

The author(s) shown below used Federal funds provided by the U.S. Department of Justice and prepared the following final report:

Document Title: A Multi-site Study to Characterize Pressure Ulcers in Long-term Care under Best Practices

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Document No.: 231614

Date Received: August 2010

Award Number: 2006-IJ-CX-0029

This report has not been published by the U.S. Department of Justice. To provide better customer service, NCJRS has made this Federally-funded grant final report available electronically in addition to traditional paper copies.

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A Multi-site Study to Characterize Pressure Ulcers in Long-term Care under Best Practices

Final Technical Report Submission Date: August 18, 2010

NIJ Grant Number 2006-IJ-CX-0029

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This project was supported by Grant No. 2007-IJ-CX-0029 awarded by the National Institute of Justice, Office of Justice Programs, U.S. Department of Justice. Points of view in this document are those of the author and do not necessarily represent the official position or policies of the US Department of Justice.

ABSTRACT

PURPOSE: Pressure ulcers may be an indication of poor care in long-term care facilities including neglect. Despite the fact that pressure ulcers are the number one reason for legal action to be taken against a long-term care facility, no consensus exists about whether full-thickness pressure ulcers can occur under the best of care. The purpose of this study is therefore to better understand and describe advanced stage pressure ulcers in the setting of best practices in long-term care.

GOAL: to increase our understanding of advanced pressure ulcer characteristics in the context of best care in long-term care facilities and to provide useful information on advanced pressure ulcers to forensic investigators, regulators, medical personnel and others.

OBJECTIVES: to confirm full-thickness pressure ulcers development under the best of care in long-term care settings and to characterize these ulcers in order to determine if any characteristic patterns have forensic value.

RESEARCH DESIGN: case-finding through monthly screening in consenting facilities that were deemed to be top performers through Medicare and state databases.

SETTING: sixty-three top-performing skilled nursing facilities in Los Angeles/Orange Counties, greater Seattle, and Denver regions

RESEARCH SUBJECTS: twenty-four elderly residents who received confirmed excellent care and developed full-thickness ulcers that began at the facility

METHODS/MEASUREMENTS: Resident demographics, diagnoses, and medications; characteristics of pressure ulcers: location, number, size, depth, edges, undermining, dead tissue type/amount, exudate type/amount, peripheral tissue swelling, peripheral tissue induration, granulation tissue, epithelialization and skin color around the wound.

RESULTS: Mean age was 83 with 46% women and 92% Caucasian. There was a high prevalence of cardiovascular disease (92%), urinary incontinence (88%), dementia (83%), depression (63%), and renal disease (50%). The compliance rate was high for medication administration, hygiene care, turning, mobility, diet and physical therapy. On Braden risk score, most residents (75%) were not at high risk for development of pressure ulcers. One full-thickness pressure ulcers were present at the evaluation of each resident. Two subjects had an additional stage 2 ulcer. No distinct pattern in ulcer characteristics was identified. 56% of ulcers had a majority of the wound covered with necrotic tissue.

CONCLUSION: Full-thickness pressure ulcers occur even under excellent care in long-term care facilities. No single ulcer characteristic exist that can be used to differentiate an ulcer under good care from one under poor care with the possible exception that a second full-thickness ulcer does not occur under good care.

EXECUTIVE SUMMARY

Introduction

Pressure ulcers in long-term care facilities represent a significant problem with medical, economic, legal and quality of life implications. Pressure ulcers are currently used as an indicator of quality of care and are part of the required Minimum Data Set¹ that long-term care facilities must report.² Internally long-term care facilities utilize pressure ulcers as a quality control indicator and have developed policies for pressure ulcer prevention, assessment, and treatment as part of their quality improvement process. Externally public and private entities look at pressure ulcers as a measure to hold facilities accountable for the care they provide. These external actions include regulations, monitoring, investigations, and lawsuits. In fact, pressure ulcers are the number one reason legal action is taken against long-term care facilities.³ However, the scientific evidence supporting the use of pressure ulcers as a forensic marker is scant.

A debate exists about the relationship between pressure ulcers and the quality of care. Consensus does not exist even among the experts as to whether pressure ulcers are preventable. Some experts believe that all pressure ulcers are preventable or that stage 3 or 4 ulcers always result from poor care.⁴ Similarly some of these experts considered a stage 3 or 4 ulcer by itself as evidence of neglect. This divergence of opinion is not surprising considering the conflicting evidence and studies that come to differing conclusions.

Some studies suggest that the development of pressure ulcers is related to factors that can be changed. A study of VA nursing homes found that the rates of pressure ulcers could not be

¹ MDS 3.0 for Nursing Homes. Available at http://www.cms.gov/nursinghomequalityinitiatives/25_nhqimds30.asp. Accessed August 7, 2010.

² Zimmerman DR. Improving nursing home quality of care through outcomes data: the MDS quality indicators. Int J Geriatr Psychiatry. 2003 Mar; 18(3):250-7.

³ Iyer P. Liability in the care of the elderly. J Obstet Gynecol Neonatal Nurs. 2004 Jan-Feb;33(1):124-31.

⁴ Brandeis GH, Berlowitz DR, Katz P. Are pressure ulcers preventable? A survey of experts. Adv Skin Wound Care. 2001; 14(5):244-8.

explained by the severity of the residents' illness alone.⁵ The authors concluded that pressure ulcers "could mostly be prevented." Several studies have shown a relationship between pressure ulcers and staffing at nursing homes. For example, data from the National Pressure Ulcer Long-Term Care Study showed that more registered nurse direct care time per resident was associated with fewer pressure ulcers.⁶ Similarly more certified nursing assistant and licensed practical nurse time was also associated with fewer pressure ulcers.⁷ A quality improvement initiative resulted in a significant decrease in pressure ulcers in a nursing home.⁸ The success of such quality improvement studies suggests that facility level factors affect care practices and in turn pressure ulcer development.

The counter argument, that pressure ulcers are not preventable, states that pressure ulcers are largely due to resident factors rather than the quality of care. Experts in this camp argue that pressure ulcers are a natural consequence of residents' functional decline from severe illness. They argue that no intervention strategy has ever been reported that consistently and reproducibly reduces the incidence of pressure ulcers to zero.⁹ Some experts have even suggested that "consideration must be given to the growing body of evidence indicating that some patients are incapable of mounting a 'normal' response to the physical forces responsible for the damage observed with pressure ulcers."¹⁰ In fact, the National Pressure Ulcer Long-Term Care Study

⁵ Rudman D, Mattson DE, Alverno L, Richardson TJ, Rudman IW. Comparison of clinical indicators in two nursing homes. J Am Geriatr Soc. 1993;41:1317-25.

⁶ Horn SD, Buerhaus P, Bergstrom N, Smout RJ. RN staffing time and outcomes of long-stay nursing home residents: Pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care. Am J Nurs. 2005 Nov;105(11):58-70.

⁷ Hickey EC, Young GJ, Parker VA, et al. The effects of changes in nursing home staffing on pressure ulcer rates. J Am Med Dir Assoc. 2005 Jan-Feb;6(1):50-3.

⁸ Rosen J, Mittal V, Dengenholz H, et al. Ability, incentives, and management feedback: Organizational changes to reduce pressure ulcers in a nursing home. J Am Med Dir Assoc. 2006 Mar;7(3): 141-6.

⁹ Thomas DR. Are all pressure ulcers avoidable? J Am Med Dir Assoc. 2003 Mar-Apr;4(2 Suppl):S43-8.

¹⁰ Meehan M, Hill WM. Pressure ulcers in nursing homes: Does the negligence litigation exceed available evidence? Ostomy Wound Manage. 2002 Mar; 48(3): 46-54.

concluded that the “underlying physiologic conditions contribute to a greater incidence of pressure ulcers.”¹¹ Most of the factors associated with worsening of pressure ulcers are intrinsic to the resident, such as dementia and depression, rather than the care provided.

The above debate exists because of the paucity of data on the relationship between the care provision and the development of pressure ulcers. The first step is a better understanding the characteristics of advanced pressure ulcers in the setting of best practices. The ground work needs to be laid for the connection between pressure ulcers and neglect by describing the nature of advanced ulcers in the setting where neglect is clearly not occurring in the facility, i.e., a setting of best practices. To begin the exploration of this relationship, we start with the research question, “Do full-thickness pressure ulcers occur under settings of good care?” The purpose of this study was therefore to better understand and describe full-thickness pressure ulcers in the setting of best practices in long-term care. The primary objective is to determine if long-term care residents develop full-thickness pressure ulcers despite good care. Secondary objectives of this study were to document characteristics of advanced pressure ulcers (including photodocumentation) and explore if these ulcers share common characteristics that have forensic value and whether under best practices, a stage 3 or 4 pressure ulcer can present without a prior recognition of a stage 1 or 2 ulcer.

Results

- Out of 91 facilities approached, 63 agreed to participate.
 - Two were long-term acute care facilities
 - None of the research subjects came from the 2 long-term acute care facilities.
 - The rest were skilled nursing facilities.
 - Participating facilities had an average of 100 beds per facility and a range of 32 beds to 290 beds.

¹¹ Horn SD, Bender SA, Bergstrom N, et al. Description of the National Pressure Ulcer Long-term Care Study. J Am Geriatr Soc. 2002; 50:1816-25.

- 28 residents enrolled in the study.
 - 4 residents were excluded by the LEAD panel, because their quality of care was deemed to be below a score of four (very good care) on a one to five scale with five being excellent care.
 - Mean age of the subjects was 83
 - 46% were women and 92% were Caucasian.
- Subjects had a high prevalence of
 - cardiovascular disease (91.7%)
 - urinary incontinence (87.5%)
 - dementia (83.3%)
 - depression (62.5%)
 - renal disease (50%).
- Most of the subjects (75%) were not at high risk for the development of pressure ulcers based on the Braden risk score:
 - 41.7% in the low risk group
 - 33.3% in the moderate risk group.
- The compliance rate was high for
 - medication administration (100%)
 - hygiene care (95.8%)
 - turning (91.7%)
 - mobility (91.7%)
 - diet (83.3%)
 - physical therapy (70.8%).
- Four subjects (16.7%) were referred to or thought to be eligible for hospice care.
- A total of 26 pressure ulcers were present at the time of evaluation.
 - Only two subjects had a second ulcer, and both of these ulcers were stage 2.
- No distinct pattern in ulcer characteristics was identified. These characteristics included:
 - edges, undermining
 - necrotic tissue type, exudate type
 - peripheral tissue edema, peripheral tissue induration,
 - granulation tissue, epithelialization and skin color around the wound.
- Initial stages of the ulcers when first detected were widely distributed:
 - 16% stage 1 (n=4)
 - 44% stage 2 (n=11)
 - 4% stage 4 (n=1)

- 20% deep tissue injury (n=5)
 - 16% unstageable (n=4)
 - 4% unrecorded stage (n=1).
- The depth of the ulcers at time of evaluation by our nurses were
 - partial thickness (n=2)
 - full thickness (n=10)
 - obscured by dead tissue (n=12)
 - damage down to muscle or bone (n=2)
- The location of the ulcers were
 - sacrum (n=8)
 - heel (n=8)
 - ischial tuberosity (n=4)
 - trochanter (n=3)
 - lateral ankle (n=1)
 - other (n=2).
- The size (length x width) of the ulcers also varied:
 - <4 cm squared (n=12)
 - 4 -16 cm squared (n=11)
 - 16.1 – 80 cm squared (n=2)
 - >80 cm squared (n=1)
- The amount of dead tissue covering the wound ran along a spectrum:
 - none (n=9)
 - more than 75% (n=12)
 - one ulcer having less than 25%
 - one ulcer between 25 and 50%
 - 2 ulcers between 51 and 75%.
- The amount of drainage varied from none (n=13), to scant (n=4), small (n=6), and moderate (n=3).

Discussion

Our study found that full-thickness pressure ulcers do develop even under the best of care in long-term care facilities. These ulcers occur even in residents who are cooperative with their care and therefore cannot be attributed to behavioral difficulties despite the high prevalence of dementia, depression, and other psychiatric conditions. Most of the subjects were not at high risk

for development of a pressure ulcer according to accepted scales, had improving nutritional status and were not thought to be at the end of their lives.

No single pressure ulcer characteristic was consistently found in all ulcers and therefore could be used to distinguish full-thickness ulcers that develop under good care from those that develop under less optimal care settings. The one possible exception is that no resident had a second full-thickness ulcer. If this finding can be confirmed in future studies, it may have forensic implications. For example, a resident who has a single full-thickness pressure ulcer may have been receiving excellent care as oppose to a resident receiving poor care who has multiple full-thickness ulcers.

Evidence-based guidelines for the treatment of pressure ulcers state that debridement of dead material is essential for wound healing. The implication is that the presence of significant dead material suggests the resident has not received adequate care. Our study findings suggest that even under good care most full-thickness ulcers have a significant amount of dead material covering the majority of the ulcer.

Our study has several limitations. These limitations are primarily related to the case-finding methodology. This method has an inherent selection bias, in that only confident facilities were willing to participate. The bias favors the intent of our study but nevertheless limits our access to residents who have full-thickness ulcers and who may be receiving excellent care at facilities who were not willing to participate. Despite efforts to enroll as many facilities as possible in multiple states, only a small number of subjects who were receiving excellent care could be found to have full-thickness pressure ulcers. This small number may be due to the low prevalence of such ulcers in high performing facilities. This study was not designed to examine the prevalence rate of full-thickness ulcers in best performing facilities. A larger future study is needed to confirm the findings of our study. Future research is also needed to compare the characteristics of full-thickness pressures ulcers that develop under good care to those that develop under poor care. Such comparative research would have forensic implications for elder

neglect cases and malpractice lawsuits. Our study could not independently confirm the high quality of care at the time that these residents developed their ulcers. We had to rely on the documentation of care that had been provided by the facilities.

Conclusion

Full-thickness pressure ulcers do occur under the setting of excellent care in long-term care facilities. Our study suggests that no single characteristic exist in these ulcers that can be used to identify an ulcer that develops under good care from one that develops under poor care. One possible exception is that only one full-thickness ulcer occurs at any one time under good care. More research is needed to examine forensic issues of pressure ulcer development in long-term care settings.

Introduction

Statement of the Problem

Pressure ulcers that arise in long-term care facilities are a significant problem from medical, economic, and quality of life perspectives. They may be an indicator of elder neglect. With the aging of America, more and more people are expected to spend some time in a long-term care facility. In the United States there are an estimated 17,000 nursing homes that care for 1.6 million residents. By the year 2050 the number of residents in nursing homes are predicted to reach 6.6 million.¹ When people are in a long-term care facility, they are generally at their weakest, most dependent, and therefore most vulnerable state. More than one million long-term care residents are estimated to develop pressure ulcers each year.² In fact, pressure ulcers are the number one reason legal action is taken against long-term care facilities.³ There is a clear need to better determine when pressure ulcers are forensic markers of neglect.

The rate of occurrence of pressure ulcer formation is used by government regulators, investigators, and monitors to assess the quality of care in long-term care facilities. Internally long-term care facilities utilize the number of pressure ulcers as a quality control indicator and have developed policies for pressure ulcer prevention, assessment, and treatment as part of their quality improvement process. Externally both public and private entities look at pressure ulcers as a measure to hold the facilities accountable for the care they provide. These external actions include regulations and lawsuits. However, the scientific evidence supporting the use of pressure ulcers as a forensic marker is scant.

A great debate currently exists about the relationship of pressure ulcers to the quality of care. Pressure ulcers occur under settings of good care as well as poor care. Some experts argue that all pressure ulcers are theoretically preventable and that if sufficient resources and care were provided pressure ulcers would never occur.⁴ Others claim that pressure ulcer development is partly due to factors intrinsic to the resident, factors that facilities cannot change. They argue that pressure ulcers are sometimes and in part a natural consequence of the residents' functional

decline from severe illness. These experts point to the low rate of healing of full-thickness stage ulcers (stages 3 and 4) despite aggressive treatment as evidence supporting their view.⁵

This debate exists because of the paucity of data on the relationship between the care given and the development of pressure ulcers. There is no doubt that deep or full-thickness stage ulcers may indicate negligence or neglect. On the other hand, there is debate over whether full-thickness stage ulcers always indicate negligence or neglect. An understanding of the relationship between pressure ulcers and care is therefore critical to the investigation, prosecution, and protection of full-thickness pressure ulcer cases. Foundational research is sorely needed to address when a pressure ulcer is a marker of neglect. Indeed, more needs to be understood about the range of situations from unavoidable pressure ulcers despite good care, to poor care that leads to their development, to cases that constitute neglect. Research on the relationship of pressure ulcer formation in the context of clinical care is therefore, foundational to determining when a pressure ulcer is a marker of neglect.

Recently challenges have arisen to the traditional staging of pressure ulcers. The current staging system (from 1 to 4) was developed in 1975 from a theoretical model that assumed the pathology of pressure ulcers began from the surface of the skin and developed downward.⁶ This staging system was adopted by the International Association of Enterostomal Therapist in 1991 and has been widely promulgated.⁷ AHCRP incorporated this staging into its guidelines. However, in 2005 both the National Pressure Ulcer Advisory Panel and the Wound-Ostomy-Continence-Nurses Society have raised concerns about the current staging system, particularly in regards to “unstageable” ulcers and deep tissue injuries.⁸ The current system requires identification of the depth of the true wound bed, i.e., down to healthy tissue, for assignment of an ulcer stage. In reality, most ulcers are covered with some degree of dead material, and for many ulcers this dead tissue cannot be successfully removed and thus makes them “unstageable.” Deep tissue injuries are areas of deep bruising or discoloration under intact skin.⁹ These are often mislabeled as stage 1 ulcers. However, when the covering layers of tissue eventually slough off,

revealing the depth of injury, the ulcer is then classified as stage 3 or 4, giving the false impression that ulcer has rapidly advanced.

The notion that pressure ulcers progress predictably from stage 1 to stage 2 and then to stage 3 and finally to stage 4, is being challenged.¹⁰ This staging system was originally intended only to identify the depth of tissue damage, not to reflect stages of development. Recent animal models and human physiological data suggest that pressure ulcers may develop from the “bottom-up” rather than from the “top-down” as the current staging system suggests.^{11,12} A recent review article concluded “it remains somewhat unclear whether pressure ulcers occur from the ‘muscle/bone up’ or from the ‘epidermis down’.”¹⁰

The next step therefore is a better understanding of the characteristics of full-thickness pressure ulcers in the setting of best practices. The ground work needs to be laid for the connection between pressure ulcers and neglect by describing the nature of full-thickness ulcers in the setting where neglect is clearly not occurring in the facility, i.e., a setting of best practices. This approach is similar in philosophy to our bruising studies, funded by the U.S. Department of Justice’s National Institute of Justice in 2001 (NCJ 214649) and 2005 (NCJ 226457). In the first bruising study we analyzed the personal factors and bruise characteristics when a bruise was not the result of abuse.¹³ In the second bruising study we compared the results of the first study with personal factors and bruise characteristics in people who have confirmed physical abuse.¹⁴ Similarly our first pressure ulcer study will describe the significant characteristics and patterns of pressure ulcers that occur in good care settings. A follow up study will need to examine the characteristics of pressure ulcers when neglect is confirmed. This first pressure ulcer study will lay the ground work for comparing the differences in full-thickness pressure ulcer patterns between good care and poor care.

Review of Relevant Literature

The primary literature on the correlation of pressure ulcers to the quality of care in long-term care facilities is scant. To our knowledge, no research study has attempted to examine the

characteristics of pressure ulcers related to elder neglect or mistreatment in long-term care. The medical literature and the lay press report only cases of negligence or neglect,^{15,16} including some that have lead to charges of homicide.¹⁷ The following therefore is a review of available relevant studies on pressure ulcer development related to quality of care as a surrogate measure of neglect.

Pressure Ulcers as Indicators of Quality of Care

In the early 1990's, the Agency for Health Care Policy and Research (AHCPR), now renamed the Agency for Healthcare Research and Quality (AHRQ), developed a clinical practice guideline for pressure ulcers through a multidisciplinary panel based upon the best available evidence.^{18,19} The best available evidence, however, consisted largely of expert opinion, and the panel commented that only a "fair research base" existed. The guidelines were updated in 2000, but due to the paucity of new evidence, little was changed.²⁰

Despite these guidelines being recognized and accepted as the standards of care in long-term care, there is considerable variability in adherence to these guidelines. A recent study of long-term care facilities in Missouri showed that less than 13% of facilities actually use these guidelines for pressure ulcers.²¹ A study of 191 nursing home residents with pressure ulcers showed wide variability of adherence to pressure ulcer guidelines ranging from 0 to 98%.²² In a similar study of 35 Veterans Administration (VA) nursing homes, adherence to the recommendations of guidelines was overall only 41%, ranging from 29% to 51%. Standard assessment of pressure ulcer risk was performed in 61% of residents for whom it was indicated.²³

In the late 1980's, the Minimum Data Set (MDS)²⁴ was implemented by mandate for assessment of all residents in nursing homes receiving federal funding. One of the major domains of the MDS is pressure ulcers. Dr. David Zimmerman, PhD and his colleagues at the University of Wisconsin Center for Health Systems Research and Analysis (UW-CHSRA) were among the first to develop, test and apply the MDS as quality care indicators.²⁵ The current MDS Quality Indicators include 24 variables that measure both processes and outcomes of care at both the resident and facility levels.²⁶ Since then, Dr. Zimmerman has used these quality indicators in

regulatory survey processes and in quality improvement initiatives in long-term care.^{27,28} This survey process also incorporates the most recent guidelines from AHRQ and the American Medical Director's Association. Dr. Zimmerman's team at UW-CHSRA has applied this process under a series of contracts associated with the U.S. Department of Health and Human Service's Office of the Inspector General Corporate Integrity Agreements with nursing home corporations to monitor quality improvement for nursing homes.²⁹

Conflicting Opinions

There is no consensus even among the pressure ulcer experts as to whether pressure ulcers are preventable or are evidence of neglect. A recent survey of 65 experts found divergent opinions.⁴ In this study 62% disagreed with the statement that all pressure ulcers are preventable, but more than 37% agreed with the statement. Forty-two percent agreed that stage 3 or 4 ulcers always resulted from poor care. On the other hand, only 26% believed that full-thickness ulcers are preventable with resources currently available in the nursing home. Even with unlimited resources, only 69% felt that 80% or more of these full-thickness ulcers were preventable. Forty-two percent considered a stage 4 ulcer by itself as evidence of neglect, and 38% considered a stage 3 ulcer as a sign of neglect. This divergence of opinion is not surprising considering the following set of studies that come to differing conclusions.

Some studies suggest that the development of pressure ulcers is related to external factors that can be changed. A study of 30 VA nursing homes found that the rate of pressure ulcers varied from 0% in lowest prevalence facilities to 15% in the highest prevalence facilities.³⁰ This discrepancy could not be explained by the severity of illness alone. The authors concluded that pressure ulcers "could mostly be prevented." In another study that looked at state variability in indicators of nursing home quality of care, significant variability of pressure ulcer scores existed after adjusting for the resident's risk of developing one. This study suggested that pressure ulcer development is a valid indicator of the care provided to long-term care residents.³¹

Several studies have shown a relationship between pressure ulcers and staffing at nursing homes. For example, data from the National Pressure Ulcer Long-Term Study showed that more registered-nurse direct-care time per resident was associated with fewer pressure ulcers.³² Similarly more certified nursing assistant and licensed practical nurse time was also associated with fewer pressure ulcers. In another VA nursing home study, reduction of staffing levels or a down-grading of the staffing mix (from licensed personnel to nursing assistants) led to a significant increase in the rate of pressure ulcer development.³³ A recent quality improvement initiative resulted in a significant decrease in pressure ulcers in a single nursing home.³⁴ The success of such quality improvement studies suggested that facility level factors do affect pressure ulcer development.

The counter argument, that pressure ulcers are not preventable, also has research support. This perspective argues that pressure ulcers are largely due to factors associated with the resident's morbidity rather than the quality of care. Experts in this camp argue that no intervention strategy has ever been reported that consistently and reproducibly reduces the incidence of pressure ulcers to zero.⁵ They point to a study that showed no change in national pressure ulcer prevalence since the enactment of the Omnibus Budget Reconciliation Act of 1987 (which led to the implementation of the MDS) as epidemiologic evidence that the underlying factors that lead to pressure ulcers are not amenable to external influences.³⁵ Another study found no relationship between quality indicators and the prevalence of pressure ulcers at nursing homes.³⁶ There was no difference in the MDS pressure ulcer quality indicator between nursing homes with low prevalence of pressure ulcers and nursing homes with high prevalence. However, this study also found that neither low-prevalence or high prevalence nursing homes routinely repositioned residents every two hours, even though such turning was documented in the medical records for nearly all residents.

Some experts have even suggested that “consideration must be given to the growing body of evidence indicating that some patients are incapable of mounting a ‘normal’ response to the

physical forces responsible for the damage observed with pressure ulcers.³⁷ In fact, the largest study ever done on pressure ulcers, the National Pressure Ulcer Long-Term Care Study, concluded that the “underlying physiologic conditions contribute to a greater incidence of pressure ulcers.”² This same conclusion is shared by authors of other studies.^{38,39} Most of the factors associated with worsening of pressure ulcers are intrinsic to the resident, such as dementia and depression, rather than the care provided.⁴⁰ Other associated factors, such as enteral feeding and incontinence, are a mix of intrinsic characteristics and the care provided.³⁹ Finally, in a study of 542 patients at high risk for developing pressure ulcers in a Canadian palliative care unit, 11% of the new ulcers that developed were stage 3 or 4. This study suggested that full-thickness stage ulcers do occur in patients with advanced illness even under the setting of optimal care.⁴¹

Summary

Because the literature regarding elder mistreatment and pressure ulcers consists largely of case studies, we must extrapolate from the available research on pressure ulcers and quality of care in long-term care. Even in this literature, there is no agreement as to whether pressure ulcers are preventable and a reflection of the care provided or whether they are due to characteristics intrinsic to the resident and therefore unavoidable. Recent studies are challenging the long-held conceptual framework of the staging and progression of these ulcers. The fundamental pathophysiology of pressure ulcers is still unclear as is the relationship between quality of care and pressure ulcer occurrence. As one author pointed out, we “must focus on establishing a...far more nuanced body of knowledge” for the evidence necessary for legal actions.³⁵

Statement of Rationale for the Research

The purpose of this study was to better understand and describe full-thickness pressure ulcers in the setting of best practices in long-term care and to determine if long-term care residents develop full-thickness pressure ulcers despite good care.

Goals

The goals of this study were to increase our understanding of full-thickness pressure ulcer characteristics in the context of good care in long-term care facilities and to provide useful information on full-thickness pressure ulcers to forensic investigators, regulators, medical personnel and others. To achieve these goals, we examined the characteristics of these ulcers, the care of the residents who have these ulcers, and the overall quality of care at the facilities. We confirmed the quality of skin care at the facility level and for the individual resident.

Objectives

Our main objective was to determine if long-term care residents may develop full-thickness pressure ulcers despite good care. Secondary objectives were to determine if these pressure ulcers will have been noticed prior to becoming a stage 3 or 4, and whether these ulcers will share some common characteristics that have forensic value. We focused on full-thickness ulcers, which are the most common concern in cases of neglect, and therefore, have the most forensic value. To achieve the main objective, our corollary objectives were to address the following study questions:

- Do full-thickness pressure ulcers develop in the setting of best care practices in long-term care?
- What are the characteristics (e.g. size, location, presence of dead tissue) of full-thickness pressure ulcers in the setting of best practice* in long-term care?
- Under best practices, can a stage 3 or 4 pressure ulcer present without a prior recognition of a stage 1 or 2 ulcer?
- What are the characteristics of a resident who develops a full-thickness pressure ulcer despite good care?

*Note on Definitions: Quality of care can be described at two levels, at the overall level of the facility and at the level of the individual resident. The term, “best practices”, refers to the care at the facility level. At this level, care can be measured by prevalence of pressure ulcers adjusted to the risk of the resident population, by comparison of the facility’s policies to national guidelines, and by adherence of the residents’ care to the facility’s policies. Institutional best practices makes good care at the resident level more likely but does not necessarily guarantee it. Best practices reduce the likelihood of neglect by individual staff by placing in systemic measures that encourages good care and discourages bad care. Therefore, while the term “good care” can be used at both the facility and resident levels, the term “best practice” was used in this study to be equivalent to good care provided at the facility level.

Methods

Identifying Best Performing Facilities

Long-term care facilities with best practices were sought in the Los Angeles – Orange County and greater Seattle regions. For this study, best practices were defined as high performance in the top 33% of Medicare data bases⁴² without a deficiency for pressure ulcers in the prior 12 months or in the top category of the California state data base of long-term care facilities (four out of four stars).⁴³ The headquarters of the national corporations of long-term care facilities were also contacted for their permission to involve their best facilities in the study. However, of the national corporate facilities, only facilities in the Denver area contributed subjects to this study. Cooperation and permission were obtained from the administration of each facility. This study was approved by the Institutional Review Boards of the University of California, Irvine; the University of Washington, Seattle; and the University of Wisconsin, Madison.

Monthly contact was made to a designated contact person at each participating facility to see if they had a resident who has full-thickness pressure ulcer that developed in their facility. When such a resident was identified, the research nurses screened the quality of the overall care and of the skin care at each facility using an approach similar to that of federal monitors. The research nurses spent up to one full day reviewing the facility's quality of care, as well as reviewing policies on pressure ulcer prevention and care. Through observation, research nurses confirmed staff adherence to these policies and the accuracy of their assessment and documentation. Once the facility's performance was confirmed to be at or above their rating in the data bases, residents at the facility were eligible for the study.

Staff Training and Inter-rater Reliability

A two-day training course was held at the beginning of the project to ensure consistency and inter-rater reliability among the sites. All the co-investigators and the four research nurses attended the course. The research nurses were educated on the use of the Decision-Making

Capacity Assessment Tool (Appendix A), the Bates-Jensen Wound Assessment Tool (BWAT – Appendix B)⁴⁴ and the use of the Pressure Sore Status Tool (PSST – Appendix C). Using photographs from non-study-related clinical settings from nurse wound experts in the area, the reliability of the research nurses' assessments using the BWAT was measured by comparison to assessments by two certified wound nurses who were part of the research team. Research nurses independently assessed photographs. Scores were compared, and kappa statistics were calculated for inter-rater reliability. When there was disagreement on any individual item, areas of discrepancy were discussed and resolved until 90% consensus was achieved.

Recruitment of Residents with Full-thickness Pressure Ulcers

Once the quality of care at the facility level was confirmed, elderly residents at the facilities who had at least one pressure ulcer of stage 3 or 4 were recruited within one week of the facility assessment. Inclusion criteria for the residents included:

- 1) Age 65 years or older
- 2) Current occurrence of at least one stage 3 or 4 (full-thickness) pressure ulcer
- 3) The full-thickness pressure ulcer developed at the facility, i.e., the resident did not come into the facility with the ulcer
- 4) Ability to obtain informed consent, either from the resident or an appropriate proxy decision maker

Because of the low prevalence of qualifying full-thickness ulcers, no facility required a second reassessment in order to enroll additional residents. An initial attempt was made to obtain informed consent from the resident to enter the study. If the resident's ability to give consent was in doubt, i.e., the resident did not demonstrate complete understanding or there was suggestion of some confusion, the research nurse employed a Decision-Making Capacity Assessment Tool required by the state of California. If the resident was clearly unable to provide consent, consent was obtained directly from the proxy decision maker; however, if the resident did not want to participate those wishes were honored, regardless of the decision of the proxy. A copy of the

signed consent was given to the patient or designated decision-maker, and a copy was placed into the resident's chart (Appendix D).

Data Collection

Descriptive data for the facility and individual residents were collected. The size (number of beds) and type of facility was recorded. Outcomes of the facility-level assessment of quality of care discussed above were recorded including adherence to quality of care indicators. Residents were enrolled from August 2007 through August 2009. Resident demographics, diagnoses, and medications were recorded. The resident's risk for pressure ulcer was recorded using a Braden score (Appendix E).

The research nurses used the PSST to collect data on all of the residents' pressure ulcers. The PSST is a validated instrument that has been tested on thousands of subjects in many research studies.⁴⁵ It has demonstrated good inter-rater and intra-rater reliability.⁴⁶ In addition, the research nurses documented 1) the location of each full-thickness pressure ulcer on the body with both a written description and a body diagram, 2) the total number of pressure ulcers (stage 2 or greater), 3) the date each full-thickness pressure ulcer was first detected, and 4) the initial stage at the time of discovery. If the initial presentation was unstageable or was a suspected deep tissue injury, the research nurse recorded why the ulcer was unstageable. The research nurses assessed the pressure ulcers only once during routine wound care so as to minimize the discomfort to the resident and disruption of the staff's work flow. No attempts at debridement were made. With permission from the resident or proxy, the research nurses took color photographs of each full-thickness ulcer using a high-resolution digital camera and a standardized protocol. Pictures were stored in secure computer files for evaluation of characteristics for potential forensic relevance or in the event questions about the ulcer arose during data analysis for the main study aims. No follow-up evaluation of the ulcers was performed.

Confirmation of Quality of Care at the Resident Level

In order to confirm that the quality of care provided to the individual resident was good or excellent, the research nurses abstracted relevant information from individual medical records. This conformational process ensured not only that the conglomerate care provided at the facility level was of high quality, but that the individual resident actually received this high quality care. The information included but was not limited to medical diagnoses (especially the presence of dementia or depression), medications, nutritional status, mental status (including cognition and behavioral problems), mobility, incontinence, and the care provided for the pressure ulcers. Specifics of the pressure ulcer care provided were examined in detail including support/pressure reduction surfaces, turning schedules, nutritional interventions, debridement, and topical treatments.

Since there is no gold standard for assessing the quality of care for an individual resident, a LEAD panel reviewed the care provided. A LEAD (Longitudinal, Expert, All Data) panel is a multidisciplinary team of experts who review all the available information to reach a consensus.⁴⁷ Such panels have been used to assess the quality of care in elder abuse studies.⁴⁸ Our LEAD panel consisted of two board-certified, fellowship-trained geriatricians and two doctoral prepared nurse researchers with expertise in geriatric nursing and wound care. A quorum of three panel members was required. The research nurse who assessed the resident and the facility presented each case to the panel and was present for the discussion. The LEAD panel was blinded to the specific details of the current ulcer or ulcers, so that these findings would not biases their determination of the quality of care the subject received. Panel members were permitted to know the initial presentation of the ulcers (such as initial stage and characteristics) and the history of their care. After reviewing information provided by the research nurse and listening to the discussion by the panel, panel members rated the quality of care for the resident on a 5-point Likert scale, from excellent care = 5 to poor care = 1 (appendix F). Any resident whose care was

rated with a score of 3 (good care) or less was excluded from the study. The panel met via video- or tele-conferencing on a monthly basis to review the cases.

Analysis

Descriptive analysis was performed. The purpose of this analysis was to identify patterns of distribution in order to understand the “normal range” of full-thickness pressure ulcer under good care. Patterns of characteristics were sought. A standard computer statistical package, SPSS version 17.0 (Chicago, IL), was used.

Results

Out of 91 facilities approached, 63 agreed to participate. (Please also see exhibits 1 & 2.) Of these 2 were long-term acute care facilities, and the rest were skilled nursing facilities. None of the research subjects came from the two long-term acute care facilities. Participating facilities had an average of 100 beds per facility and a range of 32 beds to 290 beds. One facility closed one year into the study.

Forty-six residents were identified as eligible for the study. (Please also see exhibits 1 & 3.) Nine residents or their families declined consent. Six were not available to provide consent due to illness or hospitalization, and three died before consent could be obtained. Twenty-eight residents enrolled in the study. Information about the residents who did not enroll was not collected. Four cases were excluded because the LEAD panel determined the quality of care provided to the individual did not meet study criteria for inclusion (score of 4 or 5).

Characteristics of the remaining 24 residents who were analyzed for the study are shown in Exhibit 4. Participants had a high overall prevalence of cardiovascular disease (91.7%), urinary incontinence (87.5%), dementia (83.3%), depression (62.5%), and renal disease (50%). Despite the combined high prevalence of dementia, depression, or other psychiatric disorders (91.7%), patient compliance with medication, hygiene care, turning, mobility, diet, and physical therapy interventions was high. (See Exhibit 5.) Four subjects (16.7%) were on or referred to hospice care.

Based on the Braden Risk Score, most of the subjects (75%) were not at high risk for the development of pressure ulcers, with 41.7% in the low risk group and 33.3% in the moderate risk group. Seven (29.2%) subjects had a history of other pressure ulcers that developed at the skilled nursing facility, and six (25%) subjects had a history of pressure ulcer(s) that developed outside of the facility.

A total of 26 pressure ulcers were present at the time of evaluation by the research nurse. Two subjects had a second ulcer, both of which were Stage 2 ulcers. Characteristics of the 26 ulcers according to the Pressure Sore Status Tool are listed in Exhibit 6. One ulcer that was a Stage 4 at the time of detection was on the ischial tuberosity of a resident who had a previous Stage IV ulcer at the same site that had healed. The skin was documented to be intact the day before the index ulcer appeared.

Exhibit 1: Eligible Facilities and Residents

	Seattle	Orange County	National Corporations	Total
Eligible facilities	40	34	17	91
Participating facilities	25	21	17	63
Reasons for not participating			Not applicable	
No response	8	0		
Declined	5	10		
Too Busy	1	2		
No full-thickness ulcers	1	1		
Eligible residents	27	8	11	46
Enrolled residents	20	4	4	28
Reasons for not participating				
Declined	4	2	3	9
Not available	2	0	4	6
Death	1	2	0	3

Exhibit 2: Facility Participation

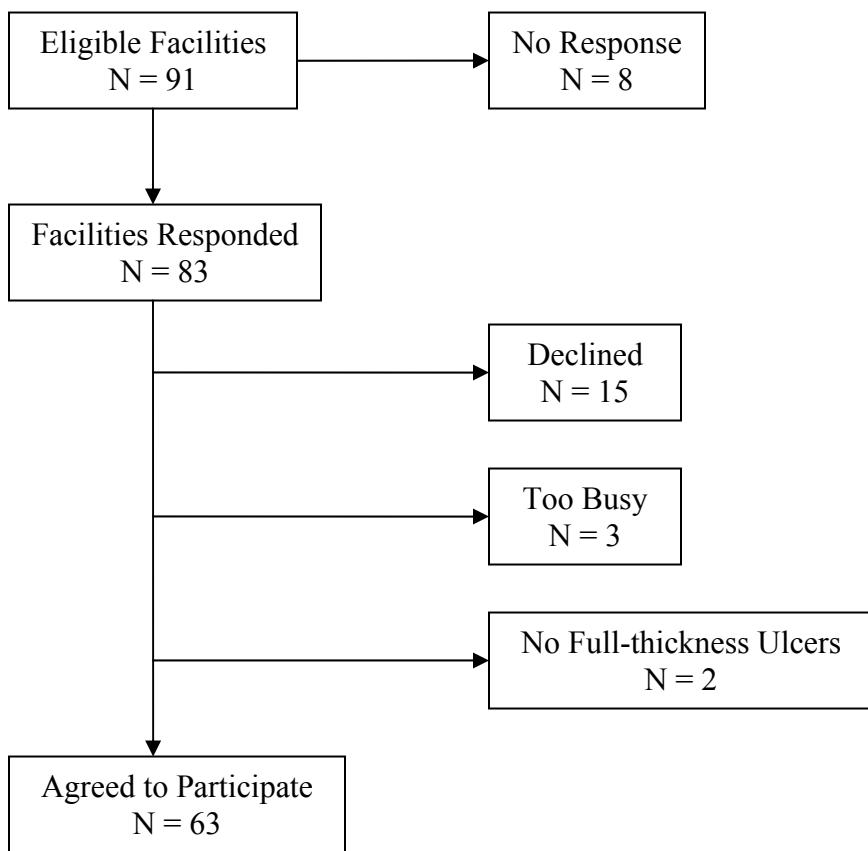


Exhibit 3: Resident Participation

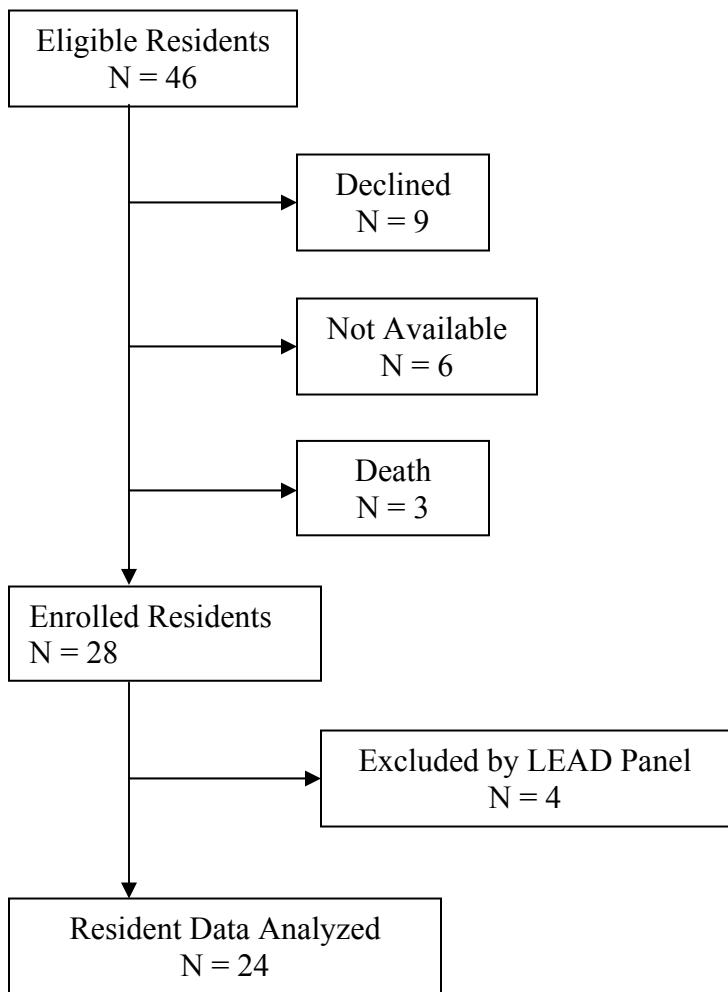


Exhibit 4: Subject Characteristics (n = 24)

Mean Age (Range)	83 (69 – 93)
Female Gender	11 (46%)
Race	
Caucasian	22 (92%)
African American	2 (8%)
Cardiovascular Disease	22 (91.7%)
Urinary Incontinence	21 (87.5%)
Diagnosis of Dementia	20 (83.3%)
Diagnosis of Depression	15 (62.5%)
Renal Disease	12 (50%)
Fall in the last 6 months	11 (47.8%)
Other Psychiatric Conditions	7 (29.2%)
Pulmonary Disease	6 (25%)
Peripheral Vascular Disease	5 (20.8%)
Diabetes	4 (16.7%)
Contractures	
None	16 (66.7%)
Mild	3 (12.5%)
Moderate	4 (16.7%)
Severe	1 (4.2%)
Mean number of prescribed medications	17

Exhibit 5: Resident Compliance with Care

Medication	24 (100%)
Hygiene	23 (95.8%)
Turning	22 (91.7%)
Mobility	22 (91.7%)
Diet	20 (83.3%)
Physical Therapy	17 (70.8%)

Exhibit 6: Pressure Ulcer Characteristics

	N = 26	%
Initial Stage when 1 st detected		
Stage 1	4	16
Stage 2	11	44
Stage 4	1	4
Deep Tissue Injury	5	20
Unstageable	4	16
No stage recorded	1	4
Depth at time of Evaluation		
Partial Thickness	2	7.7
Full Thickness	10	38.5
Obscured by Necrosis	12	46.2
Full thickness loss (damage to muscle, bone, supporting structures)	2	7.7
Location		
Sacrum	8	31
Heel	8	31
Ischial Tuberosity	4	15.5
Trochanter	3	11.5
Lateral Ankle	1	4
Other	2	8
Size (Length x Width)		
<4 cm squared	12	46.2
4 -16 cm squared	11	42.3
16.1 - 36 cm squared	1	3.8
36.1 – 80 cm squared	1	3.8
>80 cm squared	1	3.8
Amount of Necrotic Tissue		
None Visible	9	36
<25% of wound covered	1	4
25% to 50% of wound covered	1	4
>50% and < 75% of wound covered	2	8
75% to 100% of wound covered	12	48
Amount of Exudate		
None or dry	13	50
Scant or moist	4	15.4
Small	6	23.1
Moderate	3	11.5

Conclusion

Discussion of Findings

Our study found that full-thickness pressure ulcers do develop even under the best of care in long-term care facilities. These ulcers occurred even when residents were cooperative with their care and with a high prevalence of co-morbid dementia, depression, and other psychiatric conditions. Most of the subjects were not at high risk for development of a pressure ulcer according to Braden risk scoring and were generally not on hospice care. Conclusions from this study must be tempered by the small sample size. This small sample size was due to the strict and multiple layers of assurance that high quality care was being provided and due to the natural low prevalence of the condition. Results as discussed here are more descriptive than quantitatively conclusive.

Evidence-based guidelines for the treatment of pressure ulcers state that debridement of dead material is essential for wound healing.⁴⁹ The implication is that the presence of significant dead material suggests the inadequate care. Decisions about debridement however are based on goals of care, types of topical treatments, some of which act as debriding agents, and also the availability of providers trained in debridement methods. Nonetheless, our study findings suggest that, even under good care, most full-thickness ulcers have a significant amount of dead tissue covering the majority of the ulcer on presentation.

We observed one pressure ulcer that was a stage 4 at the time of discovery in a person who had a stage 4 pressure ulcer at the same site that had previously healed. Findings in this case are consistent with research that identifies increased risk for full-thickness pressure ulcer recurrence at the site of a previous full-thickness ulcer.^{50,51} The develop of this stage 4 ulcer over scarred tissue does not generalize to normal intact skin. We are therefore unable to answer our third research question about whether full thickness ulcers can develop directly from normal intact skin.

Our study has several other limitations. These limitations are primarily related to the case-finding methodology. This method has an inherent selection bias given that we had a convenience sample. The bias favors the intent of our study but, nevertheless, limits our access to residents who have full-thickness ulcers and who may be receiving excellent care at facilities who were not willing to participate. Despite efforts to enroll as many facilities as possible in multiple states, only a small number of subjects who were receiving excellent care could be found to have full-thickness pressure ulcers. This small number may be due to the low prevalence of such ulcers in best care facilities. This study was not designed to examine the prevalence rate of full-thickness ulcers in best performing facilities.

Because of the cross-sectional nature of our study, we could not independently confirm the high quality of care at the time that these residents developed their ulcers. We relied partially on documentation of care that had been provided by the facilities and on discussions with the patient, family, and facility staff. The possibility exists that the care these subjects received at the time of the development of their ulcers was not of the same quality as they were receiving at the time of our evaluation.

Implications for Policy and Practice

Our study results have implications for legal and regulatory policy and practice. We believe that the presence of a single full-thickness pressure ulcer cannot and should not be used by itself as an indicator of poor care. Rather as in most forensic situations, the overall pattern of care is more important than a single physical finding. As with bruises, the overall context of the physical finding is more important than the characteristics of the skin lesion. Just as a bruise may be an indication of abuse with one story and the same bruise not related to abuse in a different context, pressure ulcers are only one piece of the larger puzzle. Because of the multi-factorial nature of pressure ulcers, the quality of care is only one determinant of the development and healing of ulcers. This multi-factorial nature also makes the development and progression of

pressure ulcers the culmination or final common pathway for many problems. They therefore serve as a sentinel marker of dysfunction, a breakdown that results from the interplay between the psychosocial and biomedical aspects of a resident.

Our results call into question whether pressure ulcers are an accurate indicator of the quality of care provided in skilled nursing facilities. Since not all full-thickness pressure ulcers can be prevented even in the best facilities, should pressure ulcers be used to hold facilities accountable for the level of care they provide? If no single indicator is reliable, then a more global approach is needed. We have demonstrated that such an approach can be done and has been done. However, our study does not speak to those with multiple full-thickness pressure ulcers. Certainly these residents with multiple ulcers have been known to be victims of neglect. If anything, our study further supports the notion that multiple full-thickness ulcers may be an indication of poor care.

We hope our study will help those who investigate and prosecute elder mistreatment be more efficient. The results of this study may assist law enforcement, ombudsman, Adult Protective Services, and prosecutors in eliminating cases of pressure ulcers that are not due to poor care. This efficiency would not only save time and money but allow them to focus more effectively on their other cases of mistreatment.

Finally we hope the results of this study will reduce unnecessary civil lawsuits. Long-term care facilities that provide good care will hopefully see a reduction of lawsuits over the development of a single full-thickness pressure ulcer. If a reduction in the initiation of these lawsuits or an enhancement their resolution can occur, then millions of dollars could potentially be saved.

Implications for Further Research

More research is needed to examine the forensically relevant characteristics of pressure ulcers. Further research should examine how deep-tissue injuries can be undetected one day and

become a full-thickness pressure ulcer the next. Because of the small size of our study, more research needs to be conducted to confirm our findings. Future research is needed to compare the characteristics of full-thickness pressures ulcers that develop under good care to those that develop under poor care. Such comparative research would have forensic implications for elder neglect cases and malpractice lawsuits.

Summary

Full-thickness pressure ulcers do occur under the setting of best care in long-term care facilities. Our study suggests that no single characteristic existed in these ulcers that could be used to identify an ulcer that developed under good care from one that developed under poor care. One possible exception is the suggestion that only one full-thickness ulcer occurs at any one time. More research is needed to examine forensic issues of pressure ulcer development in long-term care settings.

Appendix A: Decision-Making Capacity Assessment Tool

Potential Subject: _____ Date: _____

Protocol Title

Protocol IRB #

There are four elements of decision-making capacity that will be assessed for this specific research protocol:

1. **Understanding:**

What is the purpose of the research study? _____

What will happen to you in this research study? _____

2. **Appreciation:**

What are the potential risks of this research study? _____

What are the potential benefits of this research study? _____

3. **Reasoning:**

What alternative is there if you choose not to participate in this study? _____

4. **Expressing a Choice:**

Does the individual express a choice about whether or not to participate? _____

5. **Does the individual have the decision-making capacity to give informed consent for this study?**

Yes No

Printed Name of Evaluator

Signature of Evaluator

Appendix B: BATES-JENSEN WOUND ASSESSMENT TOOL

Instructions for use

General Guidelines:

Fill out the attached rating sheet to assess a wound's status after reading the definitions and methods of assessment described below. Evaluate once a week and whenever a change occurs in the wound. Rate according to each item by picking the response that best describes the wound and entering that score in the item score column for the appropriate date. When you have rated the wound on all items, determine the total score by adding together the 13-item scores. The HIGHER the total score, the more severe the wound status. Plot total score on the Wound Status Continuum to determine progress.

Specific Instructions:

1. **Size:** Use ruler to measure the longest and widest aspect of the wound surface in centimeters; multiply length x width.
2. **Depth:** Pick the depth, thickness, most appropriate to the wound using these additional descriptions:
1 = tissues damaged but no break in skin surface.
2 = superficial, abrasion, blister or shallow crater. Even with, &/or elevated above skin surface (e.g., hyperplasia).
3 = deep crater with or without undermining of adjacent tissue.
4 = visualization of tissue layers not possible due to necrosis.
5 = supporting structures include tendon, joint capsule.
3. **Edges:** Use this guide:
Indistinct, diffuse = unable to clearly distinguish wound outline.
Attached = even or flush with wound base, no sides or walls present; flat.
Not attached = sides or walls are present; floor or base of wound is deeper than edge.
Rolled under, thickened = soft to firm and flexible to touch.
Hyperkeratosis = callous-like tissue formation around wound & at edges.
Fibrotic, scarred = hard, rigid to touch.
4. **Undermining:** Assess by inserting a cotton tipped applicator under the wound edge; advance it as far as it will go without using undue force; raise the tip of the applicator so it may be seen or felt on the surface of the skin; mark the surface with a pen; measure the distance from the mark on the skin to the edge of the wound. Continue process around the wound. Then use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.
5. **Necrotic Tissue Type:** Pick the type of necrotic tissue that is predominant in the wound according to color, consistency and adherence using this guide:
White/gray non-viable tissue = may appear prior to wound opening; skin surface is white or gray.
Non-adherent, yellow slough = thin, mucinous substance; scattered throughout wound bed; easily separated from wound tissue.
Loosely adherent, yellow slough = thick, stringy, clumps of debris; attached to wound tissue.
Adherent, soft, black eschar = soggy tissue; strongly attached to tissue in center or base of wound.
Firmly adherent, hard/black eschar = firm, crusty tissue; strongly attached to wound base and edges (like a hard scab).

6. **Necrotic Tissue Amount:** Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.
7. **Exudate Type:** Some dressings interact with wound drainage to produce a gel or trap liquid. Before assessing exudate type, gently cleanse wound with normal saline or water. Pick the exudate type that is predominant in the wound according to color and consistency, using this guide:
Bloody = thin, bright red
Serosanguineous = thin, watery pale red to pink
Serous = thin, watery, clear
Purulent = thin or thick, opaque tan to yellow
Foul purulent = thick, opaque yellow to green with offensive odor
8. **Exudate Amount:** Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to determine percent of dressing involved with exudate. Use this guide:
None = wound tissues dry.
Scant = wound tissues moist; no measurable exudate.
Small = wound tissues wet; moisture evenly distributed in wound; drainage involves \leq 25% dressing.
Moderate = wound tissues saturated; drainage may or may not be evenly distributed in wound; drainage involves $> 25\%$ to $< 75\%$ dressing.
Large = wound tissues bathed in fluid; drainage freely expressed; may or may not be evenly distributed in wound; drainage involves $> 75\%$ of dressing.
9. **Skin Color Surrounding Wound:** Assess tissues within 4cm of wound edge. Dark-skinned persons show the colors "bright red" and "dark red" as a deepening of normal ethnic skin color or a purple hue. As healing occurs in dark-skinned persons, the new skin is pink and may never darken.
10. **Peripheral Tissue Edema & Induration:** Assess tissues within 4cm of wound edge. Non-pitting edema appears as skin that is shiny and taut. Identify pitting edema by firmly pressing a finger down into the tissues and waiting for 5 seconds, on release of pressure, tissues fail to resume previous position and an indentation appears. Induration is abnormal firmness of tissues with margins. Assess by gently pinching the tissues. Induration results in an inability to pinch the tissues. Use a transparent metric measuring guide to determine how far edema or induration extends beyond wound.
11. **Granulation Tissue:** Granulation tissue is the growth of small blood vessels and connective tissue to fill in full thickness wounds. Tissue is healthy when bright, beefy red, shiny and granular with a velvety appearance. Poor vascular supply appears as pale pink or blanched to dull, dusky red color.
12. **Epithelialization:** Epithelialization is the process of epidermal resurfacing and appears as pink or red skin. In partial thickness wounds it can occur throughout the wound bed as well as from the wound edges. In full thickness wounds it occurs from the edges only. Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved and to measure the distance the epithelial tissue extends into the wound.

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BATES-JENSEN WOUND ASSESSMENT TOOL

NAME

Complete the rating sheet to assess wound status. Evaluate each item by picking the response that best describes the wound and entering the score in the item score column for the appropriate date.

Location: Anatomic site. Circle, identify right (**R**) or left (**L**) and use "**X**" to mark site on body diagrams:

Sacrum & coccyx Lateral ankle

Trochanter Medial ankle

Ischial tuberosity Heel Other Site

Shape: Overall wound pattern; assess by observing perimeter and depth.

Circle and date appropriate description:

Irregular Linear or elongated

Round/oval Bowl/boat

Shape Item	Assessment	Date Score	Date Score	Date Score
1. Size	1 = Length x width <4 sq cm 2 = Length x width 4--<16 sq cm 3 = Length x width 16.1--<36 sq cm 4 = Length x width 36.1--<80 sq cm 5 = Length x width >80 sq cm			
2. Depth	Non-blanchable erythema on intact skin Partial thickness skin loss involving epidermis &/or dermis 3 = Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; &/or mixed partial & full thickness &/or tissue layers obscured by granulation tissue Obscured by necrosis Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures			
3. Edges	1 = Indistinct, diffuse, none clearly visible 2 = Distinct, outline clearly visible, attached, even with wound base 3 = Well-defined, not attached to wound base 4 = Well-defined, not attached to base, rolled under, thickened 5 = Well-defined, fibrotic, scarred or hyperkeratotic			
4. Undermining	1 = None present 2 = Undermining < 2 cm in any area 3 = Undermining 2-4 cm involving < 50% wound margins 4 = Undermining 2-4 cm involving > 50% wound margins 5 = Undermining > 4 cm or Tunneling in any area			

5. Necrotic Tissue Type	1 = None visible 2 = White/grey non-viable tissue &/or non-adherent yellow slough 3 = Loosely adherent yellow slough 4 = Adherent, soft, black eschar 5 = Firmly adherent, hard, black eschar
6. Necrotic Tissue Amount	1 = None visible 2 = < 25% of wound bed covered 3 = 25% to 50% of wound covered 4 = > 50% and < 75% of wound covered 5 = 75% to 100% of wound covered
7. Exudate Type	1 = None 2 = Bloody 3 = Serosanguineous: thin, watery, pale red/pink 4 = Serous: thin, watery, clear 5 = Purulent: thin or thick, opaque, tan/yellow, with or without odor
8. Exudate Amount	1 = None, dry wound 2 = Scant, wound moist but no observable exudate 3 = Small 4 = Moderate 5 = Large
9. Skin Color Sur-rounding Wound	1 = Pink or normal for ethnic group 2 = Bright red &/or blanches to touch 3 = White or grey pallor or hypopigmented 4 = Dark red or purple &/or non-blanchable 5 = Black or hyperpigmented
10. Peripheral Tissue Edema	1 = No swelling or edema 2 = Non-pitting edema extends <4 cm around wound 3 = Non-pitting edema extends \geq 4 cm around wound 4 = Pitting edema extends < 4 cm around wound 5 = Crepitus and/or pitting edema extends >4 cm around wound
11. Peripheral Tissue Induration	1 = None present 2 = Induration, < 2 cm around wound 3 = Induration 2-4 cm extending < 50% around wound 4 = Induration 2-4 cm extending \geq 50% around wound 5 = Induration > 4 cm in any area around wound
12. Granulation Tissue	1 = Skin intact or partial thickness wound 2 = Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth 3 = Bright, beefy red; < 75% & > 25% of wound filled

4 = Pink, &/or dull, dusky red &/or fills \leq 25% of wound

5 = No granulation tissue present

13. Epithelialization

1 = 100% wound covered, surface intact

2 = 75% to <100% wound covered &/or epithelial tissue

extends >0.5cm into wound bed

3 = 50% to <75% wound covered &/or epithelial tissue

extends to <0.5cm into wound bed

4 = 25% to < 50% wound covered

5 = < 25% wound covered

TOTAL SCORE

SIGNATURE

Appendix C: Scoring of the Pressure Sore Status Tool

Overview :

The Pressure Sore Status Tool (PSST) was developed to standardize the description of pressure ulcers. This can help both in communication between clinicians and in the evaluation of therapeutic interventions. The authors are from UCLA.

NOTE: The instrument is copyright by Barbara Bates-Jensen.

Parameters (definitions and instructions for use are given in Figure 1 on page 24)

- (1) size
- (2) depth
- (3) edges
- (4) undermining
- (5) necrotic tissue type
- (6) necrotic tissue amount
- (7) exudate type
- (8) exudate amount
- (9) skin color surrounding wound
- (10) peripheral tissue edema
- (11) peripheral tissue induration
- (12) granulation tissue
- (13) epithelialization

Parameter	Finding	Points
size (length * width)	< 4 square cm	1
	4 16 square cm	2
	16.1 36 square cm	3
	36.1 80 square cm	4
	> 80 square cm	5
depth	non-blanchable erythema on intact skin	1
	partial thickness skin loss involving epidermis and/or dermis	2
	full-thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through the underlying fascia and/or mixed partial and full thickness and/or tissue layers obscured by granulation tissue	3
	obscured by necrosis	4
	full-thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures	5
edges	indistinct, diffuse, none clearly visible	1
	distinct, outline clearly visible, attached, even with wound base	2
	well-defined, not attached to wound base	3
	well-defined, not attached to base, rolled under and thickened	4
	well-defined, fibrotic, scarred or hyperkeratotic	5
undermining	< 2 cm in any area	1
	2 4 cm involving <= 50% of wound margin	2
	2 4 cm involving > 50% of wound margin	3
	> 4 cm in any area	4
	tunelling and/or sinus tract formation	5
necrotic tissue type	none visible	1
	white/grey non-viable tissue and/or non-adherent yellow slough	2
	loosely adherent yellow slough	3
	adherent, soft black eschar	4
	firmly adherent, hard, black eschar	5
necrotic tissue amount	none visible	1
	< 25% of wound base covered	2
	25 50% of wound covered	3
	50.1 74.9% of wound covered	4
	>= 75% of wound covered	5
exudate type	none or bloody	1
	serosanguinous, thin, watery, pale red/pink	2
	serous, thin, watery, clear	3
	purulent, thin or thick, opaque, yellow/green	4
	foul purulent, thick, opaque, yellow/green with odor	5
exudate amount	none	1
	scant	2
	small	3
	moderate	4

	large	5
skin color surrounding wound	pink or normal for ethnic group	1
	bright red and/or blanches to touch	2
	white or gray pallor, or hypopigmented	3
	dark red or purple and/or non-blanchable	4
	black or hyperpigmented	5
peripheral tissue edema	minimal swelling around wound	1
	non-pitting edema extends < 4 cm around wound	2
	non-pitting edema extends >= 4 cm around wound	3
	pitting edema extends < 4 cm around wound	4
	crepitus and/or pitting edema extends >= 4 cm around wound	5
peripheral tissue induration	minimal firmness around wound	1
	induration < 2 cm around wound	2
	induration 2-4 cm extending < 50% around wound	3
	induration 2-4 cm extending >= 50% around wound	4
	induration > 4 cm in any area	5
granulation tissue	skin intact or partial thickness wound	1
	bright, beefy red; with 75-100% of wound filled and/or tissue overgrowth	2
	bright, beefy red with 25.1 74.9% of wound filled	3
	pink and/or dull, dusky red and/or fills <= 25% of wound	4
	no granulation tissue present	5
epithelialization	100% of wound covered with surface intact	1
	75 99% of wound covered and/or epithelial tissue extends > 0.5 cm into wound bed	2
	50 74.9% of wound covered and/or epithelial itssue extends to <= 0.5 cm into wound bed	3
	25 49.9% of wound covered	4
	< 25% of wound covered	5

where:

For epithelialization it appears as if there is minimal extension of epithelial tissue into the wound bed.

total score =

= SUM(points for all 13 parameters)

Interpretation:

minimum score: 13 (although the scale on page 25 indicates that intact skin might be scored as 0)

maximum score: 65

The higher the score, the more severe the findings.

Performance:

Inter-rater reliability: $r = 0.96$ to 0.99

Test-retest reliabiity: $r = 0.91$ to 0.92

References: Bates-Jensen BM, Vredevoe DL, Brecht M-L. Validity and reliability of the Pressure Sore Status Tool. Decubitus. 1992; 5(6): 20-28 (Table, page 25)

Appendix D: Informed Consent Form

UNIVERSITY OF CALIFORNIA, IRVINE CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

A Multi-site Study to Characterize Pressure Ulcers in Long-term Care under Best Practices

You are being asked to participate in a research study. Participation in this study is completely voluntary. Please read the information below and ask questions about anything that you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions. If the candidate participant is not able to consent on their own behalf, the remainder of the consent form is addressed to the legally authorized representative and “you” means “the subject” where applicable.

RESEARCH TEAM AND SPONSORS

Lead Researcher:

Solomon Liao, MD

Program in Geriatrics

Telephone Number: 714-456-5530

24 Hour Telephone number: 714-506-3189

Other Researchers:

Raciela Austin, RN

**Study Location(s): Long-term Care facilities throughout Southern California and the
United States**

Study Sponsor(s): National Institute of Justice

PURPOSE OF STUDY

The purpose of this research study is to better understand and describe advanced stage pressure ulcers in the setting of best practices in long-term care.

WHY IS THIS RESEARCH?

This is a research study because we do not know how the development of pressure ulcers is related to the care provided at long-term care facilities. Therefore, we need to describe the characteristics of advance pressure ulcers when good care is being provided.

Study Design

If you agree to participate, you will allow a research nurse to take measurements and pictures of your pressure ulcers at the time of your routine wound care. The nurse will also gather information about your care from your medical records and from your healthcare providers. She will obtain information such as medical problems, medications, mental status, nutrition, mobility, and incontinence.

SUBJECTS

Inclusion Requirements

You are eligible to participate in this study if you

- are age 65 years or older
- currently have at least one advanced (stage 3 or 4) pressure ulcer, and the advanced pressure ulcer developed at this facility, i.e., you did not come into the facility with the ulcer
- sign a release for us to review your medical records and a HIPAA authorization for us to use your health information for the research study

Exclusion Requirements

You are not eligible to participate in this study if you

- are currently under the care of a study team member

Number of Participants and Time Commitment

This study will include approximately 100 subjects and will involve approximately 30 to 60 minutes of your time over the next week.

PROCEDURES

The following procedures will occur: During the wound care that you normally receive, our research nurse will take measurements of your pressure ulcer. She will also take digital photographs. The nurse will review your medical records and talk to the healthcare professionals who take care of you about your medical condition and the care you receive.

RISKS AND DISCOMFORTS

The possible additional risks and/or discomforts associated with the procedures described in this study include the mild embarrassment of another nurse seeing your ulcers and body parts and having these areas photographed. You may experience some mild discomfort from the assessment of your wound during your routine wound care.

BENEFITS

Subject Benefits

You will not directly benefit from participation in this study.

Benefits to Others or Society

The following are potential benefits of this study for our society. A better understanding of the characteristics of advanced pressure ulcers may reduce law suits against long-term care facilities that provide good care. Such information could prevent unnecessary lawsuits or help protect innocent facilities. This study will also serve as a baseline comparison for future research on advanced pressure ulcers in setting of poor care.

ALTERNATIVES TO PARTICIPATION

There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

COMPENSATION, COSTS AND REIMBURSEMENT

Compensation for Participation

You will not be paid for your participation in this research study.

Costs

There is no cost to you for participation in this study.

Reimbursement

Not applicable.

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES

You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately.** The research team may also end your participation in this study if your safety and welfare are at risk.

CONFIDENTIALITY

Subject Identifiable Data

- All identifiable information that will be collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.
- Identifying marks will either be covered during photography or digitally removed.

Data Storage

- All research data will be maintained in a secure location at UCI. Only authorized individuals will have access to it.
- All research data will be stored electronically on a secure computer with password protection.

Data Access

The research team, authorized UCI personnel, the study sponsor (the National Institute of Justice) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you.

Data Retention

The researchers intend to keep the research data indefinitely.

NEW FINDINGS

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

IF YOU HAVE QUESTIONS

If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact UCI's Office of Research Administration by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@rgs.uci.edu or in person at University Tower - 4199 Campus Drive, Suite 300, Irvine, CA 92697-7600.

VOLUNTARY PARTICIPATION STATEMENT

You should not sign this form unless you have read the attached "Experimental Subject's Bill of Rights" and have been given a copy of it and this consent form to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

I agree to participate in the study.

Subject Signature

Date

Printed Name of Subject

**Legally Authorized Representative/
Guardian Signature**

Date

Printed Name of Legally Authorized Representative/Guardian

Researcher Signature

Date

Printed Name of Researcher

Witness Signature

Date

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections Program in the Office of Research Administration by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@rgs.uci.edu; or by writing us at University Tower - 4199 Campus Drive, Suite 300, Irvine, CA 92697-7600.

Appendix E: Braden Risk Assessment

<i>Braden Risk Assessment Tool</i>		Affix patient identification label in this box		
		Date of Assessment		
CATEGORY	DESCRIPTOR	SCORE	SCORE	SCORE
Sensory Perception Ability to respond meaningfully to pressure related discomfort	Completely Limited: Unresponsive (does not moan, flinch or grasp) to painful stimuli due to diminished level of consciousness or sedation. OR , limited ability to feel pain over most of body surface.	1	1	1
	Very Limited: Responds to only painful stimuli. Cannot communicate discomfort except by moaning or restlessness; OR has sensory impairment that limits the ability to feel pain or discomfort over half of body.	2	2	2
	Slightly Limited: Responds to verbal commands, but cannot always communicate discomfort or need to be turned; OR , has sensory impairment that limits the ability to feel pain or discomfort in one or two extremities.	3	3	3
	No Impairment: Responds to verbal commands. Has no sensory deficit that would limit ability to feel or communicate pain or discomfort.	4	4	4
Mobility Ability to change and maintain own position	Completely immobile: Does not make even slight changes in body or extremity position without assistance.	1	1	1
	Very limited: Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	2	2	2
	Slightly limited: Makes frequent though slight changes in body or extremity position independently	3	3	3
	No limitations: makes major and frequent changes in position without assistance.	4	4	4
Activity Degree of physical activity	Bedfast: confined to bed (can't sit at all).	1	1	1
	Chairfast: Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	2	2	2
	Walks occasionally: walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	3	3	3
	Walks frequently: Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.	4	4	4
Moisture Degree to which skin is exposed to moisture	Constantly moist: skin is kept moist almost constantly by perspiration, urine, drainage etc. Dampness is detected every time patient is moved or turned.	1	1	1
	Very moist: Skin is often, but not always, moist. Linen must be changed at least every 8 hours. Dry 2-3 hours at a time	2	2	2
	Occasionally moist: Skin is occasionally moist, requiring linen change every 12 hours	3	3	3
	Rarely moist: Skin is usually dry, linen only requires changing every 24 hours.	4	4	4

Braden Risk Assessment Tool		Affix patient identification label in this box		
Date of Assessment				
CATEGORY	DESCRIPTOR	SCORE	SCORE	SCORE
Friction Shear	<p>Problem: Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. spasticity, contractures, itching or agitation leads to almost constant friction</p> <p>Potential problem: Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against sheets, chair, restraint or other devices. Maintains relative good position in chair or bed most of the time but occasionally slides down.</p> <p>No apparent problem: Able to completely lift patient during a position change, moves in bed and in chair independently and has sufficient muscle strength to lift completely during move. Maintains good position in bed or chair at all times.</p>	1	1	1
		2	2	2
		3	3	3
Nutrition	<p>Very poor: NPO and/or maintained on clear fluids, or IVs for more than 5 days OR never eats a complete meal. Rarely eats more than 1/3 of any food offered. Protein intake includes only 2 servings of meat or dairy products per day. Takes fluids poorly. Does not take a liquid dietary supplement.</p> <p>Inadequate: Is on a liquid diet or tube feedings/TPN, which provide inadequate calories and minerals for age OR rarely eats a complete meal and generally eats only half of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement</p> <p>Adequate: Is on tube feedings OR eats over half of most meals. Eats a total of 4 servings of protein each day. Occasionally eats between meals. Does not require supplementation.</p> <p>Excellent: Is on TPN, which provides adequate calories and minerals for age OR Is on a normal diet providing adequate calories for age. For example, eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.</p>	1	1	1
		2	2	2
		3	3	3
		4	4	4
mild risk- 18-15 moderate risk - 14-13 TOTAL SCORE high risk - 12-10 severe risk - ≤ 9				

PATIENTS SCORING 12 OR BELOW SHOULD BE CONSIDERED FOR A DYNAMIC

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Appendix F: LEAD Panel Rating Form

Subject ID:

	Poor	Fair	Good	Very Good	Excellent
Quality of Individual Resident Care	1	2	3	4	5

Presenting nurse: RA PB KH

Scores for first poll: **Second poll (if needed):**

SL	—	—
MB	—	—
JW	—	—
LM	—	—

LEAD cannot see:

- Photo of pressure ulcer
- Description or measure of the pressure ulcer
- Position of PU on the body

Reasons for Decision:

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-
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