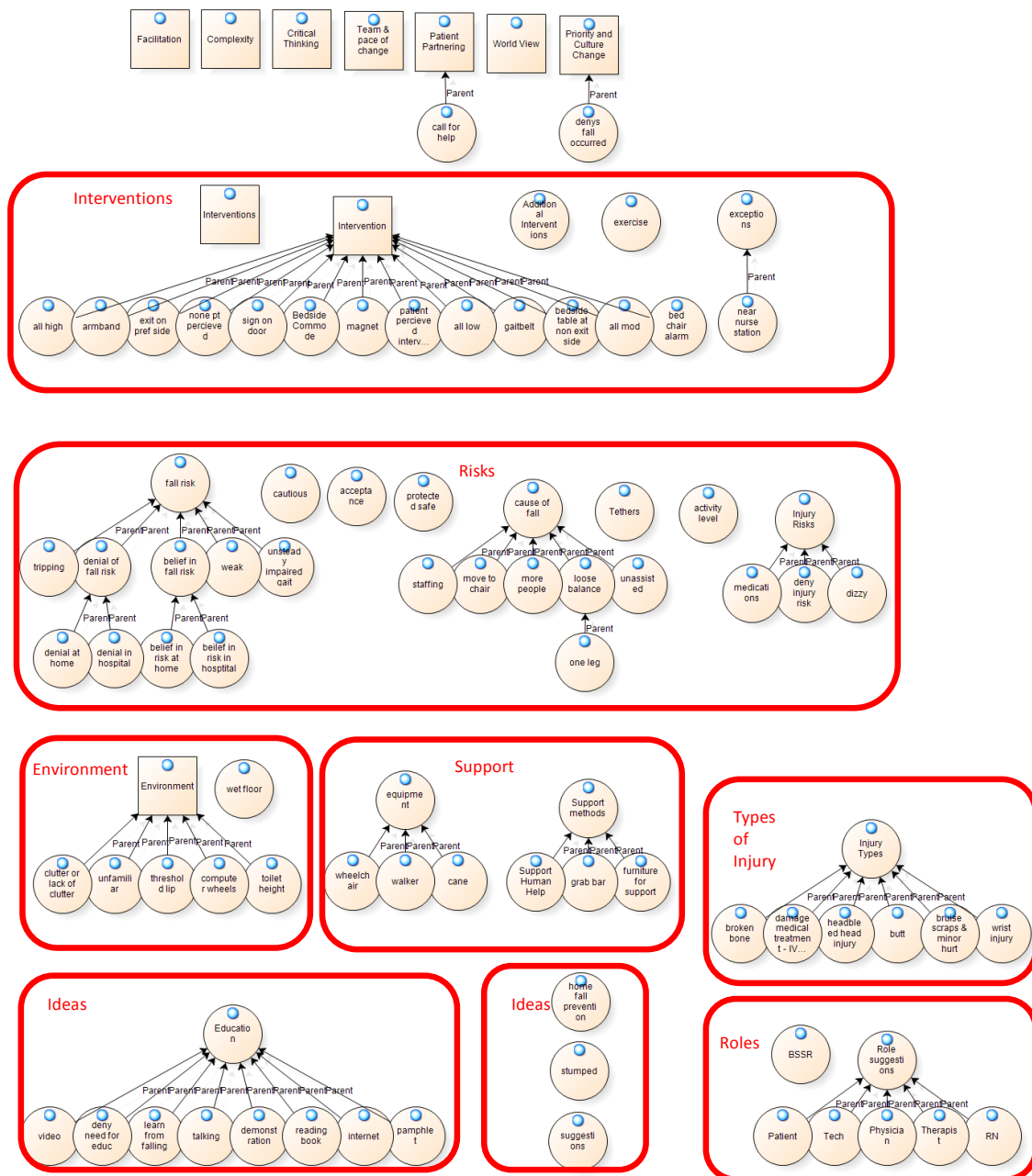


Figure 6-3 Model of Categories from Participants 1-10 before Fall Panel Review

First Fall Panel Review. The Fall Panel reviewed the model in Figure 6-3. Each category was reviewed and discussed during a three hour session. A consensus method was facilitated to achieve agreement with categorizations and revise the

model. Changes made to the model are indicated by a diamond shape in Figure 6-4 and Figure 6-5. Changes were based on the following discussions:

- **Risks:** Patients did not seem to understand the difference between a risk of falling and risk of injury. Fall experts realize that if a patient has low platelets as a result of medication they are at extreme risk for a head injury because the blood will not clot normally causing a possible head bleed with minimal impact. A side effect of chemotherapy can be brittle bones putting a patient at high risk for a broken bone upon impact of a fall. In addition patients can experience neurological disease that impacts their gait making them a high risk for falling. When patients were asked what might make them at risk for injury if they did fall, they responded saying dizziness or medications that can cause fatigue or weakness. These responses are risks for falling not risk for injury. This is an important distinction that should have an impact on the focus of patient partnering and fall education. The decision was made at this time to combine “Injury Risks”, “Denial and Belief in Fall Risk” and “Cause of Fall” all together under the overall category of “Risk”.
- **Risks:** “Activity Level” was added to the Risk category in response to comments that indicated inactivity could put a patient at greater risk and a history of activity may decrease risk of a fall.
- **Risks:** It was also suggested to combine tethers into the Risk category. The Fall Panel felt it was important to differentiate between the types of tethers that were present: IV, Foley catheter, or sequential device. The device mentioned most frequently was the IV. For all other tethers they referred to as “all these wires & tubes” or “connected to all this equipment”.
- **Cautious, Protected and Acceptance** were kept as independent categories to determine how future responses would develop. They were located in close proximity to “Belief or Denial” with the thought that they might tie together with data from future participants.
- **Environment:** The wet floor category was combined under Environment. Individual comments would detail the location of the wet floor (e.g. bathroom, bedside or hallway).
- **Injury Types:** The focus was not on the risk of injury because it was just not in the patient’s awareness. However, the category of “Injury Type” remained

because when specifically asked “What kind of injury could happen to you if you did fall?” they did have comments that may help understand why falls are not perceived as a high priority.

- **Role Suggestions:** The category of “Bedside Shift Report - BSSR” was moved as a subcategory under the nursing role.
- **Suggested Interventions:** The three categories under “ideas” were put into a new category called “Suggested Interventions”. Home fall prevention became “Home Suggestions”, “Suggestions” became “Hospital Suggestions” and “stumped” became “No Suggestions”.
- **Intervention:** The only change in this category was to move “Exercise” into the intervention category. Patient comments did not contribute much information to the category beyond what was listed in the Preventable Harm Report. An additional question was added to the interview proforma in effort to enhance the understanding of why patients were not aware of fall interventions that had been implemented for them.

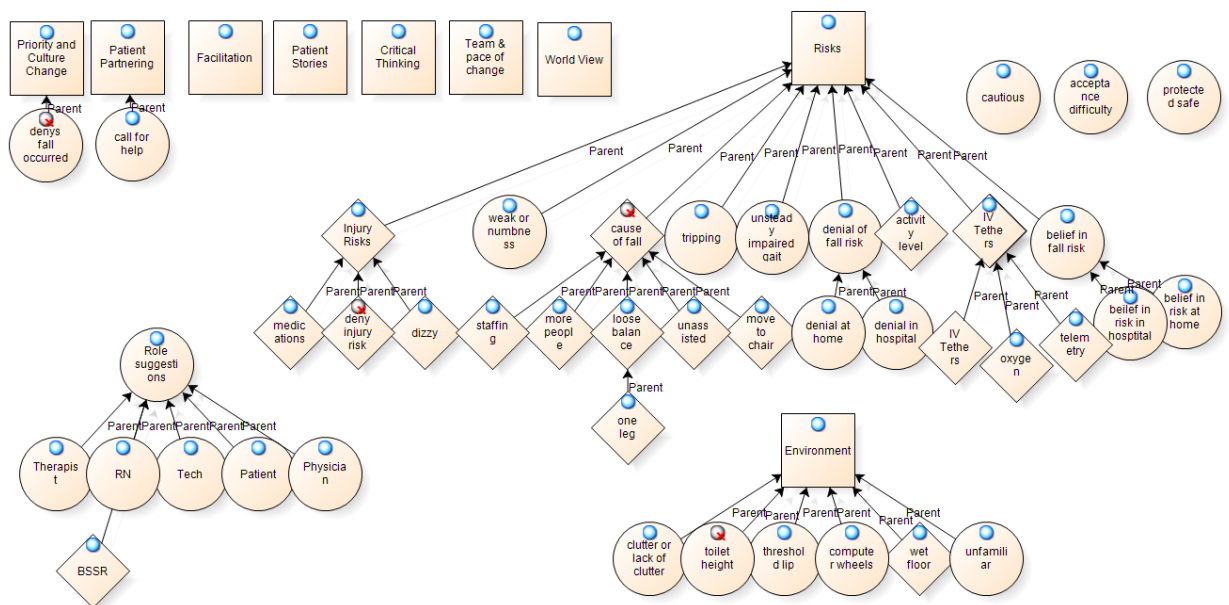


Figure 6-4 Model of Categories from Participants 1-10 after Fall Panel Review – Part 1

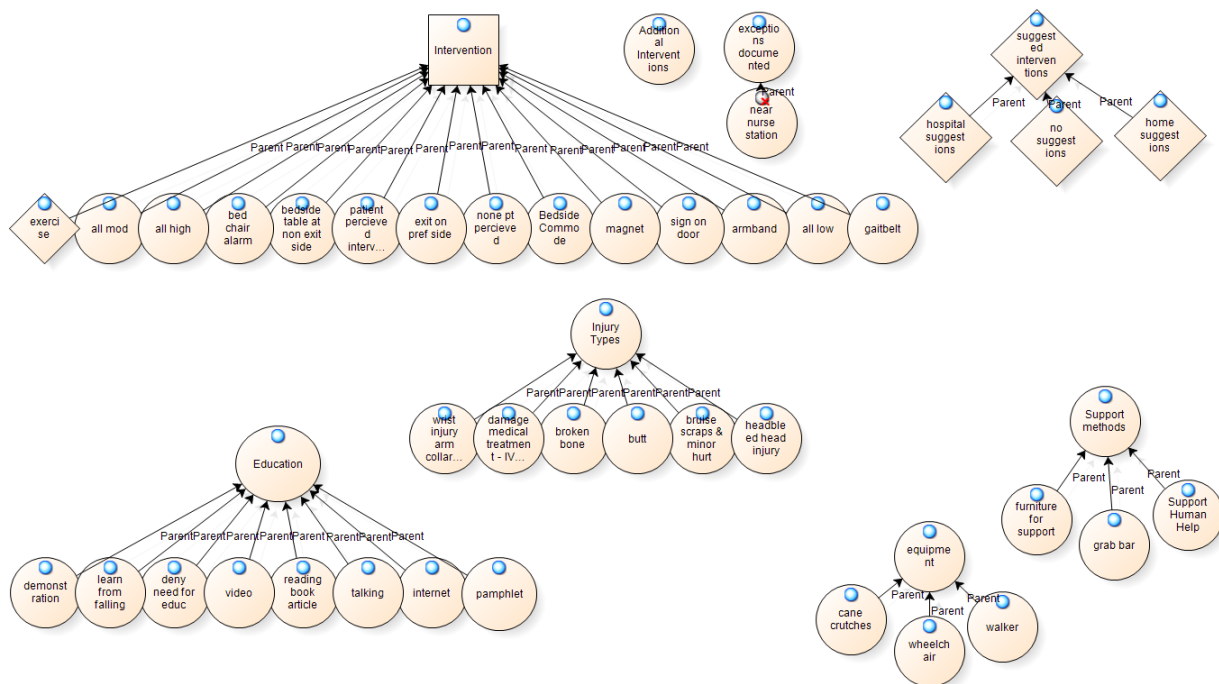


Figure 6-5 Model of Categories from Participants 1-10 After Fall Panel Review – Part 2

Revised Interview Proforma. Because only three participants mentioned a fall discussion with their nurse and most seemed to be unaware of the difference between risk of falling and risk of injury; a specific question about education was added for the last 20 patients. Immediately after the question, “How do you prefer to learn about your risk of falling and possible injury?” this question was added; “Did someone sit down and review your risk of falling during this hospital stay?” The goal was to determine if the patient’s lack of understanding was due to misunderstanding or simply because nobody had provided information or had conversations about their risk. Only eight percent (two out of 24) of patients thought that anyone had discussed their risk of falling during this admission. Five of them mentioned that they were told to call for help but did not seem to understand the link to fall risk. Two mentioned that fall risk had been discussed in a previous hospital stay but not during this admission.

The second question added to the interview proforma was an extension of the question “Have any fall prevention activities been implemented? The added question

was “Did someone point out any fall prevention strategies to you?” These additional questions were addressed with the remaining participants.

As each interview was completed, the data were downloaded into NVivo-10. The open coding methodology categories were developed and expanded as needed according to interview data. No additional new codes were needed for the last three patients leading to the conclusion that saturation had been achieved.

During the up-coding of participants 11 – 20 a new category call “Denials” was created. There were so many reasons why patients did not think they were at fall risk, it was important to capture this in a separate category. The subcategory of “deny risk in hospital” and “deny risk at home” were also moved to the new “Denials” category. Comments from patients that did believe they were at risk remained under the “Risk” category.

Second Fall Panel Review. The Fall Panel reconvened for a second review session after information from all 30 participants was coded in NVivo-10. This four-hour session was more detailed than the first Fall Panel review. The goal of this session was to conduct axial coding and consensus on the categories and to discuss the connection or links between them. This time each category from the coding scheme was printed on large posters shown in Figure 6-6. A projector was used simultaneously to display all participant responses coded under each category as it was discussed. Every code and content was reviewed and discussed by the panel. This deep discussion allowed understanding of each code and the relationship and alignments between the categories.

During the discussion the Fall Panel came to agreement on the appropriateness of the comments that were coded together into a category. The name of the category was approved or modified until consensus was reached. The final Axial coding structure that resulted from this consensus is listed in Appendix G.

The discussion highlights are described according to the most applicable category:

- **Belief or Denial:** Originally comments from patients that believed they were at risk were imbedded in the “Risk” category. Patients that commented on denial of risk were under the “Denial” category. The panel decided to combine the issue of patient belief or denial of fall risk into a new category called “Belief or Denial” (see Figure 6-7). Comments in this new category were the qualitative story that aligned with the Likert scale questions that revealed patients do not think they are at risk of falling and even feel more protected while in the hospital.

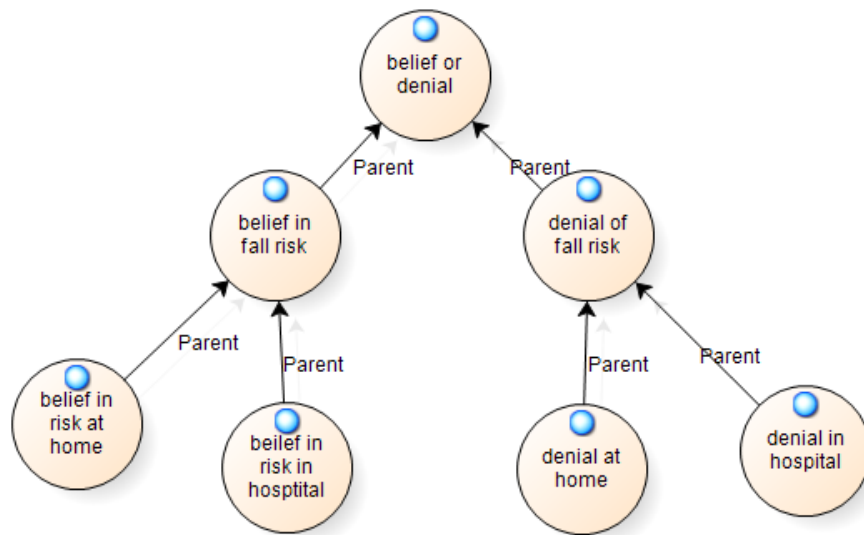


Figure 6-7 New coding structure for “Belief or Denial” of fall risk after Fall Panel review #2

- **Denial Reasons:** After removing the category of “belief or denial” of fall risk, all remaining comments in the “Denial” category were reasons that participants gave to support their belief that they would not fall or be injured if they did fall. The category title was changed to “Denial Reasons” (see Figure 6-8). The next two categories were associated but kept separate from this category.
- **“Experienced Patient”:** Patients that had received several chemo therapy treatments were very familiar with the hospital and the medications they were receiving (Figure 6-8). Some of them had experienced more than ten treatments and others had been through treatments with more than one

cancer diagnosis over several years. These patients had endured numerous procedures without falling and did not see why that would be any different during this hospital stay. The longer they had undergone treatments the less likely they felt they were for falling.

- **Other guy – not me:** Almost every patient that denied they were at risk for falling mentioned examples of what might make someone else at risk (see Figure 6-8). One patient explained he was perfectly safe bending over to mop up the wet floor after a shower but someone else might get dizzy and fall over. Another patient acknowledged that her roommate was very sick and should call for help but that she herself was “overly cautious” and therefore not at risk for falling. Yet another patient said “I don’t see anything that is that hazardous to me, I can see where other people might have a problem.”

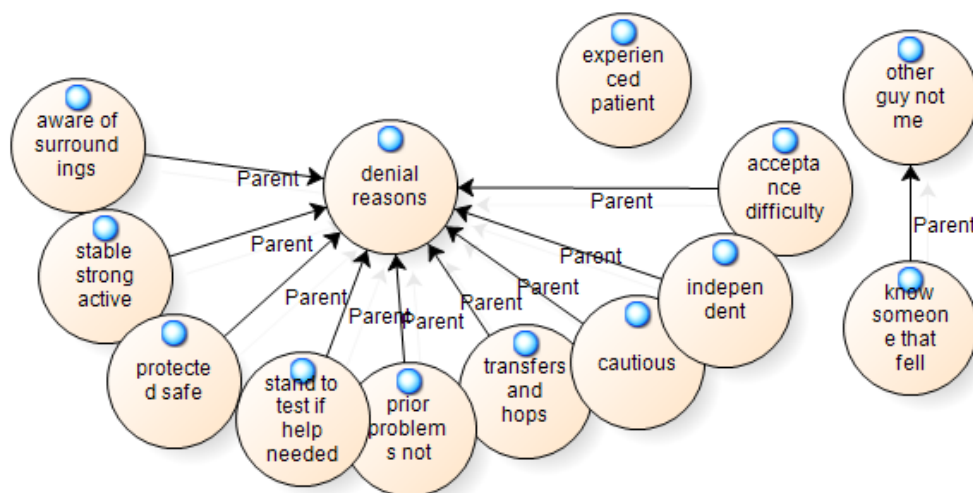


Figure 6-8 New coding structure for “Reasons for Denial” of fall risk after Fall Panel review #2

- **Education:** The only additions to education in the last 20 patients included comments regarding the “timing and frequency” of fall education (see Figure 6-9). No matter what type of fall education was provided patients wanted the education to happen when they were ready for it. A patient can receive devastating and life changing news making it impossible to fully absorb all the information about their disease process. Many comments were made that they may need to receive the same message several times as they learn to

deal with their new situation. Although patients differed in their preference of style of education (video, pamphlet, demonstration) they all agreed they wanted some conversation about the topic.

- Anybody educate you on falls or interventions?: This category remained separate since the question was added to the interview proforma that asked if someone reviewed falls risks during this hospital stay (Figure 6-9). As mentioned previously, only eight percent of patients thought anyone had discussed their risk of falling with them during this admission.

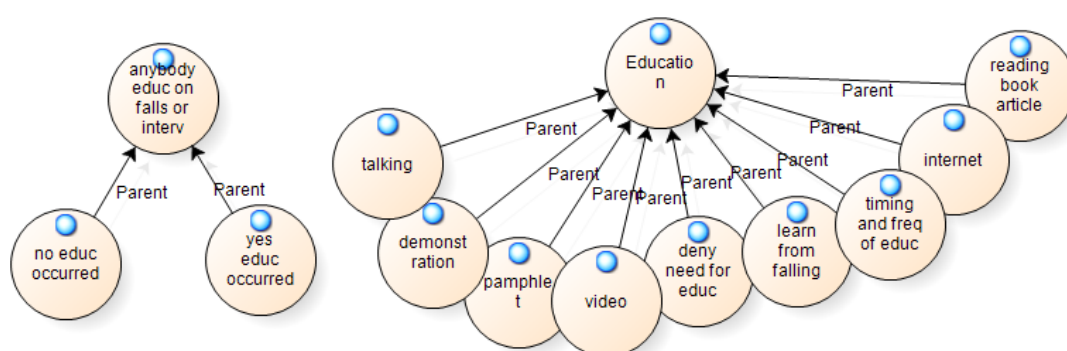


Figure 6-9 New coding structure for “Education” of fall risk after Fall Panel review #2

- **Environment:** This original category was expanded to include more features as mentioned by additional participants (Figure 6-10). The “threshold/lip” category expanded to include threshold from patient room into bathroom, threshold into shower and threshold/or gaps encountered outside the patient room (e.g. elevators or pavement outdoors). This issue was aligned with the risk of pushing IV pole over the thresholds. Difficulty with the call light remained in the “Environment” category but is closely aligned with the patient’s frustration in getting the level of help that they need when they need it that is under the original code of “Patient Partnering”. Clutter in the room and lack of space in the semi-private rooms and IV pole connections were all environmental issues that limited patient’s mobility. Patients expressed frustration in the difficulty getting where they needed to go at the time they wanted to get there.

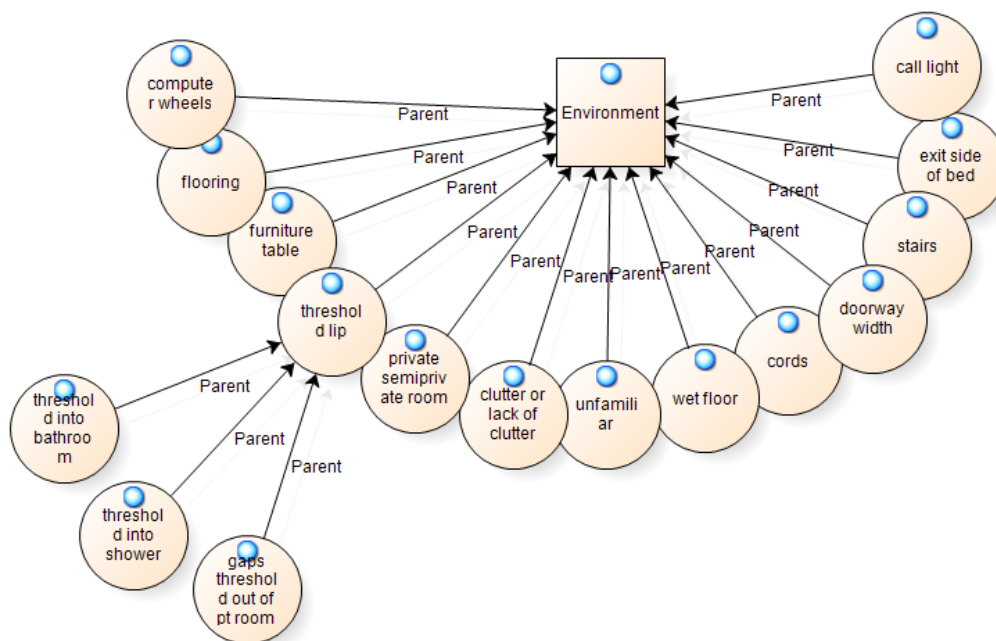


Figure 6-10 New coding structure for “Environment” after Fall Panel review #2

- Equipment:** Equipment was not included in the environment category because the types of equipment mentioned by participants were used during mobility (Figure 6-11). The shower chair remained in this category instead of environmental because it was mentioned as a transfer method from wheel chair or walker into the shower.
- Support Methods:** Although the support methods category in Figure 6-11 was kept separate from the “Equipment” category they were related because participants mentioned things they used for support during mobility, including getting human help for support.

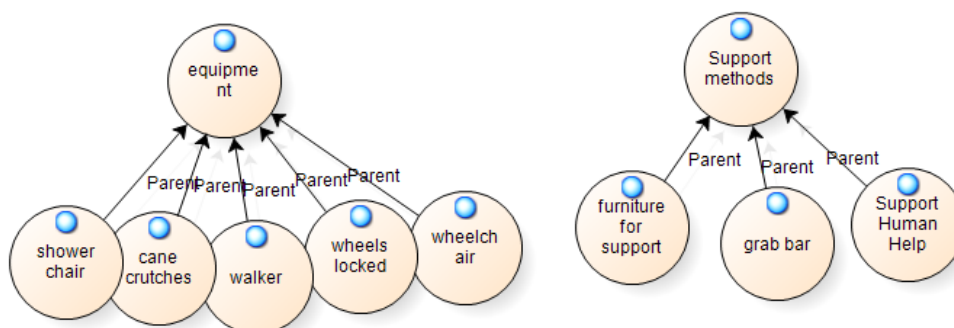


Figure 6-11 New coding structure for “Equipment and Support” after Fall Panel review #2

- **Intervention:** This category shown in Figure 6-12 was expanded to include interventions documented in the medical chart for each patient as well and comments from interviews. Although “exit on preferred side” and “bedside table on non-exit side” were documented for every patient, it had little to do with which side of bed the patient used to get up. None of the patients mentioned that anyone had discussed this concept with them.
 - **“Awareness of Interventions”:** As a result of the question that was added to the interview proforma to enhance understanding a patients’ awareness of fall interventions, a new category called “Awareness of Interventions” was added to the “Interventions” category.
 - **Suggested Interventions:** The original “Ideas” category was moved under the “Intervention” category and called “Suggested Interventions” with separate sub categories and suggestions for improvement at home verses in hospital. The category called “Stumped” where patients did not have any suggestions for improvement remained under “Suggested Interventions” but was called “No suggestions”. About half of the participants had some suggestion for the hospital to mitigate fall risk.
 - **Exceptions Documented:** This category was moved under the “Interventions” category. Items in this category were noted if there was a contraindication making the intervention inappropriate for the patient (e.g. yellow socks if patient had no feet, or gait belts if patient had abdominal incision).

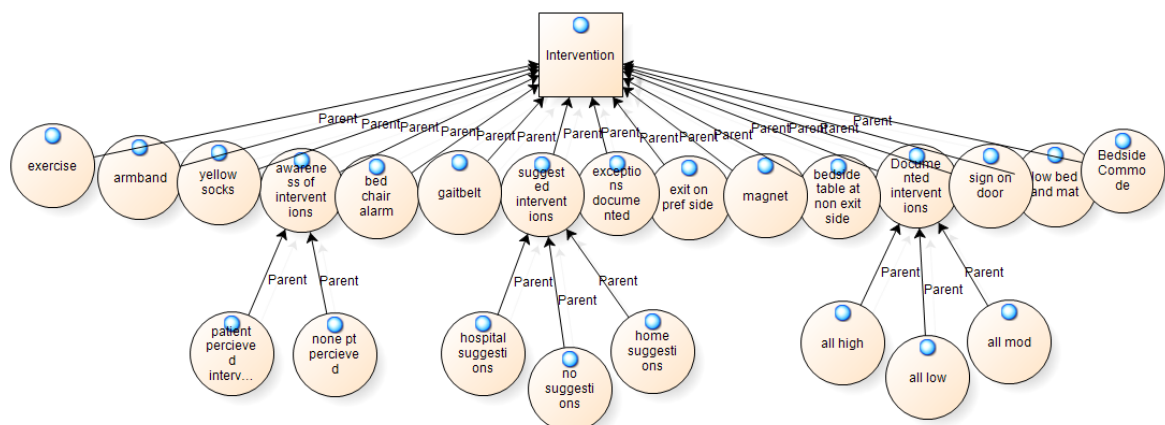


Figure 6-12 New coding structure for “Interventions” for fall prevention after Fall Panel review #2

Injury Types: Additional subcategories were added to the “Injury Type” category to expand the severity of injury and parts of the body (Figure 6-13). The most common injury mentioned was a broken bone followed by head injury. A unique dimension called “Embarrassed or Ego” was added after a comment by one patient that they had an injury to the ego due to embarrassment of a fall. The term “Ego Bruising” was mentioned when asked about possible injuries from a fall.

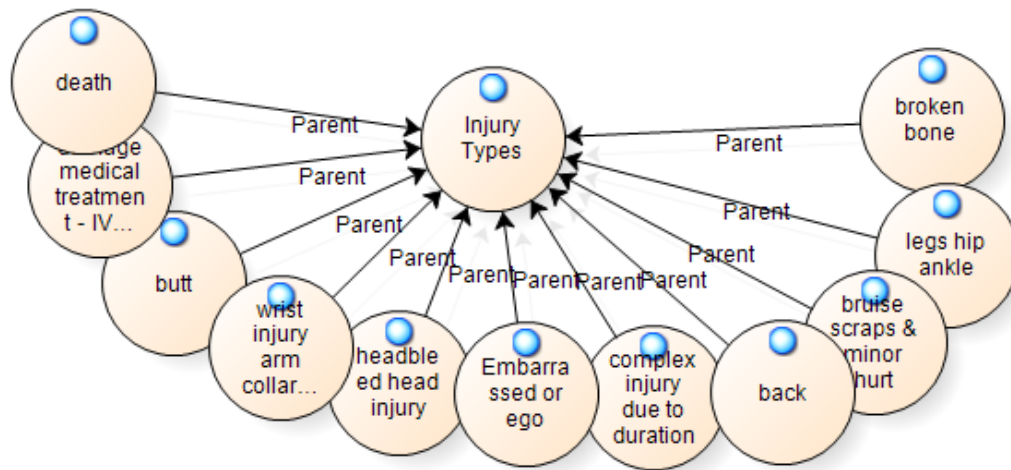


Figure 6-13 New coding structure for “Type of Injury” after Fall Panel review #2

Patient Partnering: Patient Partnering was a category that originated from Study #1 and #2. Figure 6-14 shows three subcategories were added with information learned from the interviews that involved communication issues with the nurse and requests for help, especially with toileting issues. This category aligns with the patients’ frustration with getting the assistance they want when they want it.

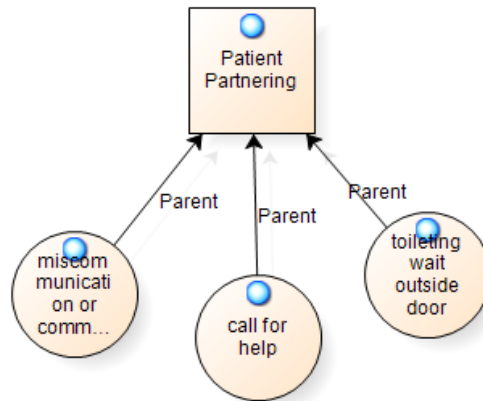


Figure 6-14 New coding structure for “Patient Partnering” after Fall Panel review #2

- Risks:** Causes of falling combined under the general risk category after discussion in the second Panel Review (Figure 6-15). Topics under causes of falls and risk included issues such as getting tangled in the sheets, walking without assistance, and lack of staffing. As mentioned earlier patients did not recognize the difference between risk of injury and risk of falling. Consequently the risk of injury was left under “Risk”. Only one patient that had several types of cancers over many years mentioned that brittle bones (a possible side effect of chemo treatments) might contribute to the risk of injury.

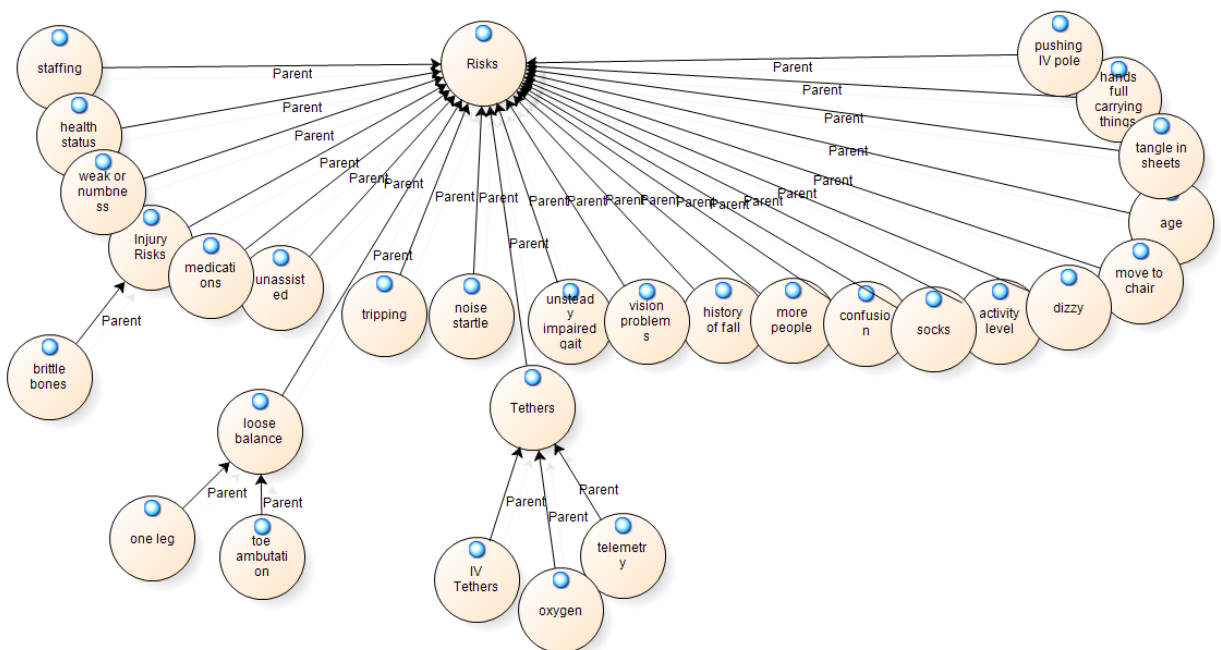


Figure 6-15 New coding structure for “Fall Risks” after Fall Panel review #2

Role Suggestions: This category shown in Figure 6-16 came from the questions that involved suggestions the participants had for each role (nurse, doctor, therapist, and technician). Patients were even asked to give suggestions they might do to keep themselves from falling.

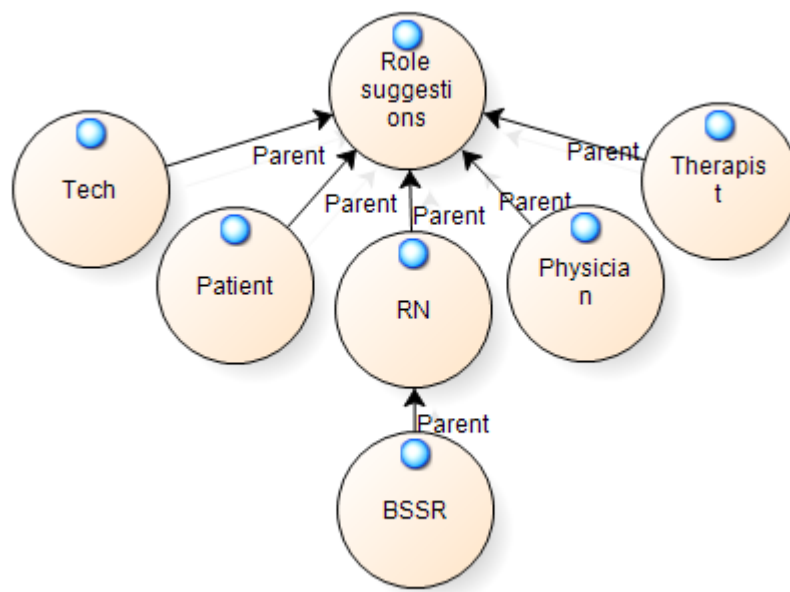


Figure 6-16 Suggestions for care team to prevent falls

- **Complexity/World View/Patient Stories:** Complexity was a category that originated from Study #1 and #2. The category was originally for the numerous facets of fall risk and the 38 possible interventions that had to be appropriately matched to mitigate fall risk. Types of data in this category were the stories that each patient told about their journey with cancer and how they came to be in the hospital at this point in time. Initially their stories were categorized as complexity because there were many facets to each story and the combination of all the factors added up to the current situation. The Fall Panel decided to move all the stories into a new category called Patient Stories. This left no remaining comments in the Complexity category. The patient story category is closely aligned with the original World View category. This has information from a few patients about how they felt about incidents that have occurred during their hospitalization.

- **Critical Thinking:** This is another original category made up of the numerous facets of a fall that must be linked together to compile the risk of falling and understand the most appropriate intervention. At the time of the panel review, concepts in this category were from patients that were able to link all their issues together and realized that they were at risk for falling. These concepts were moved to the Risk category because they contributed to the discovery of patient's understanding of their own fall risk. This left no remaining comments in the Critical Thinking category.
- **Priority and Culture Change / Facilitation / Complexity / Critical Thinking / Team & Pace of Change:** Categories in Figure 6-17 were from the original categories developed from Study #1 and #2. There were no comments collected during the patient interviews that remained in these categories. One explanation is that the patient's perspective is different than the investigators. The original categories were developed by the investigators based on lessons learned from facilitating Lean and Six Sigma projects. It is interesting to note that out of nine original categories; only three were used to contain comments from the patients (Environment, Intervention and Patient Partnering). This may be in part due to the nature of the interview questions. See the limitation section for further discussion.

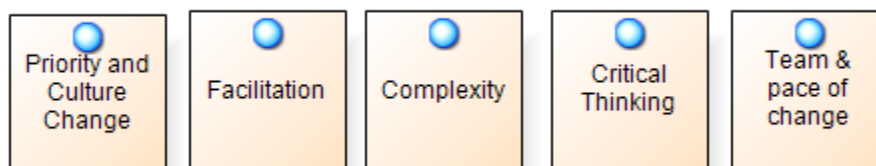


Figure 6-17 Categories from Studies #1 and #2 unused by participants in Study #3

Another way to look at the evolution of the coding model is with a word frequency query (Figure 6-18). The top 1,000 most frequently mentioned words that were four letters or longer from the coding source are visualized in this word cloud. The larger the word's font size indicates a greater frequency of use. The first word cloud was calculated from participants one to ten. The most frequently mentioned word was "fall". The second word cloud represents data from all 30 participants and shows



Figure 6-19 Flip charts to guide discussion during selective coding session

A crosswalk with all subcategories (from the final Axial coding) corresponding to each theme from Selective coding can be found in Appendix H. The three overall themes were: Lack of Patient Control, Self-Perception and Patient Background.

6.3.5.1 Lack of Patient Control

Lack of Patient Control was an overarching theme that involved the patient's frustration about their lack of control with the following three areas: 1) Space / Environment, 2) Assistance and 3) Information.

- Space / Environment** – Patients find it difficult to get where they want to go because of clutter in the room and hallway causing trip hazards. They found it difficult to push their IV pole over bathroom thresholds. Patients seemed unaware of environmental interventions that were in place for them (like low beds and fall signs on the door). The most noticed intervention was the “Call-Don’t-Fall” magnet that is in every patient room.
 - “It happened so fast (describing a fall during a previous hospital visit), I was pulling the IV pole and all of a sudden I was tangled up in my feet and the tubing, there was not enough space to get through” (participant no. 21)
 - “The threshold going into the bathroom has a small change in elevation this is harder than a step up because it tips over the IV pole.” (participant no. 22)

- “For me The IV pole is a hazard... when I go over a threshold I have to kick the IV pole to get it over the bump you can’t push it because it is like a brake and it tips so I kick it up in the air and push it like that.” (participant no. 20)
- “Tile may not be best thing if you have nothing but plain socks on and only have one leg and a walker” (participant no. 13)
- “make sure there are no entanglements, last visit my feet got tangled up in the sheets, I had socks with grippy things on it and Ted-hose (compression stockings) and all the material from the sheets got caught up, so they need to focus on the feet as the patient gets out of bed” (participant no. 26)
- **Assistance** – Patients want help when they say they need it in the way they want it. They feel they are capable of determining when they need to call for help. Several patients expressed difficulty finding and using the call light. The call light icon located on the bed rail does not work and gives the patient no indication that their request for help was not received. One patient demonstrated how to use the call light by picking up the phone and pushing the red light instead of the hand-held pendant with the red call light.
 - “They keep an eye on you. If you do happen to get out of bed and have a little accident, they are there to pick you up immediately. They are very quick.” (participant no. 6)
 - “It would be nice if they would wait right outside the bathroom door while I have a bowel movement in case something happens. I may need help and I can pull the cord but it can take five minutes to get help.” (participant no. 13)
 - “When the IV pump started beeping we pushed the call light three times and it didn’t work – it usually takes three or four times to get the button to work.” The patient and family member were pushing on the pendant, but the button did not work. Earlier, the nurse had told them to look for the red light and they thought she meant the red light on the phone not the red light on the wall plate. See photograph shown in Figure 6-20. (participant no. 26)



Figure 6-20 Photograph of confusing call lights and telephone

- **Information** – Patients want information at the time it is needed and when they are ready for it. Although some wanted information by video and others wanted written material, they all wanted to discuss the information with someone.
 - “In person is always better, in person is best so you can ask questions.” (participant no. 10)
 - “I’m a hard headed person so I guess I will need to fall first and then I will listen.” (participant no. 17)
 - “Fall education should be done prior to giving me the drug – not when I am admitted at 11:00 at night.” (participant no. 23)

6.3.5.2 *Self-Perception*

Almost all patients denied their risk of falling and believed they were the best judge of their own risk. Inexperienced patients (with recent cancer diagnoses) did not think they were at risk for falling because they have been healthy and strong with no history of falling. Experienced patients (those that had received numerous chemotherapy treatments) also did not think they would fall because they have been through so many treatments and had not yet fallen. They get irritated when nurses continually remind them to call for help or check on them too often.

- “I sit on the edge of the bed before I get up and not get up too quickly. If I get up and felt weak, I would call for help.” (participant no. 21)

- “I prefer to take care of myself to the extent that I can. I try to do it myself first. If I thought I really was unstable then I wouldn’t do it myself. Take your time, remember to slowly get up and make sure feet are solid and test out a walk along-side the bed to see if you need to call and get assistance, someone like me (used to being in hospital) just needs to slow down and take time.” (participant no. 15)
- “I would probably sit up in bed and then stand up beside the bed and assess myself, and then I would call if I needed it.” (participant no. 30)
- “No, I won’t fall here.”, “It’s too protected here. My nurse is driving me crazy because she is always in here with me, except now because you are in here.” (participant no. 2)

This theory is also linked to the Category of “Other guy-not me”. It is human nature to think that bad things will happen to the other guy.

- “I don’t need that kind of care, but others I see might need the help. I’m still not very sick yet, but others can’t even walk down the hallway. I could run down the hallway if I wanted to. I don’t see anything that is that hazardous to me. I can see where other people might. (participant no. 20)
- “I can bend over without losing balance and get dizzy, but someone else might not be able to dry the floor. I mop it up before I try to walk on the wet floor.” (participant no. 18)

6.3.5.3 *Patient Background*

Each patient had a story about how they got to where they are today and incidents along the way that created the perceptions they had at this time.

- “Nurses and doctors need to speak with each patient individually about what is in their head... how they feel about their body or situation (where their head is at) then they can decide on the best approach for me.” (participant no. 17)
- “Last two years have not been kind to me, went through Chemo and all that and then I had metastasized tumors and get all that taken care of and now this comes up and they think that this is cancer again – all in two years, I am

just having a ball. There is a point of diminishing returns that I am passing rapidly I think. My body did not tolerate the chemo and radiation well last time. I'm not looking forward to another go round, so falls is not high on my priority list, just getting by day to day.” (participant no. 23)

- “I stepped out of the front door of my house without my brace on, it wasn't a high step and I didn't realize this leg was as weak as it was and started wobbling like a little toddler – and a voice told me if you don't stand up you are going to break your leg, I couldn't find anything to grab onto; next thing I know, it felt like I was falling down hill and I heard a POP and I fell over in my rock bed and in a few seconds my leg was this big, fell into a rock bed with head inches from a retaining wall. Paramedics came to get me” (participant no.13)
- “The day of the brain problem (less than a week ago), I had baked a cake to prepare for company and I started sneezing and my eye saw black fuzzy stuff and I got up and looked at my hands and my husband came in and said, I think you're having a stroke and he took me to the hospital.” (participant no. 26)

6.4 Discussion for Patient Interview

Comments from participants in this study can be divided along the HFE systems framework shown in Figure 6-21 (Holden et al., 2013). Comments about their environment and equipment involve the work system. Frustration with getting information and assistance when needed is in the Process category. Understanding the difference between patient and care team goals aligns with the Outcomes category. Chapters 8 and 9 discuss the importance of achieving a balance between environmental, behavioural and process components in this framework to prevent patient falls.

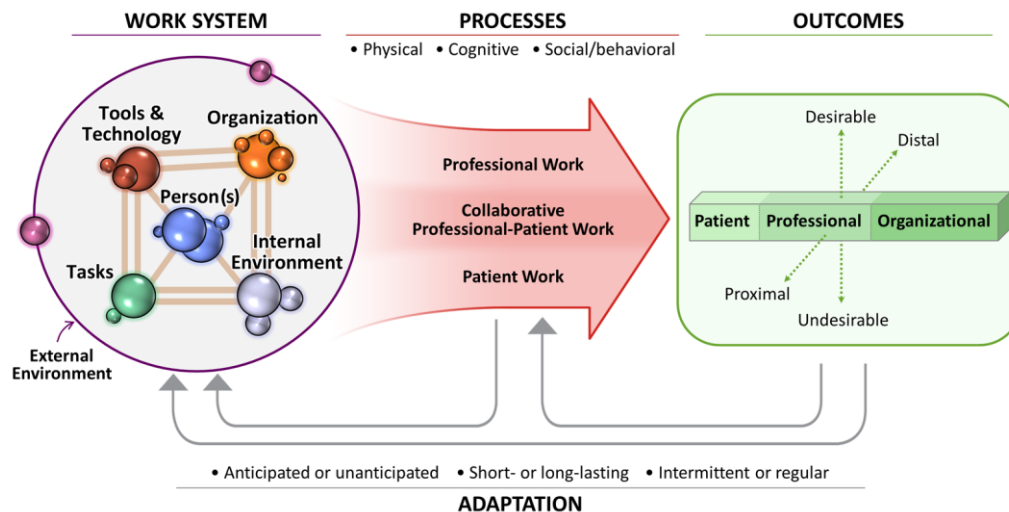


Figure 6-21 SEIPS 2.0 Model of Human Factors Framework for Healthcare

6.4.1 Environmental Suggestions

Participants had suggestions for environmental and equipment improvements such as eliminating thresholds and eliminating confusion around call light buttons. Although these suggestions sound simple, these two examples have been under investigation for several years. Environmental changes can be more complex than it appears and extremely cost prohibitive.

An IV pole catching on thresholds is a widely recognized problem. Eliminating thresholds has been incorporated into guidelines for new architectural designs. When trying to eliminate threshold in existing space it can be difficult to achieve. Some renovated areas have been successful in extending the slope of a threshold to make a more gradual transition. However the division where patients were staying that participated in Study #3 is an old area of the hospital that is scheduled to move into a newly constructed hospital building in less than two years. It's very difficult to get money to fund renovations in an area scheduled to move.

The call light issue is even more complex. The most obvious plan would be to make the call light button on the bed work and perhaps select an alternative pendant call light or phone that does not look so similar. The solution required to make the call light on the bed work would require installing an additional outlet in the wall. The decision was made that if we made this fix to one area it would be needed for all 1,200 beds in the hospital. In addition, several hundred beds needed a retrofit kit so they could be adapted to the wall outlet. As this solution became too daunting, the

next solution investigated was to cover up the call lights that did not work. Several techniques to cover the light were investigated over three years. The solution must not let light through at night, adhere to infection prevention requirements and not add to cleaning time for housekeeping. This issue is still under investigation at the time of this writing. The most recent purchase of new beds did not include the call light in the control panel on the bed. The problem with this solution is that the only call light remaining is located on the hand-held pendant shown in Figure 6-20 and it tends to slide off the bed and can be difficult to reach.

6.4.2 Patient Background

Every patient also has a story of how they came to be in the hospital, where they are in the acceptance of their disease process as well as pressures from finances, home and family. Knowing the patient as a person is critical to understand their baseline (what they were like before entering the hospital). This understanding helps the nurse provide interventions that are founded by the patient (Tanner et al., 1993).

It is human nature to think that bad things will not happen to them. Fifty percent of the participants thought “Other guy – not me” about fall risk Haines found this phenomenon and called it “better for others than for me” (Haines et al., 2014). They found between 25%-34% of elderly adults (age 70 and older) thought a fall prevention strategy was fine for someone else but not needed for themselves. Perhaps this study had an even greater percentage because the population was younger with an average age of 56 years old (Haines et al., 2014).

Patients often receive life altering, devastating news in the hospital and have concerns for family and responsibilities. They are often overwhelmed with information about the new disease and treatment options and decisions that are difficult to understand. They need time to process what is happening while they are often feeling very ill. It is understandable that risk of falling may not be their highest priority. Huang recognized the importance for a patient to achieve self-efficacy by feeling in control of their fall risk and have confidence to achieve mobility without falling (Huang et al., 2015). The study goes on to recognize that cancer patients must have a fall prevention program that includes education in addition to the importance of enhancing patient confidence to managing their own risk of falling. Although implications of the study reveal that education can decrease falls in the

hospital, they fail to consider how this interacts with the priority of other oncology patient concerns. They did mention that 19 out of 72 (26%) patients were unable to complete the follow up survey due to degrading medical concerns. In Study #3 there were 64 patients offered the opportunity to participate but only 31 (48%) agreed or were feeling well enough to be interviewed 24 hours later.

Perhaps it is the combination of the lack of priority and misunderstanding of injury risk that contribute to patient denial of fall risk. Data from this study showed that patients do not think they are at risk for falling and feel particularly safe and protected during their hospital stay. This finding was also observed by Haines where patients acknowledged fall risk in others more easily than in themselves.

A unique finding in Study #3 was that patients also have a lack of understanding of the difference between what puts them at risk for falling verses their risk of injury from that fall. Patients do not understand the difference between what may put them at risk for falling (dizziness, weakness) and risk of injury (brittle bones, low platelets – thin blood, prone to head bleed). Only one patient mentioned an injury risk factor although almost all of them had injury risk factors. Not realizing their grave risk of injury combined with the perception that they feel safe in the hospital and their distraction with a new diagnosis made it understandable that they are not concerned about fall prevention. This new discovery emerging from this research has not been cited in previous literature. It is in agreement with a 2014 article that states that patients' perception of fall risk does not match their clinical risk or actual fall experience and they overestimate the ability of their care team to prevent falls (Sonnad et al., 2014).

6.4.3 Patient Partnering

Partnership between a nurse and a patient may be difficult when the two partners have different goals and tasks. According to the Merriam Webster Dictionary a "partner" is a person who takes part in an undertaking with another (Merriam-Webster Inc., 2005). Simply having the desire to partner is not enough – each individual's mindset can sabotage the partnership. Patients and nurses certainly have the potential to have different mindsets. A true partnership emphasizes equality. A partnership where one person is a dominator creates disparity. This implies a power hierarchy where the dominate partner is right or overpowering/controlling (Montuori

and Conti, 1995). It would be easy to see how the nurse could be perceived as having more power since patients can be in a weakened condition and confused. When communication occurs between two people with unequal power the dominant person constantly reiterates their point of view until the other person submits to their request. This does not mean mutual agreement was reached. This is a similar approach as was used in the Patient Partnering approach in Study #2 where the nurse would come back several times to make patients adhere to the agreement to call for help before getting out of bed. The true goal of an equal partnership is to link two people together in a mutually beneficial relationship to figure out how to blend each individual's responsibilities and contributions to achieve extraordinary creative results (Montuori and Conti, 1995). This type of partnership takes time to clarify each individual's purpose and goal and to figure out how to help each other achieve their goals. The nurse may perceive this as extra time that will take away from other critical tasks. Nursing practice models may provide inadequate support for time to know the patient in the acute care environment (Zolnierrek, 2014).

One consideration would be to determine if someone other than a nurse would be capable of partnering with the patient on fall prevention. Study #2 demonstrated that the Advanced Practice Nurse (APN) was able to understand patient's unique characteristics and match to fall prevention interventions. This success is understandable since the APN has clinical knowledge required for critical thinking to link components together in order to understand a patient's unique fall risk factors. Further investigation would be required to determine if alternative models could be successful with non-clinical partners (e.g. reducing clutter or responding to call lights).

6.5 Model for Study #3

There is a lack of connection between how patients and their hospital staff perceive risk of falling and the importance of mitigating that risk. This disconnect is illustrated in Figure 6-22. The fact that this interaction involves two people means that each human brings their own viewpoint, personal history and personality to the interactions. For example a nurse brings pressures from the daily workload with other patients, regulatory requirements in addition to personal issues outside of work into the relationship with each patient. Nursing responsibilities are incredibly

complex and they can feel very busy completing all required tasks. It is easy to see how fall risk assessment and documentation can become a “checklist” type task, going through the motions without taking time for critically thinking through the meaning and beyond the immediate task (Tanner, 2006). For example, fall assessment documentation noted that every patient had “bedside table on non-exit side” and “patient exits on preferred side”. However, every patient got out of bed on the side closest to the bathroom regardless of equipment in the way or what side they were accustomed to getting out of bed at home. If nurses were attempting to explain these interventions to patients, the message was not understood by the patient.

Even the tasks and goals to be achieved in a day are different for patients and nurses. Nurses have medications, procedure preparations, patient care, documentation and numerous other tasks to perform for several patients at once. Patients feel a lack of control over their environment and find it difficult to move around their room to get personal items and use the toilet with dignity and independence. They want to be the one to determine if they need help and then when they decide they need assistance it they want the “right” kind of help within a minute or two. They also want the right information, at the right time, in the way they want it.

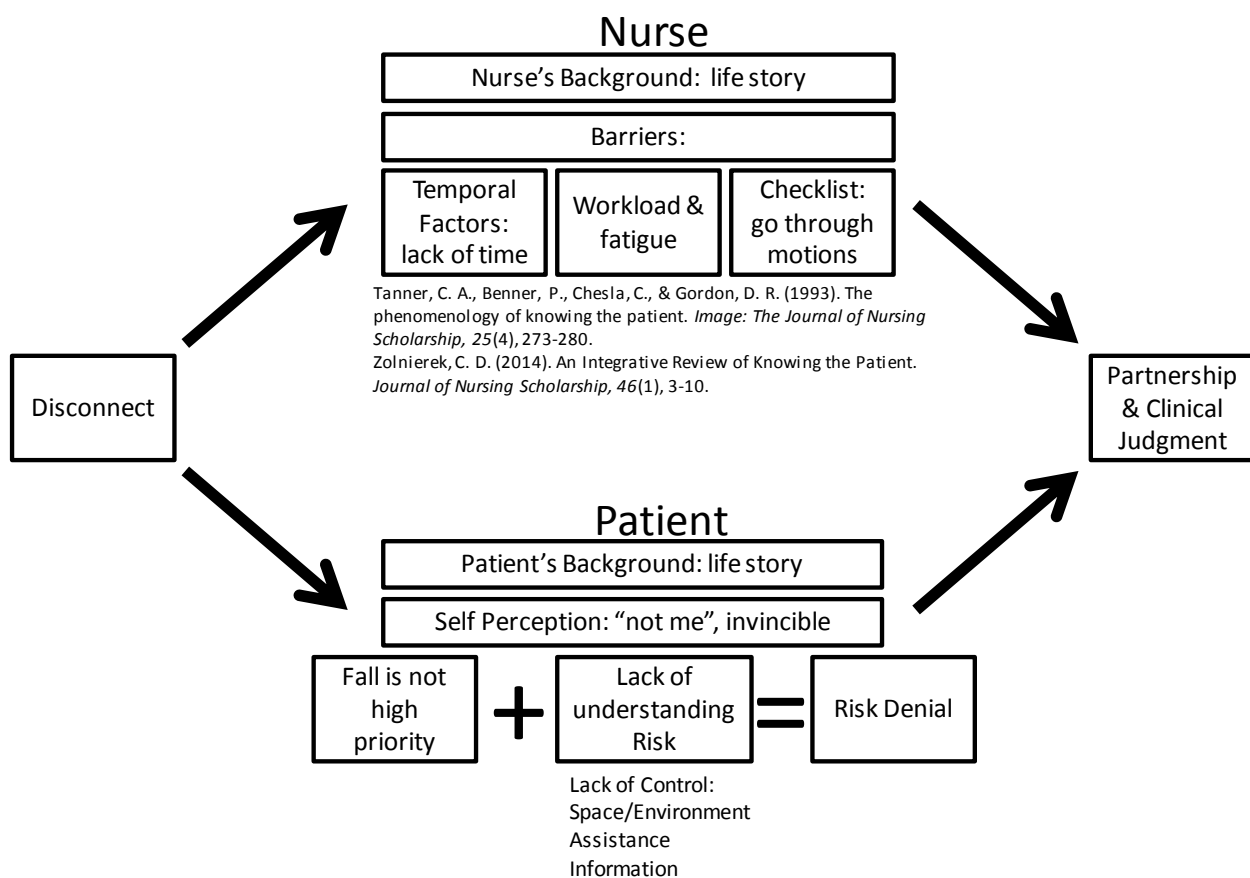


Figure 6-22 Model After Study #3: Disconnect Between Nurse and Patient

The challenge is to determine how to align nurse and patient to make an alliance and create autonomy for partnership when each may not have falls as their highest priority. One opportunity to improve alignment is individualized communication. Interviews revealed that patients wanted information in an ongoing way as it was needed. Education was perceived more positively with conversations face to face occurring throughout the patient's stay. The lack of control the patients feel over their ability to move around their room, the information they need and problems getting assistance as they need it all indicate the patient has very little perception of control. This also indicates that the patient must be a critical participant for a partnership to be successful. Patients can't be forced to partner but if the opportunity is presented on their terms, mutually beneficial team work can be achieved. When given the opportunity, patients demonstrated in the interviews that they can define problems and brainstorm possible solutions.

A project reducing the total fall rate took place in an academic medical center in Philadelphia using Six Sigma methodology to develop an intervention called “Proactive Rounding”. It allowed the care team to understand and plan for the unique needs of each patient. The extra time strain on the nurse seemed to be relieved in this study by many disciplines of the care team contributing to patient specific interventions (e.g. pharmacy reviewed medications if patient experienced previous fall due to dizziness) (Christopher et al., 2014). It is essential for healthcare workers to partner with patients so they can know their patients’ needs in order to achieve a mutual understanding of fall and injury risk.

6.6 Limitations and Strengths of Study #3

6.6.1 Limitations of Study #3

Due to the nature of field research, there were some limitations to this study. Since the scope of this study was patient perceptions, it only explored the patient’s opinion of the situation. When the patient said nobody had discussed risk of falls or interventions it is impossible to determine if education actually did occur but the patient did not remember or comprehend the conversation.

Another limitation was that in order to achieve a coherent interview none of the participants had any cognitive impairment. Altered mental status is associated with risk for falling (Hignett et al., 2013) especially when combined with altered elimination issues. Only 10% of participants were assessed as having an issue with altered elimination.

The format of the interview proforma was unique in that five objective (Likert style) questions were verbally administered prior to the open ended questions. The intent of this style question was to quantify feelings of fall risk and understand the priority of the topic of fall prevention. This method is not typically performed in a qualitative interview and potentially may have biased subsequent answers. With the benefit of hindsight, this strategy would not have been implemented. The richness of the qualitative answers was strong enough to provide an understanding of patient perceptions without introducing the risk of bias from Likert scale questions.

Even the direction provided by a semi-structured interview guide can lead conversation into areas causing unintentional paths. The categories that were unused

from Studies #1 and #2 did not closely map the area of questioning in Study #3. For example there were no questions about Critical Thinking, Facilitation or Team Pace of Change. Even though these topics are not especially relevant to a patient scope it is not too surprising when these topics were not mentioned by the participants. The resulting conversation seemed to be guided into the direction of the interview questions.

None of the participants in these interviews experienced a fall during their stay. All patients were able to stand on their own and 63% of them passed the “Go” portion of the Get up and Go test – meaning they could safely walk a few steps. Only 10% were at high risk for falling (according to Johns’ Hopkins Fall Risk Assessment) and only 20% had fallen within the last six months. These factors may have contributed to the finding that they did not feel they were at risk for falling.

Seventy-three percent of the participants were connected to at least one type of tether and there were 29 comments made about IV poles. This could be one reason for the frequent mention of this specific fall hazard. It certainly was mentioned as contributing to the frustration of mobility.

6.6.2 Strengths of Study #3

Strength of this study was in the timing of the interview. Talking with the patients during their hospital stay allows the opinions to be fresh as they are felt in real time. Many patient surveys happen after the patient has returned home and they may have difficulty recalling specific details. The advantage of interviewing a patient during their hospital stay also had a limitation. Patients are very ill and dealing with life altering procedures during their hospitalization. The Thesis Author had to partner with the nurse of each participant to ensure that the interview would not interfere with the patient’s medical treatment. One patient became ill during the interview and did not have the strength to continue.

The most predominate strength of this study was taking the time to talk with the participant. Each interview was allowed to go as long as the participant was willing to keep talking. The semi-structured nature of the questions allowed participants to expand on issues they felt were most important. Each participant was initially contacted the day before the interview and provided an information sheet about the

study. This allowed them the choice to participate in the interview and built trust that the interviewer would return the following day. The rapport and respect built during the interview helped to further the trust allowing the participant to provide honest responses.

6.7 Conclusion for Patient Interview

Qualitative interviews provided an understanding of the patient perspective that revealed an opportunity to rethink the Patient Partnering process. Patient partnering needs to create an opportunity to exchange information in a way that is needed by that patient at that point in time. It is also an opportunity for the nurse to understand a patient's perception of fall risk and adjust interventions accordingly. It is critical to maintain communication throughout the hospital stay with frequent short discussions. The result may help create a sense of urgency to bring both partners' goals into closer alignment. The partnership must strive for an equal foundation (common understanding) to work toward a common goal and not to force the patient into submission (adherence).

Patients, Fall Experts and staff can have varying perspectives on fall prevention. Before these perceptions can be aligned they must be thoroughly understood. Study #3 made strides in understanding the patient perspective. The next opportunity would be to investigate the congruency between patient and various healthcare workers perceptions of falls. The nurse's perspective was not included in the scope of this study. Literature around "knowing the patient" indicate that it is critical for a nurse to get to know a patient's pattern of responses and know them as a person before they are able to achieve "clinical judgment" for that patient (Tanner et al., 1993). In order to know the patient, a nurse must understand a specific patient's needs and select the most appropriate interventions accordingly. This is an ongoing process that is constantly changing. Barriers to finding the time to devote to knowing the patient can include organizational constraints such as staffing assignments that may not promote continuum of care, different assignments each day or even the model of care (where unlicensed personnel provide blood pressure checks) removing an opportunity for communication and interaction (Zolnierek, 2014). Clinical reasoning is not achievable until a nurse becomes engaged and has concern for a particular patient. Combining this understanding with the knowledge

of interventions evolves the nurse into an advocate of the most appropriate fall prevention plan for their patient. Knowing the patient is necessary to achieve patient participation (Zolnierek, 2014). Before we can expect a true partnership each perspective must be understood and progress made to align the goals of the nurse and patient by improving communication and understanding to achieve mutual success.

7 CHAPTER 7: TEMPORAL ANALYSIS OF FALL INCIDENCE THROUGHOUT THE DURATION OF THE RESEARCH

7.1 Introduction

As mentioned in previous chapters, fall prevention has been an ongoing effort in the oncology department at Barnes Jewish Hospital (BJH) mirroring similar challenges in many hospitals throughout the country (Christopher et al., 2014). This chapter will discuss the results over five and a half years from the one oncology division that participated in all three studies in this research at BJH.

The oncology division discussed in this chapter had 38 beds with 26 in single rooms. This division primarily cares for medical oncology but admits bone marrow transplant patients as well.

7.1.1 Aim

The purpose of this chapter is to look at fall trends over an extended period of time and provide comparisons of the different phases that occurred during this time. The aim is to facilitate a better understanding of changes in falls over the entire period of the research presented in the thesis and bring results together in a coherent and insightful discussion. Additional reflections on the benefits of QI can be made by combining the 35 months of Lean (17 months) plus Six Sigma (18 months) interventions. This perspective aligns with aims of the entire thesis to (1) understand the advantages and disadvantages of QI methodologies and (2) develop innovative recommendations for fall prevention.

7.2 Time line Phases

The timeline in Figure 7-1 illustrates phases of the fall prevention strategies that occurred on one oncology division for five and a half years.

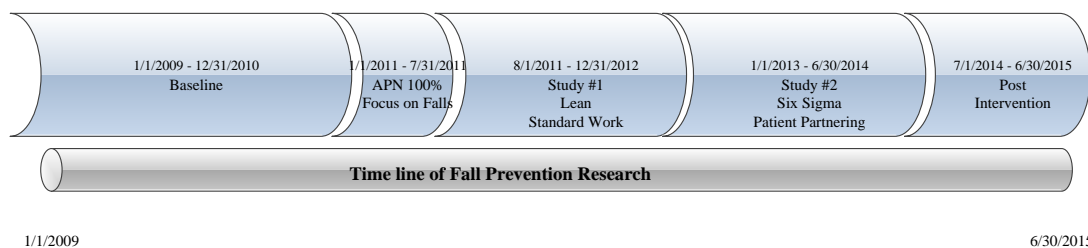


Figure 7-1 Timeline for Phases of Research 2009-2015

7.2.1 Baseline

The two year Baseline Phase was defined as January 2009 – December 2010 when fall prevention was not a primary focus for the division. During this time, the division had participated in a hospital wide initiative lead by the BJH Fall Prevention expert to ensure that falls were accurately reported into an electronic event recording system.

7.2.2 Advanced Practice Nurse 100% Focus on Falls: Best Practice

The seven month Best Practice Phase occurred between January 2011 and July 2011 – Methodology = Advanced Practice Nurse (APN) with 100% Focus on Falls, Intervention = Best Practices. An APN was hired with expertise in fall prevention. Her first 7 months in her new position were 100% devoted to preventing patient falls. She implemented best practices supported by fall prevention research (such as call light strategies, de-cluttered rooms, medication reviews, fall alert signage and armbands). She educated nursing staff on fall prevention strategies. She met with every new patient upon admission to understand their fall risk and tailored interventions and education to each patient's situation and needs. During this time she began developing the intervention strategy that would become known as Patient Partnering in Study #2.

7.2.3 Study #1: Lean: Standard Work

The seventeen month Lean Study occurred from August 2011 - December 2012 and included Lean as the methodology and Standard Work as the intervention (see Chapter 4). Results from the Lean Study in this chapter will differ from numbers reported in Chapter 4 because the analysis in Chapter 4 included two other oncology divisions participating in the Lean project. The goal of this Quality Improvement project was to include all oncology divisions experiencing high fall rates.

Lean methodology was used to develop a standard process for nurses to assess fall risk and recommend appropriate interventions. A standard post fall investigation was implemented to understand the circumstances each time a fall occurred (Wolf et al., 2013a).

7.2.4 Study #2 Six Sigma: Patient Partnering

The 18 month Six Sigma Study occurred between January 2013 and June 2014 with Six Sigma as the methodology and Patient Partnering as the intervention (see Chapter 5). The intervention developed was named “Patient Partnering” to clearly indicate its purpose; is to apprise the patient of their fall and injury risk factors, discuss and agree on prevention measures and to emphasize the importance of calling for help. Patient Partnering encourages the patient to become an active participant in preventing their own falls (Wolf et al., 2014).

7.2.5 Post Intervention

The Post Intervention Phase occurred from July 2014 to June 2015. The phase began with the departure of the APN and the end of her 100% dedication to the Patient Partnering process. Nurses were still expected to continue with fall prevention efforts but the guidance and support of the APN no longer existed. The post intervention period allowed researchers to track 12 months of fall outcomes and better understand the trend.

7.3 Results

The graph in Figure 7-2 shows a summary of the fall rates that occurred during each phase of the fall prevention project from January 2009 to June 2015.

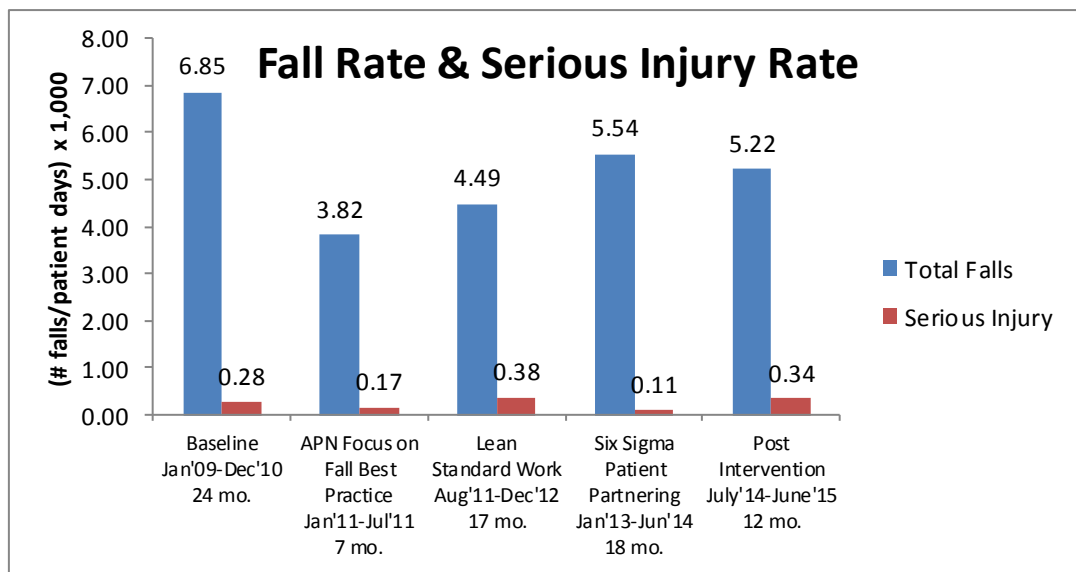


Figure 7-2 Fall and Fall with Injury Rates 2009-2015

It's useful to look at data trends over the full five and a half years of available data to compare intervention phases to a two year baseline. The best way to look at data depends on the question that is being investigated. The first aim of the thesis to determine the contributions Lean and Six Sigma to fall prevention Chapter 5 compared rates from Six Sigma using Lean as a baseline. Using Lean phase as a baseline allows a comparison of one intervention to another. Expanding the timeline allows comparisons to be made to a baseline two years prior to all fall prevention efforts. The result shows the lowest number of total falls occurred during the Best Practice phase when the APN worked full time during her first seven months on fall prevention. Unfortunately, this targeted resource was not sustainable.

7.3.1 Combining Lean and Six Sigma as a QI Phase

It is also interesting to combine Lean and Six Sigma to see if QI methods had an impact on falls. This information is represented in the "Combined" column of Table 7-1. The percent of total falls decreased by 26% (6.85 to 5.04) during the 35 months of QI work compared to the 24 months at baseline. Similar to Chapter 5 and 6, differences in rates were assessed for statistical significance by using the two-tailed Z distribution. The Z test was conducted to compare the rate for all falls at baseline of 6.85 to 5.04 rate ($Z=2.74$, $p=0.006$). An alpha level of 0.05 designated this was statistically significant. The falls with serious injury rates of 0.28 to 0.24 was not a statistically significant difference from baseline to 35 months of QI ($Z=0.25$, $p=0.802$).

	BASELINE	APN	STUDY #1		STUDY #2		Combined	
Methodology		100% Focus on Falls	Lean		Six Sigma		Lean+Six Sigma	
Intervention		Best Practice	Standard Work		Patient Partnering		Combination	POST INTERVENTION
Time frame	Jan 2009 to Dec 2010	Jan 2011 to July 2011	Aug 2011 to Dec 2012	+	Jan 2013 to June 2014	=	Aug 2011 to June 2014	July 2014 to June 2015
Number of months	24 mo	7 mo	17 mo	+	18 mo	=	35 mo	12 mo
Metric - rates	rate	rate (% change from baseline)	rate	+	rate		rate (% change from baseline)	rate
Total Falls	6.85	3.82* (44.3%)	4.49	+	5.54	=	5.04 (26.4%)* Z=2.74, p=0.006	5.22
Falls with Injury	1.79	1.16 (35.2%)	1.54	+	1.66	=	1.6 (10.8%)	1.77
Minor Injury	1.52	1.0 (34.4%)	1.15	+	1.54	=	1.36 (10.5%)	1.43
Serious Injury (mod+maj)	0.28	0.17 (39.8%)	0.38	+	0.11	=	0.24 (14.4%) Z=0.25, p=0.802	0.34
				+				
Number of Patient Days	21744	6023	15601	+	17519	=	33120	11869
	number	#	#	+	#		#	#
Number of Falls	149	23	70	+	97	=	167	62
Number of FWI	39	7	24	+	29	=	53	21
Number of Minor injuries	33	6	18	+	27	=	45	17
Number of serious injury (moderate & major)	6	1	6	+	2	=	8	4
*statistically significant Z test = compare two incidence density rates. An alpha level of 0.05 was designated as statistically significant. % change = (baseline rate - intervention rate)/baseline rate								

Table 7-1 Fall Data from 2009 - 2015

One problem with combining results from the two QI methods is that the interventions were different; the Lean project resulted in standard work and the Six Sigma project resulted in Patient Partnering. The second aim of the thesis was to make recommendations for fall prevention. This aim is better met by looking at the studies separately (Chapter 4 Lean and Chapter 5 Six Sigma).

7.3.2 Number of Days between Falls with Serious Injury

An innovative way to show the duration of infrequent events like falls with serious injury is with a G-Chart. It is an alternative to bar graphs for illustrating trends in falls. The G-Chart is designed to study the distribution of adverse events, by displaying the number of “days between events”. The interpretation of upper and lower control limits on conventional control charts can be misleading with the variation of falls and the constantly changing denominator of patient days. The G-Chart is a control chart based on the geometric distribution rather than a normal distribution and is designed specifically for monitoring rare events (Barker et al., 2009b). Because a geometric distribution is highly skewed, an upper control limit (UCL) set at three standard deviations (as in other control charts) would cause too many false alarms. Instead, the UCL in a G-Chart is a “probability limit” that is set to represent the point where 99.9% of the observations should fall below.

The graph in Figure 7-3 shows an average of 92.4 days occurred between each fall with serious injury for the period between January 2009 and June 2015. The upper control limit (UCL) for a G-Chart is set at the 99.9th percentile. In other words, 99.9% of the time, there will be no more than 888 days between falls with serious injury. On any given day the probability of a patient falling resulting in a serious injury is 0.007 or 0.7%. This also means that each day there is a 99.3% chance that no falls with serious injury will occur.

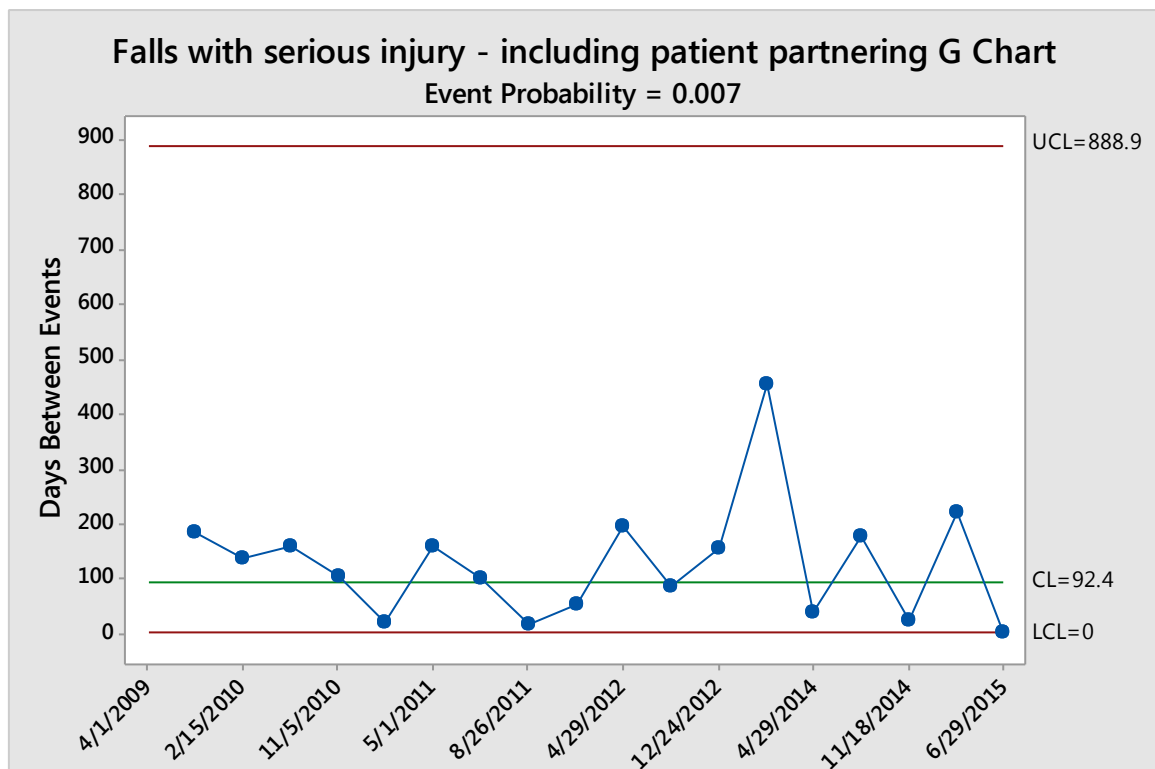


Figure 7-3 G-Chart falls with serious injury 2009-2015

This graph is shown again removing the data point that represents the 14 months (452 days) without a serious injury that occurred while the Patient Partnering intervention was in place a comparison can be made with and without Patient Partnering (see Figure 7-4). Elimination of this record of days without a fall treats the data point as an outlier allowing a recalculation to illustrate the impact of the Patient Partnering intervention.

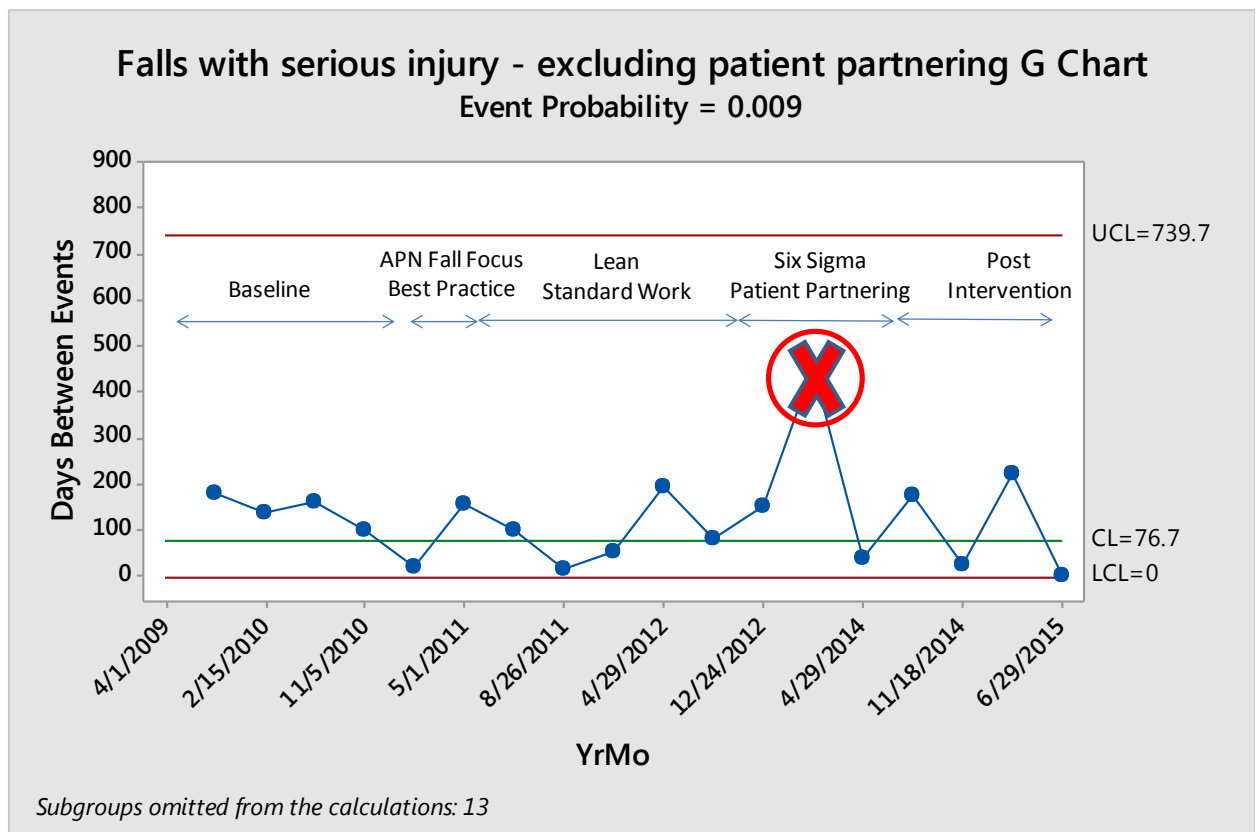


Figure 7-4 G-Chart falls with serious injury excluding patient partnering

By removing the 14 months during patient partnering intervention without a fall the results show an average of only 76.7 days went past between each fall with serious injury. This unique comparison shows that patient partnering improved the average number of days between a fall with serious injury by 15.7 days (76.7 to 92.4). The UCL shows that 99.9% of the time there will be not more than 739.7 days between one fall with serious injury and the next. On any given day the probability of a fall with serious injury is 0.009 or 0.9%. This also means that each day there is a 99.1% chance that no falls with serious injury will occur.

7.3.3 Combined Qualitative Results from QI

Notes were documented in a journal for more than two years throughout the Lean and Six Sigma projects to gain an understanding of fall issues. The journal also included notes from classes, conferences, meetings with advisors, students at Loughborough University and literature reviews. Reflection on journal notes revealed 110 insights that were consolidated into nine categories as shown in Figure 7-5. Selected insights are highlighted below to provide an understanding of each category.

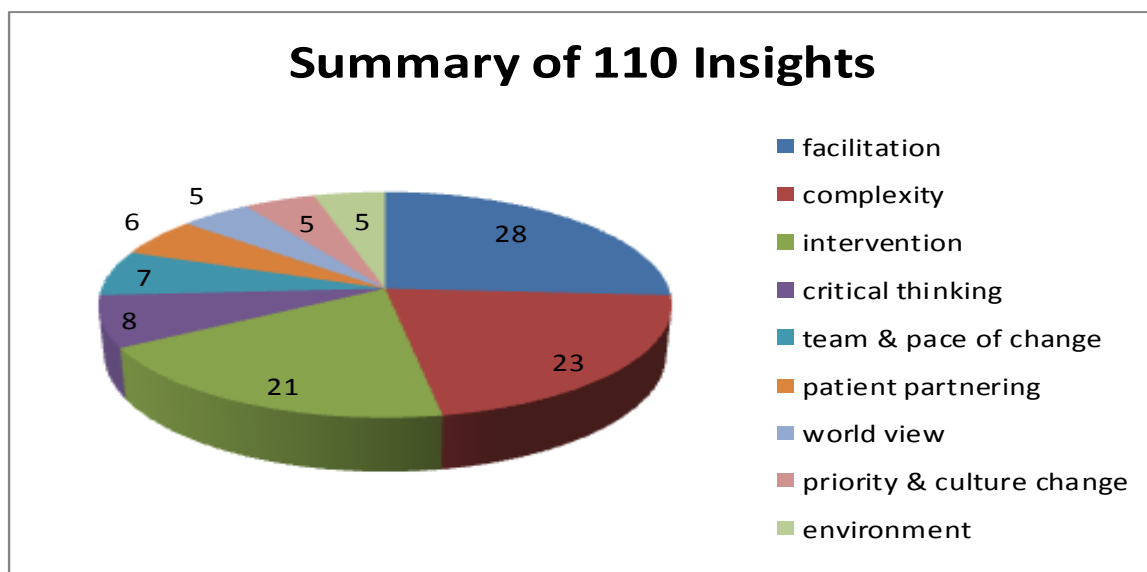


Figure 7-5 Categories of Insights.

Facilitation/Framework. This category involved understanding the flexibility of tools, strategies, statistics and preparation involved with applying Lean and Six Sigma to fall prevention. Short continuous improvement strategies are most successful in a rapidly changing environment. Several insights involved framework concepts such as macro verse micro ergonomics.

Complexity. The realization that there is no “silver bullet” or magic answer to prevent falls was the theme throughout this category. There are simply too many intrinsic and extrinsic variables for a one-size-fits-all solution. The fall risk assessment classifies patients into three levels of risk (low, moderate or high). Aligning these levels along with types of risk factors with 38 possible interventions make algorithms extremely complicated. Nurses are capable of making these decisions but often lack time to devote to critically considering all factors and implementing numerous interventions. Some interventions require additional tasks (e.g. ordering a specialty low bed from a computer system, waiting for the bed to arrive, removing the old bed, and changing sheets).

Interventions. As previously stated, dynamic assessment and interventions in a constantly changing environment are very challenging. Assessing the patient correctly to match to the most appropriate intervention at the right time was a common theme. Conflicts like privacy verses safety while toileting can make interventions difficult. Some of the insights in this category are intertwined with

complexity and critical thinking. For example one patient can have simultaneous risk factors like altered elimination indicating bedside commode along with muscle weakness indicating the need for the patient to call for help any time the patient is out of bed , and finally altered mental status indicating difficulty using the call light to ask for help so a bed alarm that automatically sounds as the patient gets out of bed should be considered. These conflicting needs create conflicting interventions.

Another example of overlap between interventions, complexity and critical thinking is when a patient preparing to be transferred to a skilled nursing facility needs a sitter to watch them for safety because they have confusion, yet the facility will not accept them until they have not had a sitter for 24 hours. These conflicts require critical thinking and are not easily reflected in a simple algorithm.

By thinking beyond the traditional interventions of signage, wristbands and footwear, further improvements in falls and falls with injury can be achieved with a systems approach (Christopher et al., 2014). A combination of environmental, organization, behavior (patient and staff) along with new technology developments will rally to convene a strategy to prevent patient falls. New technologies are constantly being developed that predict when patients are attempting to get out of bed and video technology is furthering our understanding of how falls occur. Technology will help us better predict when patients are at risk for both falls and injuries. Continuing developments are also promising to combine other patient risks like pressure ulcers and patient mobility. These combinations will also help reduce the workload demand for caregivers that will encourage better compliance with intervention implementation Patients will continue to be at risk but with technology advances and systems approach to problem solving the percentage of falls with serious injury can continue to decrease (Quigley et al., 2016).

Critical Thinking. A deep understanding of the cause of fall risk and application to each individual patient is critical to gain insight from the intersection of these factors. Nurses must think beyond a checklist mentality to gain a complete understanding of risk factors and combine the most appropriate patient safety interventions into a common strategy. This requires a holistic approach. While well-validated screening tools performed thoroughly and accurately can help hospital staff identify patient-specific fall risk factors; risk assessment alone does not prevent falls. Effective interventions must be tailored to each patient's specific risk factors

and implemented proactively, including the patient and family as active partners in care. This critical thinking component was exemplified by the APN's interactions with patient and family. She also mentored staff nurses to guide them toward linking all the risk factors together.

When the APN talked to the staff nurse about a patient's mental confusion, staff was often unaware of any problem. The nurse stated that because the patient was assessed as alert and oriented they felt the patient was not at risk for falling due to mental confusion. A new term may be needed to differentiate what is meant as "fall-confusion". When a patient is in denial of their symptoms or does not understand the implications or is impulsive or unfamiliar with their surroundings or simply prone to getting up without using the call light; these are all actions of someone with "fall-confusion". The assessment for alert and oriented does not address this type of "fall-confusion".

Team & Pace of Change. Obviously all patient care staff has an important role in fall prevention, but the patient must also be an active participant in order to achieve success. The concept of the pace of change was included in this category because the insight on the length of time required to engage staff had a large impact on team engagement. Small, quick continuous improvements are needed in this high turnover, constantly changing environment. This is easier to accomplish with Lean methodology since it can be done with a Rapid Improvement Event in just a few days. Six Sigma methodologies are much more rigorous requiring more time and are not as responsive to quick changes. This was a challenge in Study #2 since many months were required to develop the Patient Partnering intervention and get all nurses trained on the technique. Since staff turnover was 43% during this time it may have been a contributor to the lack of acceptance by the nurses.

Patient Partnering. This interactive technique between caregivers and patients is an intervention refined during Study #2 to enhance patient engagement and to encourage them to participate in their fall intervention process. Involvement has the added benefit of empowering a patient and returning a sense of control and independence. Patient Partnering is really a method to achieve patient centered care. The Institute of Medicine defines patient centered care as: "Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and

ensuring that patient values guide all clinical decisions. Recent studies have used modified QI methods to understand complex, patient centered problems like falls (Christopher et al., 2014). If time is devoted to understanding fall risk and completing interventions to mitigate the risk, as is done in Patient Partnering, falls with injury can be reduced. The process, can however, be resource intensive. Some cost benefit analysis shows that full time dedication to falls may not be sustainable. More detail can be found on this topic in the Discussion section of Chapter 5). Further research is needed to understand return on investment issues for fall prevention.

World View. This category involves the different perspective that each team member has and how critical it is that everyone understand each other's view point to obtain a common goal of patient safety. For example, the oncology population's predisposition to falls (cognition, weakness, diarrhea, etc.) and falls with injury (bone metastasis, bleeding risk, tethers) combined with being accustomed to independence and desire for privacy while toileting warrants consideration when staff encourage patients to use call lights. Throughout the hospital stay, a patient often experiences information overload. Consistent communication about the importance of fall and injury prevention with patients by all staff members is critical. Patients often view falling down as a sign of disability or clumsiness, therefore often don't want to accept the fact they are at risk. They may not cooperate or agree to the interventions needed to mitigate their risk. This view was evident to the APN during her attempts to gain agreement from patients to use their call light to ask for help. The comment of embarrassment and clumsiness was supported again during the patient interviews of Study #3 and a recent study by Tzeng that found patients denied their risk of falling (Tzeng, 2011, Wolf, 2015b).

Priority and Culture Change. Fall prevention is perceived to be a lower priority than other critical medical issues. A culture change is needed to shift importance of falls to be incorporated into medical decisions and plans of care. Management ownership of this project was critical to sustain the momentum. If falls are not a priority, prevention opportunities will be missed. Staff will not make falls a priority unless management demonstrates the importance (Weinberg et al., 2011). A shift in the culture related to fall prevention occurred as a result of this project and was evident by both staff and leadership participation. Even with high turnover there was an

awareness of fall prevention among the staff that was observed during mentoring sessions with the APN. The Six Sigma team participation in developing the Patient Partnering intervention helped improve awareness. Staff had an understanding of the importance but taking time was still a challenge with all the competing priorities. Staff was receptive to support from the APN and with implementing interventions from Patient Partnering. They were also open to ideas mentioned during mentoring and appreciative of the extra patient interaction provided by the APN.

Environment. Most environmental issues in the scope of this insight involved equipment. The design environment such as room layout and flooring is typically thought to be outside of the scope or control of the caregivers. Some seemingly simple environmental changes conflicted with hospital initiatives making them difficult to implement. For example, during the Lean phase it was noticed that a nurse must walk to the centralized supply room to get a sensor mat to connect to a bed alarm. After a patient fell while the nurse was retrieving a sensor mat it was decided to store a mat outside each patient room with the isolation gowns and gloves. The environmental safety team put a stop to this practice because the sensor mats made the hallways look cluttered with the mats hanging down from the gown supply box. Another example involved one of the falls with serious injury during the Six Sigma phase. It occurred when a confused patient was out of bed and the bed alarm did not go off. The reason for the alarm not sounding was never determined. The frustration with access to the call light issue arose in all three studies. Many environmental suggestions were made by the patients during interview sessions in Study #3 (see Chapter 6 and Chapter 9 for detailed suggestions for environmental improvements).

There is more to fall prevention than statistical improvement. Qualitative insights provide additional depth to the qualitative results from all studies. The combination of qualitative and quantitative evidence will provide a deeper understanding of issues facing patients and staff.

7.4 Advantages and Limitations of Temporal Analysis

Perhaps it is most representative to look at the trend of fall rates across the 35 months of Quality Improvement (QI) efforts combined in Study #1 and #2. As was discussed in the duration of metrics in the QI literature review chapter 2, there have

been articles written with a variety of durations of sustainment periods ranging from three months (Veluswamy and Price, 2010) to four years (Weinberg et al., 2011).

The most comprehensive understanding of the trends in this research can be obtained by looking at the effects of the combination of Lean and Six Sigma projects seen in the “Combined” column of Table 7-1 that show results over 35 months.

Reviewing fall rates in the 35 months where both approaches were implemented provides a longer period to evaluate success and consistency of a trend. Results show that by using Lean and Six Sigma over this timeframe the oncology division decreased fall rates by 26% (6.85 baseline to 5.04 falls per 1,000 patient days).

The danger in combining outcomes of the Lean and Six Sigma approach in this thesis is that the methodologies resulted in two different interventions. Standard work process around risk assessment and assigning intervention reduced total falls without reducing serious injury, while Patient Partnering reduced falls with serious injury but not total falls. Combining outcomes from Standard Work and Patient Partnering subdues the outcomes for each.

The opportunity for confounding exists. Standard work developed from the Lean methodology carried on during the Patient Partnering intervention but is difficult to quantify since no audits were performed to evaluate compliance. It appears that the additional attention by the APN to partner with the highest risk patients was successful in reducing falls with serious injury but it’s hard to discern the contribution of standard work during this time. It is important to note that a clinical partner other than an APN can be successful in bringing focus to fall prevention activities. A person with clinical knowledge and time to devote to mentoring staff in critically thinking about fall risk can fulfill the role that was provided by the APN in Study #1 and #2. Maintaining the concerted efforts to decrease falls with injury is labor intensive and difficult to sustain as shown with the increase rates during post intervention.

8 CHAPTER 8 DISCUSSION

8.1 Introduction

This chapter will combine the results and insights from Studies #1, #2 and #3, all of which aimed to reduce falls on an oncology division (Wolf et al., 2014, Wolf, 2015b). Quality Improvement (QI) methods of Lean and Six Sigma along with the framework of Participatory Ergonomics (PE) techniques were explored with patients on an oncology division of a large academic medical centre. A key finding resulting from this research is the importance of understanding the patient perspective on falls as a key stakeholder in addition to the caregiver perspective. This understanding is critical to achieve the collaboration required for an effective partnership between caregiver and patient.

This chapter begins with a review of findings from three studies and a brief discussion on the impact of this research on society. The remainder of the chapter will discuss three prevailing themes that emerged from literature and this body of research: 1) Systems Approach: Combining Methods and Balancing Components, 2) Continuous Improvement and Complexity and 3) Critically Re-thinking Falls.

8.2 Overview Summary of Three Studies

Fall rates will vary from 1.3 to 8.9 falls per 1,000 patient days depending on hospital and individual type of patient setting (Oliver et al., 2010). Injuries from these falls will vary as well with one to three percent of falls resulting in serious injury (Oliver et al., 2010). Studies rarely include enough detail to allow comparison of fall rates (Hempel et al., 2013). Risk factors contributing to these falls are typically found to be one or a combination of the following issues: gait, mental confusion, incontinence, history of falls and medications (Oliver et al., 2010). Interventions typically take a multi-faceted structured approach with moderate success that is difficult to sustain for a long duration (Huang et al., 2015). Interventions typically include education, alert of fall risk (wrist band and/or sign on door), non-slip footwear, toileting schedules, bed exit alarm, use of sitters, low beds, moving high risk patients closer to nursing station, medication review and post fall investigation plan (Miake-Lye et al., 2013, Hempel et al., 2013). Fall reduction ranges from 18% to 31% (Miake-Lye et al., 2013, Oliver et al., 2007, Hempel et al., 2013).

Study #1 used Lean techniques to improve fall risk assessment and intervention selection. Post fall investigations were standardized resulting in consistent, thorough reporting of details on every incident involving a fall. Total falls decreased but falls with serious injuries increased and further reduction of injury was desired.

Study #2 used Six Sigma tools to investigate root causes of falls. An intervention called Patient Partnering was developed to encourage patients to call for help and participate in preventing their own falls. There were no falls with serious injury during one 14 month stretch of this study. Six Sigma analyses revealed that an injury is less likely if the patient is “assisted” during a fall (receives help lowering to the floor). The number of assisted falls during 2012 with Lean was 12% (6 falls) while 19% of falls (14) were assisted during 2013 with the Patient Partnering intervention. However, Patient Partnering was difficult to sustain due to resistance from both nurses and patients. Nurses felt Patient Partnering required more time than typical care and patients had other priorities (e.g. new treatment plans, privacy and independence) that took precedence over fall prevention. Falls with injuries resumed as the intervention diminished.

Insights from Study #1 and #2 lead to the realization of a lack of understanding of the patient perspective of fall risk. Therefore the focus of Study #3 was formed around understanding the patient perspective.

Study #3 was a qualitative study to understand patient’s perception of fall risk. It was found that patients did not think they would fall and felt particularly safe and protected while in hospital. They found it difficult to get around with IV tubes and crowded spaces. They wanted information and assistance when they needed it, in the format they preferred (customized for each individual patient). This finding is a good fit with the concept of patient partnering which had the greatest influence on falls with injury. Patient partnering results in knowing the patient and understanding how they prefer communication and assistance. Incorporating this knowledge would help align fall prevention strategies to patient desires improving receipt of information and helping to close the gap between nurse and patient goals.

8.2.1 *Impact on Society*

Fall prevention interventions need to be designed for all the stakeholders (patients and staff). Patients think nurses will keep them safe and are willing to participate with fall prevention if they feel it is tailored to their needs. Until all perspectives are taken into account it is unlikely that there will be sustained and embedded improvements.

Nursing care paths are evolving with the changing landscape of financial and outcome pressures in the healthcare environment. The premise of combining QI and Human Factors Engineering (HFE) methodologies to efficiently address risks from many adverse events with simultaneous interventions will help to achieve better outcomes with fewer resources. The workload will be reduced if common themes can be addressed simultaneously even if the problems initially appear to be very different and complex.

The remainder of this chapter will highlight three themes that emerged from literature reviews and thesis studies (Systems Approach, Continuous Improvement & Complexity, and Critically Re-thinking Falls). The themes will meld together to bring focus to several sub-themes summarized in “feature boxes” throughout the chapter.

A. Systems Approach: Combining Methods and Balancing Components:

Methodology for falls & patient safety historically has been QI based with a focus on caregiver behavior. HFE is relatively new to healthcare and is well positioned to address the patient as part of the system with components such as environment, organization, and tasks, etc (Hignett et al., 2015 c).

- i. Combining and Modifying Methods: It is important to apply the appropriate method at the best time for each participant.
- ii. Systems Approach – Bundle vs. Single “Best” Intervention: Multiple solutions must be tailored to staff and patient needs. Fall risk has multiple causes and will require multiple improvement methodologies to determine a multi-faceted solution tailored to individual behaviours (both patient and staff).

- iii. **Balance:** It is critical to achieve a balance between often competing components for a system to achieve the goal of a productive, safe environment that allows for high quality of care for the patient.

B. Continuous Improvement and Complexity: HFE is needed to embrace the complexity of a non-linear system problem like falls. Organizational structure, environment, patient and caregiver differences in background along with goals and motivations must all be included in the system.

- i. **Multifaceted Issues:** Intrinsic and Extrinsic fall risk factors can constantly change for the patient and must be combined with staff awareness and ability to respond to the risk factors, all contribute to the complexity of fall prevention.
- ii. **Risk Perception:** To align differences in risk perception, the nurse's role is to listen and respect the patient voice to gain understanding of their perception of risk. Then it is critical to determine the best approach to educate and partner with the patient and communicate these findings to all members of the patient care team. The patient role is to make their voice known and convey the best educational process for their needs.
- iii. **Severity of Consequence:** If a patient's understanding of the possible severity of injury that can be caused by a fall is balanced with a caregiver's understanding of the patient's desire for autonomy (independence); it may help align patient and caregiver priorities.

C. Critically Re-Thinking Falls: Comparing falls in healthcare to other industries and other patient safety adverse events.

- i. **Analogous environments:** Insight can be gained by comparing analogous environments and situations to fall prevention.
- ii. **Analogous adverse events:** A comparison of falls and pressure ulcer prevention is discussed. Addressing several applicable safety issues at the same time improves efficiency.
- iii. **Limited resources create trade-offs:** Population health comparisons along with trade-offs between infection prevention concerns balanced against friction coefficients for fall prevention are discussed.

8.3 Systems Approach: Combining methods and balancing components

Fall prevention has been a focus of patient safety programs for many years. Various types of quality improvement methodologies have been tried yet falls still remain a risk during hospitalization. Chapter 3 introduced and compared QI methods of Lean and Six Sigma and HFE. This comparison found strengths and weaknesses of various methodologies. A combination of methods that utilize the strengths of each would allow flexibility to apply to many different divisions, cultures and situations.

Involving the patient in QI initiatives is relatively new in healthcare. A study in two Norwegian hospitals found patient involvement with QI to be limited. Existing tools to measure patient involvement and experience were undeveloped causing patient input to be underutilized without systematic involvement. Results of the study recognized the need for management and staff to involve patients in the improvement of healthcare quality (Wiig et al., 2013). HFE includes the human as a critical component of any system under evaluation. The mutual benefit of HFE and QI align to ensure patient input is included during safety improvements.

The advantages and disadvantages of using QI and HFE for fall prevention are illustrated in Table 8-1. The benefit of HFE is contribution of the system perspective that designs for human capability to achieve a solution unique to meet the needs of the patient and care-team.

	HFE	QI
Advantages for fall prevention	<ul style="list-style-type: none">• Changes environment/equipment or processes, (error proofing) does not rely on human to take “correct” action• Participation encourages compliant behaviours• Systems approach – considers environment, tasks, humans, organization, culture	<ul style="list-style-type: none">• Standardizes assessments and intervention strategies for all patients• Clarifies roles and expectations• Lean provides broad knowledge base to all staff• Six Sigma provides deep dive into narrow issues
Disadvantage for fall prevention	<ul style="list-style-type: none">• Time consuming to challenge standardized solutions, must understand individual human abilities	<ul style="list-style-type: none">• Reduces complexity of intervention selection to checklist that can discourage critical

	HFE	QI
	<p>and match to task – (one size does not fit all)</p> <ul style="list-style-type: none"> • Inadequate built environment may create hazards and limit solutions & financially feasible changes • Changes suggested late in design process can be costly 	<p>thinking</p> <ul style="list-style-type: none"> • Can create narrow improvement at expense of entire system improvement • Solutions can cause unforeseen impact in parts of system that were out of scope causing lack of sustainment

Table 8-1 Advantages and Disadvantages of HFE & QI in fall prevention.

8.3.1 Combining Methodology

If multiple improvement methodologies are not combined effectively they may actually compete for priority. Combined with the challenges of changes in healthcare this can create conflicting goals and priorities. A study by McQuillan et al., 2014 implemented a human factors approach to develop a multi-disciplinary handover protocol to improve communication between shift workers. Handovers often did not start on time due to a requirement of the entire team to be present at the same time. The protocol was modified using a Plan-Do-Study-Act improvement cycle. Shifts were staggered so handover communication could start on time but then was perceived as taking too much time. In complex systems like healthcare, trade-offs in initiatives are often required. Numerous initiatives and issues are also overwhelming to address simultaneously. This was evident in Study #2 where the patient partnering intervention was perceived by the nurses as taking time away from other nursing activities.

Combining methodologies to use the strengths of each as they are needed throughout a project is the most ideal approach in preventing falls (advantages are shown in Table 8-1). Study #1 showed Lean methods provided a standard approach to risk assessment and identification of interventions. It was also critical in establishing a standard method for post fall investigation and reporting results. This created an accurate baseline to provide data for the Six Sigma process. The detailed analysis during Study #2 allowed the team to identify the most critical factors of unassisted falls and toileting so the intervention of Patient Partnering could emerge.

Involvement of workers and management has been shown to improve participation and decrease risk factors resulting in moderate success to reduce musculoskeletal

disorders (Rivilis et al., 2008). Huang et al., (2015) found that a participatory program involving education of patients was effective in increasing knowledge about falls which in turn increases awareness of the potential of falling. To expand on this study, culture may be ready to attempt a modified PE framework with patients. This method would go beyond the patient education component used by Huang to include the patient and the entire care-team to develop a customized fall prevention plan and interventions for appropriate patients.

Combining QI and HFE methodologies provides the most robust solutions. (Combining Methodologies)

A unique combination of Lean and Six Sigma tools were developed to predict potential failures of the Patient Partnering intervention. This innovative new tool combined the simplicity of an impact matrix with the ratings of severity, occurrence and detection from a “Failure Mode Effects Analysis” (FMEA) (see Chapter 5 for further discussion). This creative approach to an FMEA was presented during an American Society of Quality meeting held in St. Louis, Missouri in May, 2015. QI experts in attendance at the conference were supportive of this innovative combination of methodologies. Several attendees requested future collaboration to implement the new technique (Wolf, 2015a).

Patient centred care is a frequently used term that is complex with many meanings. This provides the ideal opportunity for HFE and QI to contribute to improvements under a patient centred care model. A study by Groene suggests that a patient centred approach for QI should include: the improvement of patients’ rights, health gains/outcomes, and contribution to organizational learning (Groene, 2011). Respect for patient rights includes privacy and consent, as well as explanation of procedures and risks to family. Improving health gains in a patient centred manner includes providing education to achieve better patient compliance, satisfaction and follow up care. Organizational learning is a common factor addressed in QI with focus on continually improving process and product development, innovation and education for staff and leadership levels. Patients can contribute to the quality of their care by providing non-clinical information but this is often not collected, recorded or shared

in a systematic way resulting in a lost opportunity. This agrees with findings from Study #3 that found patients had many suggestions and were very willing to express their denial of risk for falling. Patients were willing to learn if the information was discussed in a way suitable to them. For example, all patients wanted to talk about falls when they determined they were ready and start conversations to follow up as needed. Patients differed in their preferences for written information about falls, videos or brochures but all desired discussion along with any type of material.

8.3.2 *Systems Approach: Bundle vs. Single Best intervention*

The term continuous quality improvement indicates that the improvements are never complete and that the system must continually strive for improved ideas and outcomes. The ideal philosophy is to apply the appropriate components of each improvement methodology with a systems approach to solving the problem of falls. As much as feasible, this system should be based on a foundation that has designed out as much opportunity for error as possible with environment, equipment, tasks and processes that match human capabilities.

A Randomized Control Trial (RCT) where one individual intervention is controlled tested and found to be best for reducing falls is very difficult to achieve on a functioning hospital division and is not frequently found in literature. Support for a single “best” fall prevention intervention is inconclusive (Miake-Lye et al., 2013, Hempel et al., 2013). Very few randomized control studies have been completed that investigate a single intervention while holding other variables constant. Several studies have shown that multi-factorial interventions can be successful in reducing falls in hospitals (Cameron et al., 2010, Oliver et al., 2007, Oliver et al., 2010, Haslam, 2006, Miake-Lye et al., 2013). The traditional approach has been to implement as many interventions as possible in the hope that something will reduce the risk of falls. Study #1 revealed 38 different possible interventions that could be implemented for a patient. Even a patient at low risk for fall had basic precautions such as locking wheels on the bed and over-bed table, clearing pathways and placing call light and personal items within reach. It has been suggested that the focus should be on ensuring interventions that are available, are distributed to the specific patients that will realise the most benefit (Oliver et al., 2010). Multiple faceted solutions must be tailored to individual behaviours (both patient and staff).

Environmental and organizational solutions should always be considered along with behavioural interventions making a systems approach essential.

*Fall risk has multiple, non-linear causes that require multiple methodologies applied with a systems approach.
(Systems Approach / Nonlinear)*

8.3.3 Balancing System Components

There are numerous components when considering the system of fall prevention. The science of HFE is a balance of psychology and engineering that is dedicated to consider all components in order to design a system that achieves productivity and safety for humans. When HFE is involved in healthcare; one goal is to consider the physical and mental workloads for staff while also achieving the goal of providing safe and high quality care for the patients (Russ et al., 2013). Components that must be balanced within a fall prevention system can include: environment vs. behaviour, fall risk vs. autonomy/independence, nurse goals vs. patient goals, and policy requirements vs. time constraints.

Since there are many components beyond the control of the patient and staff it is important to focus on designing a system that tries to balance all components as much as possible. HFE focuses on process, technology, organization or environmental changes that will achieve the desired behaviour changes instead of relying on training to change human limitations (Russ et al., 2013).

Achieve a balance between all components in the system that will achieve desired behaviors without reliance on training.

8.4 Continuous Improvement and Complexity

Managing dynamic complexity with an interdisciplinary system solution is critical in the healthcare environment. Sustaining system change with constantly changing and

often competing priorities is difficult (McQuillan et al., 2014). The more complex a process the more risk is inherent in the outcome (Pronovost and Bo-Linn, 2012). Fall prevention is a multi-faceted, non-linear complex issue. One dimension that makes the issue of falls so complex is that the patient is a critical component in the system. A patient adds more dimensions than is typically encountered in other environments.

8.4.1 Intrinsic/Extrinsic factors

Falls are multifaceted and complex as risks can arise from extrinsic (environmental based) and intrinsic (person based) factors and be influenced by individual behaviour (patient and caregiver) as well as the organization (policy and procedure) (Haslam & Stubbs, 2006: pp. 138-139).

Possible contributing causes of falls can include (Haslam, 2006):

- Foot to floor interface – types and condition of flooring and footwear (friction coefficients) – typically varies between patient and caregiver
- Personal factors – must consider both patient and caregiver in healthcare, knowledge, personal experiences, background and history
- System of work – activity at time of fall, load carried or pushed
- Environmental factors – lighting, glare, time of day

Multiple factors may contribute to one specific fall and it is critical to conduct a thorough and unbiased accident investigation (Lehane and Stubbs, 2001). Falls in the healthcare environment are especially concerning because many of the hazards are unavoidable. Medications that are essential for clinical treatment may also cause mental and physical impairment with weakness and altered status.

*Fall prevention efforts in healthcare are complex, multi-faceted and must include patient and care-team.
(Falls are Complex / Multi-faceted)*

The behaviour of the caregiver and patient can also be contributing factors to fall risk (Haslam, 2006). Lack of attention to maintaining clear pathways, carrying

objects or pushing medical equipment while walking can create hazards. Study #3 highlighted how common it is for patients to move around while pushing an IV pole. IV poles were cited as the most common type of equipment involved in injurious falls in a seven year investigation of falls comparing patients with and without cancer (Capone et al., 2013).

Fall risk in healthcare has additional risk factors due to the complexity of combining a caregiver's perception of risk with a very sick patient and rapidly changing intrinsic conditions. Study #3 revealed how critical it was to get information to patients at the right time in the way they wanted to hear it. Patients have useful ideas if caregivers take the time to listen and communicate these ideas with other staff members. Patients want the type of help they want when they want it. They want customized interventions tailored to their specific needs.

Another example of complexity centres on call lights. A patient has one button to ask for help for all issues. Reasons for using call lights vary from pain medication, personal and bathroom assistance and IV pump alarms (Tzeng, 2011). A survey by Tzeng (2011) of 122 patients revealed that 50% of the patients did not perceive that using the call light mattered to their safety. Even perception of call light response times vary from patient to care-team. Eighty percent of patients felt that someone answered the call light in an average of three to four minutes with the remaining 20% estimating response of four to six minutes or longer. When patients were asked their opinion about how soon a nurse should respond to their call light they said two minutes and 30 seconds. The study also found that 42% of the patients had pushed the call light by accident without intention to ask for the nurse. Investigation into redesign of the call light could provide patients a way to communicate priority of the reason for calling as well as preventing accidental activation.

Although collaboration between disciplines such as engineering and inpatient healthcare have been successful in some fields and situations, the practice is rare and often does not include the patient perspective (Pronovost and Bo-Linn, 2012). If the patient perspective is known, it is typically not communicated across all disciplines (Groene, 2011). Study #3 illustrated that the patient perspective must be incorporated into an intervention to prevent falls. Most patients do not think they are

at fall risk and feel they are capable of identifying if their risk increases during their hospital stay.

8.4.2 Risk perception

A study by MacLeod and Stadnyk (2015) used a similar methodology as Study #3 with qualitative semi-structured interview and grounded theory for analysis; however the focus was on the perception of health practitioners on risk of elderly adults living in the community. They found that risk was different for each individual and was defined and evaluated according to how it was perceived. Risk can only be perceived when it can be visualised then named and given meaning (MacLeod, 2015). Patients that are less educated about fall risk and do not get involved in a prevention plan may need the most understanding from a caregiver (Groene, 2011). As discovered in Study #3, patients do not recognize their risk for falling. If they don't recognise risk, they cannot be expected to engage in a prevention plan that requires them to call for help for toileting (a privacy intrusion) because they do not see any benefit.

*Know the patient: Listen and respect the patient's voice to
understand their perception of risk and how to best
communicate.*

(Patient Perception of Risk)

Both patients and practitioners use subjective judgement to determine risk levels based on personal values, beliefs and knowledge base (background/experience). MacLeod and Stadnyk (2015) found that a practitioner defined risk depending on potential impairment (i.e. cognitive), the environment (physical or social/economic), events surrounding the issue (i.e. fall) and the resulting consequence (potential harm). The similarities in findings of this study that investigated practitioners perception of risk and Study #3 is that both roles felt they were a good judge of risk themselves. All participants talked about "Knowing risk when I see it". Fall prevention self-efficacy was measured by (Huang et al., 2015) in oncology to understand a patient's belief in their ability to minimize their fall risk and found patients to have a moderate level of concern about falling. It was a common finding

that patients often see the risk in others and not in themselves. Because everyone has experienced a fall at some time and has not been injured; they just do not think an injury will happen to them. The opinion of the patient on their own ability to judge risk is given strong consideration by the nurses. Although listening to the patient voice is important, there may be some situations where the patient may not fully understand the risks and therefore not able to reliably assess their own risk (Wolf, 2015b). In both studies the definition of risk was very individualized and multi-faceted including numerous sources of risk and with varying severity of consequences. The good news is that with appropriate education, the understanding of risk perception can be altered. Huang found that with just a 20 minute education session, a patient's self-risk assessment was improved according to a test administered three days after the session. Appropriate health education is a useful strategy (Huang et al., 2015) that can be combined with Patient Partnering to ensure the message is conveyed according to patient needs and reinforced for sustainment (Wolf et al., 2014).

8.4.3 Severity of Consequence & Balance of Safety vs. Autonomy & Priorities

Severity of consequence is an important factor that may be the key to bringing practitioners and patients in alignment of risk perception. For example, falls are considered minor in risk because they may not result in a catastrophic injury in comparison to the situation where a patient is on narcotics and smokes at night with potential risk of fire (MacLeod, 2015). With this type of comparison it's difficult to proactively escalate the risk level of falls unless a severe injury has occurred. This may be perceived as "scare tactics" but patients are completely unaware of what can happen if they do fall. Practitioners must educate patients (in a meaningful way) on the potential injury that can occur if they do fall. People are willing to receive advice if it is tailored to their expectations and helps them maintain the independence they desire (Haslam, 2006, Wolf, 2015b). An alternative tactic suggested by MacLeod is a balanced approach to support safety and autonomy. The goal is to strive for a neutral definition of risk and "living at risk". There are positive consequences of risk (MacLeod, 2015). If a patient doesn't get out of bed there is no risk of falling however there are several health benefits of mobility. Focus should be on how to maintain independence and autonomy balanced with appropriate level of safety (Haslam, 2006). If practitioners and patients understand potential severity of risks

and benefits from activity they can work together to achieve a balance and collaborate on a mutually beneficial fall prevention plan.

Achieving a balance between patient understanding of injury risk and care-team understanding of patient autonomy (independence) will help to align priorities for a mutual partnership. (Balanced Understanding)

8.5 Critically Re-thinking Falls

Insight can be gained by comparing analogous environments and situations to fall prevention. When selecting an appropriate comparison it is important to understand the similarities and differences between the conditions (Kaissi, 2012). It is an advantage when a few major components are similar. For example some work was done to gain insight for health care by analysing work processes performed by a pit crew on a race track. Both environments are high stress and require quick responses that can result in life and death consequences. However it is important to recognize critical differences as well. The pit crew is a “closed” environment where access is limited to members of the crew that are experts and fully aware of expectations. Everyone has a clear understanding of purpose, mission with roles and responsibilities and feedback on progress is transparent. Healthcare involves the public where patients and families can have different expectations or motives. It is a constantly changing, dynamic, unexpected environment. Despite these differences some benefits can be realized. For example pre-packaged kits have been created that can be used to quickly treat common situations and crash carts have been assembled with all equipment that might be needed in an emergency. Standardizing some processes, implementing checklists, and optimizing communication can improve handoffs in healthcare (Catchpole et al., 2007).

8.5.1 Comparison to Non-healthcare Industries

One environment that may be appropriate for comparison is the public transportation industry. Similar to healthcare there are at least two humans that must cooperate to achieve a common goal. If you consider that once a passenger has a ticket and is on

board a bus or train, it is analogous to a patient being admitted to the hospital and the driver being compared to the caregiver. The public transportation industry has passengers that are temporary with variable “lengths of stay” and drivers to help them achieve their goal. Both customers (passenger and patient) are in a temporary, unfamiliar environment with the goal of ending up somewhere else. Preventive measures are taken to keep the public from falling such as signs to “Mind the gap or watch your step.” It takes a partnership between a passenger’s cooperation to stay seated and the driver’s awareness to proceed after all passengers are safely seated. Like patients, passengers may not have an understanding of their risk for falling, but all passengers and drivers have to collaborate to get to the next location safely.

*Care-team and patient with possible conflicting goals must
be accounted for in a system that considers fall prevention.
(Conflicting Goals)*

Comparison with the transportation industry has limitations in that a person entering public transport is not typically altered by medication or illness and therefore making passengers a better assessor of their own risk with a foundation of familiarity. Passengers will not typically have the health complications and changes that patients have in the hospital. A big difference in the hospital environment is that a patient is not used to experiencing the symptoms of the illness that they have or the medication being used to treat it or any alterations from the treatment of the illness such as being hooked up to machines. Patients can unknowingly behave in a risky manner without realizing the potential danger.

Another difference in healthcare is that patients and caregivers may have conflicting goals. Other environments that deal with human variation do not typically have to address human behaviour that can be counteractive or even sabotage the prevention intervention. For example in the transportation industry, humans waiting in a queue line and finding their seat will behave in a fairly predictable manner in which they think will help to achieve their goal. On the other hand, humans have an innate disposition to be independent and hesitate to ask for help with intimate activities

such as toileting. This will cause them to attempt to get to the bathroom without calling for assistance, not realizing they are placing themselves at risk.

If caregivers make patients feel they are too busy to come when they call for help the patient will hesitate to call and try to get up without help, since autonomy is what they desire anyway. The analogy of a person waiting on hold to talk with someone on the telephone may provide further understanding of human impatience. According to a survey by AT&T, the average business call is put on hold for 45-60 seconds. Sixty percent of callers placed on hold will hang up before getting a response. A study by North American Telecom showed that 99% of callers will hang up within 40 seconds of being put on hold. If callers hear music, they will hold for 30 seconds longer. If they hear commercial messages they will hold up to 3 minutes longer (OnHold, 2015). If callers think one minute is too long for a response, imagine how long the wait time seems to a patient that is calling for help with an urgent need to go to the bathroom. Although a three minute response may comply with hospital policy and seem fast to the nurse that has to run into the room from a few hundred feet away at the nurse station, it can be perceived as a long time by the patient depending on the urgency of their request. Certainly there needs to be an immediate verbal response to every call light so the patient knows someone is actively responding. Further improvements could be made with messages or ongoing message updates if the patient is required to wait more than a few seconds.

The waiting comparison also applies to the transportation analogy. An interesting perspective can be explored when examining human behaviour while waiting for a train to cross after the barriers have come down over the road. In the UK when an automated barrier lowers the train is expected to arrive between 27 and 75 seconds. After the train arrives the barrier is lifted within four to ten seconds (Regulation, December, 2011). Acceptable time for response can vary depending on the person and situation, but humans typically expect some type of response or feedback within one to five seconds and can detect a delay in less than one second (OnHold, 2015, Nielsen, 1993). Deadly consequences can occur when a car tries to go around a barrier, yet accidents like this occur every year.

Another example of human wait time is computer response time. After a mouse click on the computer, the user will expect some type of response in only 0.1

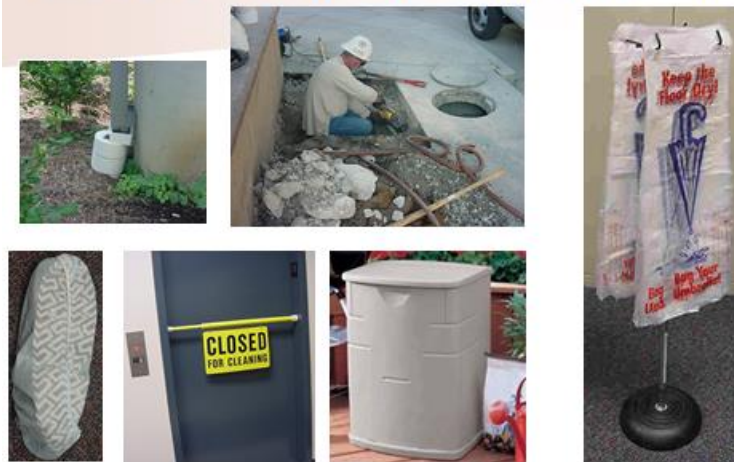
seconds. At this time some type of highlighting or feedback to the request should be received or the next reaction could begin. If the computer takes between 0.2 – 1.0 seconds the user will perceive an interruption in the flow of the task. If response takes more than 10 seconds the user will lose attention to the task and a percent completion prompt will be needed with an exit option. The user will have to reorient to the original task and should be allowed to come back at their convenience (Nielsen, 1993). This is a concern when a nurse has to log in and toggle between computer systems to get patient information from various sources that are not linked to communicate information. This causes interruptions and lapses in attention opening an opportunity for error.

Understanding prompts used by computer programmers can be used to decrease perceived wait time for a patient that has used a call light. Some type of indication that the button has been activated needs to occur in less than one second. Next there needs to be some type of response between one and ten seconds that someone has heard their request. Patients need to be updated periodically with an estimate of response time or update on progress on the requested response. There is a shortage of research on the most appropriate messaging and timing that patients need after using the call light to prevent them from getting out of bed without assistance. Nurses need to remember that perceived time goes slowly for the patient that may have an urgent need to use the bathroom. Expectations can be communicated before the call light is needed so patients will know what to expect with sequence and timing of responses. Partnering with the patient with their needs during regular rounding can also be included in the call light discussion to improve understanding of toileting needs.

8.5.2 Employee Fall Prevention Programs and Environmental Interventions

Much can be learned from fall prevention programs implemented outside of the patient care areas. The consideration of changing flooring and environmental factors seems to be a more common consideration in employee safety than it is for patient safety (Bell, 2010). One solution is to get safety and HFE more involved with construction projects so environmental solutions can be “engineered” into the design of health care facilities (Figure 8-1).

Staff Fall Prevention: Design Approach



Staff Fall Prevention: Design Approach



Figure 8-1 Environmental design solutions from employee safety programs

In addition to environmental considerations, worker behaviour, organisational policies and personal protective equipment are considered as part of a comprehensive workers' compensation program. This systems approach encompasses numerous components that impact the worker. The combination of these components have proven be very successful in decreasing worker slips, trips and falls (Bell et al., 2013, Bell et al., 2008).

Influencing behaviour includes efforts to increase worker awareness of their fall risk. A slip, trip and fall prevention program for employees at BJC HealthCare included a telephone hotline that was established for employees to report potentially dangerous walk areas or other sites of impending injury. Other initiatives included:

health fairs with fall prevention information, tips posted on employee paychecks, informational articles printed in employee newspapers and signs posted to educate and promote employee awareness, ownership and participation. An example of personal protective equipment involved a study of anti-slip shoes. After analyzing what type of shoe provided the best traction for workers on a typical hospital flooring material, the safest shoe construction features were made known to employees so that those safer types could be selected by employees (Bell, 2010).

Some interventions had a benefit for both employees and patients. Floor cleaning products and processes were optimized to prevent slips (Bell et al., 2008). Plastic umbrella sleeves were made available at hospital doorways to keep drips from forming slippery surfaces for both visitors and employees (Bell, 2010).

Another environmental intervention involved a grease bin that was located outside the building where housekeepers empty the trash. The bin faced the walkway so if a spill occurred as grease was poured it created a dangerously slippery surface on the primary pathway. The simple and inexpensive solution was to turn the grease bin so that the fill-side faced away from the pavement. A sign was posted asking employees to soak up their spills as completely as possible and notify housekeeping if further cleaning was required. Special absorbent pads hung from the wall nearby for easy clean up (Bell et al., 2008, Bell, 2010)

This theme of encouraging safe behaviour from the employees is similar to the patient partnering concept where it takes cooperation from everyone to achieve optimal safety. It also takes continued effort and ingenuity to sustain a fall prevention program. The environmental component was important to set a foundation of the safest environment possible to protect workers from unavoidable stressors such as snow/ice and wet floors.

Sustaining fall prevention programs takes continuous effort, ingenuity and creativity. (Continuous Effort)

8.5.3 *Comparison of falls and other never events*

Comparing falls to other patient safety adverse events establishes further insight with complexity. A Lean project similar to Study #1 was conducted in an Intensive Care Unit (ICU) to prevent pressure ulcers (PrU) with the Thesis Author as facilitator. A PrU is a breakdown of the skin causing a red irritated spot or an open sore in a more severe case. Patients in the ICU setting are especially vulnerable to acquiring a PrU because of their lack of mobility and equipment that must be in contact with the skin. Just like in Study #1, a three day Rapid Improvement Event was conducted and produced standard work for identifying risk, implementing interventions and investigation strategies after a PrU was detected. After all staff were trained on the standard work process the ICU unit achieved a 31% decrease in pressure ulcers from the baseline measure to yield a statistically significant (p value = 0.04) improvement. An improvement of 25% over baseline has sustained since the RIE in 2010 that was conducted at Barnes-Jewish Hospital (Wolf, 2010).

Why was Lean methodology so successful with pressure ulcers but not enough to solve the problems of falls? The risk factors of PrU are less numerous and complex than those of falls. Some insights into the differences between interventions for falls verses pressure ulcers include:

- There are a larger number of risk factors for falls than pressure ulcers (PrU).
- Fall risk factors are more dynamic than PrUs – a patient can go from low to high fall risk in minutes (so more frequent reassessment is needed).
- Predicting risk of PrU is less complex than predicting risk of falls. All patients in critical care are considered to be high risk for PrU.
- Risk factors for PrUs are more predictable (prolonged skin pressure in one area, lack of proper nutrition, damp skin conditions, and decreased oxygen perfusion to skin).
- Fall prevention strategies are more subjective and consequently appear to be less straightforward. A simple PrU worksheet identifies risk factors and incorporates intervention algorithm into a single page. For example if patient is immobile, reposition frequently and ensure skin is clean and dry with no compression.
- Interventions for falls must be tailored to each patient and are more varied than PrU. It is difficult to bundle the interventions like was possible for PrU (such as the equipment cart with “dry skin spray” and pillows/wedges to support new patient positions used during hourly turning).

- The patient's role in preventing pressure ulcers is passive meaning they are not required to assist in decreasing risk during hospitalization while caregivers are responsible for turning them frequently. Patients must have an active role in decreasing fall risk.
- Fall interventions require critical thinking to connect all assessment factors and select the most appropriate combination.

Addressing more than one applicable safety issue at the same time would improve efficiency. For example, a risk reduction activity for pressure ulcers (skin check and mobilization) could be accomplished simultaneously while a nurse assists the patient to the bathroom. Pulmonary hygiene can also be achieved during mobilization making the patient cough. Different types of risks could be bundled together so common interventions could be addressed simultaneously to reduce the workload of implementation (Miake-Lye et al., 2013). This can also be beneficial to patient healing. Activities such as administering medication, taking vital signs and feeding can be performed at the same time allowing longer periods of uninterrupted sleep thus reducing stimulation for brain injury patients.

“Harms are interdependent not independent” (Pronovost and Bo-Linn, 2012). It is common that a patient with one type of harm creates more risk for experiencing another type of harm. QI projects can have a narrow scope that can create a “silo” or separate solution that may solve one issue but create a problem in another area. Many communication patterns and processes exist in silos causing rework between disciplines. Nurses may know something about a patient and pass it on to the nurse on the next shift but not to the physician or physical therapist. This can cause different disciplines to ask the patient the same question causing duplicate work for staff and irritation for patients giving the impression of lack of coordination of care. Addressing several patient safety issues at the same time that are applicable to one patient improves efficiency. (van Gaal et al., 2011, Wolf et al., 2014)

*Addressing several patient safety issues at the same time
that are applicable to one patient improves efficiency.
(Address Multiple Risks Simultaneously)*

One drawback from combining risk factors to be resolved by the same intervention is that the overall risk factor can become too general and may yield several types of long term complex interventions. For example, an intervention that would improve teamwork or communication has the potential to improve falls, medication errors and pressure ulcers. However, the topic of communication is general and can be difficult to achieve; requiring process and computer changes and time consuming design changes or education (Wong et al., 2015). This was experienced during Study #2 when the Six Sigma process took more than a year to complete analysis before the patient partnering intervention could be implemented. The project took so long that 43% of the staff had changed, all original management leaders were gone and only one original team member remained on the project.

8.5.4 Conflicting Benefits and Limited Resources Create Trade-offs

Hospitals, like any other business with limited resources must carefully weigh numerous trade-offs when considering where to best spend time and money. Although a fall with serious injury can be catastrophic to patient and family and even result in death, these incidents are rare occurrences. Some environmental interventions such as impact absorbing subflooring are very expensive and cost justification for return on investment evaluations can be difficult.

This is a similar argument with population health which involves health outcomes for an entire group of people. Systematic methodology is used to develop measurement methods to select the most appropriate and useful process for improving the health of the entire population (Stoto, 2014). Epidemiologists use statistics to determine what initiatives and programs work best for certain populations. They are trying to find a balance between outcome measures and financial incentives. They attempt to determine if certain preventive procedures (like vaccinations or mammograms) provide a financially feasible return on investment for the population. One individual can attest that a procedure (such as an early mammogram) resulted in a lifesaving discovery in their diagnosis. However as a diagnosis procedure for the entire population it just may not be economically feasible. Organizations such as National Institute for Clinical Excellence (NICE), National Institute of Occupational Safety and Health (NIOSH), Joint Commission Centre for Transforming Healthcare (CTH) and National Occupational Research

Agenda (NORA) conduct research and compile evidence from studies and evidence based practice to help make decisions about treatments and interventions that can be recommended when balancing cost and evidence for improvement (Chalkidou, 2009).

Financial, ethical and preventive trade-off decisions are especially difficult in complex issues like fall prevention. Trade-off decisions are often needed within one specific type of intervention. When selecting the “best” type of flooring there can be conflicting requirements from different disciplines. Rough, textured flooring may be recommended for the best friction coefficient under wet floor conditions to prevent patients from slipping. The same texture can create a problem for housekeeping to clean and consequently create infection control problems that must be considered. Proper cleaning and maintenance regimes are critical components of flooring decisions (Di Pilla and Di Pilla, 2010).

Interventions may have conflicting benefits and compete for limited resources; demanding difficult trade-offs. (Limited Resources)

Fall prevention recommendations can be costly in terms of staff time and financial costs so it is important to prove that the gains are worth the investment. Falls are the most frequently reported adverse event in the adult inpatient setting ranging from 0.86 to 9.2; with geriatric areas as high as 10.7 average rate of hospital falls per 1,000 patient bed days (Sands et al., 2010). The National Health Service of the United Kingdom reports an average fall rate of 4.8 falls/1,000 patient days nationwide (Currie, 2008). Most falls seem to occur at bedside or bathroom (Hignett et al., 2013). Due to the possible underreporting of self-reported incidents, injury rate would be the preferred metric to determine success of fall prevention interventions (Currie, 2008). Approximately 30% of inpatient falls result in an injury (Drahota et al., 2007) with four to six percent of those resulting in serious injury (Hitcho et al., 2004). Patients that fall can incur physical and psychological effects and a longer stay in the hospital (Ulrich et al., 2008). Falls create a substantial financial burden on healthcare resources in terms of cost and additional care (Zacker

and Shea, 1998). It is also important to be sure that the investment in fall prevention will not adversely impact other potential adverse outcomes with limited resources.

Healthcare often relies too heavily on education for an intervention. Most education programs are targeted at healthcare provider behaviour and do not consider or involve the patient (Hempel et al., 2013).

A systems approach must include all disciplines involved in fall prevention. Caregivers must recognize and value the contributions that patients can make to improve quality and prevent falls (Wiig et al., 2013). Compliance with interventions that are customized to a patient's fall risk factors is essential for both staff and patient (hence accountability is critical for success). (van der Helm et al., 2006). A lack of accountability can lead to missed preventive opportunities (Weinberg et al., 2011).

8.6 Models

Just as the topic of falls is complex and multi-faceted, attempts to model these concepts are equally complex. There are numerous models in publications that attempt to model systems thinking and fall prevention (Holden et al., 2013, Haslam, 2006, Hignett, 2013a, Hignett, 2013b). Several were developed and considered during the progression of each study of this research and contributed to the subthemes discussed earlier in this chapter (explained in the feature boxes throughout this chapter). The final model for this research emerged by considering these subthemes as they are categorized in Table 8-2 and where cross over concepts occur.

Sub-themes (described in feature boxes)		Constructs of Theoretical Model		
		Systems Approach: Combining and Balancing	Continuous Improvement: Complexity	Critically Re-thinking falls
a.	Combine methodologies	X	X	
b.	System approach (not linear)	X	X	X
c.	Falls are complex, multi-faceted		X	X
d.	Knowing the patient's perception of risk	X	X	
e.	Balance of patient's understanding of risk and caregiver's understanding of autonomy		X	

Sub-themes (described in feature boxes)		Constructs of Theoretical Model		
		Systems Approach: Combining and Balancing	Continuous Improvement: Complexity	Critically Re-thinking falls
f.	Achieve balance between all components	X	X	X
g.	Caregiver and patient conflicting goals		X	X
h.	Sustainment requires continuous effort and ingenuity		X	X
i.	Address multiple risks simultaneously		X	X
j.	Limited resources with conflicting benefits & difficult trade-offs	X	X	X

Table 8-2 Cross over table of sub theme topics

The number of subthemes that cross over to the three categories in this chapter is another illustration of how difficult it is to design interventions to prevent patient falls. It is interesting to note that every subtheme can be linked to complexity.

The model in Figure 8-2 was developed by considering the categories and subthemes in Table 8-2. The model centers around a board balancing on a fulcrum like a seesaw on a child's playground. The components on top of the board represent issues to be considered in a systems approach to fall prevention (e.g. staff, patient, intrinsic and extrinsic factors, organization, environment, behavior and medication). The number of relevant components in the system can vary and each individual component is constantly changing. This represents the complexity of the topic of falls. The pivot point or fulcrum is represented by the Yin-Yang symbol because it is responsible for bringing balance to the system. It is also an appropriate symbol because it is round indicating how unstable and changing the balance can be. Continuous improvement is needed to keep moving the fulcrum to keep balance as the components move and change. The fulcrum must be agile to respond quickly to the constantly changing components of the system. In order to determine the correct response to bring balance, the situation needs ongoing critical evaluation. This includes critical thinking of interactions between all components and understanding the best response to bring balance to the system.

This model reveals how important it is to make each component as stable and optimal as possible. For example the environmental component could be designed to

reduce fall risk with shock absorbing subfloors, no thresholds, optimal layout, no sharp edges, and adequate storage to reduce clutter. The behavioral component still requires staff and patients to store items properly to prevent creating a trip hazard. A continuous improvement response (that would move the fulcrum to balance the lack of environmental error proofing) would be to create a culture where hospital staff looks for clutter each time anyone enters a patient's room.

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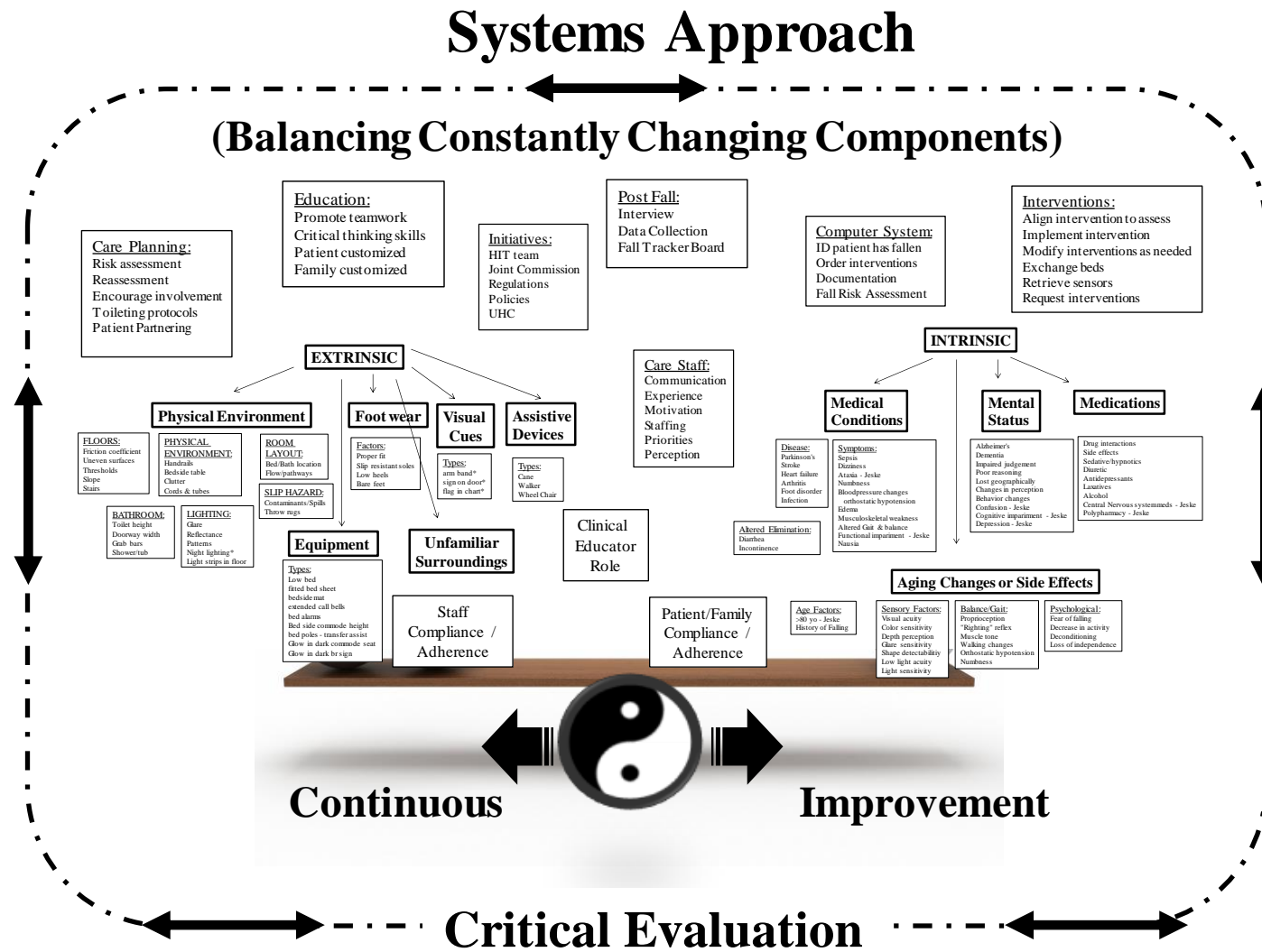


Figure 8-2 Model of Systems Approach Balances Components with Continuous Improvement Driven by Critical Evaluation

There are some recent examples of QI studies that have successfully been applied to fall prevention. A study conducted at the Hospital of Urban Pennsylvania used Six Sigma methodology to achieve a patient centered approach to fall prevention. They followed the DMAIC process to develop an intervention of proactive rounding. Toileting was found to be the most common reason for falls. The proactive rounding tool enabled the team to evaluate the unique needs of high risk patients. This study showed that with some adaption the QI process could be successfully applied to decrease fall rates by 27% (Christopher et al., 2014). Another example of a study that used patient participation involved education on fall risk to improve patient knowledge about fall safety. Education increased awareness of fall risk and promoted patient safety (Huang et al., 2015).

There are other equally complex issues in healthcare that must be addressed like readmission rates for chronically ill patients. A readmission rate for chronically ill patients is a metric payors are currently prioritizing. Recent focus has turned to high reliability organizations (HRO) like the nuclear power industry and aviation. These are organizations that have achieved greater than Six Sigma level defects by becoming diligent about identifying possible errors and defects before they cause injury (Perrow, 1999).

8.7 Limitations of study

Due to the nature of field research, there were some limitations to this study. All three studies were conducted with oncology patients. The average age of oncology patients tend to be young (56 years old in Study #3 and 47.8 in a participatory program conducted by (Huang et al., 2015). This gives the appearance that falls in oncology patients may be related to factors other than age (Huang et al., 2015). The limitation of field research is also the advantage of learning to conduct applied research in a fully functional hospital environment.

Study #3 involved patient interviews and did not include interviews with the care-team. This made it impossible to analyze the congruency between perceptions of the patient and caregiver. The disadvantage of this one sided approach was overcome by the advantage of the depth of interview that provided a more complete understanding of the patient perspective.

Another limitation was that in order to achieve a coherent interview none of the participants had any cognitive impairment. Altered mental status is associated with risk for falling especially when combined with altered elimination issues (Miake-Lye et al., 2013). Only ten percent of participants were assessed as having an issue with altered elimination. None of the participants in these interviews experienced a fall during their stay. All patients were able to stand on their own. Almost all had IV poles which could explain the high number of comments around this type of equipment.

Rapidly changing patient conditions and short duration of hospital stay was a limitation throughout this research. Study #2 experienced high staff turnover in the Six Sigma team and Study #3 involved a one-time interview with patients so it was not possible to identify changes in perception over time.

Another limitation of Study #3 was the rating scale used to measure the patient's belief in risk of falling (a simple one to ten Likert scale). It would have been interesting to use the fall prevention self-efficacy score method used by Huang to understand patients' belief in their ability to minimize their fall risk. However, this study was unavailable at the time Study #3 was developed (Huang et al., 2015).

8.8 Strengths of study

This research provided a unique opportunity to apply various improvement methods to the same oncology division and to review the impact on patient fall trends for over five years. All research activities were performed in real world conditions under normal workloads and actual staffing levels.

Feedback from nurses and patients were collected in their authentic environment in real time. Although team members changed in each study, fall specialist leaders and the Thesis Author as facilitator were consistent investigators throughout this entire span of research.

Research of this magnitude involved staff from many disciplines such as physicians, nurses, technicians, physical therapists, pharmacists and executives. Their involvement included investigating root causes of falls, developing interventions and implementing improvements. The multidisciplinary team members gave ongoing feedback on success and failure of methodologies & interventions.

This body of research makes a unique contribution to the body of knowledge of fall prevention as well as provides an understanding of pros and cons of quality improvement methodologies.

9 CHAPTER 9 CONCLUSION

This chapter will conclude and summarize research from all three studies and briefly review the methods and implications and recommendations from this study.

Although it is not possible to prevent every fall, if a balance between a safe environmental design and awareness of safe behavior/culture can be achieved (e.g. assisted falls), the severity of injury resulting from the fall can be reduced. ☯

9.1 Background

In response to the ongoing problem of patient falls, the early intent of this research initiative was to create a patient room that would prevent injury if a fall occurred. The first milestone resulted in a white paper with a literature review that indicated a shock absorbing sub floor would reduce fractures during a fall. During a presentation of these findings to the BJC HealthCare advisory committee, they realized that financial and time barriers with environmental solutions would be insurmountable and rejected the proposal for environmental changes. As an alternative, BJC HealthCare was looking for help applying QI to change behaviors that contribute to falls. The committee guided research toward a focus on behavior changes using Lean and Six Sigma methodologies.

9.2 Restated Purpose and Aims of Research

This research has provided insight into the benefits and limitations of QI and HFE and their contributions to fall prevention. Two studies were conducted with different QI methods and a third study involved interviewing patients to gain an understanding of patient perceptions of fall prevention.

- Aim #1: Understand the advantages and disadvantages of QI methodologies:
 - The contributions of QI and HFE to fall prevention were investigated in three studies and results were discussed in Chapters 4, 5, 6, and 7.
 - Studies used different methodologies to develop and implement interventions with the goal of decreasing total falls and falls with injury (Chapter 4, 5 and 6).
 - Methodologies of HFE and QI were compared to understand their benefits and limitations (Chapter 8). A chart was compiled to

compare advantages and disadvantages of using HFE and QI for fall prevention (see Table 8-1),


- Aim #2: Develop innovative recommendations for fall prevention (see 5.3, 6.3.3, 8.3.2 and 8.3.3).
 - Interventions were investigated and assessed for success in preventing falls (Chapter 5, 6 and 8).
 - Insights of interventions that prevent falls and injury are discussed in Chapters 4, 5, 6 and 8.

9.3 Summary of Results

Study #1 showed that Lean methods made it possible to achieve a standardized approach to assess patients and assign interventions according to that assessment. It also showed the importance of a standard foundation to collect critical information in a consistent manner after a fall occurred. Visual success of the post fall investigations was evident in the display of Fall Tracker boards. Standardizing the process increased staff's awareness of fall prevention and was successful in reducing the total number of falls (Chapter 4).

Study #2 showed the Six Sigma methodology was helpful to realize that a customized approach was needed to address the falls with injury. This multi-factorial problem improved if patient and nurse partnered to develop a fall prevention plan that addresses mutually beneficial priorities. A success of 14 months with no falls resulting in serious injury was achieved and falls with injuries decreased if the patient was assisted during the fall (Chapter 5).

The total fall rate during the Six Sigma study was higher than during Lean because the first had more repeat fallers with some patients falling as many as five times. However, in this same comparison period, there were fewer falls with injury because more patients experienced an assisted fall.

Since interventions from Study #1 and #2 focused on behavior changes (both staff and patient), sustainment was a challenge. Environmental design and equipment selection must be better utilized to achieve more robust interventions to achieve the safest environment possible. Design solutions and behavior changes must balance to prevent injuries from falls. 

9.4 Conclusions

To conclude meaning from the discussion chapter (Chapter 8), this section highlights concepts from the nine feature boxes into the following three important areas: 1. Systems Approach (Combining Methods & Balancing Components), 2. Complexity and Continuous Improvement, and 3. Critically Rethinking Falls.

9.4.1 Systems Approach: Combining Methods & Balancing Components

The advantage of the Lean method was to put a standard processes in place to establish a consistent foundation for further analysis of fall prevention. This provided data for the Six Sigma method to systematically identify issues allowing the intervention of Patient Partnering to be developed. The benefit of this research spanning 5.5 years is that it allowed analysis of long term trends to reveal when innovative ideas were needed to boost compliance. Combining tools from Lean and Six Sigma developed flexible, new methods that can be efficiently applied as needed. This gave teams agile tools needed to solve problems that occur in constantly changing situations. HFE provided an understanding of the patient perception and gave voice to their lack of awareness of fall risk and showed that behavior changes can occur through patient partnering that is based on respectful and mutual understanding which will help to align priorities between patient and staff (see 8.3.1).

Key Observations: Combining Methods and Balancing Components:

- *Combining QI and HFE methodologies provides the most robust solutions.*
- *Understanding fall risk has multiple, non-linear causes requiring methodologies applied with a systems approach.*
- *Knowing the patient: Listening and understanding their perception of risk and how to best communicate.*
- *Achieving a balance between patient understanding of injury risk and care-team understanding of patient autonomy (independence) will help align priorities for a mutual partnership.*
- *Achieving a balance between all components in the system to achieve desired behaviors without reliance on training.*

HFE system considerations for fall prevention include: physical and mental capabilities, environmental, organizational, and behavioral (patient and care team) issues. Environmental solutions (such redesigning IV equipment and eliminating raised thresholds to reduce trip hazards) offer strong “error proof” preventions because they don’t rely on patient and nurse time or prioritization of behaviors (Chapter 3). Undoubtedly a safe environment should be the foundation of a fall prevention program. However, environmental changes that involve building configuration can be costly and beyond the control of process improvement teams. Environmental solutions like improving usability of call lights must be combined with behavioral compliance encouraged by patient/nurse partnering and organizational process/policies. Understanding human expectations of response to a request (like pressing the call light) is also a benefit of incorporating HFE into fall prevention since caregiver and administrative policy may not align with patient expectations. Environmental, technology, tasks, organizational and behavioral components must align and balance as a system to achieve success (see 8.3.3).

In a complex, changing environment, a balance must be achieved between all components of the system to achieve positive outcomes. This takes constant vigilance to critically understand the status of each component and the interactions.

It may require continued adjustment of interventions to abate risk factors that occur as components of the system shift and change to upset the balance (see 8.4.3).

9.4.2 Complexity and Continuous Improvement

There are many intrinsic and extrinsic aspects of fall risk that change dynamically and contribute to complexity. A unique finding from Study #3 was that patients do not recognize the difference between the risk of falling and the risk of injury as a result of a fall. This contributes to their low prioritization of falls (see 8.4). It is ironic that both patient and staff tend to put falls low on the priority list while it continues to be a critical factor in many Patient Safety and Quality agencies. The patient that is facing multiple cancer diagnoses and prioritizes living day to day does not have the capacity to think of falls as high priority; likewise nurses have competing tasks on their daily list which appear more important to the patient's immediate health and survival (see 8.4.2). This conflict in hierarchy also highlights the importance of multi-faceted interventions with safe design when possible and constant rejuvenation of behaviors to customize interventions and sustain momentum.

Key Observations: Complex Issues, Continuous Improvement:

- *Fall prevention efforts in healthcare are complex, multi-faceted and must include patient and care-team in the safest possible environment.*
- *Sustaining fall prevention programs takes continuous effort, ingenuity and creativity.*

9.4.3 Critically Re-thinking Falls

As demand for resources in healthcare continue to increase, it is important that interventions combine and be supported by technology. This will allow for tradeoffs to be made through critical thinking that considers both clinical and resource issues. Patient safety must begin thinking beyond one individual risk and develop interventions that will address problems with similar interventions in combination. For example, patient mobility, fall risk, patient handling and pressure ulcers have overlapping features in assessment and interventions. Combining effort could save

time for nurses if they were addressed simultaneously. As conditions continually change critical thinking brings the appropriate balance between the tradeoffs of system components to reduce injury from patient falls (see 8.5.4).

Key Observations: Critically Re-Thinking Falls

- *Addressing several patient safety issues at the same time improves efficiency. Understanding the intersection of the issues is critical.*
- *Interventions may have conflicting benefits and compete for limited resources; demanding difficult trade-offs.*
- *Care-teams and patients with possible conflicting goals must be accounted for in a system that considers fall prevention.*

9.4.4 Model of Systems Approach

The model shown in Figure 8-2 is described in detail in Discussion Chapter 8 (see section 8.6). The components on top of the seesaw represent numerous, constantly changing issues of the complex fall prevention system (patient, nurse, environment, tasks, organization, etc.). The Yin-Yang symbol represents the pivot point that must continually adjust to balance all system components. It requires critical evaluation about the status of each component and their interactions to understand which interventions will achieve the best balance at any point in time.

9.5 Recommendations

In considering all the theories, concepts and data that were reviewed, analysed and discussed, it is clear that a systems approach is needed for fall prevention (see 8.4.3). HFE is ideally suited for this challenge since it is a science that works to design systems that support performance and are resilient to errors (Russ et al., 2013). HFE expertise strives to achieve a process that will comply with human physical and mental capabilities (caregiver or staff) to achieve a safe, efficient environment that prevents harm. QI also commonly has a focus on process changes making the two disciplines a logical fit. After the most optimal system or process design has been achieved, training staff is beneficial to achieve the most efficient performance. This is where Lean can aid in consistent training messages (standard work) to teach the

best way to perform a task. It is difficult to sustain a behaviour change with a single training session. However, there are culture-change tools that are quite successful but usually require an extended period of time (Leape, 2007).

The following components should be considered as fall prevention programs are developed:

- **Environment:** A basic component of a fall prevention program is to design a safe environment for caregiver and patient (Leape, 2007). Changing the building environment or even equipment can be challenging in the healthcare environment. However, environmental engineering fixes must be considered when trying to reduce risk of injury (see 8.5.2). Occasionally there is an opportunity to participate in a new hospital floor design but more often it's just a face-lift improvement (new paint, not new floor plan layout). More obtainable opportunities can be found in equipment selection e.g. IV pole design, mobility devices and patient call light design (Chapter 8).
- **Organization (Chapter 8):** Sustained leadership support is critical (Study #2). Audits should be conducted to understand staff compliance and barriers to standard work. HFE can focus on organizational issues and work to change technology, tools or processes to redesign the system before considering behaviour modification (training).
- **Multi-disciplinary:** Programs are most successful if everyone is involved in developing the fall prevention program including the patient (Wolf et al., 2014). Fall program guidance should be provided by a multi-disciplinary team (Miake-Lye et al., 2013) (Chapter 5 and 8.4.3).
- **Culture:** The basic belief structure for falls must change so caregivers believe it is possible to achieve zero injuries from falls (Leape, 2007). Attitudes must change about falls so staff won't think falling is an inevitable part of a hospital stay (Miake-Lye et al., 2013) see 8.6 and 8.4.3 and 8.5.4). Front line staff must be engaged with getting to know the patient and using critical thinking to compile a customized intervention for each specific patient (Miake-Lye et al., 2013).
- **Behaviour:** We must achieve accountability for safe behaviour at all levels of the organization (see 8.3.2). Just as staff and patients must not be allowed to

deviate from infection prevention practices (Leape, 2007), similar behaviour must align to prevent falls (see Chapter 5 with Study #2).

- **Technology:** Electronic Medical Records (EMR) can compile systems information to encourage critical thinking. There is an opportunity to use technology to assist in compiling information needed by the care team to critically think through various issues to develop the safest plan. For example, the Preventable Harm report pulls information (lab values, vitals, cognitive and physical assessments) from the EMR and displays it in one location. Technology should be driven by clinical needs to provide critical, timely information as it is needed (Chapters 4 and 5).

9.6 Impact on society

Falls are a multi-faceted, complex problem that needs constant vigilance and continuous improvement to sustain patient safety. Patients feel safe in the hospital and perceive they are less likely to fall while the opposite can be true if weakness, confusion and/or altered elimination issues are experienced as a result of medication or procedures. If fall prevention interventions consider needs of patient and staff a safe hospital stay can be achieved. The cost of patient falls adds to the growing cost of healthcare. Efforts to minimize these costs benefit the patient, the hospital and society.

9.7 Future Research Recommendations

- Although some recent studies have successfully applied QI methods to fall prevention short term success (Christopher et al., 2014, DuPree et al., 2014), there is further opportunity for sustainment by exploring the alignment of perceptions of nurses, providers and patients. Possible topics of incongruity include: timely response to call lights, content of fall education and understanding of risk of injury from falling.
- Further research could help clarify which environmental interventions are most effective. For example the small sample size in Study #2 revealed that the number of injuries from falling from a low bed and a regular bed were equal. A weakness in this study was that the height of the low bed at the time of fall was not recorded. A future study of falls from bed that recorded height as part of the post fall investigation would be useful.

- As recommendations support more environmental improvements to reduce falls more research is needed on financial benefit. Design and construction budgets are based on cost benefit trade-offs making it difficult to justify expensive interventions to prevent very rare occurrences. Further analysis of complete costs of falls (with and without injury) would benefit return on investment decisions.

9.8 Closing Statement

Lean methods like Standard Work are useful to build a foundation of consistent processes. Some complex problems will need a deep dive provided by Six Sigma methods to discover causes that are difficult to visualize. HFE is needed to provide a system approach for complex, multifaceted problems. Patient perceptions revealed in Study #3 show that traditional approaches to fall prevention will always have limitations because they don't consider the patient's behavior. Interventions also need to integrate technology to compile risks as an aide to critical thinking. Improved environmental and equipment design is essential as a foundation to achieve a safe environment.

There is no "silver bullet" or "one-size fits all" solution that will prevent all falls. Leadership and multidisciplinary teams need to understand that fall prevention is not a one-time, quick intervention, but takes constant vigilance with consistent, reliable effort from patients and staff.

9.8.1 Key Message

Falls with injury are rare events with complex root causes that require agile solutions with constant revision to align with rapidly changing patient and staff. Reducing injuries from falls will take a balance between safe environment, conditions and interactions. Understanding fall risk through patient centered care is critical to achieve a culture that aligns the understanding of fall risk and the autonomy between organization, processes, tasks and behaviors from staff and patients.

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A. APPENDIX A: LIST OF ACRONYMS AND DEFINITIONS

Acronym	Name	Definition
AHRQ	Agency for Healthcare Research & Quality	U.S. government agency that functions as a part of the Department of Health & Human Services to support research to help improve the quality of health care
APN	Advanced Practice Nurse	A nurse who has a master's, post-masters, or doctoral degree in a nursing specialty (nurse practitioners, clinical nurse specialists, nurse anesthetists, or nurse midwives). APNs are often primary care providers and are at the forefront of providing preventative care to the public.
BJC	BJC Healthcare	A healthcare system with 13 hospitals and 25,000 employees in the St. Louis area in USA
BJH	Barnes-Jewish Hospital	A large academic medical center with 1,200 beds, over 9,000 employees located in St. Louis
CCE	Center for Clinical Excellence	A Corporate Department in BJC with epidemiologists and researchers focused on Patient Safety and Quality
CMS	Centers for Medicare and Medicaid Services	Agency within the US Department of Health & Human Services responsible for administration of several key federal health care programs (such as Medicare – federal insurance for seniors and Medicaid – federal needs-based program)
Division	Ward, Unit, hospital floor	An inpatient area of the hospital that cares patients 24 hours a day after they are admitted into the hospital.
DMAIC	Define-Measure-Analyze-Improve-Control	The five phases of Six Sigma process improvement methodology
EMR	Electronic Medical Record	Computerized medical record that includes orders and documentation from multiple disciplines.
Fall Expert	Eileen Costantinou	BJH fall expert with over 25 years devoted to fall prevention at BJH

Acronym	Name	Definition
Feature Box	Feature Box	Box format used in the Discussion Chapter to highlight and important insight.
FRA	Fall Risk Appraisal	A standardized screening tool used by the nurse to evaluate the fall risk of a patient resulting in a score that indicates low, moderate or high risk.
GUG	Get-up-and Go Test	A screening tool used to assess a patient's gait and physical stability
HAC	Hospital Acquired Conditions	An undesirable condition or situation that affects a patient that arose during a stay in a hospital or medical facility
HFE	Human Factors Engineering	Scientific understanding of human capabilities and limitations applied to the design of products and systems to achieve a productive, safe environment.
HIT team	High Impact Team	Teams developed by CCE to address never events in BJC such as pressure ulcers and falls with injury
ICU	Intensive Care Unit	Division of the hospital that takes care of the most critically ill patients (patient to nurse ration is usually 2:1 or 1:1 depending on severity of patient illness
Lean	Lean method of process improvement	method that requires employee engagement to solve problems by eliminating waste
LEAP	Linking Evaluation And Practice	A grid developed by CCE to help link patient assessment results to the most appropriate interventions
LTCCC	Long Term Care Coordinating Council	A council appointed to identify gaps and find solutions in long term care services targeting older adults and people with disabilities
MDI board	Managing for Daily Improvement board	A data transparency technique that posts information about falls as they occur in real time
NDNQI	National Database of Nursing Quality Indicators	A national nursing database in the USA that provides reporting of structure, process, and outcome indicators to evaluate nursing care at the unit level. Over 1100 facilities contribute to this growing database used to show patient quality indicators.

Acronym	Name	Definition
NQF	National Quality Forum	A nonprofit organization based in Washington, D.C. that is dedicated to improving the quality of health care in the United States. Their mission is to set goals for performance improvement, to endorse standards for measuring and reporting on performance and to promote educational and outreach programs.
PrU	Pressure Ulcers	A localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear
QI	Quality Improvement	A formal approach to the analysis of performance and systematic efforts to improve it.
RIE	Rapid Improvement Event	A Lean methodology for implementing rapid tests of change
SEIPS	Systems Engineering Initiative for Patient Safety	A Human Factors model of work developed by Pascale Carayon at University of Wisconsin, Madison
Six Sigma	Six Sigma	A performance improvement methodology that is a systematic, fact-based, data driven problem solving process that is comprised of 5 phases: DMAIC (Define, Measure, Analyze, Improve, Control)
SNF	Skilled Nursing Facility	Highest level of care available outside of a hospital providing custodial care such as feeding, bathing, dressing and assistance with mobility
SPMSQ	Short Portable Mental Status Questionnaire	A screening tool used to assess a patient's mental ability and confusion level
TJC	The Joint Commission	The Joint Commission is an independent, not-for-profit group in the United States that administers accreditation programs for hospitals and other healthcare-related organizations.
Thesis Advisor	Dr. Sue Hignett	
Thesis Author	Laurie Wolf	

B. APPENDIX B: SEARCH STRATEGIES FOR LITERATURE REVIEW

B.1.1 Quality Improvement for Fall Prevention

Ovid Medline

(exp Accidental Falls/ or Fall*.mp. or trip*.mp. or stumbl*.mp.) and (Pc.fs. or Prevent*.mp.) and ((quality adj1 improv*) or (quality adj1 safe*) or (quality adj1 indicat*) or (quality adj1 manage*) or (quality AND safe*) or (quality AND assess*) or (risk adj1 assess*) or (safe* adj1 manage*)).mp.

Embase

'falling'/exp OR 'falling' OR fall* OR trip* OR stumbl* AND ('prevention'/lnk OR prevent*) AND (quality NEAR/1 improv* OR quality NEAR/1 safe* OR quality NEAR/1 indicat* OR quality NEAR/1 manage* OR (quality AND safe*) OR (quality AND assess*) OR risk NEAR/1 assess* OR safe* NEAR/1 manage*)

Scopus

TITLE-ABS-KEY(Fall* OR trip* OR stumbl*) AND TITLE-ABS-KEY(Prevent*) AND TITLE-ABS-KEY ((quality W/1 improv*) or (quality W/1 safe*) or (quality W/1 indicat*) or (quality W/1 manage*) or (quality AND safe*) or (quality AND assess*) or (risk W/1 assess*) or (safe* W/1 manage*))

CINAHL

(MH "Accidental Falls" OR Fall* OR trip* OR stumbl*) AND (MW "PC" OR Prevent*) AND ((quality N1 improv*) or (quality N1 safe*) or (quality N1 indicat*) or (quality N1 manage*) or (quality AND safe*) or (quality AND assess*) or (risk N1 assess*) or (safe* N1 manage*))

B.1.2 Patient Adherence for Fall Prevention

Ovid Medline

(exp Accidental Falls/ OR Fall*.mp. OR trip*.mp. OR stumbl*.mp.) AND (pc.fs. OR Prevent*.mp.) AND (exp "Patient Acceptance of Health Care"/ OR (patient* adj1 nonadherence).mp. OR (inpatient* adj1 nonadherence).mp. OR (patient* adj1 cooperation).mp. OR (inpatient* adj1 cooperation).mp. OR (patient* adj1 compliance).mp. OR (inpatient* adj1 compliance).mp. OR (patient* adj1 adherence).mp. OR (inpatient* adj1 adherence).mp. OR (patient* adj1 noncompliance).mp. OR (inpatient* adj1 noncompliance).mp. OR (patient* adj1 non-compliance).mp. OR (inpatient* adj1 non-compliance).mp. OR (patient* adj1 accept*).mp. OR (inpatient* adj1 accept*).mp. OR (patient* adj1 satisf*).mp. OR (inpatient* adj1 satisf*).mp. OR (utilization adj3 health care).mp. OR (health care adj1 behavior*).mp. OR (Patient* adj1 Preference*).mp. OR (inPatient* adj1 Preference*).mp.)

Embase

'falling'/exp OR fall* OR trip* OR stumble* AND ('prevention'/lnk OR Prevent*) AND ('patient attitude'/exp OR patient* NEAR/1 nonadherence OR inpatient* NEAR/1 nonadherence OR patient* NEAR/1 cooperation OR inpatient* NEAR/1 cooperation OR patient* NEAR/1 compliance OR inpatient* NEAR/1 compliance OR patient* NEAR/1 adherence OR inpatient* NEAR/1 adherence OR patient* NEAR/1 noncompliance OR inpatient* NEAR/1 noncompliance OR patient* NEAR/1 non-compliance OR inpatient* NEAR/1 non-compliance OR patient* NEAR/1 accept* OR inpatient* NEAR/1 accept* OR patient* NEAR/1 satisf* OR inpatient* NEAR/1 satisf* OR utilization NEAR/3 'health care' OR Patient* NEAR/1 Preference* OR inPatient* NEAR/1 Preference*)

Scopus

TITLE-ABS-KEY(Fall* OR trip* OR stumbl*) AND TITLE-ABS-KEY(Prevent*) AND TITLE-ABS-KEY((patient* W/1 nonadherence) OR (patient* W/1 cooperation) OR (patient* W/1 compliance) OR (patient* W/1 adherence) OR (patient* W/1 noncompliance) OR (patient* W/1 non-compliance) OR (patient* W/1 accept*) OR (patient* W/1 satisf*) OR (utilization W/3 "health care") OR ("health care" W/1 behavior*) OR (Patient* W/1 Preference*))

CINAHL

(MH "Accidental Falls" OR Fall* OR trip* OR stumbl*) AND (MW "PC" OR Prevent*)
AND ((MH "Patient Compliance+" OR MH "Treatment Refusal" OR MH "Patient
Satisfaction" OR (patient* N1 nonadherence) OR (patient* N1 cooperation) OR (patient* N1
compliance) OR (patient* N1 adherence) OR (patient* N1 noncompliance) OR (patient* N1
non-compliance) OR (patient* N1 accept*) OR (patient* N1 satisf*) OR (utilization N3
"health care") OR ("health care" N1 behavior*) OR (Patient* N1 Preference*))

B.1.3 Participatory Ergonomics

Ovid Medline

(participat* and ergonom*).mp.

Embase

(participat* and ergonom*) OR 'ergonomics'/exp

Scopus

TITLE-ABS-KEY (participat* and ergonom*)

CINAHL

(participat* and ergonom*)

C. APPENDIX C: LITERATURE REVIEW ON QI FOR PATIENT FALLS

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VPr)	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusions/ Summary	Comments
An inpatient fall prevention initiative in a tertiary care hospital	Weinberg, J., Proske, D. Szerszen, A., Lefkovic, K. Cline, C. El-Sayegh, S. Jarrett, M. Weiserbs, K. F.	2011	Excel, similar proj, long term, pos result	Staten Island University Hospital, Staten Island, New York (714 beds) tertiary care	Baseline assessment of compliance to fall prevention strategies, implementing a program (tweaked bed alarm and post fall information gathering) sustained improvement 64% decrease in falls 54% decrease minor inj 64% decrease mod inj	Very similar project, Fall strategies: bed alarm, post fall huddle improvement, Monthly meetings for fall review - opportunity for critical thinking, role play to overcome pt resistance * change in meds reduced sleep aids to >65, diuretics at 6pm	yes, can safety awareness, accountability, critical thinking and staff empowerment decrease falls Program used monthly meeting for fall reviews - included night & weekend meetings for accountability	pre-assessment of existing program while collecting baseline data, Chi Square - SAS	pre-assessment showed: low priority for falls, superficial post fall investigations, lack of accountability for policy infractions, missed preventive opportunities * Program had strong impact on fostering culture change by establishing critical thinking safety awareness, collaboration and accountability 12m pre-intervention = 756 falls (3.2-3.7 rate)	* Ref #6 Inouye, S.K. Medicare non-payment for falls * Ref 11,17,32,33 do not show improvement * great table 1 to show falls, pt days & improvement * great Figure 1 show timeline with fall rate & interventions * Kanter's hypothesis: power and opportunity are primary determinants of employee behaviours, encourage self-responsibility for improving one's job *How did they hold managers and staff accountable?

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Effect of a multidisciplinary fall risk assessment on falls among neurology inpatients	Hunderfund, A. N. Sweeney, C. M. Mandrekar, J. N. Johnson, L. M. Britton, J. W.	2011	adeq, only dealt with FRA not interventions	Saint Marys Hospital in Rochester, MN - tertiary hospital, Neurology unit - Medicine units were control group	MD, Nurse and Hendrich FRA were compared and consensus reach if disagreements. 66%-70% pts found at risk, Interventions were not changed, fall rates improved from 5.69 to 4.12	Idea for MD involvement, get them to include assessment of risk (Y or N) as well as encouraging pt adherence to nurses recommended interventions it supports the THREAD idea (multi-discipline, multi-faceted)	yes does MD assessment in neurology pts reduce falls?, yes they got improvement but the MD participation in assessment may have influenced subsequent medical decisions	controlled pre-post quality improvement study Poisson distribution outcomes reported as proportions with 2-tailed Chi Square tests to compare proportions	Nurses and MD FRA were not significantly different Approach must be multidisciplinary and specifically target individual risk factors (THREAD) Interventions: fall risk ID bracelet, low beds, bed alarm, bed rails (removal), medication review (not effective in isolation)	* asking MD to assess for fall risk Y or N, may alter their medical decision making and medicine prescription to consider fall prevention
I've fallen and I can't get up: reducing the risk of patient falls	Veluswamy, R. Price, R.	2010	Adequate, post intervention period only 3 mo, adding 2 FTE/shift \$\$	Wilkes Barre General Hospital in Wilkes Barre, Pennsylvania, 392 bed hospital (pilot was on a 39 bed Med/Surg unit)	Used Lean Six Sigma to implement a fall program and decreased falls the first 3 months	Similar to RIE method and program, Program had: Morse risk assessment, BSC, hourly rounds, PT eval, med screening, alarm systems, stakeholder education, added 2 nursing assistants for rounding	Can Lean Six Sigma to implement a fall prevention program reduce pt falls	fall rate, pt sat	decrease in patient falls from 8.7 to 2.2 in first 3 mo Increase in pt satisfaction Decrease in additional medical costs related to fall injury	Post data collection not long enough to draw conclusions *Adding 2 nurse assistants per shift for just 39 beds would be an expensive intervention. * gave no details on which Lean Six Sigma tools were used

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Bridging the gap between research and practice: review of a targeted hospital inpatient fall prevention programme	Barker, A. Kamar, J. Morton, A. Berlowitz, D.	2009	good, did not add anything new, but was like my RIE	The Northern Hospital in Australia - acute metropolitan hospital	fall rates varied with no significant improvement, but falls with injury did improve and sustain	Similar to RIE method and program, Program had: risk assessment, targeted interventions, fall risk sign, supervised toileting, low bed, walking aid within reach, 2hr or 4hr toileting regime, bed alarm	yes, to determine if the program was effective?	R values Poisson distribution	Number of falls unchanged - but may have been due to increased reporting, fwi did decrease	
Are call light use and response time correlated with inpatient falls and inpatient dissatisfaction?	Tzeng, H.M. Yin, C.Y.	2009	Excellent, rationale for study -	Michigan community hospital, 4 acute (87 beds), adult inpatient units (2 medical, 1 med-surg, 1 surgical)	Correlated call light usage and response time with multi-factorial measures of decrease falls and fwi and patient satisfaction Surgical floors found as call light usage increased fwi decreased and pt sat increased	we need to look at call light usage by floor (ave 8 calls/pt/day?) may need to wait until Responder 4 is implemented	Responder 4 call light tracking system. Pt sat questions % of "always" sounds like HCHAPS data 1. after call light did you get help as soon as you wanted, 2. did you get bathroom help when needed, 3. help with pain 4. control pain Archived data Feb	1 way ANOVA for difference between type of unit Pearson correlation for relationship among usage rate, response time and fall rate, all alpha level .05	Limitation - did not include staffing - nurse to pt ratios. Surgical unit had highest call light usage ave = 6 and highest pt sat scores on help to br, help pain, pain controlled When call light usage was higher, the response time was longer When call light usage was higher, pt sat was higher For surgery only, when call light usage was higher, fwi lower	nurse perceives call light as an interruption * extrinsic factors: 1. pt room design (distance from bed to bathroom, bed height, lighting, bed maintenance, ceiling lift, bed alarm, nurse not using bed functions), 2. hospital equipment (bedside commode problems, portable lift unavailable), 3. human resources (pt assignment not being close

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VPr	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusions/ Summary	Comments
							2007-June 2008			proximity, sitters' efforts to promote safety, pt care priorities, staff misconception about purpose of call lights, difficulty in toileting plans and answering call lights * look at PRC & HCAHPS call light related data for 7900 *ID call light usage per floor and encourage it to be above goal
The design of the SAFE or SORRY? study: a cluster randomised trial on the development and testing of an evidence based inpatient safety program for the prevention of adverse events	van Gaal, B. G. Schoonhoven, L. Hulscher, M. E. Mintjes, J. A. Borm, G. F. Koopmans, R. T. van Achterberg, T	2009	poor, no results yet but the attempt at cluster randomized trial was unique	10 hospitals & 10 nursing homes, Netherlands		pt safety program, education, patient involvement, computerized registration and feedback	cluster randomized trial on 10 hospitals & 10 nursing homes (5 control, 5 intervention) - baseline 3 mo, post = 14 mo Primary outcome = Incidence of PrU, falls, UTI 2ndary outcome = utilization of interventions		Guidelines for adverse event prevention exist, but compliance is low article only reviewed the design of the study, results are due in 2009	2.9 - 16% patients have an adverse event, 50% are preventable

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VPr	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusions/ Summary	Comments
A nursing quality program driven by evidence-based practice	Anderson, J. J. Mokracek, M. Lindy, C. N.	2009	poor, would have been better with results	St. Luke's Episcopal Hospital in Houston, TX	No data given, just description of evidence based process for falls, bloodstream infection, PrU, hand-off communication	Used evidence based strategy with critical appraisals QI technique, PDSA: Hendrich II FRA, toileting & meds, staff & pt education, ability to implement interventions (socks, sign on door & chart; safety huddle at change of shift, post fall debrief)	No, it was just a description of Evidence based process, PDSA	none	no data	
Falls prevention at Mayo Clinic Rochester: a path to quality care	Sulla, S. J. McMyler, E.	2007	Adequate, similar to Onc journey,	Mayo Clinic in Rochester, MN	Review of several years of a program, improved assessment, reporting and computerized documentation	Very similar project to our Onc journey with many years of improvements, and some improvements with injury reduction but falls are still occurring	Share tactics of the program and how the process has changed over the years (very similar to ours)	descriptive of path taken from 2000 to 2005 new response to Nat Pt Safety Goals	Total fall rate is unchanged, but serious falls & time between have decreased	* idea of CNS conducting audit to see if interventions match assessments *can this decrease in serious falls be linked to the decrease in unwitnessed falls * Making pts believe then need help (or compliant with interventions) Can that be house wide initiative or should it be pt specific?

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VPr)	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusions/ Summary	Comments
Evaluation of a falls prevention programme in an acute tertiary care hospital	Williams, T. A. King, G. Hill, A. M. Rajagopal, M. Barnes, T. Basu, A. Pascoe, G. Birkett, K. Kidd, H.	2007	Excel, intervention like RIE but signif improve in falls (not fwi) only 6 month duration	metropolitan , tertiary teaching hospital on 3 Medical wards (72 beds) and Geriatric (17 bed)	Intervention was stnd assessment and interventions according to hi, med, low similar to RIE, they improved falls but no change in severity, duration was on ly 6 months	Systematic approach to decrease falls: Assessment: los, age, fall hx, balance, mental state, general health, vision, meds, speech, incontinence (low, med, hi) Intervention s: listed in Table 2 by low, med, hi	yes, Before/After design to evaluate a systematic approach to limit falls and fwi in an acute care hospital	6 months intervention, falls and fwi Categorical data: Pearson chi square, interval data not normal used Mann-Whitney U-test (reported as z score), normal continuous data used Student's t test	Falls increase in 1st and 3rd week of hospital stay, Risk assessment is only effective if there is an available intervention to mitigate the risk. Interventions must be implemented early, use multiple interventions as part of ongoing care, reassessment to accommodate change Anonymous reporters of falls can't be interviewed Low risk=37%, med=58%, hi=5% Interventions appropriate 94% of the time Reassessment was done 98% falls decreased from .95 to .8 falls/1k pt days, no change in severity of injury Gender not related to falls, but Age & LOS was	It may be increase staff awareness that decreased falls more than any one specific intervention* Table 1 compares RCT studies 1993-2000.* "Pt risk of falling is dynamic and individualized while risk factors for falls are many and varied".
Sustained reduction in serious fall-related injuries in older people in hospital	Fonda, D. Cook, J. Sandler, V. Bailey, M.	2006	Excel, unique intervention	Caulfield General Medical Centre, Melbourne,, aged care services ward	Multi-strategy program reduced falls and fwi, increased FRA usage, unique interventions - glow in dark toilet seat	Unique night fall interventions: Glow in dark commode seat & toilet signs, night sensor lights	prospective non-randomized QI	Chi square test for equal proportions	19% reduction in falls (12.5 to 10.1) 77% reduction in fall w serious injury (0.72 to 0.17) FRA compliance improved from 42% to 70% 82% of falls were unobserved, 60% occurred around bed	* Ref #6 Oliver d. Do hospital fall prevention programs work? * THREAD: multisystem approach rather than single intervention

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VPr)	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusions/ Summary	Comments
When implementation fails: the case of a nursing guideline for fall prevention	van der Helm, J. Goossens, A. Bossuyt, P.	2006	Good, relevant but no improvement - lack of compliance very discouraging EFQM model	Amsterdam, Netherlands - Academic Medical Centre: Medicine (60 beds) Neurology (32 beds)	2 wards achieved 30% reduction in falls in 1993 but not sustained, tried to recreate in Jan 2000 - June 2001, but this failed too, lack of compliance with interventions	EFQM (European Foundation for Quality Management) Excellence Model education and support to management & staff Barriers ID were similar to 7900	yes, find out barriers that caused lack of sustainment and implement refreshed program	18 months intervention, falls & fwi, assessment completed, % of falls that were reported (bad baseline data)	target of 6% met on Medicine for 4 mo, and 11% in neurology for 5 mo., but compliance with interventions (that had consensus) was very low: "Assignment of accountability is necessary to solve a problem where everybody is involved and nobody is responsible" . Lack of compliance with Assessment (ask if pt fell in last 6 mo), visual cues (high risk pts not posted on overview board), environmental changes too costly (tv cables, steps to BR, side rails don't fit beds)	* Ref #4 Plsek, P>E. The challenge of complexity in healthcare - shows how a linear implementation model may not work in a large complex hospital # of actual falls are probably higher than data shows, so improvement post intervention would be difficult They seemed to have consensus and leadership support, but interventions were not completed
One-year follow-up after a collaborative breakthrough series on reducing falls and fall-related injuries	Neily, J. Howard, K. Quigley, P. Mills, P. D	May-05	Excellent, QI to achieve sustainment	Breakthrough Series (BTS) did QI in 37 VA team in various hosp & nurse homes, USA		signs to ID high risk, hip protector, staff educ, toileting interventions, enviro rounds, post fall infor	Self-reported data - resulted in lack of fall rates observational study design meant results are associative and not causal		Breakthrough Series (BTS) did QI in several VA hospitals Leadership, participation in RCA and multi-disciplinary teams were key to success Team together = 82% Collecting data = 97% Maintain gains = 93% Spread change to new location = 82% worked on new topic = 85%	More improv with spread at 1 year than 6 mo. Good overall rating of success (likert 7 pt scale) Teamwork, Leadership Strong leadership and previous QI experience helps a team sustain success - supports philosophy of spreading LEAN

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Partnering with patients and families in designing visual cues to prevent falls in hospitalized elders	Jeske, L. Kolmer, V. Muth, M. Cerns, S. Moldenhaur, S. Hook, M. L.	2006	Adequate, very relevant, but confounding - poster + other interventions	cycle 1: n=20 pts, cycle 2: n=26 pts large tertiary care hospital (telemetry) 35 beds	introduction stated that patient specific interventions most effective, but this study developed one simple poster for all pts	nursing staff worked with pt&family to develop educational poster for pt bedside Most common: personalized toileting, PT/OT, bed alarm, staff educ, high risk signs FRA = Morse Framework: used "Patient as Partner" - shared decision making between RN & pt/fam to achieve "pt-driven specified goal"	PDSA most pts that fell were at high risk, they needed a poster to comm. the need to stop and ask for help aim of developing one poster for all pts not consistent with the introduction that said pt specific intervention was needed (maybe they intended poster + other interv)	Nurses created first draft based on literature review. 4 cycles/iterations were conducted with pt/fam feedback and poster was modified	Patients want simple sign - large font with very few words. Stop Sign symbol was familiar and meaningful even without words. Patients and families like being asked their opinions	* ref#7 Rutledge DN 2003 complex, pts overestimate ability and no side rails or sitters * "Patient as Partner" RN brings expertise in pt educ & disease info, pt/fam bring circumstances, beliefs, behaviours & specific experience ** what % of our fall pts are at high risk?

D. APPENDIX D: LITERATURE REVIEW ON PATIENT ADHERENCE

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VP)	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies / Patient Education strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusion s/Summary	Comments
Perspectives of patients and families about the nature of and reasons for call light use and staff call light response time	Tzeng, H. M.	2011	Excellent	VA, inpatient acute care: oncology, telemetry, surgical (20 beds each)	Subjective data based on patient opinion about call light usage and response, increase call light usage related to less falls Pt wants response time to call light to be 2m30s	2 models as guiding framework: hot dog and Extrinsic/Intrinsic	Aim: understand patient perception of call light and link to satisfaction, Method: Self-administered survey	Exploratory, Cross-sectional survey study Reason for call light, frequency, urgency, response time, did reason get resolved? Sample: >21yo, included family, survey took 5 min, 346 approached, 122 (35%) participated, Correlation analysis = Spearman's rho	more calls assoc with less falls, longer call light response time linked to pt dissatisfaction, Reason for call light: pain med, personal assist, bathroom, IV pump (5% urgent, 42% accidental), Frequency of call lights was 3.6 calls per day. As LOS increased, call light usage increased 80% thought ave response time = 3 min, they expected response to be 2 min, 30 sec 87% satisfied or very satisfied. 99% said nurses answered call light in person.	* caution comparing subj vs quantitative data * suggest letting pt prioritize call light (urgent, normal, orderly) other reference Tzeng 2009b = MI commun hosp quantitative data from call light tracking system, 4.37 calls per day, ave response time = 3m 18s. Definition of resp time = call activated to call cancelled other reference: Quigley 2009 and Dietrick 2006
Older people's recruitment, sustained participation, and adherence to falls prevention interventions in institutional settings: a supplement to the Cochrane systematic review	Nyman, S.R. Victor, C.R.	2011	Good	subset of systematic review of RCT fall prevention with focus on elderly participation with fall interventions & studies	Focus on single factor interventions of elderly in nursing homes exercise helps but compliance is low	looks at single interventions RCT, could be helpful for THREAD, interventions: Exercise, Medication, Envir & assistive devices, Pt Education, Psychological	Meta-analysis inappropriate because of descriptive Included RCT & quasi-randomised trials, hospital inpatient of nursing care facility aged 65+, Cochrane Central Register of Controlled	Original Cochrane collaboration on RCTs to prevent falls in communities and institutions #10 ref.	Recruitment = 50%, Attrition = 15%, Adherence = 80%, in 12 months only 1/3 of nursing home residents are coming to exercise	* RCT difficult in real world due to assigning a no treatment control group, and repeated assessments, and patients refusing to participate in research * interventions may be effective but only with a self-motivated subgroup (takes extra effort to motivate elderly - in exercise and

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							trials, MEDLINE, EMBASE, CINAHL			transporting them to education or therapy sessions) THREAD IDEA *Research question: How to increase participation in interventions other references: #10: Cameron ID, Cochrane Database Syst Review 2010 - added to THREAD
Determinants of participation in a fall assessment and prevention programme among elderly fallers in Hong Kong: prospective cohort study	Wong, E.L. Woo, J. Cheung, A. W. Yeung, P.Y.	2011	Adequate - not related to my focus - move to exercise	41 hospitals in Hong Kong	Exercise programs in Community setting	exercise class, rehabilitation, medical consultation (neuro, cardiac, meds), ophthalmologist, home safety, hip protectors and walking aides, referral to social work	prospective cohort study	age 60+ people who had a fall who went to emergency room	Falls reduced in 32% of patients and Depressive symptoms improved in 36% of patients small classes most effective Older age group with chronic disease less likely to benefit because they are less likely to attend	* effectiveness of program is related to its uptakes and adherence to use
Patient preference for falls prevention in hospitals revealed through willingness-to-pay, contingent valuation survey	Haines, T. P. McPhail, S.	2011	Good	Queensland/Brisbane Australia, geriatric rehab unit	Investigates patient preference for fall interventions	which type of intervention is important to patients? Will this increase compliance? - falls consultation, exercise programme, face-to-face education, booklet-video education, hip protectors, targeted-multifactorial programme	Measure and contrast relative indirect and intangible costs and benefits of 6 approaches for preventing falls. Asked patients what they were willing to pay for interventions cross-sectional contingent	262 pts approached, 125 met criteria and accepted, (randomized order of interventions - except for multifactorial option always last) patients were told all interventions had 30% success Used Latin square design to assign order of interventions presented in survey to prevent bias Linear regression analysis with WTP dep var	Targeted multifactorial program valued higher than all other scenarios Face-to-face education not valued as highly as exercise Booklet-video was lowest then hip protector	* created sense of urgency by telling pts facts: 1 in 4 pts fall, of those that fall 1 in 3 are injured

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							valuation survey utilizing "willingness-to-pay"	then Pair-wise comparison between scenarios		
Link between patients' perceptions of their acute care hospital experience and institutions' injurious fall rates	Tzeng, H. M. Hu, H. M. Yin, C. Y. Johnson, D.	2011	Excellent	data base review: 478 hospitals in Fla, NY, CA 1. FWI rate 2. CMS-HCAHPS 3. AHA - teaching status 4. case-mix index	correlating patient satisfaction HCAHPS with FWI	I could include the HCAHPS features that are signif into the intervention for next study	Correlation between patient satisfaction and fall risk	Included 7 HCAHPS: comm w/ nurse, comm w/ MD, responsiveness of staff, pain management, comm about meds, cleanliness, quietness skewness/kurtosis value between -2.0 and 2.0 Pearson (r) Spearman (p) correlation between 2 variables at a time - perception and fall rate ANOVA and Kruskal-Wallis for difference across states and Independent t test & Wilcoxon signed rank test diff between hospitals teaching & nonteach	The higher the inpatient satisfaction levels (responsiveness, cleanliness, quietness the lower were the injurious fall rates The higher the satisfaction with commun about meds the higher the FWI rate for 0-17 year old. Teaching hospitals had higher FWI rates an lower satisfaction (except for comm about meds) and higher case-mix index	* look at PRC data and falls Inpatient falls = 2.27/1k pt days, 30% who fall get injured Multifactor: medical, functional, cognitive, envir (physical envir, staffing, delayed care)

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VP)	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies / Patient Education strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusion s/Summary	Comments
Patient and family education for fall prevention: involving patients and families in a fall prevention program on a neuroscience unit	Ryu, Y. M. Roche, J. P. Brunton, M.	2009	Good, very relevant, not very rigorous	tertiary care in New England Neurology unit	student teaches hi risk fall patients with pamphlet and makes poster for p t room - no falls during 6 week period	one on one teaching to patients at high risk done by one person, pamphlet and poster 5-20 min session, nurses were not using the pamphlet before the study (it didn't say if they used if afterward)	PDCA, FRA done by RN on admission and change in condition, sticker on chart and magnet on door as visual cues, bed alarms, toileting schedule, locking wheels of furniture, time in reach and fall pamphlet for pt educ.	One on one educ with all hi risk fall pts by the nursing student 5-20 min. FRA was Hendrich II All high risk fall patients got education on the 3-5 days per week the student was there. Some patients got more than one education session - if they were still there when the student returned for the next day of teaching	0.02 falls per 1k pt days, no falls occurred on patients that received education during the 6 weeks of the study. 2 patients fell that did not get the education.	sources: Crossing Quality Chasm from IOM 2008 and Joint commission Nat Pt Safety Goals = Goal 13 fall prevention * good study, but very simple. What happened after the study ended? Did the nurses begin to use the pamphlet and educate the patients?
Are call light use and response time correlated with inpatient falls and inpatient dissatisfaction?	Tzeng, H.M. Yin, C.Y.	2009	Excellent, rationale for study -	Michigan community hospital, 4 acute (87 beds), adult inpatient units (2 medical, 1 med-surg, 1 surgical)	Correlated call light usage and response time with multi-factorial measures of decrease falls and fwi and patient satisfaction Surgical floors found as call light usage increased fwi decreased and pt sat increased	we need to look at call light usage by floor (ave 8 calls/pt/day?) may need to wait until Responder 4 is implemented	Responder 4 call light tracking system. Pt sat questions % of "always" sounds like HCHAPS data 1. after call light did you get help as soon as you wanted, 2. did you get bathroom help when needed, 3. help with pain 4. control pain Archived data Feb 2007-June 2008	1 way ANOVA for difference between type of unit Pearson correlation for relationship among usage rate, response time and fall rate, all alpha level .05	Limitation - did not include staffing - nurse to pt ratios. Surgical unit had highest call light usage ave = 6 and highest pt sat scores on help to br, help pain, pain controlled When call light usage was higher, the response time was longer When call light usage was higher, pt sat was higher For surgery only, when call light usage was higher, fwi lower	nurse perceives call light as an interruption * extrinsic factors: 1. pt room design (distance from bed to bathroom, bed height, lighting, bed maintenance, ceiling lift, bed alarm, nurse not using bed functions), 2. hospital equipment (bedside commode problems, portable lift unavailable, 3. human resources (pt assignment not being close proximity, sitters' efforts to promote safety, pt care priorities, staff misconception about purpose of call lights, difficulty in toileting

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor, VP)	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies / Patient Education strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusion s/Summary	Comments
										plans and answering call lights * look at PRC & HCAHPS call light related data for 7900 *ID call light usage per floor and encourage it to be above goal
Perspectives of recently discharged patients on hospital fall-prevention programs	Tzeng, H.M. Yin, C.Y.	2009	Good, LLL related to bed height and sliding off bed, Human Factors link to Staff adherence	Michigan home care agency	beds in hospitals too high may cause sliding, brochures not effective pt educ, posters instead	seat height should be <120% or >80% of LLL (knee height) for safe transfer * use her concept of Human Factors link to the staff adherence for fall interventions	Cross-sectional exploratory study (March - Oct 2007), 3 RNs, 2 OT collected data Ask about inpt fall educ and LLL and link to outpt falls	subjects >65 yo, inpt d/c in last 30 days (n=91 pts) Responses categorized by 3-D typology of Tzeng for extrinsic risk factors Descriptive analysis, correlation and chi-square tests alpha = .05 Part 1: pt height, LLL, weight, height of home bed, method pt get in and out of home and hospital bed, Part 2: a. fall as inpt?, b. advice about falls as inpt? c. fall prevention educ as inpt, d. what can hospital do to prevent falls?, e. have you fallen at home since d/c - if so, describe	38% fell before hospital stay, 18% fell after d/c, 57% thought inpt fall prevention was not adequate LLL ave = 18.6" so bed height range 15"-22", however 42% home bed >24" and hospital bed was 23.5" at lowest setting Pts do not like getting a brochure w/o explanation - not considered educ - wall signs more effective Ask pt needs during hourly rounding to decrease call lights *suggests adding a button in bathroom for cleaning requests * suggests motion sensors for lighting in pt room and BR	* ref #9 Alexander, N.V 2001 for recommended % of LLL * ref #5 Tzeng, Extrinsic risk factors for inpt rooms hospital beds need to be lower than 15" (80% of LLL) * could bed height cause "slipping off bed" found by TJC? Get pt/family input on fall educ strategy, signs on wall more effective than brochure * Human Factors (staff working attitudes and negligence) must be considered because it can contribute to effectiveness and efficiency of fall prevention (maintaining safe

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									* suggests walkers in each room - I disagree - can increase risk if patient is not trained or used to using a walker	room environment and using fall prevention equipment)
Patient education to prevent falls in sub acute care	Haines, T. P.Hill, K. D.Bennell, K. L.Osborne, R. H.	2006		metropolitan sub acute/aged rehabilitation facility (nursing home) Melbourne Australia		1:1 with OT at pt bedside (15-35 min) discussion not didactic3 Phases of education:threat appraisal,protection motivation,goal setting -written in brochure	randomized control trial	signif p=0.07 of control vs intervention but relative ratio (proportion) not signif	pt educ should be part of a multiple intervention fall prevention program	Patient education components could incorporate into the patient adherence intervention
Acceptability of fall prevention measures for hospital inpatients	Vassallo, M. Stockdale, R. Wilkinson, C. Malik, N. Sharma, J. Baker, R. Allen, S.	2004	good, not very rigorous - survey only	District general hospital in Dorset	All subjects thought fall interventions are important, but HCP and pt/family differ in what interventions they think are acceptable	Must get input of pt and family to make decision about fall prevention strategy for each pt	To understand attitudes about restrains healthcare professionals vs pts/family survey 5-pt Likert scale	n=100 HCP, n=100 pt&fam, Chi-square with Yates's correction subjects with agreement or strong agreement of each question, partial correlation analysis for association between strength of opinion correcting for age & gender	99% felt fall prevention is important 98% agree fall measures important for confused pts 70% agree fall measures should include oriented pts HCP thought it was okay to provide nursing care on the floor (64%) but only 19% of pts thought it was okay Pt&family vs HCP	* must include pt and family when selecting fall intervention plan for pt

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									acceptance of interventions Combined acceptance: fall armband=95%, bed alarms=80%, bed rails=77%, at-risk label by bed=75%, tranquilisers=9%, b	

E. APPENDIX E: LITERATURE REVIEW ON PARTICIPATORY ERGONOMICS (PE)

Title of Article	Author	Year	Quality of Paper (Excel, Good, Adeq, Poor,VP	Where the study was conducted	What was paper about main findings	How is it of interest to research? Fall prevention strategies / Patient Education strategies	Aim (clear?) Methodology	Sampling / data collection / data analysis	Results/Conclusions/Summary	Comments
Contextual factors affecting task distribution in two participatory ergonomic interventions: a qualitative study	Dixon	2011	good	US, courier (labor intensive - manual material handling, and furniture manufacturer)	Are PE teams successful if developed according to Haines dimensions? Comparing 2 PE teams in 2 different companies to see how the roles and participation of the members changed as through the PDCA cycle	They think worker involvement is less during implementation - but this may be true for purchasing approvals for equipment, maybe not for process interventions	Yes, assembled 2 PE teams according to Haines dimensions Conducted 4 hr Ergo training, ID hazards, work comp data, VOC, observation, brainstorm solution, review ideal state, select solutions based on benefits & limitations	implementation on stage defined as solution is decided and roll out has begun. Interviewed PE team and corroborated findings with observations Early in project workers were involved w/ process map (accurate picture of work activities) & root cause of inj In furn manuf workers helped promote understanding of body postures and	1. do nurses think they don't have enough power to implement the interventions? 2. Courier case study found that Occ Health manager had power to get execs to purchase interventions - workers were ignored by high execs early in project so they did not try again - OH mangr became "mouthpiece" of program status and requests to execs - demonstrates lack of exec support 3. staff had trouble filing paperwork to get approval for funding proposed interventions 4. Furn manuf solutions were very complex with consequences for division of labor - workers lacked authority and expertise to be involved in implementation. 5. The right mix of PE members depends on	1. PE evolves over time and participation can vary as workers see benefits 2. deJong & Vink 2000 cover stages of PE change (hazard ID, assessment, implement solutions) - Ok for different expertise of member at different stages, 3. I disagree about role of worker in implementing solution - in Healthcare (**ask Cathie if lack of empowerment is a reason that nurses may not be doing pt partnering?**) Vink found PE team involved in hazard ID but not in solution implementation. Is

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								NIOSH lift equation exposure for experienced workers (different than exposure for novice) - less body posture risk for experienced worker due to better technique to perform same job.	organizational structure, production processes and hierarchy of authority in company to implement solutions - role and amount of participation can vary according to where the team is in the improvement process.	there a difference when solution is to get participation of staff vs. buying expensive intervention equipment - or division of labor? 4. Early frustration w/ lack of responsiveness by top execs took away empowerment of staff - so they relied on occ health mngr
Ergonomics, quality and continuous improvement conceptual and empirical relationships in an industrial context	Eklund	1997	adequate , lacked explanation of method, but is a great link between ergo & QI	review of literature comparing ergonomics and quality in various case studies conducted in industrial environments	Ergo needed to create good working enviro so employees can achieve good quality 2. article has some great definitions QI, Continuous Improve, TQM, Ergo	1. HFE adds to QI by providing an understanding of human capability and limitations to work design, QI adds to HFE by providing	review literature on industrial environments to understand the link between ergonomics and quality, aim was clear but methodology lacked detail	reviewed articles of ergonomics and several quality improvement techniques. Conclusion section compiled information from each methodology to compare and contrast	1. HFE is not perceived by management as a strategy where as QI can be a management initiative and made a priority. 2. Adverse enviro & phys conditions (noise, vibration, visual impairment - lighting, temp, chemical exposure) can lead to Discomfort, leads to Lapse in attention, leads to errors in quality	1. definition of ergo = understanding human interaction with technology and environment to design components and work processes. QI = fitness for use, TQM = customer focus, process orientation, employee/manage

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						structure and systematic approaches to understanding issues.		benefits and limitations critique - selection method for case studies was not discussed. Graphs are vague. A graph showing quality deficiencies over time with QI and ergo programs had no axis measures and did not say how many cases or what type of motivation or working conditions were improved by adding ergonomic methods to QI. Venn diagram could have been stronger if	3. Employee satisfaction and motivation leads to better quality 4. Benefit of including ergo in design of product design: a) improved product usability b) improved user performance c) differences among users accommodated d) safer product e) improved user comfort f) enhanced user satisfaction. 5. 30%-50% of quality deficiencies are related to ergo factor. Ergo deficiencies lead to 3 fold risk of quality problems. 6. QI & ergo definitions & consequences overlap, but process is different. TQI is top down, Lean is bottom-up, Ergo is expert solving with input from users & management. -- PE uses best of both processes (top down, bottom up and ergo expert) 7. QI needs ergo for work design and human capabilities, and Ergo needs QI for method and structure of improvement activities and to better link improvements to	ment participation and continued improvement. TQM assumptions: improved quality is profitable, people want to do a high quality job, all parts of organization are interdependent, quality is responsibility of top management. Continuous Improv = organized activity to involve employees to improve production, work processes and products. PDCA, PDSA from Deming = problem solving activities repeated as needed. 7QC = select theme, collect data, analyze cause, plan & implement solution, evaluate effects, standardize solution, reflect on

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								the number of case studies in each category was listed. It was difficult to connect the case studies stated in the literature review to the conclusions.	leadership and organizational strategy.	the process.QC = Quality Circles = small group activities for improvement (>50% involve ergo) 2. Eklund provides the link between what is good for the worker is good for quality (patients) - a process/design with worker benefit will result in improved quality. - Deficiencies in quality are often caused by insufficient design of work, workplace or environment or product.
Validating a framework for participatory ergonomics (the PEF)	Haines / Wilson	2002	excel	retrospective description of 7 independent studies	peer evaluation of 7 studies to classify dimensions into framework, included agreement between authors and facilitators	Identifies dimensions to include when developing PE project 2. supports the structure of applying the framework to new	Yes, very systematic (less subjective than Morag) a. peer validation of framework, b. test ergo experts understanding framework, c. determine if	1. Interview Ergo Leads/facilitators of all 7 programs 2. let project lead classify project into framework dimensions 3. Verified classification	interesting method for determining denominator for calculating percentage of agreement between authors and project experts (flipped the equation both ways) Cut off percentage of 50% seems to be acceptable (see study by St. Vincent) Fewer choices within a	

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					that were involved with studies (gauge R&R)	project (apply it to patients?)	case studies can be classified into dimensions, support the structure for new projects	s with original project team 4. Team votes on importance of dimensions. Authors also classified all 7 programs into framework and then analyzed agreement. How was framework originally derived??	category is easier to get agreement Decision making dimension is more subjective and may be harder to get agreement. Remit dimension is a confusing term	

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Space to care and treat safely in acute hospitals: Recommendations from 1866 to 2008	Hignett	2010	excel	review of 5 literature reviews	Spatial recommendations around the bedside have increase over several years, but very little evidence to support why. Future should use PE to improve commun with stakeholders & improve research on hc design	Reiling & Chernos (2007) used PE to predict pt safety risks with hospital designs Environment causes 44% of patient falls	yes, very clear - but multifaceted 1. changes in bed space recommendations 2. measure 5 hospitals to see how they match up with recommendations 3. review research evidence for 3 pt safety issues (falls, IC, noise) 4. role of HFE & design in future	Aim #1: Historical room sizes were collected from literature. 5 hospitals participated getting space measurements around the bed. Aim #2: Selected 5 articles to understand impact of design options on 3 patient safety issues	Aim #1: recommended bed space has increased in the past years to 12 m2 in 2000. Aim #2: Falls: extrinsic factors cited as the root cause in 44% of patient falls (bed rails, improper bed height, tethers - catheter, ECG leads, IVs, chest tube), improper footwear, wet floors, poor lighting, lack of safety equipment, environmental markings, doorway or furniture design. Noise: noise reduction with ceiling tile is beneficial but link to health benefits is scarce. Infection transmission: interventions are typically bundled so impact of single factor is difficult. Chaudhury (20005) suggests that single room with proper ventilation and appropriate precaution may reduce infection transmission.	Great table with information from 5 selected articles. Good explanation of selection process and overview of findings from each article. Only one study based recommended space requirements on various tasks such as manual handling, skin care and IV infusion while measuring dimensions from a 12 inch grid lines marked on the floor. (Nuffield Provincial Hospitals Trust (1955). **Lets try this idea with our design & construction mock ups.** Hospital spaces should be designed to be as flexible as possible to accommodate a wide variety of

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										patient conditions and equipment ** the goal should be for "nurses to experience greater efficiency and safety in providing patient care". This should be expanded to include all caregivers, ancillary staff and patients.** this is another link to what is right for staff is right for patients *** link up with Eklund comments**
Effect of integrated care for sick listed patients with chronic low back pain: economic evaluation alongside a randomized controlled trial	Lambeek	2010	good, but would have been excel if they gave info about PE process	PT, OT, Occ Health clinic and 5 hospitals in Netherlands	Intervention (workplace solutions using PE & graded activity) vs. usual care by Occ Health physicians - Dutch guidelines - cost of treating intervention group was less with an improved	The intervention included PE approach with injured worker and supervisor to develop a plan for adaptations at work.	yes, effect of workplace ergo on length of time to return to work & Quality Adjusted Life YearsRandomized control trial & measured cost of each treatment (complete study design was published in different	Low back pain patients selected from 5 hospitals (aged 18 - 65) working 8 hours/week on paid leave for back injury. Eligible subjects were randomly assigned to intervention or traditional	Loss of productivity was the greatest contributor to cost in both groups. Total cost of care was less with the intervention group even though the intervention care cost was £1,077. Cost of workplace intervention was not included but some patient in both groups received changes to workplace. Return to work and QALY scores were more favorable for the intervention groups over the 12 month follow up	1. one month follow up on sick days and progress of intervention ensured better participation and accurate data2. Interesting method of calculating cost effectiveness from a societal perspective using the bootstrap methodology.

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					quality of life and function		article)	treatment. Data processing and analysis was conducted with SPSS. A bootstrapping technique for cost effectiveness was conducted in R (R Foundation for Statistical Computing)	period.	

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Participatory ergonomics: Development of an employee assessment questionnaire	Matthews	2011	excel	Phase 1 was survey in manufacturing plant in New England, Phase 2 was internet survey of industry workers	developed an eight minute survey with 17 issues divided into 5 dimensions to assess PE team	Possible survey questions for PE team members for Case Study #3	Matched the EPPEQ questions to the 5 components of PE (employee involvement, knowledge base, managerial support, employee support, strain of change) - most common dimensions mentioned in 20 studies in a wide range of industries	Phase 1: Literature review and SME review combined to develop 42 items to evaluate psychometric properties of PE. These items were tested in a survey (written and verbal option) answered by 63 line workers from a manufacturing plant in New England. Principal components factor analysis was used to explore the contribution of each factor related to the corresponding dimension.	Safety (work injuries, safety communication), 2. Psychosocial (role conflict, time pressure), 3. organizational outcomes (turnover and organizational support) Five dimensions can be assessed reliably with 17 items that can be assessed in an eight minute survey: 1. Self-involvement, 2. Ergo Knowledge Base, 3. Managerial Support, 4. Employee Supportiveness, 5. Strain related to ergonomic changes	1. compare the EPPEQ (employee perceptions of participatory ergonomics questionnaire to the GRPI survey in 6 sigma. 2. definition of PE as a macro-ergonomic intervention to improve the fit between worker and environment. Projects can be on an individual (workstation) level or organizational (redesigning org structures). 3. This can be extended to employees even improving their own PE process *** maybe nurses can improve pt partnership process *** 4. Interesting idea to correlate subjective ratings by PE team to overall outcomes. 5. Dimensions

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								Factors were revised according to subject feedback and tested in Phase 2. An on-line survey was answered by 165 production-related workers answered the revised questions. During analysis, four measures of model fit were tested and correlational analyses examined the relationship of the primary dimensions to the outcome variables of interest. Five dimensions emerged as promising		need to be tested on actual PE team participants 6. Survey would be helpful in Case Study #3 to understand effectiveness of PE, to understand if there is a need for revising the program, identify if employees are engaged in the PE process

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Effectiveness of participatory ergonomic interventions on health outcome: A systematic review	Rivilis	2008	excel	review of 12 studies	reviewed 12 articles to reveal moderate evidence that PE has positive impact on msd, reducing injury & work comp claims, lost work days - magnitude of improvement is not precise	* definition of PE from Wilson & Haines = involvement of people in planning & controlling their own work activities with knowledge and power to influence outcomes to achieve goals * Use idea to show search terms in venn diagram *Use consensus form idea for meetings with Eileen ** strength of the PE approach is that interventions will vary according	yes, 1. synthesize evidence on effectiveness of PE in health outcomes 2. assess strength of PE interventions to guide future research 3. very clear figures for systematic review process	Clear criteria for inclusion & exclusion for publication type, population of interest, presence of intervention, ergonomics, participatory approach, health outcome. Then 27 quality appraisal criteria were used to examine studies and 10 important criteria emerged. Among the 23 relevant studies, only 12 used good quality methods and contributed to evidence synthesis.	PE consistently lead to improvement in MSD symptoms, injury claims and lowest workdays. - Since we know serious fall injuries result in 6.2 days longer LOS, if PE can decrease number of serious falls a successful outcome will be achieved.	1. PE can give patients control and consequently decrease their risk for errors 2. Suggestions for case study #3 to improve experimental rigor: use a control or comparison group for stronger study, stats pre/post, document participation (including percentage of population), describe any confounding factors 3. Rivilis gave a better summary of description of the selected projects (this type of summary was lacking from Haines) 4. use ideas form Table 4 to add columns to spread sheet for literature review on PE programs 5. Will is still be PE without ergo

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						to specific situations (supports that each pt is different and assessment /intervention will always change)				training? Yes, for patient the ergo training will be fall and fwi risk training and stages of change training 6. Use PEF by Haines as my framwork to develop my PE approach for Pt Partnering and RN acceptance 7. Look up Cohen J. (1988) for statistics RR and OR
Participatory ergonomics processes to reduce musculoskeletal injuries: Summary of Quebec experience	St-Vincent	2006	good	Quebec Canada, review of PE projects in 11 different types of manufacturing companies in Canada	Overall found P E to be successful and focused on the organizational benefits of PE as well as the individual workstation level of changes					

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Negotiating participation: Understanding the "how" in an ergonomic change team	Theberge	2006		175 employee automotive foam manufacturing plant	Using PE methods with an Ergonomic Change Team (ECT) to look at participation					
Process and implementation of participatory ergonomic interventions: a systematic review	van Eerd	2010	excellent	review of 52 articles	Systematic review; 1. healthcare PE work doesn't include pts or pt care staff 2. No articles done for patient safety 3. freq of PE meetings vary	provides insights into characteristics that should be included in a write up or summary of project to be published (like union vs. non, and duration of PE meetings)	1. gave questions they used to determine the quality and scoring of articles.	Search criteria were clear and organized 1. interesting use of Haines to categorize articles as they comply to each framework component	Information from 52 articles were synthesized by context, PE teams 1. Workers tasks in PE: nature of work 52%, problem ID 70%, solution development 87%, implement solution 69% 2. some articles report the reason for negative results (like increase in injury) is due to increased reporting due to increased awareness (NOT THE CASE with 7900) 3. PE methodology is flexible but key components are a) appropriate team members, b) involve the right people in PE process, c) define responsibilities, d) let group make decisions, e) provide ergo training, f) address barriers & strengths	1. Section on stakeholders - gave me idea to use my advisory team as my stakeholders. 2. Great diagram and description of the review criteria (selection) process 3. Health care PE must include pts (appropriate team members are important) 4. Ergo person facilitates and provides HF info to team 5. Nature of HF training in PE is flexible - tailor to workplace risks or targeted solution

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Positive outcomes of participatory ergonomics in terms of greater comfort and higher productivity	Vink	2006	good	review of 4 studies with success factors really resulted in improved comfort & productivity	2 approaches to PE: 1. workers make changes 2. management & ergonomist makes changes	def of PE: different parties are involved in a design process. PE adapts enviro to human with "proper people's" input. Umbrella term for different approaches - Wilson, involvement of people in planning & controlling their work activities with knowledge & power to influence process and outcomes. Common: system approach involving worker, mng, ergonomist	Goal: positive approach to ergo by focusing on comfort & productivity, Identification of success factors for participatory ergo, has a great model of these success factors (fig 1)	literature review to determine appropriate success factors. Then they wanted to select 4 studies to see if the success factors work so they developed criteria for selecting 4 studies from a selection of 100 possible cases (2 cases with worker empowerment with one success and one failure - 2 cases without worker empowerment on success and one failure)	Success factors: 1. direct worker participation, 2. management support, 3. good inventory, 4. step-by-step approach (I say systematic & systems) 5. steering group to guide process, 6. check effects & side effects, 7. focus on more than health issues, 8. describe cost/benefit ratio	Supplements Haines framework1. Rogers (1995) says 2.5 % of a group are innovators and will adopt changes even without QI, so QI must impact a larger % of employees before claiming success.2. in optimal workload design, physical stress should not be overload3. teach PE team the "optimal" way (as an ideal state) to help them create a better future state and understanding why the improvement will be beneficial

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A framework for performing workplace hazard and risk analysis: a participative ergonomics approach	Morag	2013	adeq	review of 20 studies categorized them into 5 dimensions - summary done by researchers - experts not consulted	developed a framework for providing ergo guidance	provides different dimensions to consider in addition to Haines - analysis strategy did not go back to the people that conducted the original study	Similar goal as Haines.. Why did Morag develop all new dimensions?	How were these dimensions derived? Dimensions were defined with norms - based on quartiles (lo <25%, medium 25%-75%, height >75%)	PE interventions can never be replicated as cookie cutter due to unique pt needs and unit culture - unclear how they came up with the dimension categories ***authors assumed if overall participation of workforce was not mentioned that it was not considered - it might be that it just wasn't part of that article (ie. transporter study did reach every transporter - but not entire hospital)	1. must involve end user to improve safety of workplace 2. 1st do analysis of situation (H&H/vitals/FRA) 3. as framework is developed and validated then consider the individual patient 4. PE interventions can never be replicated as cookie cutter due to unique pt needs and unit culture 5. authors rated without asking original researchers - many assumptions in dimension and categorizations 6. If my PE study involves all patients for the entire hospital stay won't that be like a within subject design (instead of "transient" team member, the intervention is completed when

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										<p>pt is discharged ***</p> <p>7. from case study - Is there a way to get our pts to ID & recognize their own risks? (educ on "gloom & doom", nutrafill count, sepsis - weakness, confusion, meds - dizzy, lasiks freq urination)</p> <p>8. idea for outcome measure pt partnering: % of pts/1000 pt days vs. % of RNs using agreement form</p> <p>9. What % of our nurses generate an SES</p>

F. APPENDIX F: INTERVIEW PROFORMA FOR CASE STUDY #3: PATIENT INTERVIEW

Subject ID:

FRA Score & Category =

Hospital Admission Date =

Date of initial interview =

Interventions =

Additional Interventions =

Exceptions =

Observed Interventions =

Record the following information from the preventable harm report:

Johns Hopkins Fall Risk Score: (as listed in the Preventable Harm Report)

Age =

Cognition =

Elimination =

Fall history =

Medication =

Mobility =

Equipment =

GUG score

Get up PASS

Go PASS

Note Gender = Female

Interview Questions:

1. I think that I will fall over sometime during my hospital stay.
Strongly Agree, Agree, Undecided, Disagree, Strongly disagree
- 1a. Based on how you feel right now, Rate your Risk of falling in the hospital
(0= no risk 10=definitely will fall)
- 1b. Based on how you feel right now, if you were at home, Rate your Risk of falling
at home (0= no risk 10=definitely will fall)
2. I think that if I were to fall during my hospital stay, I would be likely to get a
serious injury (for example, a broken bone)
Strongly Agree, Agree, Undecided, Disagree, Strongly disagree
3. The topic of falls is very important to me.
Strongly Agree, Agree, Undecided, Disagree, Strongly disagree

Rating of strategies:

4. I think that prevention strategies would decrease my risk of falling.
Strongly Agree, Agree, Undecided, Disagree, Strongly disagree
5. If I did fall, I think these prevention strategies would decrease my chance of
getting hurt?
Strongly Agree, Agree, Undecided, Disagree, Strongly disagree
- Q6. Perceptions of Fall Risk: Before you came to the hospital, did you ever consider
you might fall over sometime?
- Q7. Perceptions of Fall Risk: Since you have been in the hospital do you think you
might fall over while you are here?
- Q8. Perceptions of Fall Risk: What are some things that could cause you to fall in
the hospital?
- Q9. Perceptions of Fall Risk: Look around the room, is there anything you think
might make you fall?
- Q10. Perceptions of Injury Risk: What kind of injury could happen to you if you did
fall?
- Q11. Perceptions of Injury Risk: Can you think of anything that makes it more likely
that you will be injured if you do fall?

Q12. Ideas for fall prevention by type of role: Since you have been in the hospital, what could YOU do to keep you from falling down?

Q13. Ideas for fall prevention by type of role: What do you think your DOCTOR could do to keep you from falling down?

Q14. Ideas for fall prevention by type of role: What do you think your NURSE could do to keep you from falling down?

Q15. Ideas for fall prevention by type of role: What do you think your THERAPIST could do to keep you from falling down?

Q16. Ideas for fall prevention by type of role: What do you think your TECHNICIAN could do to keep you from falling down?

Q17. Prevention strategies: How do you prefer to learn about your risk of falling and possible injury?

Q17A. Did someone sit down and review your risk of falling – during this hospital stay?

Q18. Prevention strategies: Have any fall prevention activities been implemented? If yes, what?

Q18A. Did someone point out these strategies to you?

G. APPENDIX G: FINAL AXIAL CODING STRUCTURE

Topic or Code (Name) mentioned by number of participants (Sources) and number of comments (References)

Name	Sources	References
anybody educ on falls or interv	15	27
no educ occurred	14	21
yes educ occurred	5	6
belief or denial	30	112
belief in fall risk	13	20
belief in risk in hospital	6	7
belief in risk at home	11	12
denial of fall risk	29	92
denial at home	21	24
denial in hospital	27	48
bjh good job	14	24
Complexity	0	0
Critical Thinking	0	0
definition of fall	17	21
denial reasons	30	161
acceptance difficulty	14	18
aware of surroundings	12	26
Cautious	20	38
Independent	3	7
prior problems not	7	10
protected safe	12	24
stable strong active	15	28
stand to test if help needed	8	9
transfers and hops	1	1
Education	29	82
Demonstration	3	5
deny need for educ	3	5
internet	3	3
learn from falling	6	6
pamphlet	13	14
reading book article	11	12
talking	18	23
timing and freq of educ	5	7
video	7	7
Environment	29	152
call light	7	9
clutter or lack of clutter	24	55
computer wheels	5	6
cords	6	8
doorway width	1	2
exit side of bed	3	3

Name	Sources	References
flooring	6	9
furniture table	6	9
private semiprivate room	8	12
stairs	1	2
threshold lip	7	16
gaps threshold out of pt room	3	5
threshold into bathroom	5	9
threshold into shower	2	2
unfamiliar	7	7
wet floor	7	12
equipment	12	27
cane crutches	4	6
shower chair	2	4
walker	5	10
wheelchair	4	6
wheels locked	1	1
experienced patient	9	20
Facilitation	0	0
Injury Types	30	85
back	1	2
broken bone	17	21
bruise scraps & minor hurt	13	15
butt	5	5
complex injury due to duration	1	1
damage medical treatment - IV PICC,	3	5
death	1	1
Embarrassed or ego	1	1
headbleed head injury	11	11
legs hip ankle	11	14
wrist injury arm collar bone	8	8
Intervention	31	255
armband	10	10
awareness of interventions	28	30
none pt perceived	14	14
patient perceived interventions	14	16
bed chair alarm	2	3
Bedside Commode	8	12
bedside table at non exit side	30	30
Documented interventions	28	57
all high	3	3
all low	28	28
all mod	25	26
exceptions documented	14	15
exercise	8	10
exit on pref side	29	30
gaitbelt	5	6
low bed and mat	2	3
magnet	5	6
sign on door	2	2

Name	Sources	References
suggested interventions	18	37
home suggestions	3	3
hospital suggestions	12	27
no suggestions	5	7
yellow socks	4	4
other guy not me	15	28
know someone that fell	9	10
Patient Partnering	27	94
call for help	24	63
miscommunication or communication	6	9
toileting wait outside door	1	1
Patient Stories	4	6
Priority and Culture Change	0	0
Risks	30	207
activity level	2	2
age	5	8
confusion	2	3
dizzy	17	23
hands full carrying things	2	2
health status	6	9
history of fall	3	4
Injury Risks	4	4
brittle bones	4	4
loose balance	5	5
one leg	2	2
toe amputation	1	1
medications	12	16
more people	4	5
move to chair	1	1
noise startle	1	1
pushing IV pole	7	13
socks	7	8
staffing	2	3
tangle in sheets	3	4
Tethers	20	38
IV Tethers	20	29
oxygen	3	5
telemetry	2	2
tripping	13	15
unassisted	1	1
unsteady impaired gait	10	15
vision problems	2	2
weak or numbness	15	25
Role suggestions	30	144
Patient	21	27
Physician	13	18
RN	27	39
BSSR	1	1
Tech	18	19

Name	Sources	References
Therapist	26	41
Support methods	17	47
furniture for support	6	15
grab bar	3	5
Support Human Help	15	27
Team & pace of change	0	0
World View	5	6

H. APPENDIX H: CROSSWALK BETWEEN AXIAL CODING AND SELECTIVE CODING

Cross walk between Axial and Selective Coding Axial (Open) coding = 18 nodes with 102 categories Selective coding = 3 categories: 1. Lack of Patient Control (Space, Assistance, Information), 2. Self-Perception, 3. Patient Background			
Selective Coding	Axial Coding Category		
Theory (Core Theme)	Node Level 1	Node Level 2	Node Level 3
Control Assistance	Patient Partnering	call for help	
Control Assistance	Patient Partnering	miscommunication or communication	
Control Assistance	Patient Partnering	toileting wait outside door	
Control Assistance	Patient Partnering		
Control Assistance	Risks	confusion	
Control Assistance	Risks	dizzy	
Control Assistance	Risks	hands full carrying things	
Control Assistance	Risks	Injury Risks	brittle bones
Control Assistance	Risks	loose balance	one leg
Control Assistance	Risks	loose balance	toe amputation
Control Assistance	Risks	loose balance	
Control Assistance	Risks	medications	
Control Assistance	Risks	staffing	
Control Assistance	Risks	unassisted	
Control Assistance	Risks	unsteady impaired gait	
Control Assistance	Risks	vision problems	
Control Assistance	Risks	weak or numbness	
Control Assistance	Support methods	Support Human Help	
Control Information	anybody educ on falls or interv	no educ occurred	

Cross walk between Axial and Selective Coding

Axial (Open) coding = 18 nodes with 102 categories

Selective coding = 3 categories:

1. Lack of Patient Control (Space, Assistance, Information),
2. Self-Perception,
3. Patient Background

Selective Coding	Axial Coding Category		
Control Information	anybody educ on falls or interv	yes educ occurred	
Control Information	Education	demonstration	
Control Information	Education	deny need for educ	
Control Information	Education	internet	
Control Information	Education	learn from falling	
Control Information	Education	pamphlet	
Control Information	Education	reading book article	
Control Information	Education	talking	
Control Information	Education	timing and freq of educ	
Control Information	Education	video	
Control Space	Environment	call light	
Control Space	Environment	clutter or lack of clutter	
Control Space	Environment	computer wheels	
Control Space	Environment	cords	
Control Space	Environment	doorway width	
Control Space	Environment	exit side of bed	
Control Space	Environment	flooring	
Control Space	Environment	furniture table	
Control Space	Environment	private semiprivate room	
Control Space	Environment	stairs	
Control Space	Environment	threshold lip	gaps threshold out of pt room
Control Space	Environment	threshold lip	threshold into bathroom
Control Space	Environment	threshold lip	threshold into shower
Control Space	Environment	threshold lip	
Control Space	Environment	unfamiliar	
Control Space	Environment	wet floor	

Cross walk between Axial and Selective Coding

Axial (Open) coding = 18 nodes with 102 categories

Selective coding = 3 categories:

1. Lack of Patient Control (Space, Assistance, Information),
2. Self-Perception,
3. Patient Background

Selective Coding	Axial Coding Category		
Control Space	equipment	cane crutches	
Control Space	equipment	shower chair	
Control Space	equipment	walker	
Control Space	equipment	wheelchair	
Control Space	equipment	wheels locked	
Control Space	Intervention	armband	
Control Space	Intervention	awareness of interventions	none pt perceived
Control Space	Intervention	awareness of interventions	patient perceived interventions
Control Space	Intervention	awareness of interventions	
Control Space	Intervention	bed chair alarm	
Control Space	Intervention	Bedside Commode	
Control Space	Intervention	exercise	
Control Space	Intervention	gaitbelt	
Control Space	Intervention	low bed and mat	
Control Space	Intervention	magnet	
Control Space	Intervention	sign on door	
Control Space	Intervention	yellow socks	
Control Space	Risks	activity level	
Control Space	Risks	more people	
Control Space	Risks	move to chair	
Control Space	Risks	noise startle	
Control Space	Risks	pushing IV pole	
Control Space	Risks	socks	
Control Space	Risks	tangle in sheets	
Control Space	Risks	Tethers	Foley
Control Space	Risks	Tethers	IV Tethers

Cross walk between Axial and Selective Coding

Axial (Open) coding = 18 nodes with 102 categories

Selective coding = 3 categories:

1. Lack of Patient Control (Space, Assistance, Information),
2. Self-Perception,
3. Patient Background

Selective Coding	Axial Coding Category		
Control Space	Risks	Tethers	Oxygen
Control Space	Risks	Tethers	sequential device ICD
Control Space	Risks	Tethers	Telemetry
Control Space	Risks	Tethers	
Control Space	Risks	tripping	
Control Space	Support methods	furniture for support	
Control Space	Support methods	grab bar	
Patient Background	Nodes\\Patient Stories	Patient Stories	
Patient Background	World View		
Self Perception	belief or denial	belief in fall risk	belief in risk at home
Self Perception	belief or denial	belief in fall risk	belief in risk in hospital
Self Perception	belief or denial	belief in fall risk	
Self Perception	belief or denial	denial of fall risk	denial at home
Self Perception	belief or denial	denial of fall risk	denial in hospital
Self Perception	bjh good job		
Self Perception	denial reasons	acceptance difficulty	
Self Perception	denial reasons	aware of surroundings	
Self Perception	denial reasons	cautious	
Self Perception	denial reasons	denial reasons	
Self Perception	denial reasons	independent	
Self Perception	denial reasons	prior problems not	
Self Perception	denial reasons	protected safe	
Self Perception	denial reasons	stable strong active	
Self Perception	denial reasons	stand to test if help needed	
Self Perception	denial reasons	transfers and hops	

Cross walk between Axial and Selective Coding

Axial (Open) coding = 18 nodes with 102 categories

Selective coding = 3 categories:

1. Lack of Patient Control (Space, Assistance, Information),
2. Self-Perception,
3. Patient Background

Selective Coding	Axial Coding Category		
Self Perception	experienced patient		
Self Perception	other guy not me	know someone that fell	
Self Perception	other guy not me		
Self Perception	Risks	age	
Self Perception	Risks	health status	
Self Perception	Risks	history of fall	