FACTORS ASSOCIATED WITH CLINICAL DECISIONS AND PRESSURE ULCER DEVELOPMENT IN LONG TERM CARE RESIDENTS

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With the growing number of elderly long-term care residents in the United States, pressure ulcers (PU) represent a significant healthcare problem. The National Pressure Ulcer Advisory Panel (NPUAP) reported in 2001 that the incidence rates of PU in long-term care residents ranged from 2.2% to 23.9% and the prevalence from 2.3% to 28%. Multiple risk factors for the development of PU have been suggested, and can be divided into extrinsic factors and intrinsic factors. The aims of this study were to: (1) conduct a focused literature review of intrinsic and extrinsic factors related to PU development in elderly long-term care residents; (2) conduct a secondary analysis of demographic and clinical data from Randomized Clinical Trial on Preventing Pressure Ulcers with Seat Cushions (RCT-SC), to identify risk factors associated with acquiring/not acquiring a PU in elderly long-term care residents. Three different methods were used to analyze the data: (a) stepwise logistic regression, (b) odds ratios, and (c) Exhaustive Chi-Square Automatic Interaction Detection (CHAID); and generate a decision-making tree for the prescription of wheelchairs and seat cushions by rehabilitation practitioners for elderly long-term care wheelchair users. Inter-rater and intra-rater reliability of the rehabilitation team decisions were also established. As a result of this study it was concluded that: (a) the focused literature review provided useful information about intrinsic, extrinsic and combinations of these risk factors in PU acquisition, (b) the stepwise logistic regression, odds ratios, and CHAID analyses confirmed known risk factors and added new risk factors that predict PU development, (c) the

decision-making tree can be a starting point for rehabilitation practitioners that are new to the field of seating and mobility, and (d) the decision making tree showed that the use of a pressure mapping system is a good tool if used in combination with clinical judgment.

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PREFACE

I would like to thank the many people who helped me to complete this dissertation. First, I would like to thank the chair of my dissertation committee, Dr. Margo B. Holm, PhD, OTR/L. Dr. Holm mentored me with dedication in multiple perspectives, including research studies, data analyses, teaching, and presentations, and guided me to overcome challenges during the dissertation process.

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1.0 INTRODUCTION

With the growing number of elderly long-term care residents in the United States, pressure ulcers (PU) represent a significant healthcare problem. PU is defined as lesions caused by unrelieved pressure, resulting in damage to the underlying tissue (Kanj, Wilking, & Phillips, 1998; Margolis, 1995). They are also known as bed sores, pressure sores, or decubitus ulcers (Gosnell, 1987). They are well-known to accelerate loss of function, diminish quality of life, increase the risk of death in the elderly population, and cause significant healthcare costs (Geyer, Brienza, Karg, Trefler, & Kelsey, 2001).

The National Pressure Ulcer Advisory Panel (NPUAP) reported in 2001 that the incidence rates of PU in long-term care residents range from 2.2% to 23.9% and the prevalence from 2.3% to 28%. Multiple risk factors for the development of PU have been suggested. Risk factors can be divided into extrinsic factors (outside of the person, for example: exposure to moisture from urine, feces, perspiration or other drainage, and exposure to shear forces or friction, pressure) and intrinsic factors (within the person, for example: interstitial fluid flow, emotional stress, poor nutrition).

PUs usually occur over bony prominences such as the ischial tuberosities, sacrum, trochanteric areas, and heels (Kanj et al., 1998). The degree of soft tissue damage varies from case to case. The most commonly used grading system for PU is the National Pressure Ulcer Advisory Panel staging system (National Pressure Ulcer Advisory Panel,

2001). This classification system is based on the degree of tissue damage observed and the anatomical depth of the ulcer (see Table 1-1).

Table 1-1: National Pressure Ulcer Advisory Panel Staging System

Stage	NPUAP Definition
I	An observable pressure-related alteration of intact skin whose indicators as compared to an adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.
II	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.
III	Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
IV	Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint, capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

However, it must be noted that while the incidence of PU has been found to be a strong predictor of mortality in elderly populations (Allman, 1989), the severity and the stage of the PU has not been shown to correlate with mortality rates (Berlowitz & Wilking, 1990). A critical challenge to researchers is to identify the impact of the intrinsic and extrinsic factors associated with the incidence of PU in elderly long-term care residents so that these factors can be minimized or prevented.

The primary aim of this dissertation was to identify demographic and clinical variables that predicted the incidence of PU in elderly long-term care residents who were

participants in the experimental arm of a randomized clinical trial to prevent pressure ulcers with pressure-reducing seat cushions (NICHD Grant # 5R01HD041490-04). The secondary aim of the dissertation was to develop an empirically-based decision- making tree for the prescription of wheelchairs, and seat cushions designed to reduce the risk of PU.

The focused literature review, Chapter 2, presents intrinsic and/or extrinsic factors that are related to PU development in elderly long term care residents, as well as other related literature from laboratory studies or hospitals.

Chapters 3 is a secondary analysis of the Randomized Clinical Trial (RCT) on Preventing Pressure Ulcers with Seat Cushions (RCT-SC) (NICHD Grant # 5R01HD041490-04) examining RCT-SC demographic, clinical, and functional variables that are considered risk factors for PU in elderly long term care residents. Three methods were used to analyze the data: (a) stepwise logistic regression, (b) odds ratios (OR), and (c) Exhaustive Chi-Square Automatic Interaction Detection (CHAID). CHAID is less conservative than stepwise logistic regression and delineates associations among predictors and the target outcome (PU), and therefore complements the stepwise logistic regression analyses.

Chapter 4 describes a decision-making tree for the prescription of wheelchairs and seat cushions by rehabilitation practitioners for elderly long-term care wheelchair users. Inter-rater and intra-rater reliability of the research rehabilitation team recommendations for pressure-reducing cushions are also documented.

Chapter 5 summarizes the findings from the three studies.

2.0 FOCUSED REVIEW OF THE LITERATURE

2.1 BACKGROUND

Several studies have reported findings on the management of PU, and multiple potential risk factors for the development of PU have been suggested. However, the incidence of PU appears to be a multi-factorial problem and the exact role of extrinsic and intrinsic risk factors remains unclear. For this reason, a focused review of the literature was performed to identify factors that are known to be associated with the development of PU in elderly long term care residents. The risk factors identified in this review will be used to guide which variables will be included in our logistic regression model.

2.2 METHODS

2.2.1 Search Strategy

Research articles that matched the following inclusion/exclusion criteria were reviewed first for potential inclusion in the focused review:

2.2.1.1 Inclusion criteria

(a) Target population: elderly patients (≥ 65 years of age)

(b) Outcome measure: incidence and/or prevalence and/or severity of PU

(c) Reporting of risk factors for PU

(d) Studies conducted in long-term settings

(e) Articles published in English or Portuguese

2.2.1.2 Exclusion criteria

Studies were excluded if:

(a) Other populations were described

(b) Participants were < 65 years of age

(c) Participants were not long-term care residents

A literature search from January 1988 to March 2008 was conducted using the following electronic databases: MEDLINE, CINAHL, Global Health, OT Search, Cochrane Database Systematic Review, and the Cochrane Database of Randomized Clinical Trials. The year 1988 was chosen because it was one year after the Braden Scale was developed (Bergstrom, Braden, Laguzza, & Holman, 1987). The following search terms were used alone or in combination: pressure ulcer, pressure sore, decubitus, decubitus ulcer, and elderly, older adults, frail adults, older adults over 65 years of age, nursing home residents, long term care residents, pressure ulcer risk factors, pressure sore risk factors, decubitus risk factors.

Abstracts were retrieved and reviewed to identify articles that potentially matched the inclusion/exclusion criteria. Then full-text articles were obtained if the articles appeared to meet the study criteria. The reference list of the retrieved articles was also reviewed for additional relevant references. Finally, hand searches were conducted in journals that frequently published articles related to PU risk or management (i.e., Wound Care, Advances in Skin & Wound Care, Nursing Research) (see Figure 2-1). Fourteen articles met the inclusion/exclusion criteria.

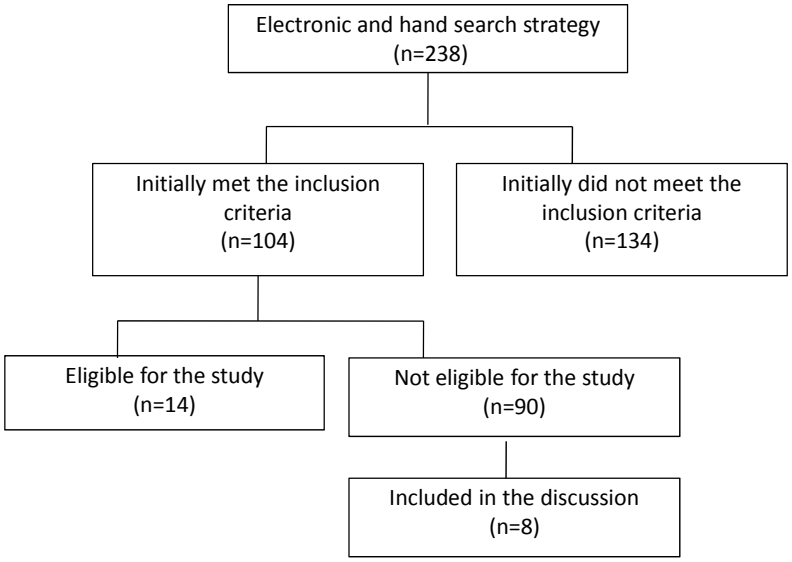


Figure 2-1: Steps performed in focused review.

Additionally, several articles were also reviewed that did not meet the primary inclusion/ exclusion criteria, but were referenced in articles that met the inclusion criteria,

and were relevant to the studies in Chapter 3 and/or Chapter 4. Those that met the criteria will be reviewed first, and the adjunct articles will be reviewed in the Discussion.

2.3 RESULTS

2.3.1 Extrinsic Factors

The following extrinsic risk factors were identified from the literature review:

Pressure: Brienza, Karg, Geyer, Kelsey and Trefler (2001), in a study of 32 male and female at-risk (Braden scores $\leq$ 18) long-term care residents, found that the incidence of PU was significantly greater ($p. < .01$) in subjects whose average (89 mmHg $\pm$ 22 mmHg) and peak (115 mmHg $\pm$ 45 mmHg) interface pressure on their wheelchair cushions was higher than who did not develop PU (average = 78 $\pm$ 22mmHg; peak = 70mmHg $\pm$ 16mmHg). Conine, Hershler, Daechsel, Peel and Pearson (1994), compared foam and gel cushions in a Canadian extended care hospital (nursing home) with 141 at-risk patients (Norton score of 12, mean of 82 years), and found that significantly more patients developed pressure ulcers ($p < .0001$) if the cushion interface pressure was > 60mmHg.

Moisture: In a nationally representative study of nursing home residents (699 facilities and 2803 residents), using the 1987 Institutional Population Component of the National Medical Expenditure Survey, (Spector, 1994) established that the probability of acquiring a PU increased with fecal incontinence several times a week (OR 2.59) or daily

urinary incontinence (OR 1.79). Similar results were found by Brandeis, Ooi, Hossain, Morris, and Lipsitz (1994) in a study of 78 National HealthCorp nursing homes, divided into high, medium and low incidence PU acquisition within 3 months of admission for 4232 nursing home residents who were free of PU upon admission. The odds of developing a PU in high incidence homes was 2.5 with fecal incontinence. Although it is still unknown how much moisture is necessary to damage the skin, it is known that moisture contributes to PU development. Moisture is considered an important risk factor, because moisture alters the resilience of skin, which then may lead to maceration of the skin especially when the skin is exposed to perspiration, urine (Spector, 1994), feces (Brandeis, Ooi, Hossain, Morris, & Lipsitz, 1994), and fistula or wound drainage (Schnelle et al., 1997).

Shear: Shear forces occur when bony prominences are moved across the tissue as the skin is held in place. These forces may result in skin breakdown by mechanical stress on the skin and may play a role in the occlusion of blood vessels, which in turn contributes to the development of PU. Bennett, Kavner, Lee, Trainor and Lewis (1981) studied 9 geriatric patients in a Veteran's hospital, and found that blood vessels occluded when the patients were tilted and the sitting interface pressure was $\geq$ 120mmHg. Souza and Santos (2007) reported a similar finding; however, they did not report how they measured occlusion or created a shear force.

2.3.2 Intrinsic Factors

The following intrinsic risk factors were identified from the literature review:

Mobility: The presence of any pathology or impairment that can affect mobility (e.g. hip fractures, gait dysfunction, and progressive neurologic disorders) to the point where the person is unable to independently move or change positions to relieve pressure increases the risk of developing a PU. Brandeis et al., (1994) in the study previously described, found that acquisition of PU increased with ambulation difficulty (OR 3.3 in high incidence homes; OR 3.6 in low incidence homes), as did the study by Spector (1994), which reported increased incidence of PU if residents were unable to walk (OR 2.12). Horn et al. (2002) in a study of 109 long-term care facilities and 2420 at-risk residents (Braden score $\geq$ 17), found that 87.3 % of residents who developed new pressure ulcers (n=457) had impaired mobility, as did 83.9 % of residents who had existing ulcers (n=534) and 95.6 % of those who had an existing PU and developed a new one during the 12 weeks of the study.

Activity: The presence of any pathology or impairment that can affect activity to the point where the person is unable to independently perform activities of daily living (ADL) increased the risk of developing PU, such as being dependent in feeding, (OR 2.2 in high incidence homes; OR 3.5 in low incidence homes), bathing (OR 2.1 in high incidence homes; OR 1.6 in low incidence homes), and transfers (OR 1.2 in high incidence homes; OR 1.8 in low incidence homes) (Brandeis et al., 1994). Unable to feed oneself was also cited by Spector (1994) as increasing the probability of developing a

PU: OR 1.15 if cognitively intact, and OR 3.74 if cognitively impaired. If residents needed help with feeding, the OR was 2.29.

Interstitial fluid flow: Increased pressure results in decreased interstitial fluid flow, which in turn has been shown as an important factor in the development of PU (Krouskop, 1983). Meijer, Germs, Schneider, and Ribbe (1994), in a study of 109 elderly nursing home residents, documented that pressure-temperature time (indirect measure of blood flow) was significantly related ($r=0.94$; $p < .005$) to PU development. In other words, the longer the blood flow recovery time after exposure to pressure, the greater the likelihood of developing a PU.

Medical co-morbidities: Several conditions are known to increase the probability of developing a PU, namely diabetes (OR 1.7 in high incidence homes, Brandeis et al., 1994; OR 1.42, Spector, 1994), Parkinson's disease (OR 1.93, Spector, 1994), and paraplegia (OR 3.32, Spector, 1994). However, neither hip fracture nor stroke were found to increase the probability of developing PU (Spector, 1994).

Previous history of PU: Elderly patients (≥ 65 years old) with an existing PU were reported as more likely to develop another PU (S. D. Horn et al., 2002).

Demographic characteristics: A number of demographic variables have been shown as risk factors for developing PU. These include: (a) age ≥ 65 years (Spector, 1994), (b) male gender (OR 1.9 in low incidence homes, Brandeis et al., 1994; Spector, 1994). In a study by (Rosen et al., 2006), it was found that African-American nursing home residents were more likely to have multiple stage II- IV PUs when compared to Caucasian nursing home residents. A study by (Baumgarten et al., 2004) also found that

African Americans had a higher incidence of PU than Caucasians. The rate of developing PU was 0.56 for African Americans and 0.35 for Caucasians ($p<.001$).

Weight loss and Body Mass Index (BMI): If a resident has a PU and has a weight loss of 20% to 30%, the PU has more difficulty healing according to a study by Cobb and Warner (2004). In addition, when the resident has a weight loss of 30%, PU are more likely to develop (Cobb & Warner, 2004). In the study by Horn et al. (2002), 51% of the residents lost an average of 5.4% of their body weight over 12 weeks, and in those who developed new PU, 58% lost weight. Spector (1994) also reported that residents who were underweight had an increased probability of developing a PU (OR 1.49). Horn et al. also reported that 45.6% of the residents in their study had a BMI less than 22 kg/m^2. Of the 534 residents who had an existing PU, 50.2% had a BMI < 22 ($p = .04$).

Cognition: Impaired cognitive status or an altered level of consciousness has also been identified as a risk factor for PU development by Horn et al., 2002 (73.4% of residents at risk for PU or with PU had cognitive impairment); Spector, 1994 (likelihood of developing a PU significantly greater for those with a cognitive impairment ($p < .02$).

Psychological status: In a study by Braden (1998) a significant association between stress and PU formation ($p <.001$) was found in residents new admitted to the nursing home, because they produced more serum cortisone (glucocorticoid), which is secreted with stress.

Nursing care or facility characteristics: Level of education of the nursing home staff has been revealed to have an effect on the development of PU in elderly nursing

home residents (Rosen et al., 2006). Horn, Buerhaus, Bergstrom, and Smout (2005) also reported that more direct care time per resident per day was associated with fewer PU.

2.3.3 Combined factors

Most PU research has focused on specific intrinsic or extrinsic risk factors, and controlled for other factors. However there have been studies that reported a combination of factors impacting PU development. The following section is a focused review of the most common combined factors, and includes only experimental study designs. Position papers and systematic reviews were not included.

In a cross-sectional research study conducted in nursing homes, Spector (1994) reported multiple factors that increased the likelihood of developing a PU: (a) Parkinson's disease, (b) diabetes, (c) paraplegia, (d) being underweight, (e) older, (f) male, (g) unable to walk, (h) needing help with feeding or unable to feed independently, (i) having frequent fecal and urinary incontinence accidents, and (j) being admitted from a hospital.

Horn et al. (2002) in a description of the national pressure ulcer long-term care study reported that nursing home residents who developed new PU were more likely to be: (a) female, (b) older, (c) cognitively impaired, and (d) immobile compared to residents who had an existing PU. In a secondary analysis of the national pressure ulcer long-term care study, Horn, et al. (2005) reported that more direct care time per resident per day was associated with fewer PU.

Brandeis et al. (1994) categorized nursing home PU rates into three categories: high, middle, and low PU incidence homes. At baseline the residents' clinical characteristics in the three categories of nursing homes differed by no more than 5%. Two similar risk factors for PU were found among both high and low incidence categories of nursing homes: (a) non-ambulation, and (b) dependence in feeding activities. Diabetes and fecal incontinence were significant only in high PU incidence nursing homes, and male gender was an important characteristic only in low PU incidence nursing homes.

2.4 DISCUSSION

PU remains a complex and costly problem to the health care system. The etiology of PU appears multi-factorial with various risk factors playing a role in the development of PU. Given the complexity of this problem and the multi-factorial etiology, it is important to evaluate the contribution of various extrinsic and intrinsic risk factors to the development of PU in elderly long-term care residents so that adjustments for confounding risk factors can be made. The objective of this article was to conduct a focused review of the literature to identify reported potential risk factors for the development of PU in elderly long-term care residents ($\geq$ 65 years old).

Although extrinsic factors such as high interface pressure (Brienza et al., 2001; Conine et al., 1994) are often cited as having a major impact on PU development, our focused literature review revealed that intrinsic factors may have a greater impact.

Demographically, older males in long-term care were shown to have a greater likelihood (OR 1.9) of developing a PU than older females (Brandeis et al., 1994), and African Americans were more likely to develop PU, and of greater severity, than Caucasians (Baumgarten et al., 2004; Rosen et al., 2006). One possible explanation for racial differences is that in darker skin it is more difficult to detect stage I PU, so that when the PU is diagnosed in a resident with darker skin, the stage is often more advanced (stage II, III or IV), as reported by Rosen et al. (2006).

The factors that showed the greatest impact on PU development were not demographic, however, but related to mobility. Long-term care residents who had ambulatory difficulty were 3.3 - 3.6 times more likely to develop PU than residents who did not have ambulatory difficulties (Brandeis et al., 1994). Similarly, Spector (1994) reported that residents who were unable to walk were 2.12 times more likely to develop a PU than residents who could walk. Additionally, Horn et al (2002) found that 87.3% of residents who developed new PU, 83.9% of residents that already had a PU, and 95.9% of residents that had an existing PU and developed a new one had impaired mobility.

Dependence in activities other than ambulation and mobility were also related to PU development. Residents who needed assistance with feeding or were dependent in feeding were more likely (OR 2.2 – 3.5) to develop PU than residents considered independent for feeding (Brandeis et al., 1994). When dependence in feeding was associated with cognitive impairment, Spector (1994) found that residents were 3.74 times more likely to develop PU than residents who had no cognitive impairments. Two studies also reported that residents with cognitive impairment alone, or as a co-morbidity, were more likely to develop a PU (Horn, et al., (2002; Spector, 1994).

Other co-morbidities and their sequelae also were important intrinsic factors in PU development. Diabetes increased the odds of acquiring a PU by 1.2 to 1.7 times compared to those without diabetes (Brandeis et al., 1994; Spector, 1994). Residents who had Parkinson's disease also had an increased probability of developing PU (OR 1.93) compared to those without the disorder, and for paraplegia, the probability was greater (OR 3.32) (Spector, 1994). However, hip fracture and stroke did not increase the probability of developing PU (Spector, 1994). In contrast, in a hospital study of older adults (≥ 65 years old) undergoing hip fracture surgery, Gunningberg, Lindholm, Carlsson, and Sjödén (2001) reported a higher probability of PU development.

Spector (1994) also reported that residents who were considered underweight were 1.49 times more likely to develop PU than residents who were not underweight. A study by Horn et al. (2002) supported that finding. Additionally, another study by Horn et al. (2005) found that 50.2% of residents who had a BMI of less than 22 had an existing PU. At the cellular level, delayed interstitial fluid flow, or the longer the blood flow takes to recovery after exposure to pressure, the greater the likelihood of residents developing PU (Meijer et al., 1994).

Although incontinence is perceived as an intrinsic factor, the moisture produced is considered an extrinsic factor, and is a major contributor to PU development. Residents with fecal incontinence, even if only several times a week, have an increased chance of developing a PU (OR 2.50 – 2.59) compared to those who are not incontinent. Likewise, residents with urinary incontinence also have an increased probability of developing a PU (OR 1.79) compared to those without incontinence (Brandeis et al., 1994; Spector, 1994).

Another critical extrinsic factor was pressure. Elderly long-term care residents who had a higher peak pressure interface when seated were more likely to develop a PU (Brienza et al., 2001; Conine et al., 1994). Pressure alone, however, is not always the issue, but duration of pressure is also important. Reswick and Rogers (1976) modeled a pressure-time relationship, based on subjects with spinal cord injuries, which showed pressures below 400 mmHg being acceptable for less than1 hour and pressures well below 100 mmHg being acceptable for up to 6 hours. However, Sprigle, Dunlop and Press (2003), based on their laboratory studies, stated that it is still unknown what an "acceptable" pressure is when interface pressure is being investigated.

Brandeis et al. (1994), Spector (1994) and Horn et al. (2002) conducted large multi-site investigations of multi-factorial contributors to PU development. Immobility was the only factor that was common to all three studies. Factors common to two of the studies were diabetes, cognitive impairment, fecal incontinence, dependent in feeding, being older, and male gender. Factors that were unique to a single study were Parkinson's disease, paraplegia, underweight, urinary incontinence, being admitted from a hospital, and female gender. It remains unclear if the identified risk factors are truly independent predictors or if it their combination that contributes to the development of PU. This will need to be tested in further multivariate analyses and with appropriate adjustments for confounding factors.

(Rosen et al., 2006) identified nursing home staff level of education as an important factor contributing to the development of PU and Horn (2002) identified that more direct care time per resident per day was associated with fewer PU. Education of

long-term care staff on intrinsic and extrinsic factors that contribute to PU and the critical role staff play in preventing PU may help to reduce PU incidence. For example, for residents who are immobile, turning schedules, and weight shift reminders can be built into the residents' care plans. Likewise, given the contribution of moisture to skin breakdown, more frequent toileting schedules and incontinence checks and changes can also be built into residents' care plans as preventive measures. Similarly, for male residents, and those with diabetes, cognitive impairment, dependence in feeding, or advanced age for the nursing home population, more frequent skin checks should be included in their care plans.

This focused literature review was not meant to be all inclusive. The inclusion/exclusion criteria for this study were meant to delimit the literature to studies of elderly long-term care residents with PU as an outcome. There are many laboratory and hospital studies that were not included because they were not in the scope of the inclusion/exclusion criteria. These studies often focused on other factors that were more easily studied in a laboratory, such as friction (Dinsdale, 1974; Krouskop, 1976; Reichel, 1958), and temperature (Elliot, 1982; Kokate et al., 1995; Sprigle, Linden, McKenna, Davis, & Riordian, 2001; Tzen, 2008), both of which are known to impact PU development.

2.5 SUMMARY

In summary, the results of this review demonstrate that multiple intrinsic and extrinsic risk factors for the development of PU have been identified in the research literature. In contrast to previous reviews on this topic, which tended to focus on specific risk factors, specific designs, this review addressed multiple risk factors, alone and in combination, known to play a role in the development of PU in elderly long-term care residents. However, it is still difficult to draw any conclusions on the exact contribution of each risk factor to PU development. Thus, it remains to be determined which, if any, risk factor by itself increases the risk of PU, which risk factors are more important than others, and which combinations of risk factors appear to be the major contributors to the development of PU. However, based on the literature reviewed, the evidence suggests that a combination of risk factors, intrinsic and extrinsic, is more likely to predict the development of PU than any one risk factor by itself.

3.0 MODELS OF PRESSURE ULCER RISK FACTORS

3.1 BACKGROUND

Risk factors for development of pressure ulcers (PUs) in elderly long term care residents were described in the previous chapter. In this chapter, using data from the Randomized Clinical Trial (RCT) on Preventing Pressure Ulcers with Seat Cushions (RCT-SC), we will identify which variables were risk factors for a sample of elderly long term care residents in Allegheny County.

3.1.1 Aim of the Study

The proposed study contributes to the body of knowledge by identifying demographic and clinical factors associated with developing and not developing PUs in a sample of older adult long-term care residents who were provided with custom fit wheelchairs and presssure-reducing cushions for the purpose of preventing PU.

3.2 METHODS

3.2.1 Design

The study is a secondary analysis of a fixed (or established) dataset from the Randomized Clinical Trial (RCT) on Preventing Pressure Ulcers with Seat Cushions (RCT-SC) (IRB #0403061).

3.2.2 Overview of the Randomized Clinical Trial (RCT) on Preventing Pressure Ulcers with Seat Cushions (RCT-SC) (IRB #0403061).

The primary purpose of the RCT-SC was to establish the efficacy of using pressure-reducing wheelchair seat cushions for at-risk, elderly, long-term care (LTC) facility residents. The hypothesis of the RCT-SC was that the incidence of sitting-acquired PUs is greater for at-risk elderly wheelchair users using segmented-foam seat cushions (SFC) than for those using appropriate pressure-reducing seat cushions (PRC). Positive results of the RCT-SC trial have the potential to provide the level of evidence needed to change the standard of care to include the routine evaluation of at-risk residents for seating and positioning needs as well as the provision of pressure-reducing cushions as a preventive measure against sitting-acquired PUs. The RCT-SC trial used a completely randomized design with 240 patients being assigned at random to either a PRC or a SFC. Participants were classified according to their initial Braden Scale score as being *very* high risk (Braden score of 8 to 13) or *lower* high risk (Braden score of 14 to 18) for later use in

testing equivalence between the groups. Participants in the study completed six phases, and for each phase, a description of what happened in that phase, and forms used for documentation are shown in Table 3-1. Each phase will be discussed later in the Chapter.

Table 3-1: Overview of Each Phase of the Randomized Clinical Trial on Preventing Pressure Ulcers with Seat Cushions

Phases	Description of the what happened in the phase	Forms used
Screening: stage I	Research nurse checked the participant's skin to be confident that it was free of PU and evaluated the risk of PU using the Braden Scale	Braden Score and Skin Check
Screening: stage II	Research nurse repeats Screening stage I, but 1 week later.	Braden Score and Skin Check and Subject Baseline Form
Screening: stage III	Research rehabilitation team assessed the participant's physical characteristics (e.g. checking for spine and hip deformities) and body measurements were taken. If the participants passed this phase, they would be enrolled in the study.	Seating Needs Assessment
Intervention	Provision of a custom-fitted wheelchair and randomized seat cushion. Participants randomly assigned to the experimental condition received one of the three PRCs. The PRC cushion selected for each participant was based on the participant's clinical needs, and included use of pressure mapping data. The research rehabilitation team prescribed the cushion.	Cushion Selection Evaluation and Seating Needs Assessments and Equipment Issued Form
Follow-up	The research team followed participants every week for 24 weeks. The research nurse checked the skin and evaluated the risk of PU using the Braden Scale each week. The research rehabilitation team checked the participant's equipment and positioning each week.	Weekly Monitoring Form and Braden Score and Skin Check
End point	When end point was reached, each participant underwent a repeat pressure mapping	End Point Form

3.2.3 Participants

3.2.3.1 Nursing home residents

Participants were recruited from Skilled Nursing Facilities (SNF) in Allegheny County, Pennsylvania. Consent for participation was obtained from either the participants or their healthcare proxies. The inclusion and exclusion criteria for the RCT-SC are described on Table 3-2.

To date, 178 participants, including, those in the control group (n = 92), and those in the experimental group (n = 86) have entered the study. Participants had a mean age of 86.16 (± 7.7) and had lived in a nursing home for a mean of 2.29 (± 2.1) years. All participants in this analysis reached the end point of the study for one of the following reasons: (a) by participating for 24 weeks, (b) formation of a PU in the sacrum/coccyx, left or right ischial tuberosities, (c) voluntary withdrawal, (d) death, or (e) change in medical condition which required changing a wheelchair or seat cushion. Participant demographic characteristics are shown in Table 3-3, and participant functional status characteristics are shown in Table 3-4.

Participants were primarily Caucasian (92%) and female (85%), with the majority having the following conditions: vascular (89%), musculoskeletal/ integument (64%), psychiatric (87%), urine and fecal incontinences (87% and 75%, respectively), and spine and pelvic deformities (73% and 67%, respectively). The percentage of participants independent in functional tasks performed from their wheelchairs were as follows:

transfers (3%), reaching forward to a table (26%), and reaching side to side (26%). In rank order, participants method of propelling their chairs was: neither hands nor feet (30%), both hands and feet (27%), feet only (25%) and hands only (17%).

Table 3-2: Randomized Clinical Trial on Preventing Pressure Ulcers with Seat Cushions (RCT-SC) Inclusion and Exclusion Criteria

Criteria
Inclusion Criteria
Male or female
Age ≥ 65 years
Sitting in a wheelchair for 6 or more hours/day
Free of existing pressure ulcers (sitting surface) at the time of skin checking
Braden score ≤ 18, scored by research staff
Combined Braden Activity/Mobility subscale score ≤ 5
Exclusion Criteria
Body weight ≥ 250 pounds
Hip width > 20 inches
Cannot be well positioned in the study equipment
Current use of any cushioning material(s) superior than the study cushioning material

Table 3-3: Participants' Demographic Characteristics

Demographic variables	Frequency (n= 178)	Percentage (%)
Gender		
Female	151	85
Male	27	15
Weeks in the study		
< 22	57	32
≥ 22	121	68
Race		
White	164	92
African-American	14	08
Diagnosis variables		
Heart	97	55
Vascular	158	89
Hematopoietic	48	27
Respiratory	48	27
Eyes/ears/nose/throat/larynx	77	43
Upper gastrointestinal	66	37
Lower gastrointestinal	34	19
Liver	1	06
Renal	22	12
Genitourinary	54	30
Musculoskeletal/integument	113	64
Neurological	41	23
Endocrine/metabolic and breast	86	48
Psychiatric illness	149	84
Diabetes	50	28
Incontinence		
Urine	155	87
Feces	134	75
Pressure ulcer history	40	23
Hip surgery history	42	24
Deformity		
Spine	129	73
Pelvic	120	67

Table 3-4: Participants' Functional Characteristics

Functional Tasks	Frequency (n=178)	Percentage (%)
Transfers		
Unable	54	30
Physical assistance	118	66
Verbal cueing	1	06
Independent	5	03
Reach Forward		
Unable	53	30
Physical assistance	26	15
Verbal cueing	53	30
Independent	46	26
Reach Side to Side		
Unable	53	30
Physical assistance	26	15
Verbal cueing	52	30
Independent	46	26
Wheelchair Propulsion		
Dependent	52	29
Assisted	52	29
Independent	72	40
Missing	2	01
Type of Propulsion		
Hands	31	17
Feet	44	25
Both	48	27
None	53	30

3.2.3.2 Research Team

The research team that conducted the assessments and prescribed wheelchairs and PRC cushions consisted of a research nurse, and one or more research physical therapists (PTs), and one or more research occupational therapists (OTs) (research rehabilitation team). The PTs and OTs were also assisted by graduate students in the physical therapy and occupational therapy curricula.

The research nurse was a female with 32 years of experience, 8 of which involved research study experience. The two research PTs were 1 female (MPT) and 1 male PT PhD student, each with approximately 2 years of experience, all in wheelchair/mobility assessment and intervention. The research OTs were 1 male (PhD) and 2 females (MS, PhD student). The male OT had 16 years of experience, all in seating/mobility assessment and intervention, and 10 years of research responsibility. One of the female OTs had 20 years of experience, 4 of which were in seating/mobility assessment and intervention, and 3 of which included research responsibilities. The second female OT had 10 years of experience, all in seating/mobility assessment and intervention, and 6 of those years included research responsibilities. Not all research rehabilitation team members were present for each assessment, but rather combinations of team members and graduate students.

3.2.4 Equipment used in the study

Two types of manual wheelchairs were used in the RCT-SC: Guardian Escort (Sunrise Medical Products, Inc, Carlsbad, CA), and Breezy Ultra 4 (Sunrise Medical Products, Inc, Carlsbad, CA). These two types of wheelchairs were chosen because they offer some adjustability to accommodate the participant's needs.

The wheelchair seat cushion used in the control condition was a Segmented Foam Cushion (SFC), which was a cross-cut, 3-inch segmented-foam cushion with a fitted incontinence cover, and solid seat insert. This cushion was chosen for use in this trial because it was representative of a large number of Medicare approved cushions currently

used in long-term care facilities. The PRCs chosen for the experimental condition were: (a) viscous fluid and foam, (b) segmented air bladder, and (c) foam and gel. These three types were chosen to represent different categories of seat cushions that meet Medicare guidelines. Participants were randomly assigned to the control or experimental condition, and then the research rehabilitation team assessed the participants to fit them with the most appropriate type of wheelchair and cushion (see Table 3-5).

Table 3-5: Equipment Used in the Randomized Clinical Trial on Preventing Pressure Ulcers with Seat Cushions (RCT-SC)

Equipment	Frequency (n=178)	Percentage (%)
Wheelchair type		
Escort	72	40
Breezy Ultra 4	106	60
Cushion type		
Segmented foam	93	52
Viscous fluid and foam	49	28
Segmented air bladder	25	14
Foam and gel	11	06

3.2.5 Data

In the RCT-SC, data were derived from the following variables and measures:

3.2.5.1 Demographic and diagnostic characteristics

Data were obtained from the RCT-SC Subject Baseline Data Form (SBD) (see Table 3-6). The nurse on the RCT-SC study obtained these data from a medical chart review.

Table 3-6: Main Content of the Subject Baseline Data (SBD) Form

Form	Appendix
Subject Baseline Data	A
Gender	
Race	
Ethnicity	
Diagnosis	
Height and weight	
Years living in nursing home	
History of pressure ulcers	
Incontinence status	
Medication current used	
Means of mobility	
Hip surgery	
Transfers	
Alert and oriented	
Combative	

3.2.5.2 Participant's physical/motor characteristics

To meet RCT-SC inclusion criteria, participant's physical/motor condition was assessed, to ascertain that the two types of wheelchairs used in the study would accommodate the participant's needs. The research rehabilitation team conducted the assessment. The protocol and data collected for the physical/motor evaluation are included in the RCT-SC Seating Needs Assessment Screening Form (see Table 3-7).

Table 3-7: Main Content of the Seating Needs Assessment Screening Form

Form	Appendix
Seating Needs Assessment Screening	B
Cardiopulmonary status	
Hearing and vision status	
Incontinence status	
Strength status	
Cognition status	
Spine deformity	
Hip deformity	
Type of propulsion	
Level of independence in propulsion	
Participate in any type of therapy	
Muscle tone status	
Level of independence in hygiene	
Level of independence in feeding	
Level of independence in dressing	
Level of independence in communication	
Body measurements	

3.2.5.3 Functional Status

These data were collected using the RCT-SC Cushion Selection Evaluation Form (CSE) (see Table 3-8). The data were obtained by a member of the research rehabilitation team

during the performance of the functional tasks. Once participants received the custom-fitted wheelchair and the randomized cushion, they were asked to perform 4 different tasks: transfer, propel the wheelchair, reach forward, and reach side to side.

Table 3-8: Main Content of the Cushion Selection Evaluation Form

Form	Appendix
Cushion Selection Evaluation	C
Seat cushion comfort	
Seat cushion that offered the best pressure distribution image	
Cushion provided	
Level of independence in transfers	
Level of independence in propulsion	
Level of independence in reach forward and reach side to side	

3.2.5.4 Participant's risk of developing PU

The PU risk assessment tool used in the RCT-SC study was the Braden Scale (Bergstorm & Braden, 1992). It is a composed of six subscales: sensory perception, moisture, activity, mobility, nutritional status, and friction/shear (see Table 3-9). Operational definitions are given for each subscale, and they are rated from 1 (least favorable) to 3 or 4 (most favorable). The scores range from 6 to 23 and the cutoff score was 13. For scores raging from 8 to 13, the participant was considered at *very* high risk for developing a PU, whereas for scores ranging from 14-18, the participant was considered at a *lower* high

risk for developing PU. These ranges are consistent with other research studies (Brienza et al., 2001; Geyer et al., 2001). For score ranging from 19-23, participants were not considered at-risk for developing a PU. The research nurse completed the Braden scale form.

Table 3-9: Main Content of the Braden Scale Form

Form	Appendix
Braden Scale	D
Sensory Perception	
Moisture	
Activity	
Mobility	
Nutrition	
Friction/Shear	

The second PU risk assessment tool used was the Force Sensing Array (FSA) (Vista Medical, Winnipeg, Canada). The FSA yields objective data about peak pressure and overall pressure distribution when the user is seated on the FSA mat and a PRC. Research shows that the FSA system has an estimated output accuracy of 95% (Parent, Lacoste, & Dansereau, 1999). Pressure values and pressure distribution were measured with a thin sensor mat that was placed between the seating surface and the user's buttocks. The thin sensor mat (48cm x 48cm) contains 225 sensors, and is connected through an interface module to a computer. The data computed from the sensors are

presented in two different ways: (a) colored countered map, and (b) numerical values (see Figure 3-1). The map generated an image of the pressure distribution of the user's buttocks for each cushion sat on. Red indicates high pressure, and blue indicates low pressure. The peak pressure index (PPI) was chosen to be computed in this study because it gives a single value and was reported in a study by Brienza, et al. (2001) to have a positive relationship with PU acquisition. According to (Sprigle et al., 2003), "PPI is defined as the highest recorded pressure values within a 9-10 cm^2 area (approximately the contact area of an ischial tuberosity and other bony prominences) under one of the load-bearing surfaces (ischial tuberosities, greater trochanters, and sacrum/coccyx)"(p.54). To calculate PPI using an FSA pressure mapping system, four cells were averaged since its cells are spaced at 2.5cm centers. Once the peak pressure is located, the adjacent cells that comprise the highest total are averaged (2 x 2 array) which then becomes the PPI for the map. For the RCT-SC study purposes the FSA system was calibrated in a systematic way every two weeks to maintain accuracy throughout the study.

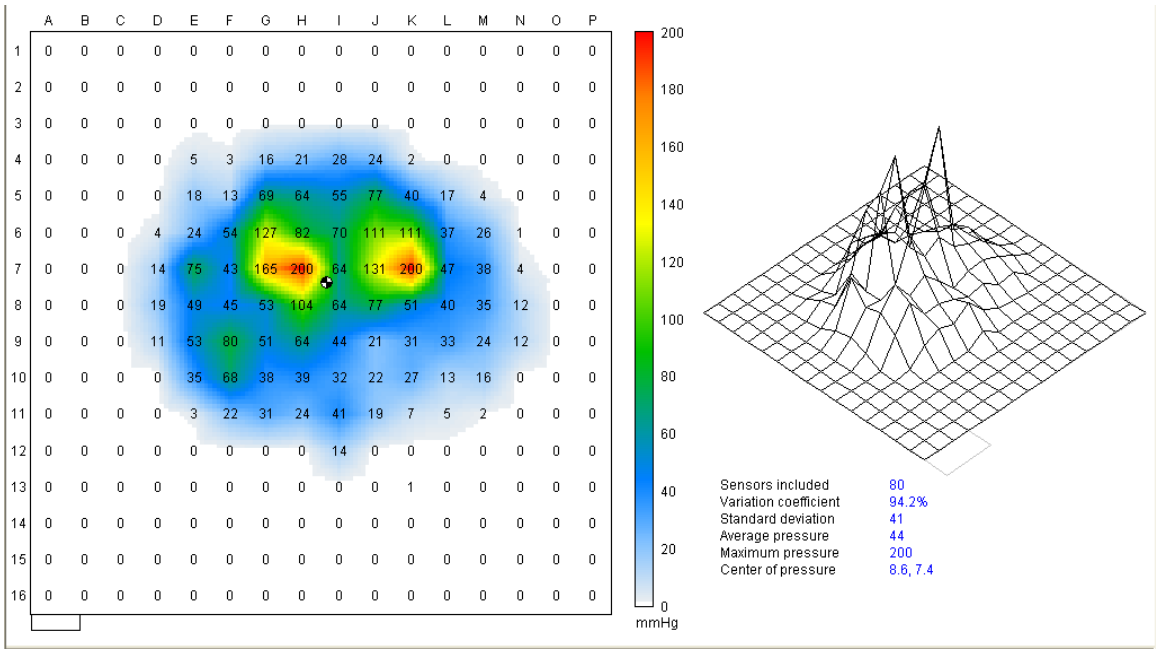


Figure 3-1: Pressure mapping output with colored map of the pressure distribution and numerical values.

3.2.6 Procedures

In the RCT-SC, once consent was obtained and the participant was enrolled in the study, there were six phases: (a) three screening phases, (b) the intervention phase, (c) the follow up phase, and (d) an end point evaluation phase.

3.2.6.1 Screening phase

Screening stage I. The research nurse checked the participant's skin to be certain that it was free of PU and evaluated the risk of PU using the Braden scale. Therefore, for Screening stage I there were two forms that were completed by the research nurse: (1) the Braden scale form, and (2) the skin check form (see Tables 3-9 and 3-10).

Table 3-10: Main Content of the Skin Check Form

Form	Appendix
Skin Check	E
Check the color of the skin	
Checking right ischial tuberosities	
Checking Left ischial tuberosities	
Checking sacrum	
Checking coccyx	
Checking right great trochanter	
Checking left great trochanter	
Checking right heel	
Checking left heel to check for pressure ulcer	

Screening stage II. The second screening occurred 1 week later, with the nurse checking the skin again to ascertain that the skin was still free of PUs. She again completed the same forms used for screening stage I (see Table 3-9 and Table 3-10), in addition to the SBD form (see Table 3-6).

Screening stage III. The research rehabilitation team assessed the participant's physical, and functional characteristics (e.g. checking for spine and hip deformities) to make sure one of the two types of wheelchairs used in the RCT-SC study was appropriate. At this stage, the participant's body dimensions were measured to again verify that the inclusion criteria were met, and if so, to verify that one of the study wheelchairs would be the appropriate size for the participant (e.g., participant's with

shorter leg length require a wheelchair with a drop seat, e.g., a Breezy Ultra 4), and meet the participant's needs. If the participant passed the third screening stage, the participant was enrolled in the study. The form used in this phase was the Seating Needs Assessment Screening Form (see Table 3-7).

3.2.6.2 Intervention phase

The intervention phase began with a more detailed physical/functional assessment by the research rehabilitation team and ended with the provision of a custom-fitted wheelchair and randomized seat cushion. The team decided what type of a wheelchair the participant would receive based primarily on type of propulsion (e.g., if a participant was a foot propeller the team prescribed the Breezy Ultra 4 because it could be adjusted with a low seat-to-floor height). When the wheelchair was decided on, a call was made to the University of Pittsburgh Epidemiology Data Center randomization line, and the participant was randomly assigned to either the control or experimental condition. Participants assigned to the control condition received the SFC and then underwent pressure mapping.

Participants randomly assigned to the experimental condition received one of the three PRCs. The PRC cushion selected for each experimental participant was based on its compatibility with the participant's clinical needs, as determined by the team, who used data from the RCT-SC Seating Needs Assessment Screening Form (see Table 3-7) and the RCT-SC Cushion Selection Evaluation Form (CSE) (see Table 3-8). Additionally, participants assigned to the experimental condition underwent pressure mapping with each PRC cushion type in their new chair, and those data were also used by the team to

decide which cushion was most appropriate. Participant preference was also elicited. When the wheelchair and the cushion were selected, the Equipment Issued form was completed (see Table 3-11).

Table 3-11: Main Content of the Equipment Issued Form

Form	Appendix
Equipment Issued Form	F
Type of wheelchair prescribed and size	
Type of cushion prescribed and size	
Type of armrest prescribed	
Type of footrest prescribed	

3.2.6.3 Follow-up phase

The research team followed participants every week for 24 weeks. The research nurse checked the skin and evaluated the risk of PU using the Braden Scale (see Table 3-9). The research rehabilitation team checked the participant's equipment and positioning, using the weekly monitoring (WM) form (see Table 3-12).

Table 3-12: Main Content of the Weekly Monitoring Form

Form	Appendix
Weekly Monitoring	G
Report the Braden score of the week	
Report the skin check status of the week	
Sitting time	
Staff report about any medical changes	
Equipment status	
Incontinence status	
Cognitive status	

3.2.6.4 End point evaluation phase

When end point was reached, each participant underwent pressure mapping once again and an end point form was completed (see Table 3-13).

Table 3-13: Main Content of the End Point Form

Form	Appendix
End Point	H
Data end point was reached	
Number of the weeks in the study	
Number of days in the study	
Type of end point	
Nursing home staff reported the end point	
End point seating evaluation completed	

3.2.7 Data Analysis

Statistical analysis was done using SPSS 14.0 for Windows (SPSS Inc., Chicago, IL). Descriptive statistics were calculated for demographic and clinical variables. In preparation for the stepwise logistic regression, chi-square analysis and *t*-tests were used to screen independent variables (see Table 3-14) that had a potential affect on the development of PU (outcome variable). In this screening phase, a p-value was set at $p \leq 0.10$ as suggested by Hosmer and Lemeshow (1989). With the chi-square analyses, categories were collapsed when possible or eliminated when necessary to avoid small cell sizes. There were 26 variables in the screening phase for the logistic regression. Additionally, odds ratios were calculated for demographic and clinical variables that did not enter the logistic regression to compare our results with the research literature.

Table 3-14: Set of Predictor Variables Analyzed in the Screening Phase for the Logistic Regression and Exhaustive Chi-Square Automatic Interaction Detection (CHAID)

Predictor variables	Type of factor	Data derived from
Age	Intrinsic factor	SBD
Gender	Intrinsic factor	SBD
Race	Intrinsic factor	SBD
Time living in a nursing home	Extrinsic factor	SBD
Selected primary diagnosis	Intrinsic factor	SBD
Incontinent for urine	Extrinsic factor	Seating Needs Assessment Screening Form
Incontinent for feces	Extrinsic factor	Seating Needs Assessment Screening Form
Catheterized	Intrinsic factor	Seating Needs Assessment Screening Form
Previous history of PU	Intrinsic factor	SBD
History of hip surgery	Intrinsic factor	SBD
Spine deformity	Intrinsic factor	Seating Needs Assessment Screening Form
Hip deformity	Intrinsic factor	Seating Needs Assessment Screening Form
Able to follow command	Intrinsic factor	Seating Needs Assessment Screening Form
Sitting balance	Intrinsic factor	Seating Needs Assessment Screening Form
Strength	Intrinsic factor	Seating Needs Assessment Screening Form
Currently in pain	Intrinsic factor	Seating Needs Assessment Screening Form
Type of cushion	Extrinsic factor	EI
Type of wheelchair	Extrinsic factor	EI
Type of wheelchair propulsion	Intrinsic factor	Seating Needs Assessment Screening Form
Time spent in a wheelchair each day (average)	Intrinsic factor	Weekly Monitoring Form
Transfer	Intrinsic factor	CSE
Reach forward	Intrinsic factor	CSE
Reach side to side	Intrinsic factor	CSE
Total Braden Score	Intrinsic factor	Braden Scale
Cognition	Intrinsic factor	Seating Needs Assessment Screening Form
Independence in feeding	Intrinsic factor	Seating Needs Assessment Screening Form
Independence in dressing	Intrinsic factor	Seating Needs Assessment Screening Form
Independence in hygiene	Intrinsic factor	Seating Needs Assessment Screening Form
Braden Activity and Mobility combined score	Intrinsic factor	Braden Scale
Peak Pressure Index (PPI)[a]	Extrinsic factor	Pressure mapping

Note. CSE = Cushion Selection Evaluation. EI = Equipment Issued. PU = Pressure Ulcer. SBD = Subject Baseline Data.
[a]PPI was chosen because it is a value that has been referenced in other studies (Sprigle, Dunlop, & Press, 2003; Brienza, et al., 2001).

3.2.7.1 Logistic regression

The variables that were significant at the screening phase were included in a stepwise logistic regression, thus the "best" set of predictors were selected, hence maximizing the strength of prediction while minimizing the number of predictors. Stepwise procedures serve to eliminate predictors that are highly correlated with other predictors and do not contribute in a unique way. The method of forward selection was used. In general, the procedure is carried out in the following way: the first model considered is one with no predictors (Step 0). The variable that would produce the greatest significant improvement in prediction (compared to a model with no predictors) is added on Step 1. The variable that would produce the most significant improvement, given a model that includes the variable added at Step 1, is added on Step 2. The procedure continues in this manner until none of the remaining variables would significantly improve prediction.

After this procedure, in a separate analysis, we entered the predictor variables with significant relationships with the outcome variable (development of PU) using a "forced" logistic regression. In the first forced logistic regression, the forced variable was cushion type. The purpose of this analysis was to see if cushion type was a significant predictor after controlling for/ accounting for the other variables. In the second "forced" logistic regression the forced variable was wheelchair type. The purpose of this analysis was also to see if wheelchair type was a significant predictor after controlling for/ accounting for the other variables.

3.2.7.2 Exhaustive Chi-Square Automatic Interaction Detection (CHAID)

In addition to logistic regression, Exhaustive Chi-Square Automatic Interaction Detection (CHAID) was used to identify associations between predictor variables (the same ones entered into the stepwise logistic regression; see Table 13) and a target variable (PU acquisition). CHAID identifies the associations between multiple independent variables (categorical or continuous) and a target variable (PU acquisition) creating a data-driven model without the researcher bias that can come from setting arbitrary cutoff scores. CHAID is less conservative than logistic regression, unraveling associations that may not be detected by regression analysis (Grill, Joinsten, Swoboda, & Stucki, 2007).

3.3 RESULTS

When the *t*-test and chi-square analyses were performed, there were 10 variables that were significant: (1) musculoskeletal/integument, (2) neurological, (3) endocrine/metabolic, (4) psychiatric illness, (5) previous history of PU, (6) type of wheelchair propulsion, (7) transfer, (8) reach forward, (9) reach side to side, (10) total Braden score (see Table 3-15 and 3-16).

Table 3-15: Significant Variables at the Screening Phase- Chi-square Analysis

Screening variables	x^2	*df*	*p* value
Musculoskeletal/integument	4.769	1	.029
Neurological	3.777	1	.052
Endocrine/metabolic	5.673	1	.017
Psychiatric illness	4.699	1	.03
Previous history of PU	7.905	1	.005
Type of wheelchair propulsion	6.276	3	.099
Transfer	13.926	3	.003
Reach forward	11.628	3	.009
Reach side to side	11.628	3	.009

Note. PU = Pressure ulcer

Table 3-16: Significant Variables at the Screening Phase- *t*-test Analysis

Screening variables	*F*	*t*	*p* value
Total Braden score	2.341	3.057	.003

After running the chi-square analyses, reach forward and reach side to side seemed to be perfectly correlated. To ascertain their relationship, a correlation analysis was performed for these particular variables. We found that reach forward and reach side to side were perfectly correlated ($r = 1.0$, $p < .001$) so only reach forward was used in the stepwise logistic regression. Therefore, the 9 remaining variables (musculoskeletal/integument, neurological, endocrine/metabolic, psychiatric illness,

previous history of PU, type of wheelchair propulsion, transfer, reach forward, total Braden score) that were significant at the screening phase were plugged into a stepwise logistic regression. As a result of the stepwise logistic regression, the variables with significant bivariate relationships with the dependent variable (PU) were, in order of contribution: musculoskeletal/ integument, previous history of PU, endocrine/metabolic, and total Braden score (see Table 3-17). For participants in our study with musculoskeletal/integument problems, the odds of acquiring a PU was 3.16 times greater than those with no skin problems. Similarly, for participants who had a previous PU, the odds of acquiring a PU was 2.96 times greater than those who never had a PU. Again, for participants who had an endocrine/metabolic condition, the odds of acquiring a PU was 2.78 times greater than those who did not have this condition. Finally, for participants with higher Braden scale scores, the odds of acquiring a PU was less than for those with lower Braden scale scores.

Table 3-17: Best set of Predictors Related to PU in the Stepwise Logistic Regression

Predictor variables	β	S.E	*p* value	Exp(β)(OR)
Musculoskeletal/integument	1.151	.515	.026	3.160
Previous history of PU	1.085	.458	.018	2.960
Endocrine/metabolic	1.023	.453	.024	2.780
Total Braden score	- .496	.176	.005	0.609

Note. OR = Odds ratio. PU = Pressure ulcer.

Once the best set of predictors related to PU was found, the forced logistic regressions were performed. The first forced logistic regression entered cushion type. However, cushion type was not a significant predictor (p = 0.16) after controlling for: musculoskeletal/ integument, previous history of PU, endocrine/metabolic, and total Braden score. In the second forced logistic regression, the same procedure was used for wheelchair type. However, wheelchair type was not a significant predictor (p = 0.14) after controlling for: musculoskeletal/ integument, previous history of PU, endocrine/metabolic, and total Braden score. The frequency, location and stage of the PU acquired in our sample are delineated in Table 3-18.

Table 3-18: Participants' Pressure Ulcer Frequency, by Location and Stage.

Pressure Ulcer Location	Frequencies (n=31)
Sacrum (Stage 2)	9
Coccyx (Stage 2)	6
Right Ischial Tuberosity (Stage 2)	5
Left Ischial Tuberosity (Stage 2), and Coccyx (Stage 3)	2
Coccyx (Stage 1)	1
Coccyx (Stage 1), and Coccyx (Stage 2)	1
Coccyx (Stage 2), and Coccyx (Stage 3)	1
Left Ischial Tuberosity (Stage 1)	1
Right Ischial Tuberosity (Unstageable)	1
Sacrum (Stage 1), and Coccyx (Stage 1)	1
Sacrum (Stage 1)	1
Sacrum (Stage 1), and Sacrum (Stage 2)	1
Sacrum (Stage 2), and Coccyx (Stage 2)	1

Odds ratios were calculated for several demographic and clinical variables that were reported in the literature, but did not enter the logistic regression. In our sample, the odds of acquiring a PU was 2.42 times greater for participants with urinary incontinence than for those who were not incontinent. This was followed by dependence in feeding

(OR 1.87), cognitive impairment (OR 1.70), fecal incontinence (OR 1.29), Caucasian race (1.28), and female gender (OR 1.25) (see Table 3-19).

Table 3-19: Odds Ratios of Relevant Demographic and Clinical Variables Not Entering the Logistic Regression.

Demographic and Clinical Variables	Odds Ratio for Pressure Ulcer Acquisition
Urinary incontinence	2.42
Dependence in feeding	1.87
Cognition impairment (unable to follow 3-step directions)	1.70
Fecal incontinence	1.29
Race (Caucasian)	1.28
Gender (female)	1.25
Dependence in hygiene	1.12
Dependence in dressing	1.03

Other predictors related to PU development were detected utilizing CHAID and the associations between these predictors and PU were delineated in a model (see Figure 3-2). The strongest factor associated with PU development was musculoskeletal/integument (x^2= 6.28, p = 0.01), dividing our sample into 2 subsamples; participants who had musculoskeletal/integument problems (n = 47) and participants who did not have musculoskeletal/integument problems (n = 37). Of the participants who had musculoskeletal/integument problems, 21% developed PU compared to only 3% of the participants who did not have musculoskeletal/integument problems.

For participants who had musculoskeletal/integument problems (n = 47), the next strongest factor was diabetes (x^2 = 6.64, p = 0.01). The model divided the sample into two subsamples, participants with diabetes (n = 13) and participants who did not have

diabetes (n = 34). Of the participants who had diabetes, 46 % developed a PU compared to only 12% of the participants who did not have diabetes.

In the CHAID model (see Figure 3-2), the strongest factor associated with PU acquisition was participants' ability to transfer independently (x^2= 8.04, p = .01), dividing our sample into 2 significantly different subsamples; participants who were unable to transfer independently (n = 54) and participants who were able to transfer independently (n = 124). Thirty percent of the participants who were unable to transfer independently acquired a PU compared to 12% of the participants were able to transfer independently.

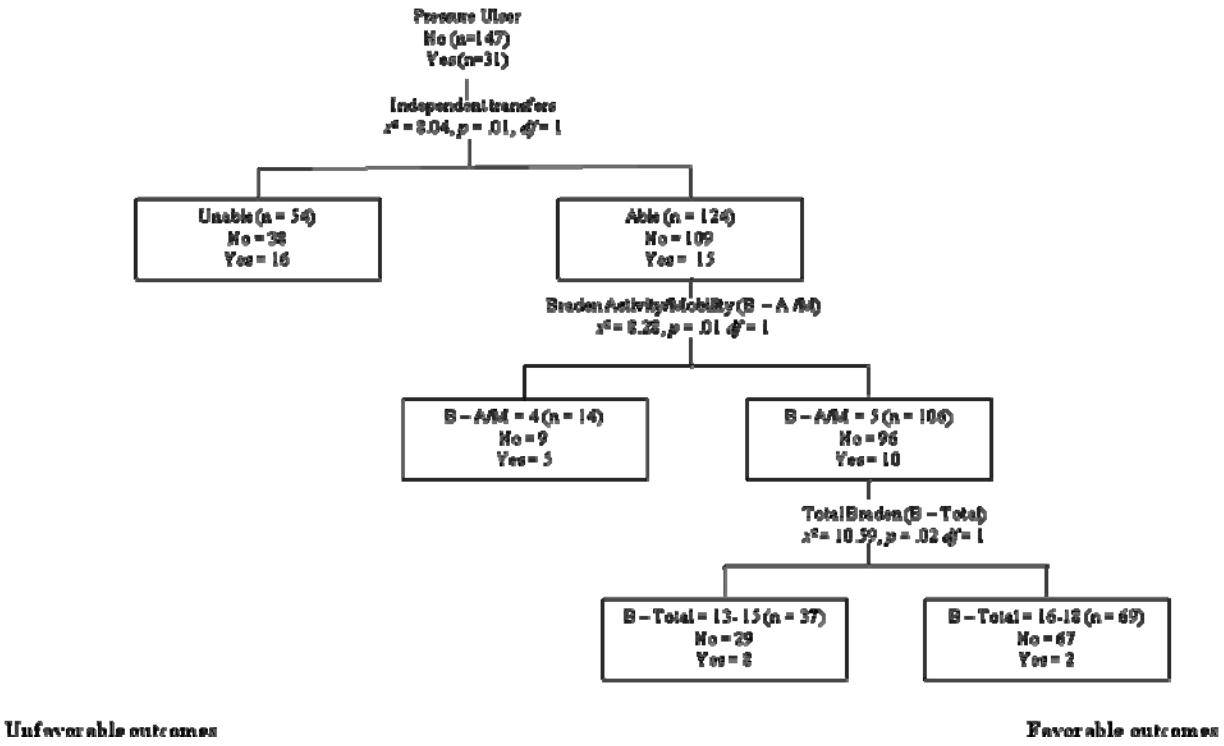


Figure 3-2: CHAID model of factors associated with pressure ulcer acquisition.

For participants who were able to transfer independently the next strongest factor was the Activity/Mobility Braden (B–A/M) score ($x^2 = 8.28$, $p = .01$). The sample was divided into two significantly different subsamples, participants with B–A/M score of 4 (n = 14) and participants with a B–A/M score of 5 (n = 106). Thirty-six percent of the participants who had a B–A/M of 4 acquired a PU compared to 9% of the participants who had a B-A/M of 5.

Participants who had a B–A/M of 5 were further divided into two significantly different subsamples by the Braden total (B–Total) score ($x^2 = 10.59$, $p = .02$); participants who had a B–Total of 15 or lower (n = 37) and participants who had a B-Total of 16 and higher (n = 69). Of the participants who had a B–Total of 15 or lower, 28% acquired a PU compared to 3% of the participants who had a B–Total of 16 or higher.

3.4 DISCUSSION

This study contributes to the body of knowledge by identifying demographic and clinical factors associated with developing and not developing PUs in a sample of older adult long-term care residents who were provided with custom fit wheelchairs and presssure-reducing cushions to prevent PU. Unlike previous studies that identified PU risk and acquisition with secondary analyses of large federal or corporate databases (Brandeis et al., 1994; S. D. Horn et al., 2002; Spector, 1994) data for this study were collected in person by members of the research team (i.e., research nurse and research rehabilitation team) as part of a randomized clinical trial for preventing pressure ulcers with the prescription of custom-fit wheelchairs and randomized wheelchair cushions. This design was similar to that of Brienza et al. (2001) and Geyer et al. (2001).

Using logistic regression, we found that the best set of predictors for acquisition of PU, in order of influence was: musculoskeletal/ integument, previous history of PU, endocrine/metabolic, and total Braden score. Odds ratios of demographic variables that did not enter into the logistic regression model, but have been reported in the research literature, in order of strength were: urinary incontinence, dependence in feeding, cognitive impairment, fecal incontinence, Caucasian race, and female gender. In our CHAID model, however, two of the three predictors that emerged were not in the logistic regression (independent transfers, Braden activity/mobility score), and one was a repeat factor (total Braden score).

Musculoskeletal/integument is a broad term used to describe musculoskeletal and skin conditions, and our findings indicated that odds of participants who had any type of skin condition developing a PU were 3.16 times greater than those who did not. We also know that 87% of our participants were incontinent for urine (OR 2.42) and 75% for feces (OR 1.29), and previous studies have shown that moisture from urine and feces can contribute to skin breakdown (Allman et al., 1986; Fischer, Wells, & Harrison, 2004; Markleburst, 1997; Reuller & Cooney, 1981; Schnelle et al., 1997). Our OR findings on incontinence were less than Spector and Brandeis et al. (1994) for fecal incontinence and greater than those of Spector (1994) for urinary incontinence. The odds of PU acquisition with increased incontinence suggests that increased attention to toileting schedules and changes of incontinence pads have the potential to decrease PU in older long-term care residents.

Consistent with prior research (Allman, Goode, Patrick, Burst, & Bartolucci, 1995; Bader & White, 1998; Garber, Rintala, Hart, & Fuhrer, 2000; S. D. Horn et al., 2002), we found that the odds of acquiring a PU was 2.96 times greater for those participants with a previous history of PU. It is unclear whether those participants were more vulnerable because of other factors such as skin conditions or neuropathies, or tissue vulnerability from their previous PU. However, because these residents are at greater risk for PU acquisition, frequent and routine skin checks should be incorporated into their care plans.

An endocrine/metabolic condition was the third strongest predictor in our logistic regression model, indicating that for those participants with such a condition the odds of acquiring a PU was 2.78 times greater than those without the condition.

Endocrine/metabolic is another broad term that includes multiple conditions and disorders. However, under this category, diabetes was the single most common condition. Consistent with our findings, Greenhalgh (2003) found that with diabetes, a person is more likely to have vascular, neuropathic, and immune dysfunction, diminishing the body's ability for tissue repair. Again, because of increased risk for PU acquisition among these residents, frequent and routine skin checks should be incorporated into their care plans.

The final predictor in our regression, the total Braden score has also been reported in other research studies as a good tool for detecting the risk of developing PU (B. Braden & Maklebust, 2005; Fischer et al., 2004; Hamilton, 1992). For our participants, with higher Braden scores the odds of developing a PU were less than for lower Braden scores.

Among the demographic and clinical factors for which odds ratios were calculated, our findings that Caucasian race had a greater chance of PU acquisition (OR 1.28) was in contrast to the findings of Rosen et al. (2006) and (Baumgarten et al., 2004). However, the African American demographics of the facilities in our study more closely represent the African American demographics of Allegheny County, Pennsylvania, which is 12.41 % of the population. This is in contrast to the Baumgarten study, in which 16 % of the sample were African Americans, and the Rosen study, in which 28.9% of the sample was African American.

Our findings regarding gender indicated that for female residents there was an increased chance of PU acquisition (OR 1.25) compared to male residents. This finding was consistent with Horn et al. (2002), who reported that significantly more females

acquired a new pressure ulcer compared to males, but in contrast to Brandeis et al. (1994), and Spector (1994). The difference among studies may have been due to the proportion of females in our study: 85% of our sample was females, whereas 72.6% of Spector's sample was female, and 73% of the sample in the Brandeis et al. study was female.

The clinical variables in our study related to function were not reported elsewhere in the research literature (ability to follow 3-step commands, dressing, hygiene), or they were consistent with other research (feeding). Among the residents in our study, 81.5% had cognitive impairment, 99.4 % needed help with dressing and 99 % needed help with hygiene. For residents whose cognitive impairment did not allow them to follow a 3-step command, the chance of PU acquisition was greater than those who could (OR 1.70). Those residents who were totally dependent in dressing had only a slightly increased chance of PU acquisition (OR 1.03) compared to residents who only needed assistance, and for those who were totally dependent in hygiene, the odds of PU acquisition was 1.12 greater than those who only needed assistance. For the residents in our sample who were dependent in feeding, the odds of PU acquisition were 1.87 times greater than for those who were independent feeders. Our findings regarding feeding are somewhat lower than those reported by Brandeis et al. (1994) (OR 2.2 - 3.5), and Spector (1994) who reported that residents with cognitive impairment and dependence in feeding were 3.74 times more likely to acquire a PU than those who were cognitively intact and independent in feeding. Although the contribution of our clinical variables to PU acquisition was marginal at best, we did attempt to examine the contribution of functional indicators in the multi-factorial PU risk factors, but they still need to be explored further.

In our CHAID model, the strongest factor associated with PU acquisition was independence in transfers, which was also reported by Brandeis et al. (1994). For those residents who were able to transfer independently, the second strongest factor associated with acquiring/not acquiring a PU was the Braden Activity/Mobility score. Again, Brandeis et al., Horn et al. (2002), and Spector (1994) also reported that immobility was a strong risk factor for PU acquisition. Horn et al. reported that the majority of residents with PU also had impaired mobility (87.3% - 95.6%). In our sample, 100 % of the residents had impaired mobility, because that was one of the inclusion criteria for the RCT-SC, however only 17.4% of the residents had a sitting-acquired PU, and 4% acquired a non-sitting surface PU during the 6 months of the study. For residents who had a Braden Activity/Mobility score of 5/8 the third variable in the CHAID model was the total Braden score, with two significantly different subsamples; total Braden score of 13-15 (moderate to mild risk) and total Braden score of 16-18 (mild risk). Of those with a moderate to mild risk on the Braden, 22% acquired a PU, and of those with a mild risk, only 3% acquired a PU. Although only one of the factors in our CHAID model entered the logistic regression model (total Braden score), the CHAID model helps to unravel some of the associations among predictors. For example, for those residents who have a total Braden score $\geq$ 16, a Braden Activity/Mobility score of 5, and are able to transfer independently, they will be less likely to develop a PU. Similarly for residents with a total Braden score of $\leq$ 15, a Braden Activity/Mobility score of 4, and are able to transfer independently, they will be more likely to develop a PU, as will those residents who are unable to transfer independently.

Limitations and Future Recommendations

Although this study had strengths, including data from the direct assessment of long-term care residents enrolled in a randomized clinical trial and multiple statistical perspectives of PU risk factors, it also had limitations that must be considered when interpreting our findings. Because our sample consisted of elderly long-term care residents, the predictors in this study cannot be generalized to other populations or older adults who are not long term care residents. The variables analyzed in this study were the variables collected for the RCT-SC, and this study was limited to only those variables. Additionally, some of the variables were categorical, and their specificity was limited (e.g., musculoskeletal/integument = yes or no). Finally, because some of the numbers in the CHAID subsamples were small, and these analyses were exploratory, they should be interpreted carefully.

Recommendations for future studies primarily address the limitations of this study, and extend its findings. To provide greater specificity for the medical condition predictor variables, we would recommend use of the Cumulative Illness Rating Scale for Geriatrics (CIRS-G) (Miller et al., 1992). The CIRS-G uses ordinal rather than dichotomous scales and thus addresses the severity of a condition, not just its existence. Because the numbers in the CHAID subsamples were small, larger samples, with greater numbers of PU are needed to confirm the associations found in the current study. Because musculoskeletal/integument was the strongest predictor in the regression model,

and moisture is a factor known to contribute to skin breakdown and PU, attention to frequency of toileting schedules and time between incontinence checks should be included in future research as well as in long-term care staff education. Similarly, because independence in transfers was strongly associated with PU outcomes in the CHAID model, attention to promotion of independent transfers could be important for prevention of PU.

3.5 SUMMARY

In conclusion, for older adults in long-term care facilities who were prescribed a custom fit wheelchair and a pressure reducing cushion we developed two models that identified factors contributing to or associated with the acquisition of PU. Musculoskeletal/integument conditions and independence in transfers were identified as the strongest factors contributing to the acquisition of PU. These were followed by a previous history of pressure ulcers, an endocrine/metabolic condition (e.g., diabetes), the Braden Activity/Mobility score, and the total Braden score. Both models identify factors that are associated with increased risk of PU acquisition, many of which can be addressed in residents' long-term care plans, including increased frequency of toileting schedules and incontinence checks, and increased emphasis on mobility and activity.

4.0 DECISION MAKING TREE

4.1 BACKGROUND

A variety of risk assessment scales have been developed with the objective of identifying or predicting individuals who are at risk for developing pressure ulcers (PU) (McDonald, 2001). Ideally, PU risk should be assessed using the combination of a risk assessment scale and the clinical judgment of professional personnel (Ferguson-Pell, 1990). The most commonly used risk assessment scale is the Braden Scale (Bergstrom et al., 1987) and less so, the Norton Scale (Berglund & Nordstrom, 1995). The Braden scale is often thought to be the most valid risk assessment scale. However, it is mainly used in research rather that clinically (Bridel, 1994; Hamilton, 1992).

A more objective method of identifying individuals at risk for developing PU is pressure mapping. Over the last decade, the development of pressure mapping systems has advanced the field of PU risk assessment for individuals who use wheelchairs, and this is due to their ability to measure objectively interface pressure using computer generated data (Taylor, 1999). One of the best means of judging a wheelchair cushion's ability to reduce interface pressure is to measure the pressure at the buttock-seat interface using a pressure mapping system (Roesler, 1997; Sprigle, 2000). However, rehabilitation

practitioners still frequently rely on their clinical judgment as the basis for selecting a pressure-reducing cushion.

Ragan, Kernozek, Bidar and Matheson (2002) suggested that pressure mapping systems are useful tools for rehabilitation practitioners who assess and prescribe wheelchair seating systems. These authors reported that their pressure mapping system allowed for a reliable assessment of the effectiveness of specific cushions. However, (Levy, 1997) recommended that pressure mapping systems be used as an adjunct to support clinical decisions rather than for making decisions that are solely based on the results of pressure maps.

Holm and Rogers (1989), in an article on the therapist's thinking behind functional assessment, suggested that practitioners use combinations of patient data (e.g., subjective and objective data from interviews and assessments), as well as their own clinical reasoning (based on their education, knowledge and experience) when making decisions about interventions. Clinical reasoning is defined as the cognitive operations that underlie the therapeutic reasoning process (Rogers, 1983). In a similar article on clinical reasoning, Rogers and Holm (1991) emphasized that it was important for practitioners to gather not only data on a patient's deficits, but also on the patient's assets.

A decision making tree analysis can be one way of showing the clinical reasoning or clinical decision-making of rehabilitation practitioners. Clinical decision-making is defined as the cognitive process used in the evaluation and management of a patient (Gambrill, 2005). Terms such as clinical judgment also appear in the literature and are frequently used interchangeably with clinical reasoning and clinical decision making (Jones, 1992).

When prescribing a wheelchair or a pressure-reducing wheelchair cushion, rehabilitation practitioners must think about intrinsic factors (e.g., immobility, level of activity, nutrition, age, race, previous history of PU) (Allman et al., 1995; Bergstorm, Braden, Laguzza, & Holman, 1987; Bergstrom, Braden, Kemp, Champagne, & Ruby, 1996; Fischer et al., 2004; S. D. Horn et al., 2002; Maklebust et al., 2005; Margolis, Bilker, Knauss, Baumgarten, & Strom, 2002; Rosen et al., 2006), and extrinsic factors (e.g., pressure, moisture, friction, shear, and temperature) (Allman et al., 1986; Bennett, Karvner, Lee, & Trainor, 1979; Bergstorm et al., 1987; Brienza et al., 2001; Krouskop, 1976). Then, decisions must be made about the data that must be collected to decide which wheelchair and which cushion is most appropriate for the patient. According to (Gambrill, 2005), the ability to think critically about one's clinical decisions and judgments is one method of increasing the accuracy of one's clinical decisions. It is with this purpose in mind that a decision-making tree analysis was generated to reflect the clinical reasoning and decision-making of rehabilitation practitioners when prescribing wheelchairs and pressure-reducing cushions in elderly long-term care residents.

4.1.1 Aims of the Study

The primary aim of the study was to develop an empirically-based decision-making tree for the prescription of wheelchairs and seat cushions by rehabilitation practitioners for elderly long-term care wheelchair users. The second aim of the study was to establish inter-rater and intra-rater reliability of members of the research rehabilitation team in

regard to recommendations for wheelchair pressure-reducing cushions for elderly long-term care residents.

4.2 METHODS

4.2.1 Design

This study consisted of a retrospective analysis of the decisions made by research rehabilitation team members when prescribing one of three types of pressure reducing seat cushions (PRCs): (a) viscous fluid and foam, (b) segmented air bladder, and (c) foam and gel for experimental subjects in a randomized clinical trial. Data used in this study were from data collected during the screening, intervention, and follow-up phases of the Randomized Clinical Trial (RCT) on Preventing Pressure Ulcers with Seat Cushions (RCT-SC) (IRB #0403061).

4.2.2 Overview of the Randomized Clinical Trial (RCT) on Preventing Pressure Ulcers with Seat Cushions (RCT-SC) (IRB #0403061).

The main aim of the RCT-SC was to establish the efficacy of using pressure-reducing wheelchair seat cushions for at-risk, elderly, long-term care (LTC) residents. The hypothesis of the RCT-SC was that the incidence of sitting-acquired PUs would be higher for at-risk elderly wheelchair users using segmented-foam seat cushions (SFC) than for those using appropriate PRC. If the results support the hypothesis, then they will provide

the level of evidence that is needed to change the standard of care for elderly long term care residents at high risk of developing sitting-acquired PU. The RCT-SC trial used a completely randomized design with an anticipated 240 residents assigned at random to either a PRC or an SFC. Participants were also classified according to their initial Braden Scale (Bergstorm et al., 1987) score, which would be used later for equivalence testing between groups. Classifications were: (a), *very* high risk of developing a PU (Braden score of 8 to 13), or (b) *lower* high risk of developing a PU (Braden score of 14 to 18) (Brienza et al., 2001).

4.2.3 Participants

Participants for the RCT-SC were recruited from skilled nursing facilities (SNF) in Allegheny County, Pennsylvania. The inclusion criteria for the RCT-SC were: (1) male or female LTC resident over the age of 65; (2) uses a wheelchair for 6 or more hours/day; (3) free of pressure ulcers (sitting surface) at the time of skin checking; (4) Braden score of less than or equal to 18, as scored by research staff; (5) combined Braden Activity/Mobility subscale score of less than or equal to 5. The exclusion criteria were: (1) body weight more than 250 pounds.; (2) hip width greater than 20 inches (width limit of the wheelchair used in the study), (3) does not meet all criteria on the Seating Needs Assessment (e.g., has spine or hip deformities that need a more specialized seating system than the study wheelchair can offer); (4) current use of any cushioning material(s) better or equivalent to the cushions in the study (the standard of care could not be lowered by the study seat cushion).

In this study, only participants randomized to the experimental group (n= 84) were included. Participants had a mean age of 86.10 (± 7.5) years and had lived in a nursing home for a mean of 2.26 (± 2.2) years. All participants reached the end point of the study for one of the following reasons: (a) by participating for 24 weeks, (b) formation of a PU on the sacrum/coccyx, left or right ischial tuberosities, (c) voluntary withdrawal, (d) death, or (e) change in medical condition which required changing a wheelchair or seat cushion. Participant demographic characteristics are shown in Table 4-1, and participant functional status characteristics are shown in Table 4-2.

Table 4-1: Participants' in the PRC Group Demographic Characteristics

Demographic variables	Frequency (n= 84)	Percentage (%)
Gender		
Female	66	79
Male	18	21
Weeks in the study		
< 22	23	38
≥ 22	61	62
Race		
White	77	92
African-American	7	08
Diagnosis variables		
Heart	48	57
Vascular	75	89
Hematopoietic	21	25
Respiratory	23	27
Eyes/ears/nose/throat/larynx	39	46
Upper Gastrointestinal	28	33
Lower Gastrointestinal	13	16
Liver	0	00
Renal	11	13
Genitourinary	24	29
Musculoskeletal/Integument	47	56
Neurological	22	26
Endocrine/Metabolic and Breast	41	49
Psychiatric Illness	71	85
Diabetes	23	27
Incontinence		
Urine	76	90
Feces	64	76
Pressure ulcer history	22	26
Hip surgery history	22	26
Deformity		
Spine	63	75
Pelvic	63	75

Table 4-2: Participants' in the PRC Group Functional Characteristics

Functional Tasks	Frequency (n=84)	Percentage (%)
Transfers		
Unable	22	26
Physical assistance	60	71
Verbal cueing	0	00
Independent	2	03
Reach Forward		
Unable	21	25
Physical assistance	14	17
Verbal cueing	26	31
Independent	23	27
Reach Side to Side		
Unable	21	25
Physical assistance	14	17
Verbal cueing	26	31
Independent	23	27
Wheelchair Propulsion		
Dependent	24	29
Assisted	29	34
Independent	31	37
Missing	0	00
Type of Propulsion		
Arm	16	19
Foot	17	20
Both	27	32
None	24	29

4.2.4 Protocol

All study subjects were prescribed one of three cushion types: (a) viscous fluid and foam, (b) segmented air bladder, or (c) foam and gel. The decision as to which specific cushion the research rehabilitation team prescribed was based on the knowledge and experience of the team involved in the RCT-SC and the use of the pressure mapping system as a

clinical tool. Clinical decision-making also used the intrinsic and extrinsic factors gathered during the clinical assessment as well as resident preferences.

4.2.5 Equipment used in the study

The two types of manual wheelchairs used in the RCT-SC are listed on Table 4-3. These two types of wheelchairs were chosen because they offered some adjustability in order to accommodate the participant's needs. The PRCs chosen for the experimental condition are also listed in Table 4-3. These three types were chosen to represent different categories of seat cushions that met Medicare guidelines.

Table 4-3: Equipment Used in the Randomized Clinical Trial on Preventing Pressure Ulcers with Seat Cushions (RCT-SC)

Equipment	Frequency (n=84)	Percentage (%)
Wheelchair type		
Escort	29	35
Breezy Ultra 4	55	65
PRC cushion type		
Viscous fluid and foam	50	59
Segmented air bladder	23	28
Foam and gel	11	13

Note. PRC = Pressure reducing cushion

Another piece of equipment used in the RST-SC study was the Force Sensing Array (FSA) (Vista Medical, Winnipeg, Manitoba, Canada). FSA is a pressure mapping system consisting of a thin mat of sensors (18 x 18 inches). It yields 256 pressure values arranged in a 16 x 16 sensor array. The thin mat of sensors is placed between the seating surface and the user's buttocks and it is connected through an interface module to a computer. FSA was chosen to be used in the RCT-SC because it has an estimated output accuracy of 95% (Parent, Lacost, & Dansereau, 1999). Two types of data are yielded by the sensors: (a) a colored map of the pressure distribution, and (b) numerical values (see Figure 1). The map generates an image of the pressure distribution of the user's buttocks while seated on the wheelchair seat cushion. Areas that are red indicate the highest pressure and areas that are blue indicate the lowest pressure. Several numerical values are generated by the FSA (e.g. peak pressure, number of sensors, average pressure), but there is not agreement on which is the best indicator of pressure. Therefore, for the purpose of this study, the colored contoured map image was used by the research rehabilitation team when deciding the most appropriate cushion for each participant. The map is more commonly referred to as a "pressure mapping image" (see Figure 4-1).

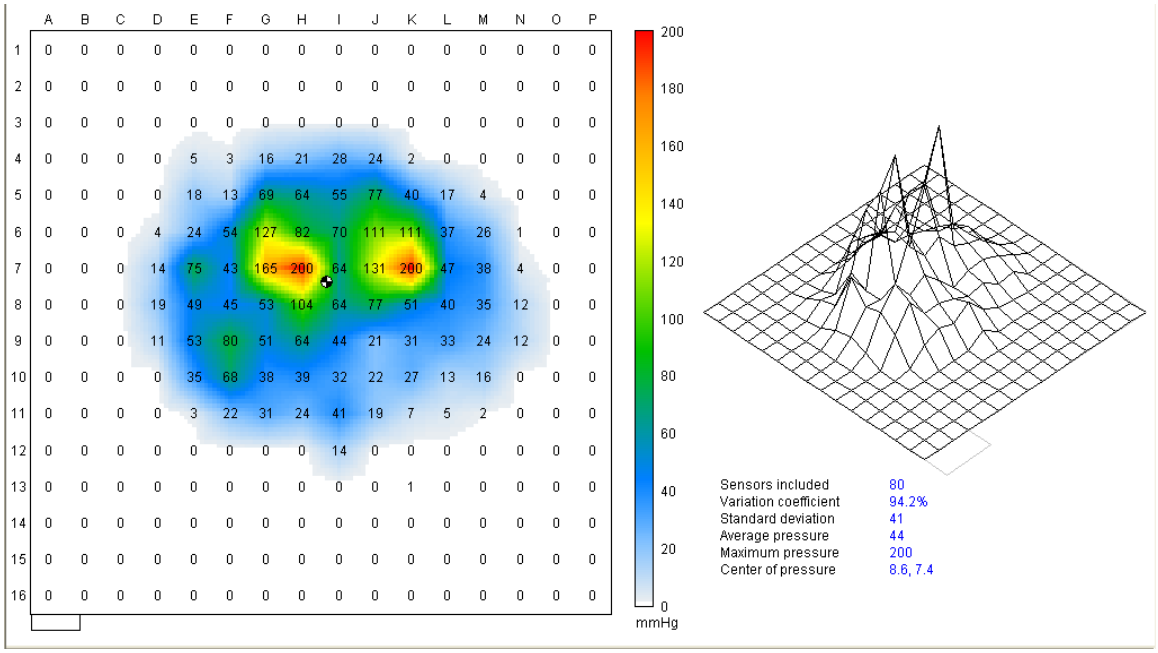


Figure 4-1: Pressure mapping output with colored map of the pressure distribution and numerical values.

4.2.6 Measures

In the RCT-SC, once the participant was enrolled in the study there were six phases: (1) screening stage I, (2) screening stage II, (3) screening stage III, (4) intervention phase, (5) follow up phase, and (6) an end point evaluation phase (see Table 4). For each of these phases there was a different form that was developed by the research team to ensure systematic data collection based on current practice (see Table 4-4 and 4-5). For a better understanding of the content of each form used in the study (see Table 4-5).

Table 4-4: Screening, Assessment and Intervention Phases of the Randomized Clinical Trial on Preventing Pressure Ulcers with Seat Cushions (RCT-SC)

Phases	Description of the what happened in the phase	Forms used
Screening: stage I	Research nurse checked the participant's skin to be confident that it was free of PU and evaluated the risk of PU using the Braden Scale	Braden Score and Skin Check
Screening: stage II	Research nurse repeats Screening stage I, but 1 week later.	Braden Score and Skin Check and Subject Baseline Form
Screening: stage III	Research rehabilitation team assessed the participant's physical characteristics (e.g. checking for spine and hip deformities) and body measurements were taken. If the participants passed this phase, they would be enrolled in the study.	Seating Needs Assessment
Intervention	Provision of a custom-fitted wheelchair and randomized seat cushion. Participants randomly assigned to the experimental condition received one of the three PRCs. The PRC cushion selected for each participant was based on the participant's clinical needs, and included use of pressure mapping data. The research rehabilitation team prescribed the cushion.	Cushion Selection Evaluation and Seating Needs Assessments and Equipment Issued Form
Follow-up	The research team followed participants every week for 24 weeks. The research nurse checked the skin and evaluated the risk of PU using the Braden Scale each week. The research rehabilitation team checked the participant's equipment and positioning each week.	Weekly Monitoring Form and Braden Score and Skin Check
End point	When end point was reached, each participant underwent a repeat pressure mapping	End Point Form

Table 4-5: Content Addressed in Each Data Form in the Study

Forms	Main Categories	Appendix
Braden Score	Sensory perception Moisture Activity Mobility Nutrition Friction/Shear	D
Skin Check	Check the color of the skin Checking right ischial tuberosity, left ischial tuberosity, sacrum, coccyx, right great trochanter, left great trochanter, right heel, and left heel for PU	E
Subject Baseline Form	Gender Race Ethnicity Diagnosis Height and weight Years living in nursing home History of PU Incontinence status Medication current used Means of mobility Hip surgery Transfers Alert and oriented Combative	A
Seating Needs Assessment	Cardiopulmonary status Hearing and vision status Incontinence status Strength status Cognition status Spine deformity Hip deformity Type of propulsion Level of independence in propulsion Participate in any type of therapy Muscle tone status Level of independence in hygiene, feeding, dressing, and communication	B

Table 4-5 (Continued)

Cushion Selection Evaluation	Seat cushion comfort Seat cushion that offered the best pressure distribution image Cushion provided Level of independence in transfers Level of independence in reach and carry out Level of independence in propulsion	C
Equipment Issued Form	Type of wheelchair prescribed and size Type of cushion prescribed and size Type of armrest prescribed Type of footrest prescribed	F
Weekly Monitoring Form	Report the Braden score of the week Report the skin check status of the week Sitting time Staff report about any medical changes Equipment status Incontinence status Cognitive status	G
End Point Form	Data end point was reached Number of the weeks in the study Number of days in the study Type of end point Nursing home staff reported the end point End point seating evaluation completed	H

4.2.7 Decision Making Tree and Flow Chart

Data and procedures for the 84 participants, who were enrolled in the experimental arm of the RCT-SC, were used to develop the research rehabilitation team decision-making tree and the flow chart. A decision tree was used to identify the decision making process of prescribing a custom-fit wheelchair and a pressure-reducing seat cushion. A decision tree is a graphic model that can be used to make decisions, and it shows alternative

choices as well as factors that may influence decisions (Olivas, 2007). The decision tree in this study was enhanced with American National Standards Institute (ANSI) standard symbols, shown in Figure 4-2 (Chapin, 1971). According to Olivas (2007), the advantages of using a decision-tree to delineate a complex process is that it is (a) graphic, and the user can see decisions, alternatives, and potential outcomes; (b) it is efficient, because complex alternatives can be seen quickly; (c) it is revealing, because alternatives can be compared, which is important if costs vary widely; and (d) it can be complementary to other methods, such as flow charts and project management tools.

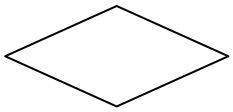
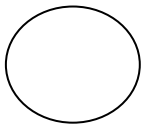
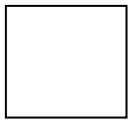
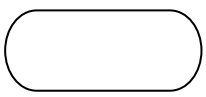
ANSI Symbol	**Meaning**
	Process
	Decision
	Data
	Operation
	Inspection/ Measurement
	Terminator

Figure 4-2: American National Standards Institute (ANSI) symbols and their meanings when used in decision-trees.

To further examine the decision-making process of the research rehabilitation team, based on use of pressure mapping image data, a flow chart identifying other relevant factors in the decision-making process was generated. Data were separated for participants whose prescribed cushion did not match the best pressure mapping image (Group I) and for participants whose prescribed cushion did match the best pressure mapping image (Group II).

4.2.8 Evaluation of Inter-Rater Reliability

First, the inter-rater reliability of the clinical decision making prescription of pressure reducing cushions was evaluated. All study procedures, risks and benefits, were discussed and informed consent was obtained prior to the beginning of the study in compliance with the policies of the Institutional Review Board (IRB) at the University of Pittsburgh.

The three participants involved in the inter-rater reliability study analyzed random case studies (n=10) from the RCT-SC. The case studies were presented to the participants by a co-principal investigator of the RCT-SC, and included baseline data (e.g., age, gender, marital status, and diagnosis); (b) a seating needs assessment screening form (e.g., spine deformity, hip deformity, type of propulsion; and (c) body measurements (hip width, seat depth, and foot height). In addition, data from the pressure mapping studies were provided for each cushion, for each case. However, the participants were masked to the residents' names, identifiers, and seat cushions previously described. Participants were instructed to choose a seat cushion, based on the

data available, and following the decision-making process used in the RCT-SC as closely as possible. Participants made their decisions independently and were not allowed to discuss the cases with each other. They completed the equipment issued form (see Table 4-5), on which they reported the type of wheelchair and cushion that they would prescribe for each case. To gather responses from the participants, the same forms used in the RCT-SC study were used in the inter-rater reliability study to avoid any confusion or bias. The participants were given 90 minutes to complete the forms for the 10 cases. All forms were completed under the same conditions with regards to office location, temperature in the office, and time of the day. The testing office was located at 2310 Jane Street in Pittsburgh, PA 15203.

4.2.9 Evaluation of Intra-Rater Reliability

Second, the intra-rater reliability for the interpretation of pressure mapping images was evaluated, as this was an important part of the clinical decision making process. Because no "gold standard" index for pressure has been uniformly accepted, for the purpose of this study, only the pressure mapping image was used, not the numerical numbers associated with the pressure mapping image.

Pressure mapping images of the first 73 participants who were enrolled in the RCT-SC experimental group were used in the intra-rater reliability study. For each resident participant, three pressure mapping images were available (viscous fluid and foam, segmented air bladder, and foam and gel). All three images for each resident were presented to one (n = 1) rehabilitation practitioner involved in the study (AA). The cases

were presented in a random order, and the practitioner was masked to the residents' identifiers, clinical history, and current treatment. Based on the pressure mapping images, the practitioner prescribed one of the three cushion types, and the responses were recorded. Each available pressure mapping system was presented to the practitioner twice, in a random sequence by a doctoral student not involved in the RCT-SC.

4.2.10 Data Analysis

Statistical analyses were done using SPSS 14.0 for Windows (SPSS Inc., Chicago, IL). Inter-rater reliability among practitioners, as well as intra-rater reliability, were calculated using the Intraclass Correlation Coefficient (ICC) test for Model Goodness of Fit. According to Portney and Watkins (2000), ICCs between 0.70 and 0.90 are categorized as moderate, whereas those below 0.70 are considered weak, and those above 0.90 are considered good to excellent.

4.3 RESULTS

The primary aim of this study was to develop a decision-making tree for the prescription of wheelchairs and seat cushions, for use by rehabilitation practitioners, with elderly long-term care wheelchair users. A priori, the research rehabilitation team identified and codified into protocol forms the factors they believed to be relevant for the prescription of

wheelchairs and pressure-reducing seat cushions. The decision-making trees shown in Figures 4-3 to 4-9 reflect the decision-making process of the research rehabilitation team.

Prior to making any decisions, the research rehabilitation team checked for any severe anatomical deformities (severe scoliosis or kyphosis that would require customized backrests or back supports), took body measurements (seat width, seat depth, and back of knee to floor distance), and inquired about type of propulsion currently used (feet, hands, feet and hands, and neither). Also nursing staff recommendations and/or physicians orders were reviewed (see Figure 4-3). If such an order existed it was followed, unless it was determined that a footrest or other part would bring discomfort to the participant. If so, a team member spoke with nursing staff and/or physician to resolve the issue.

4.3.1 Decision-making trees for wheelchair prescription -- foot propellers

The type of propulsion started the decision-making process. Therefore, there were four different decision-making trees that began with type of propulsion. The first decision tree described was propulsion with feet only (see Figure 4-4). Therefore, in order to enable optimal foot propulsion, an appropriate seat-to-floor height was the first goal. To get the appropriate seat-to-floor height either the research rehabilitation team provided a wheelchair of the correct height or made adjustments to the wheelchair, such as adding a drop seat, or changing the casters to a smaller size, and lowering the rear wheels. For foot propellers with low seat height, it can be a problem for transfers. However, some participants already needed assistance with transfers, and for the others transfers were not

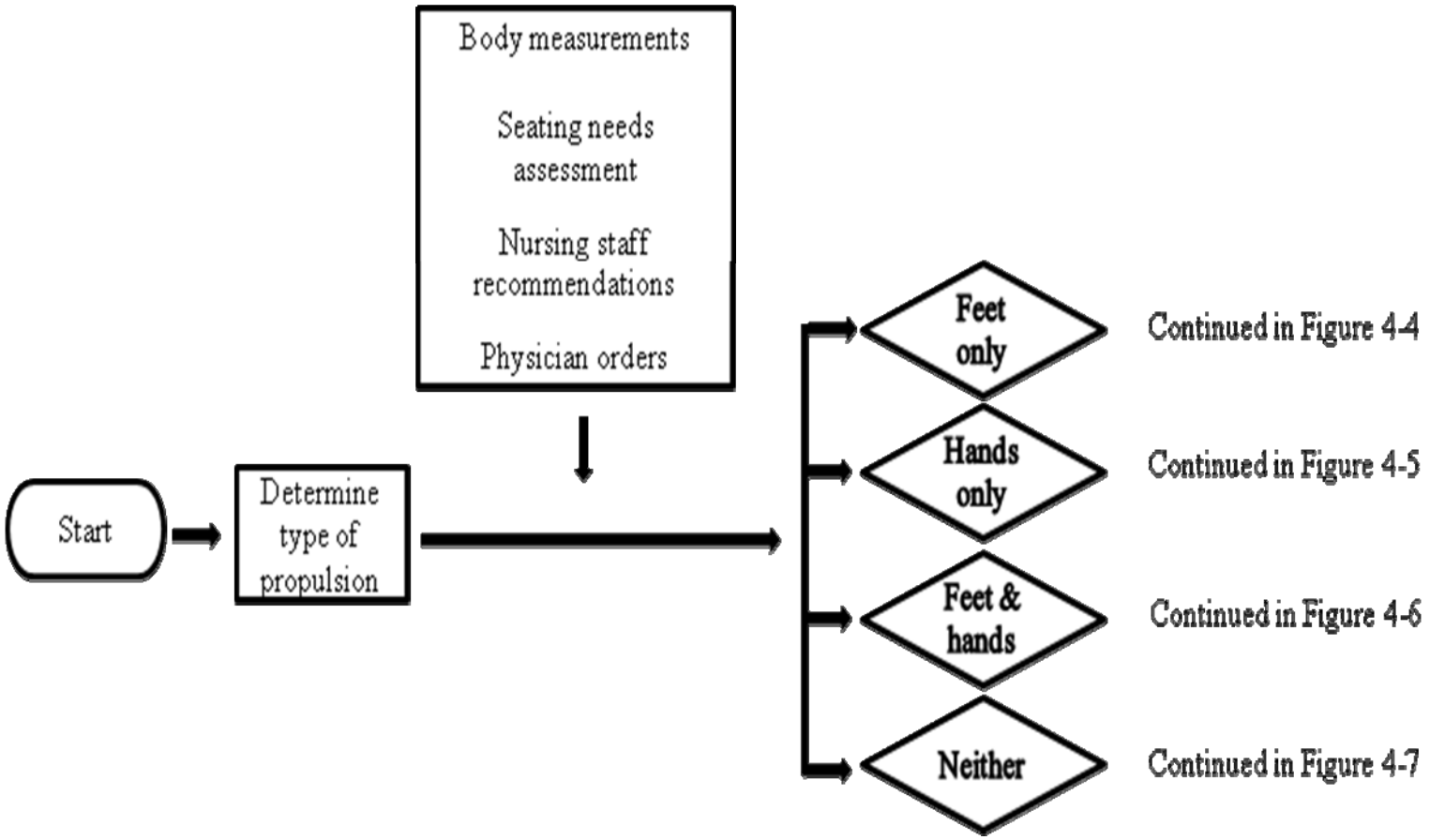


Figure 4-3: Initial components of decision-making tree for wheelchair prescriptions for long-term care residents.

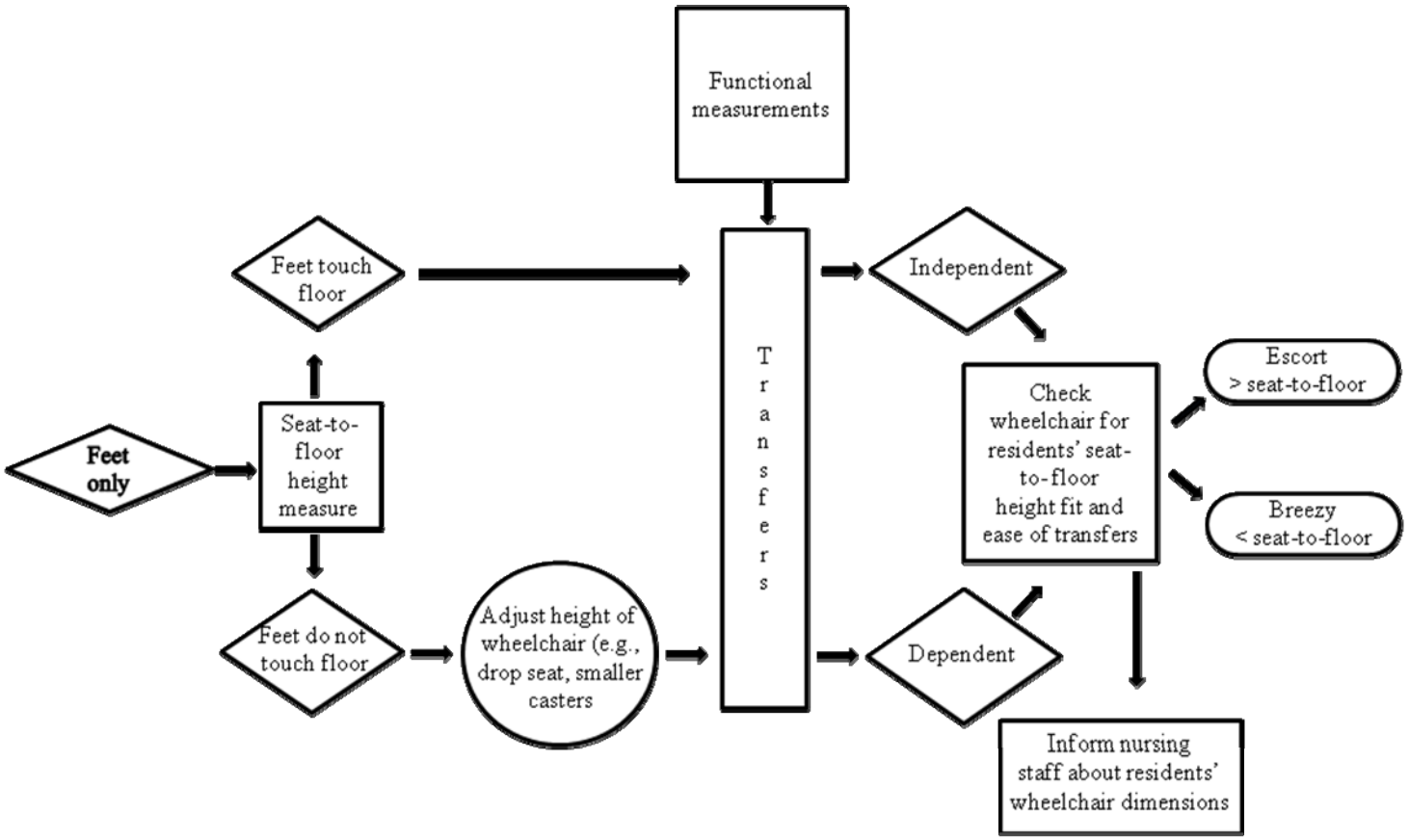


Figure 4-4: Decision-making tree for wheelchair prescriptions for residents who used only their feet for propulsion.

a problem. Additionally, functional tasks like reaching forward, and reaching side to side were also relevant at this point. Once the research rehabilitation team determined that a participant was independent or dependent in transfers, they would double check to make sure that the height of the wheelchair was optimal for both transfers and propulsion. The nursing staff agreed that mobility was a priority over transfers, and if we could make the resident mobile, then they did not mind giving them a "little" bit of extra help with transfers, if needed. When a decision was made about which chair the resident would receive, the research rehabilitation team notified the nursing staff about the wheelchair dimensions and the participant received either an Escort or a Breezy Ultra-4.

4.3.2 Decision-making trees for wheelchair prescription -- hand propellers

For participants who used only their hands to propel the wheelchair (Figure 4-5), the research rehabilitation team first checked to see if there was a need for elevating footrests. Next, the participant was evaluated for independence in transfers, as well as functional tasks such as reaching forward and side to side. Over the years in the study, the team learned that the need for nursing staff assistance in transfers was more important to nursing staff than to the participant, because of the extra effort needed on the part of the staff. For hand propellers, unlike foot propellers who gained increased mobility with the study wheelchairs, the new wheelchair maintained them at the same

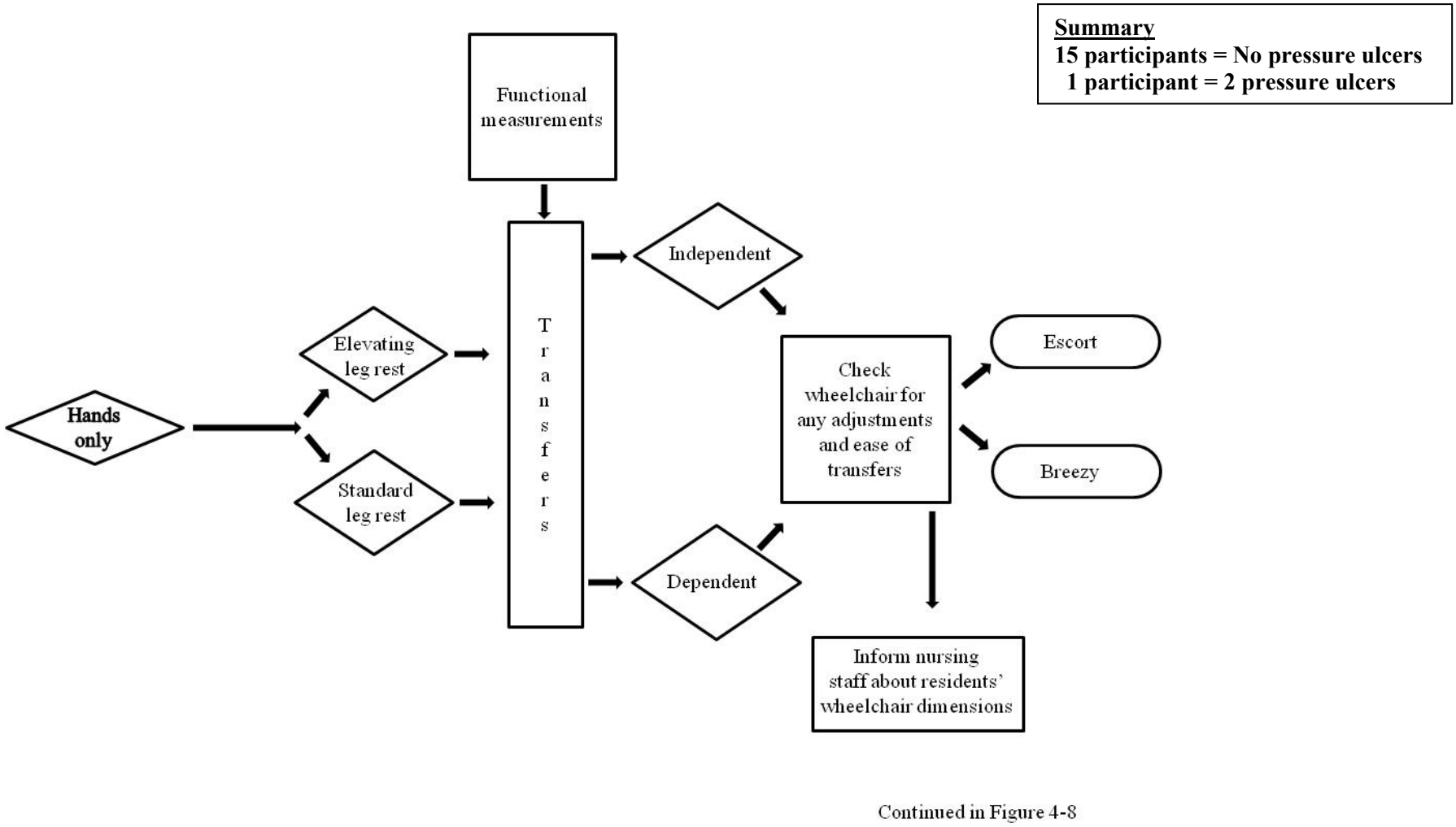


Figure 4-5: Decision-making tree for wheelchair prescriptions of residents who used only their hands for propulsion.

level of functionality. Once the team determined that the participant could reach the wheels adequately for propelling, adjustments in the wheelchair were done when necessary, the nursing staff was informed of the wheelchair dimensions, and the participant received either an Escort or a Breezy Ultra-4.

4.3.3 Decision-making trees for wheelchair prescription -- hand and foot propellers

Participants who used both feet and hands for propelling their wheelchairs constituted our third group (Figure 4-6). The decision-making tree for foot and hand propellers is similar to the tree for foot propellers, because these participants also had to have their feet on the floor. However, it was also similar to the tree of the hand propellers, because the size of the wheels that would optimize hand propulsion also had to be assessed to enable independent propulsion. Again, the research rehabilitation team evaluated independence in transfers and functional reach from the wheelchair. Depending on whether the participant was independent or dependent in transfers, the team would make sure that the height of the wheelchair would optimize both propulsion and transfers. When a decision was made, the research rehabilitation team would notify the nursing staff about wheelchair dimensions and the participant would receive either an Escort or a Breezy Ultra-4.

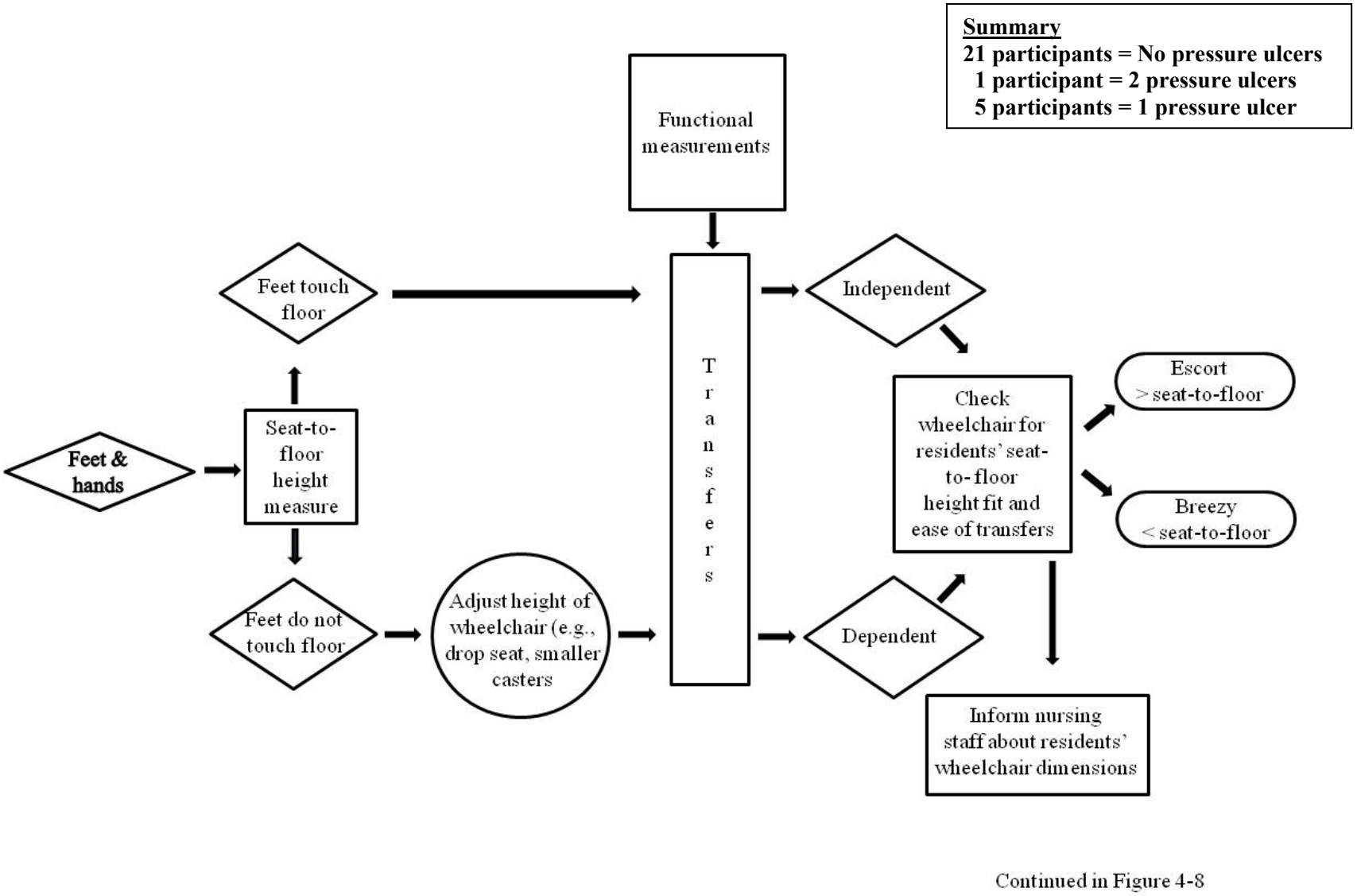


Figure 4-6: Decision-making tree for wheelchair prescriptions for residents who used their feet and hands for propulsion.

4.3.4 Decision-making trees for wheelchair prescription -- neither hand nor foot propellers

The final propulsion decision-making tree was for the group that used neither feet nor hands to propel the wheelchair they needed to be pushed (Figure 4-7). The variable that was considered most relevant was transfers, because of the nursing staff. Participants who did not propel needed a lot of assistance and were usually unable to transfer independently. Therefore, the height of the chair was based on the most favorable height for nursing staff. Final checks were made, and adjustments were sometimes made to the push handles on the chair so their height would be convenient for nursing staff and family members. When a decision was made, the nursing staff were informed about the dimensions of the wheelchair and the participant received either an Escort or a Breezy Ultra-4.

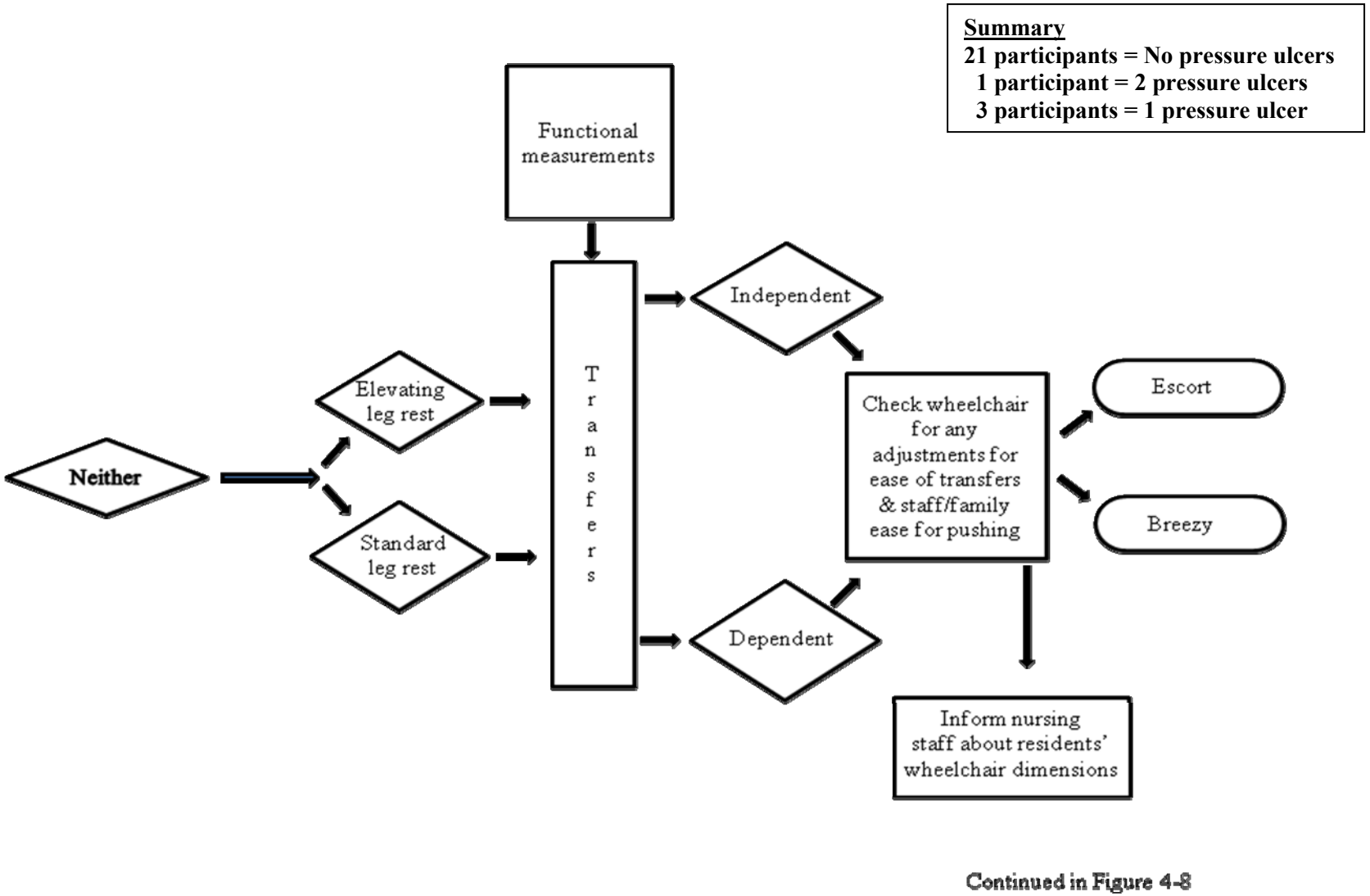


Figure 4-7: Decision-making tree for wheelchair prescriptions for residents who used neither their feet or hands for propulsion (they were pushed by staff or family).

4.3.5 Decision-making tree for wheelchair cushion selection

Once the wheelchair was prescribed, the research rehabilitation team had to decide which of the three types of seat cushions would be the best for a participant's needs (see Figure 4-8). This process started with a seat cushion trial using pressure mapping as a clinical tool. In our study, there were three types of pressure-reducing cushions: (a) air bladder, (b) viscous fluid and foam, and (c) foam and gel. Prior to beginning the procces, the team had to prepare the air bladder cushion, letting it reach the same atmospheric pressure as the room. Participants sat on each cushion in their new wheelchair, and a pressure mapping image was taken with each cushion type. If a participant was able to express a preference, the research rehabilitation team respected the preference and performed the functional tasks while the participant was seated on the preferred cushion. The team also took into consideration the image from the pressure mapping. If the image showed a "red" spot, the team educated the participant about how to relieve pressure from that area and provided the cushion that the participant preferred. Sometimes participants changed their minds when they saw the pressure mapping image, and selected one with lower pressures points.

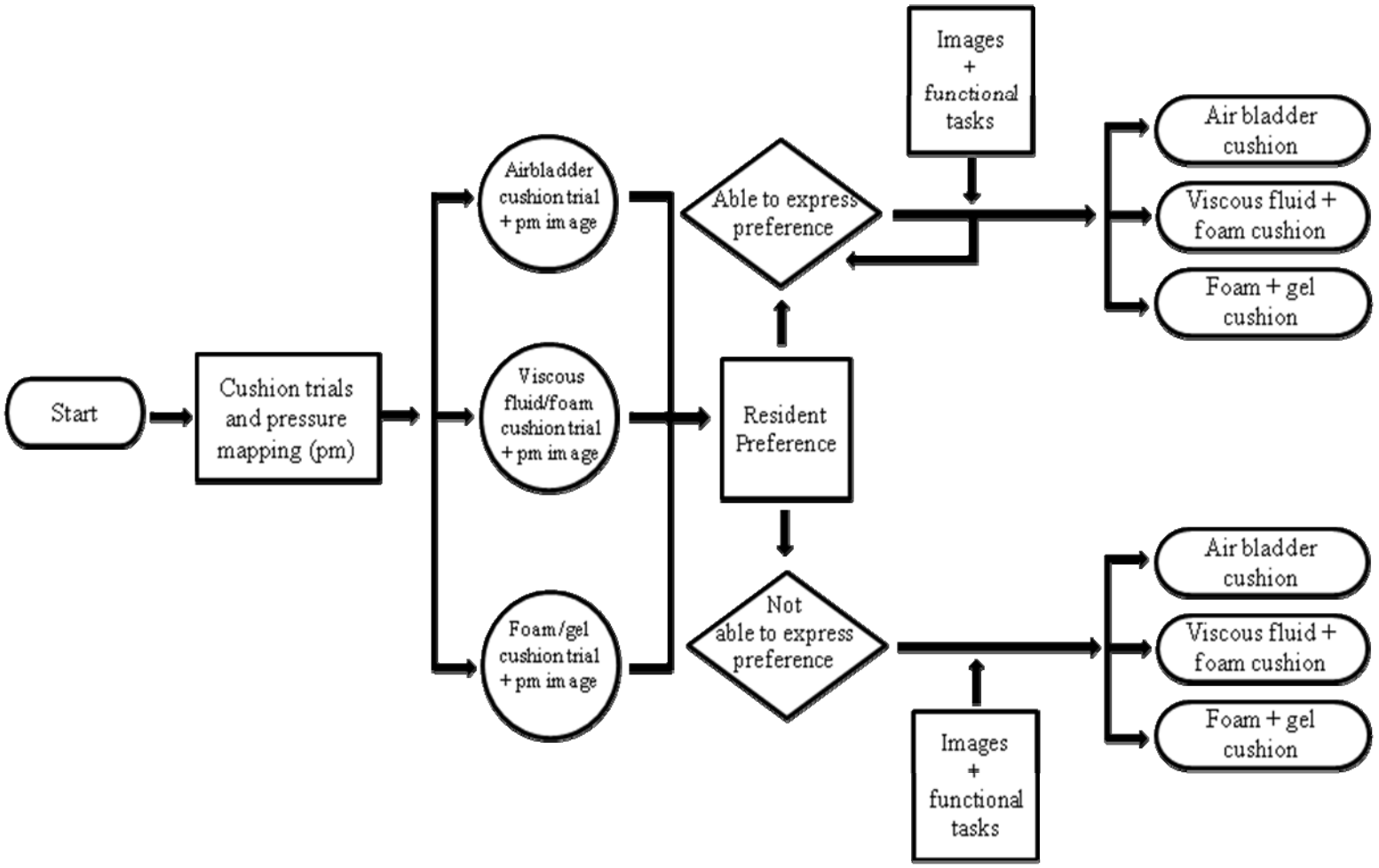


Figure 4-8: Decision-making tree for pressure-reducing wheelchair cushions for long-term care residents.

If the participants were not able to express their preferences, the team had them perform the functional tasks, when possible, and also considered at the pressure mapping images. Usually participants who could not express their preferences had dementia, or were too confused, so the team chose the best cushion, using the functional task information and the pressure mapping images.

4.3.6 Decision-making tree -- wheelchair and cushion together

Once the wheelchair and cushion were selected, the research rehabilitation team made sure that everything was properly fitted to the participant (see Figure 4-9). The team double checked body and wheelchair measurements and the need for adjustments, such as changing the standard backrest to an adjustable backrest, determining if an elevating footrest was needed, determining the need for a drop seat now that the cushion was added, and deciding if there was a need for smaller casters or brake extensions. Finally, the functional tasks were repeated with the participants in their new chair and cushion, and if no further adjustments were necessary, their chosen chair and cushion now belonged to them.

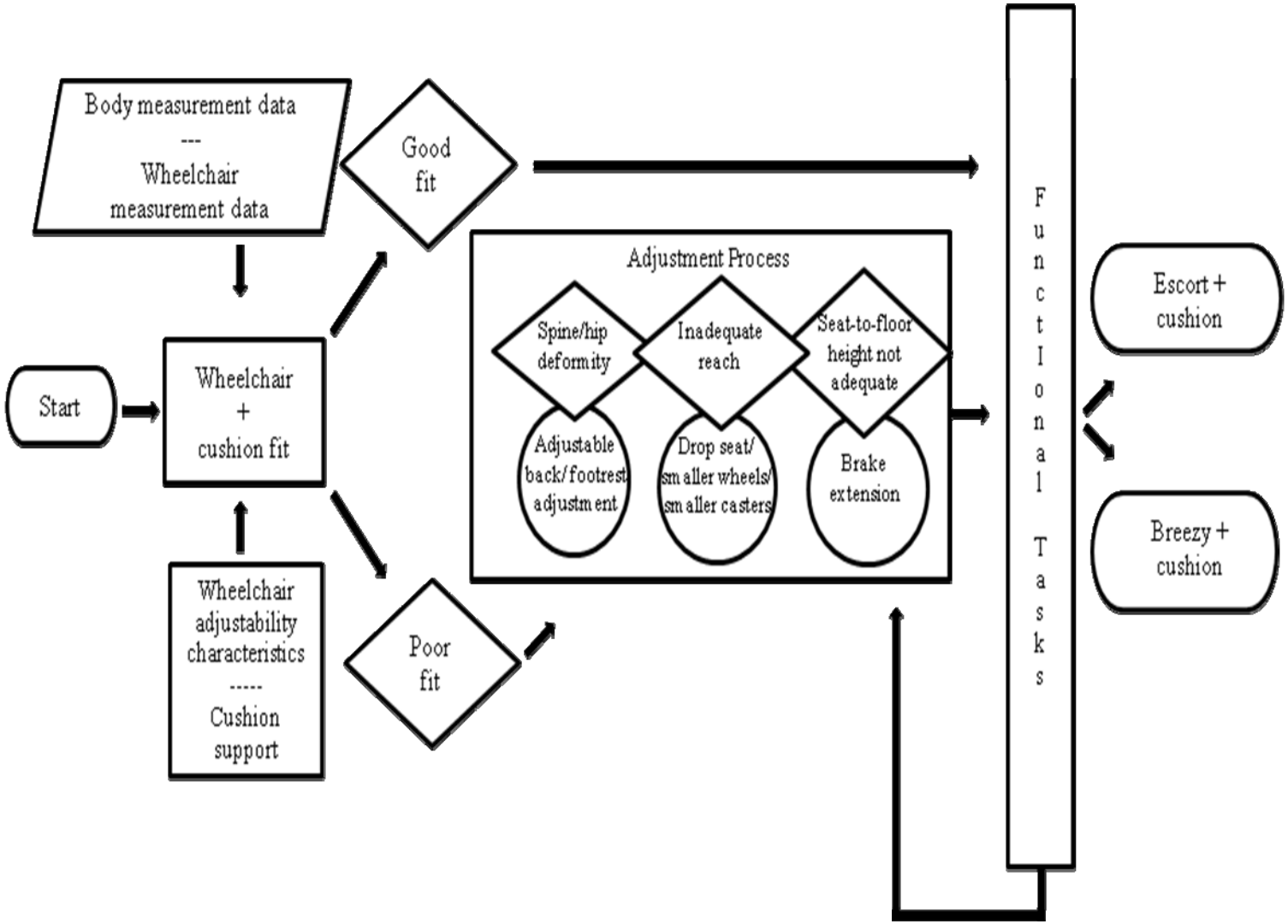


Figure 4-9: Decision-making tree for final fit of wheelchair and cushion for long-term care residents.

4.3.7 Decision-making tree outcomes

None of the 17 independent foot propellers acquired a PU. Of the participants who used their hands only, 1 of 16 participants acquired 2 PU (6.25%). For participants who used both their hands and feet, 5 of the 27 participants acquired 1 PU and 1 participant acquired 2 PU (18.5%), and for participants who used neither their feet nor hands for propulsion (needed to be pushed), 3 of 24 participants acquired 1 PU and 1 participant acquired 2 PU (12.5). Furthermore, of the 11 participants who acquired the 14 PU, 1 participant had an air bladder cushion, 2 had foam + gel cushions, and 8 had viscous fluid cushions. Although some participants acquired a PU, most participants did not: 100% of the foot propellers were PU free, as were 93.75% of the hand propellers, 81.5% of foot and hand propellers, and 87.5% of those who could not self-propel.

4.3.8 Flow chart with frequency of factors impacting research rehabilitation team decisions

To examine the relevance of factors that the research rehabilitation team deemed critical when generating the clinical assessment protocol, a process flow chart was developed to identify the frequency with which those factors impacted team decisions, by use and non-use of pressure-mapping images (see Figure 4-10), and the cushions and outcomes associated with those factors. For group I, 41 participants used a viscous fluid and foam cushion, of 41 participants, there were 9 acquired PU and they were all in the sacrum.

Eleven participants used foam and gel cushion, and in this group there were 2 acquired PU, one in the sacrum and one in the right ischial tuberosities. There were no participants using an air bladder cushion in group I. For group II, there were 9 participants who used the viscous fluid and foam cushion and 23 who used the air bladder cushion. For the 9 participants who used the viscous fluid and foam, there were 2 acquired PU in the sacrum area, and for the participants who were sitting on the air bladder cushion there was 1 acquired PU, also on the sacrum area. There were no participants in this group who used the gel and foam cushion. Of the 11 participants who developed PU, 3 participants got the cushion that had the best positioning and the best image (1 air bladder, and 2 viscous fluid), and 8 participants got the cushion that offered the best positioning (2 foam + gel, and 6 viscous fluid) but not the best image.

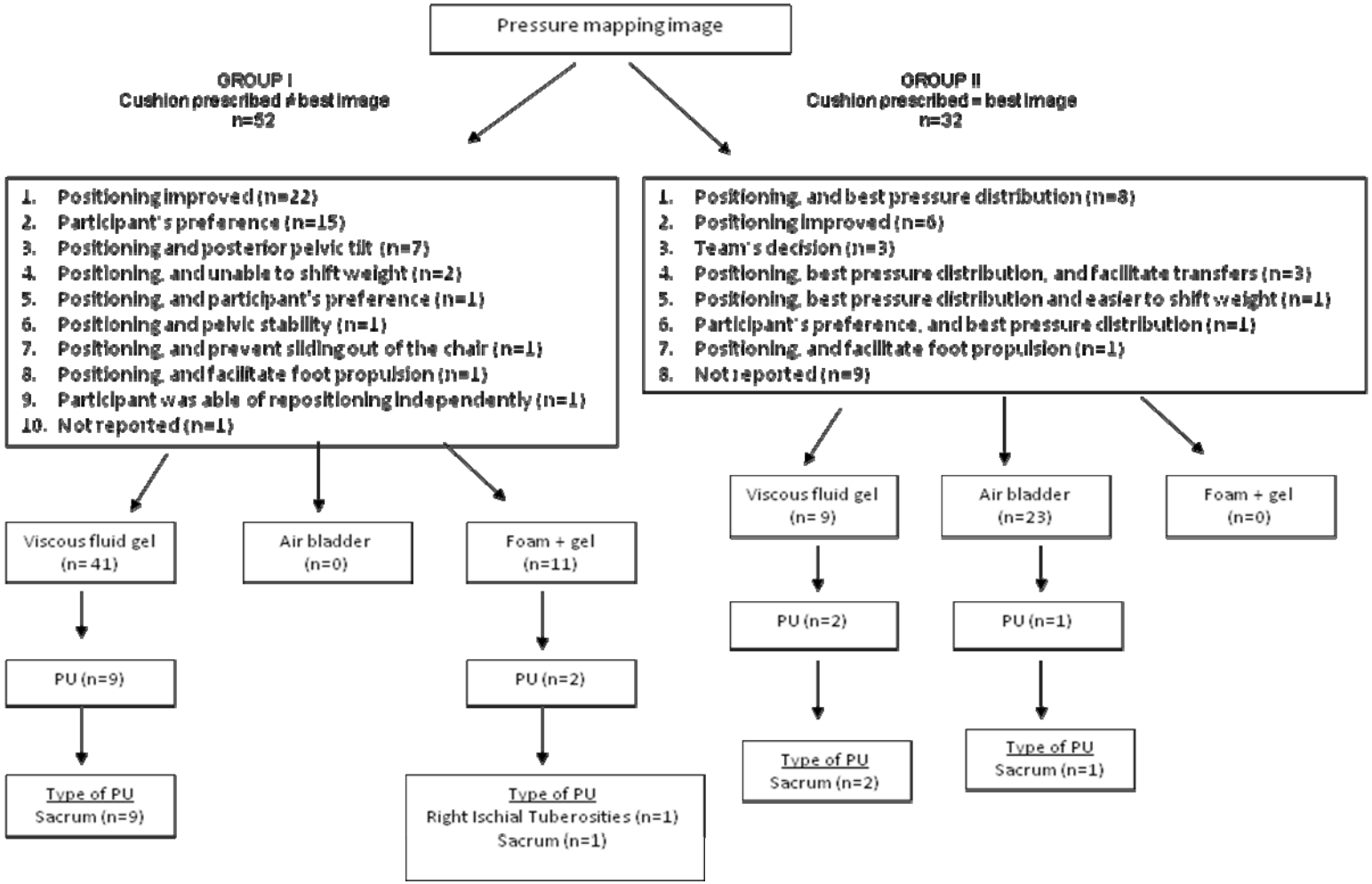


Figure 4-10: Flow chart of relevant factors affecting two groups, based on use/non-use of the pressure mapping image.

Table 4-6 provides descriptive data about demographic and clinical factors, based on whether or not the cushion with the best pressure-mapping image was prescribed. There were no significant differences between the two groups, except type of cushion.

Table 4-6: Physical and Functional Characteristic of the Participants Analyzed for the Decision Tree and the Flow Chart

	Best image ≠ prescribed (n=52)	**Best image = prescribed (n=32)**	**p value**
Age (Mean/SD)	86.5 (±7.9)	85.5 (±7)	.55
Years living in a nursing home (Mean/SD)	2.5 (±2.2)	1.85 (±2)	.17
Braden score (Mean/SD)	16 (±1.3)	16 (±1.3)	.71
Activity/mobility of the Braden (Mean/SD)	5 (±.37)	5 (±.37)	.93
PPI (Mean/SD)	82 (±25.5)	77 (±23.2)	.52
Gender			.72
Female	40 (87%)	26 (81%)	
Male	12 (23%)	6 (19%)	
Race			.25
Caucasian	49 (94%)	28 (88%)	
African America	3(6%)	4 (12%)	
Spine deformity	42 (81%)	21 (66%)	.09
Hip deformity	41 (77%)	22 (69%)	.51
Transfers			.51
Dependent	50 (96%)	32 (100%)	
Independent	2 (4%)	0	

Table 4-6 (Continued)

Reach			.53
Dependent	36 (69%)	25 (78%)	
Independent	16 (31%)	7 (22%)	
W/C propulsion			.45
Dependent	31 (60%)	22 (69%)	
Independent	21 (40%)	10 (31%)	
Type of w/c propulsion			.71
Arm	10 (19%)	6 (19%)	
Foot	8 (15%)	9 (28%)	
Both	17 (33%)	10 (31%)	
None	17 (33%)	7 (22%)	
Type of wheelchair			.42
Breezy	32 (62%)	23 (72%)	
Escort	20 (38%)	9 (28%)	
Type of cushion			.001
Viscous fluid and foam	41 (79%)	9 (28%)	
Segmented air bladder	0	23 (72%)	
Foam and gel	11 (21%)	0	

Note. Chi-square and independent *t*-tests were performed as appropriate.

Table 4-7 lists the factors and the frequency with which they influenced the clinical decisions made by the research rehabilitation team when choosing the most appropriate seat cushion for participants whose prescribed cushion did not match the best pressure mapping image. Improved positioning and participants' preferences were the most relevant factors impacting cushion selection.

Table 4-7: Reasons Influencing Clinical Decisions when the Cushion Prescribed Does Not Match the Best Pressure Mapping Image.

Reasons	Frequency (n=52)
Positioning was improved (better postural alignment)	22
Participant's preference	15
Positioning and posterior pelvic tilt was improved	7
Positioning was improved, and able to shift weight	2
Positioning was improved, and participant's preference	1
Positioning was improved, and pelvic stability improved	1
Positioning was improved, and sliding out of the chair prevented	1
Positioning was improved, and foot propulsion facilitated	1
Participant was able of reposition self independently	1
Not reported	1

Table 4-8 lists the factors and their frequency influencing the clinical decisions made by the research rehabilitation team when choosing the most appropriate seat cushion for participants whose prescribed cushion matched the best pressure mapping image. Improved positioning and best pressure distribution were the two most relevant factors when selecting the seat cushion.

Table 4-8: Reasons Influencing Clinical Decisions When the Cushion Prescribed Matched the Best Pressure Mapping Image.

Reasons	Frequency (n=32)
Positioning was improved, and best pressure distribution	8
Positioning was improved (better postural alignment)	6
Team's decision	3
Positioning was improved, best pressure distribution, and facilitate transfers	3
Positioning was improved, best pressure distribution and able to shift weight	1
Participant's preference, and best pressure distribution	1
Positioning was improved, and foot propulsion facilitated	1
Not reported	9

Of the 84 participants, 11 (15%) participants developed 14 PU, and 75 (85%) did not develop a PU. To better understand the characteristics of those who did develop a PU and those who did not, see Tables 4-9 and 4-10. Because the disparity in numbers do not allow valid statistical analyses, obvious differences between the characteristics of the two groups may still be relevant. For those whose prescribed cushion matched the best pressure image, and who developed a PU, the time since admission was less than 6 months, compared to the other groups, who had been residents for 2 or more years. Also, those who did not develop PU had lower PPI levels, and proportionately lower levels of musculoskeletal/integumentary deficits (48% vs. 91%) and diabetes (23% vs. 55%).

Table 4-9: Characteristic of the Participants Who Developed PU

Characteristics	Cushion prescribed ≠ best image (n=8)	Cushion prescribed = best image (n=3)
Age	Mean/SD= 84.75 (± 9.22)	Mean/SD= 82 (±1.73)
Years living in a nursing home	Mean/SD= 2.45 (±1.72)	Mean/SD= 0.53 (±0.37)
Braden Score	Mean/SD= 14.88 (±.84)	Mean/SD= 15.33 (±1.52)
Activity/mobility of the Braden	Mean/SD= 4.63 (±.518)	Mean/SD= 5.0 (0)
PPI	Mean/SD= 86.75 (±16.25)	Mean/SD= 97.33 (±38.6)
Gender		
Male	2	0
Female	6	3
Race		
Caucasian	8	2
African American	0	1
Diagnosis variables		
Heart	5	1
Vascular	8	3
Hematopoietic	2	0
Respiratory	2	0
Eyes/ears/nose/throat/larynx	2	1
Upper Gastrointestinal	3	1
Lower Gastrointestinal	0	0
Liver	0	0
Renal	0	0
Genitourinary	3	2
Musculoskeletal/Integument	7	3
Neurological	2	0
Endocrine/Metabolic and Breast	6	2
Psychiatric Illness	8	2
Diabetes	4	2
Incontinence		
Urine incontinence	8	3
Feces Incontinence	7	2
History of PU	1	3
Deformities		
Spine	7	1
Hip	5	2

Table 4-9 (Continued)

Type of wheelchair propulsion		
Arm	0	1
Foot	0	0
Both	6	0
None	2	2
Wheelchair Propulsion		
Independent	4	0
Dependent/assisted	3	1
Unable	1	2
Ambulation		
Independent	0	0
Dependent/assisted	6	0
Unable	2	3
Reach Forward		
Independent	1	1
Dependent/assisted	4	0
Unable	3	2
Reach Side to Side		
Independent	1	1
Dependent/assisted	4	0
Unable	3	2
Transfers		
Independent	0	0
Dependent/assisted	5	1
Unable	3	2
Type of wheelchair		
Breezy	6	1
Escort	2	2
Type of Cushion		
Viscous fluid	6	2
Air bladder	0	1
Foam and gel	2	0

Table 4-10: Characteristic of the Participants Who Did Not Develop PU

Characteristics	Cushion prescribed ≠ best image (n=44)	Cushion prescribed = best image (n=29)
Age	Mean/SD= 86.77 (± 9.22)	Mean/SD= 85.90 (±7.27)
Years living in a nursing home	Mean/SD= 2.52 (± 2.31)	Mean/SD= 2.00 (±2.00)
Braden Score	Mean/SD= 15.79 (± 1.30)	Mean/SD= 15.76 (±1.27)
Activity/mobility of the Braden	Mean/SD= 4.88 (±.324)	Mean/SD= 4.83 (±.39)
PPI	Mean/SD= 81.09 (±26.95)	Mean/SD= 75.33 (±21.01)
Gender		
Male	10	6
Female	34	23
Race		
Caucasian	41	26
African American	3	3
Diagnosis variables		
Heart	25	17
Vascular	40	24
Hematopoietic	10	9
Respiratory	11	10
Eyes/ears/nose/throat/larynx	21	15
Upper Gastrointestinal	17	7
Lower Gastrointestinal	7	6
Liver	0	0
Renal	7	4
Genitourinary	11	8
Musculoskeletal/Integument	25	12
Neurological	8	12
Endocrine/Metabolic and	22	11
Breast		
Psychiatric Illness	36	25
Diabetes	9	8
Incontinence		
Urine incontinence	40	25
Feces Incontinence	34	21
History of PU	8	10
Deformities		
Spine	35	20
Hip	36	20
Type of wheelchair propulsion		
Arm	10	5
Foot	8	9
Both	11	10
None	15	5
Wheelchair Propulsion		
Independent	17	10
Dependent/assisted	13	12
Unable	14	7
Ambulation		
Independent	0	0
Dependent/assisted	16	10
Unable	28	19

Table 4-10 (Continued)

Reach Forward		
Independent	15	6
Dependent/assisted	18	18
Unable	11	5
Reach Side to Side		
Independent	15	6
Dependent/assisted	18	18
Unable	11	5
Transfers		
Independent	2	0
Dependent/assisted	33	21
Unable	9	8
Type of wheelchair		
Breezy	26	22
Escort	18	7
Type of Cushion		
Viscous fluid	35	7
Air bladder	0	22
Foam and gel	9	0

4.3.9 Evaluation of Inter-Rater Reliability

Demographic characteristics of the three most consistent research rehabilitation team members who participated in the inter-rater reliability study are shown in Table 4-11. Inter-rater reliability (ICC) among the three practitioners was .74, which is considered moderate (Portney & Watkins, 2000).

Table 4-11: Inter-rater Reliability Participants' Sample Characteristics

Demographic variables	Frequency (n= 3)
Age (mean)	43.33 (± 12.7)
Years of experience as an occupation therapist	14 (± 3.6)
Years of experience in seating and mobility assessments	9 (± 8.1)
Gender	
Female	2
Male	1
Race	
Caucasian	2
Hispanic	1
Occupation	
Professor	2
PhD candidate	1
Certification	
MS, OT	1
OTR/L	1
OTR/L, ATP	1

4.3.10 Evaluation of Intra-Rater Reliability

The research rehabilitation team member who served as the intra-rater reliability participant was a 32 year old Hispanic female, with 10 years of professional experience as an occupational therapist, and 7 years of experience as a seating-mobility specialist.

She is also the principal investigator of this study. Intra-rater reliability (ICC) was found to be .90, which is considered good - excellent (Portney & Watkins, 2000).

4.4 DISCUSSION

The primary aim of this study was to develop a decision-making tree for the prescription of wheelchairs and seat cushions for use by rehabilitation practitioners working with elderly long-term care wheelchair users. This study was seminal, in that it delineated the decision-making process by a research rehabilitation team as they prescribed wheelchairs and pressure reducing cushions (PRC) for elderly long-term care residents. The wheelchairs and PRC were prescribed as part of the experimental arm of a randomized clinical trial to prevent PU.

The clinical decision making tree outlined different decision-making pathways used by the research rehabilitation team for choosing one wheelchair versus another, and also one cushion versus another. Before the study began, the team combined their clinical expertise, knowledge, and experience to generate "clinical reasoning" protocols. The content of the Seating Needs Assessment and the Cushion Selection Evaluation (including pressure mapping images) protocols reflected what the team believed to represent "best practice." For this sample of participants, the first variable that the research rehabilitation team considered important was type of propulsion. This was considered first because it influenced which of the two wheelchairs would be appropriate (e.g., the participants who used their feet as a method of propulsion would need a lower wheelchair and independent propulsion would enable the residents to move around the

nursing homes by themselves). If they were not independent in wheeled mobility they would have limited opportunity to move around the facility. Following method of propulsion, the team next considered: independence in transfers, anatomical deformities, best supportive position and pressure mapping images. For the best cushion, the team took into consideration the participants' preference when they were able to identify it, and when they were unable, the research rehabilitation team selected the cushion.

However, in the field of seating and mobility it is very difficult to find a balance between positioning, functioning, and the best distribution of seating pressure. Therefore, decisions often had to focus on improving positioning and functioning, regardless of the best pressure image distribution (e.g., for 89% of participants, the air bladder cushion had the best pressure distribution based on the pressure mapping image). For example, for some participants, the perceived instability when sitting on an air bladder cushion negatively influenced their functioning in transfers and independent propulsion, especially for foot propellers who tended to slide out of the chair because the air offered lower friction and shear (Ferguson-Pell, 1990). When improved functioning was not a primary factor, as in those who could use neither their hands or feet to propel their chairs, decisions were based on improving positioning and achieving the best pressure distribution, based on the pressure mapping image.

Despite improved positioning and consideration of the best pressure image some participants developed a PU. For those participants who developed a PU and the best pressure mapping image did not match the prescribed cushion, the mean PPI was 97.33 (±38.6). For participants who developed a PU and the best pressure mapping image did match the prescribed cushion, the mean PPI was 75.33 (±21.01). Peak pressure interface

was previously reported (Brienza et al., 2001; Conine et al., 1994) as having a positive relationship with PU acquisition, and this held true in the current study. The group that developed PU had higher values of PPI. Although the small sample did not allow for valid statistical analyses, for the 3 participants who developed PU sitting on the cushion that had best pressure-mapping image, the means years of living in a nursing home was only 0 .53 (±0.37) compared to the 8 participants who were sitting on a cushion that did not have the best pressure-mapping image, the mean years equaled 2.42 (±1.72). In a study by (Baumgarten et al., 2003) it was shown that newly admitted nursing home residents from hospitals had a higher incidence of PU (11.9%) than those admitted from home or other settings (4.7%). Therefore, although the cushion prescribed matched the best pressure distribution image, other factors, such as recent admission to the nursing home from a hospital may have had a greater impact on PU acquisition.

It could easily be concluded that pressure mapping system is a good clinical tool, and should always be incorporated into the clinical reasoning process of practitioners. Other studies have demonstrated its clinical utility (Crawford, Strain, Walsh, & Porter-Armstrong, 2005; Ferguson-Pell, 1990; Levy, 1997; Ragan et al., 2002; Stinson, Porter, & Eakin, 2002). In the study by Crawford et al. (2005), it was found that 30 % of the seat cushions recommended were changed when the pressure mapping data were considered, however, 70 % of the decisions did not change their prescription based on the pressure mapping data. In our study, we found that 60% (n=52) of the decisions were based on clinical expertise and 40% (n=32) were based on clinical expertise and the use of pressure mapping as a clinical tool during the decision making process. Only 9% of the participants for whom the pressure mapping image entered the decision acquired a PU

versus 21% of those for whom pressure mapping did not enter the final decision. However, in the latter cases, the best positioning and patients' preferences (e.g., fear of instability on the air bladder cushion) had to be balanced against the pressure distribution, based on the pressure mapping image. Thus, while we were able to develop a decision-making tree for the prescription of wheelchairs and pressure reducing cushions, it is clear that it is still challenging to balance position, function and best pressure distribution at the same time.

Our research rehabilitation team worked well together, and the inter-rater reliability among the three practitioners was .74 which is considered moderate (Portney & Watkins, 2000). This means that the practitioners had different points of view during the decision-making process, but they ultimately came to a consensus for each participant and prescribed what they agreed as being the most appropriate seat cushion using the data they had before them as well as participant preferences. The intra-rater reliability was. 90, what is considered good by Portney and Watkins (2000). This demonstrates that the individual interpretation of the pressure mapping image by the most consistent rehabilitation research practitioner was consistent and reproducible.

While the decision-making tree was effective for the purposes of this study, there were factors that the research rehabilitation team did not anticipate prior to the study. For example, one of the participants got a 20 inch wheelchair width because she wanted to carry her Kleenex box on the side of the wheelchair. However, wheelchair width made it very difficult for her to open the bathroom door and enter the bathroom. Hence, the research rehabilitation team switched her from a 20 inch to an 18 inch wheelchair width. Another example was the functional propulsion task used by the team to determine if the

participant was able to propel independently. Although participants mastered the propulsion task, it required only about 5 feet of propulsion, and did not adequately represent the distances that participants were required to functionally propel -- from their rooms to the dining room or activities room. Also, the clinics in which the functional tasks were performed had linoleum, and sometimes the facility hallways had carpet -- making it much more difficult to propel independently. Additionally, for foot propellers, the low wheelchair height put them at a disadvantage in the dining room, because the dining tables were of a fixed height, and "assigned" dining places had to be maintained.

Although this study had strengths, it also had limitations. By design, data were analyzed retrospectively. Moreover, the conclusions that can be drawn from this study are limited to: (a) the population of elderly long-term care resident, (b) only two types of manual wheelchairs (Escort and Breezy), and (c) three types of pressure-reducing wheelchair seat cushions (viscous fluid and foam, segmented air bladder, and foam and gel). Also, although the rehabilitation research team members varied, based on year of the study, they all had at least 2 years of experience, many with years of seating/mobility experience, and inexperienced practitioners may not make the same decisions. Additionally, a pressure mapping system was available to the research rehabilitation team, and this equipment is not typically available in long-term care facilities. Finally, rehabilitation practitioners have to be aware that although our decision-making process was clearly delineated, its generalizability may be limited, because decision-making can be a very individualized process (Rogers, 1983).

Further studies are necessary to systematically examine factors such as: (a) identifying the PPI ranges that would be considered safe for long-term care residents with

specific characteristics, (b) developing the habit of using the numerical data in combination with the pressure mapping image, (c) generating better ways of documenting the decision-making processing, (d) examining changes in medical conditions and functioning throughout a study's duration in a more efficient way to identify factors that influence the risk of PU regardless of the resident's positioning, and (e) evaluating the activities that participants usually perform during a typical day to ensure that the seating system will keep or optimize their levels of function. Additionally, further studies are needed that describe the factors other rehabilitation practitioners deem to be most important when prescribing wheelchairs and pressure-reducing cushions, and the PU outcomes related to their decision-making processes.

4.5 SUMMARY

In conclusion, although our study delineated a decision-making process for choosing the ideal wheelchair and pressure-reducing seat cushion for elderly long-term care residents enrolled in the experimental arm of a randomized clinical trial to prevent PU, the decision-making process remains challenging. The decision-making tree and flow chart that were developed in this study can serve as a starting point for further investigations of the decision-making processes used by rehabilitation practitioners who prescribe seating/mobility interventions for long-term care residents.

5.0 CONCLUSION

The general aims of this study were to:

(1) Identify available literature on extrinsic, intrinsic, and combinations of extrinsic and intrinsic risk factors in pressure ulcer (PU) acquisition in long term care residents.

(2) Identify demographic and clinical variables that predicted the incidence of PU in elderly long-term care residents who were participants in the experimental arm of a randomized clinical trial to prevent pressure ulcers with pressure-reducing seat cushions (NICHD Grant # 5R01HD041490-04).

(3) Develop a decision-making tree for the prescription of a custom-fit wheelchair, and a pressure-reducing seat cushion designed to reduce the risk of PU, and to establish the inter-rater and intra-rater reliability of members of the research rehabilitation team.

A focused literature review of 14 research studies was completed examining extrinsic, intrinsic, and combinations of extrinsic and intrinsic risk factors that contribute to PU development. The results of this review established that risk factors for the development of PU are multi-factorial. The studies reviewed indicated that demographic factors such as male gender and African American race increased the risk of PU acquisition in long-term care. Functional mobility, ambulation impairments, and

dependence in feeding were also associated with increased risk of PU acquisition. Other risk factors that were common to more than one study were diabetes, cognitive impairment, and fecal incontinence. However, it remains to be determined which, if any risk factor by itself increases the risk of PU, which risk factors are more important than others, and which combinations of risk factors appear to be the major contributors to the development of PU. However, based on the literature reviewed, the evidence suggested that a combination of risk factors, extrinsic and intrinsic, is more likely to predict the development of PU than any one risk factor by itself.

Although most of the data for the larger studies in the focused literature review were derived from federal or corporate databases, the data for the current study was derived from the direct assessment of participants in the Randomized Clinical Trial on Preventing Pressure Ulcers with Seat Cushions (RCT-SC). A secondary analysis of demographic and clinical data from the RCT-SC was done to identify what variables were risk factor for PU acquisition in elderly long term care residents who participated in the RCT-SC. With the objective of capturing all variables that would be predictors for developing a PU, data were analyzed using three different methods: (a) stepwise logistic regression, (b) odds ratios, and (c) Exhaustive Chi-Square Automatic Interaction Detection (CHAID).

The results of a stepwise logistic regression showed that the best set of PU predictors were musculoskeletal/ integument, followed in order of influence by: previous history of PU, endocrine/metabolic, and total Braden score. Based on odds ratios, the odds of acquiring a PU was 2.42 times greater for participants with urinary incontinence than for those who were not incontinent. This was followed by dependence in feeding

(OR 1.87), cognitive impairment (OR 1.70), fecal incontinence (OR 1.29), Caucasian race (OR 1.28), and female gender (OR 1.25). In the CHAID model, the strongest factor associated with PU acquisition was independence in transfers, and the second strongest factor associated with acquiring/not acquiring a PU was the Braden Activity/Mobility score, followed by the total Braden score. Therefore, the three models added to the body of knowledge by confirming known risk factors and adding new risk factors such as: hygiene and dressing. The CHAID model also illustrates the linkages among risk factors, which has not previously been reported. The risk factors identified in our study have the potential to be reduced or prevented with increased frequency of toileting schedules and incontinence checks, which could be incorporated into resident care plans.

The last study involved the generation of a decision-making tree for the prescription of a wheelchair and a seat cushion designed to reduce the risk of PU acquisition. The decision- making tree outlined different decision-making pathways used by the research rehabilitation team for choosing one wheelchair versus another, and also one cushion over another. For this sample of participants, the first decision that the rehabilitation practitioners considered important was type of propulsion, because: (a) it impacted which of the two wheelchairs would be appropriate (e.g., the participants who used their feet as a method of propulsion would need a lower wheelchair), and (b) independent propulsion would enable the residents to move around the nursing homes by themselves. To choose the best seat cushion, decisions often had to focus on improving positioning and functioning, regardless of the best pressure image distribution. However the group of participants that received the seat cushions when the research rehabilitation team considered the pressure mapping image, had a lower incidence of PU acquisition.

Therefore, it was concluded the use of a pressure mapping system is considered a good clinical tool to incorporate into the clinical reasoning process of practitioners. The research rehabilitation team involved in the study worked well together, and the inter-rater reliability among the three practitioners was considered moderate (.74) and the intra-rater reliability was .90, which was considered good to excellent.

In summary, this study has strengths and limitations. The strengths are: (a) the focused literature review provided useful information about intrinsic, extrinsic combinations of these risk factors in PU acquisition, (b) the stepwise logistic regression, odds ratios, and CHAID analyses confirmed and added new variables that predict PU development, (c) the decision making tree can be a starting point for rehabilitation practitioners who are new to the field of seating and mobility, and (d) the decision making tree showed that the use of the pressure mapping system is a good tool if used in combination with clinical judgment.

Limitations of the studies were: (a) the focused literature review was limited to the population of elderly long term care residents, therefore the risk factors described cannot be generalized to other population, (b) the rehabilitation practitioners were very experienced in the field of seating and mobility, therefore the decision-making process for less experienced rehabilitation practitioners in the field of seating and mobility may differ, and (c) the research rehabilitation practitioners had just two types of manual wheelchair to choose from, and only three types of seat cushions, and in the "real word" there are many more options, so deciding which is the most appropriate wheelchair and seat cushion can be challenging.

APPENDIX A

SUBJECT BASELINE FORM

Subject Baseline Data (SBD)

Date __ __ / __ __ / __ __ __ __

1. Date of Birth: __ __ / __ __ / __ __ __ __
   m m d d y y y y

2. Sex: ❑ Male ❑ Female

3. Race (check all that apply):

   ❑ White or Caucasian
   ❑ Black or African-American
   ❑ Asian
   ❑ American Indian or Alaska Native
   ❑ Native Hawaiian or other Pacific Islander
   ❑ Other (specify)_____

4. Measurements

   Height: ____ ft. ____ in

   Weight ___ ___ ___ . ___ ___ lbs

5. Nursing Home Admission Date __ __ / __ __ / __ __ __ __ Time : ____ : ____ (military time) ❑ time not available

6. Primary Diagnosis(es) (why hospitalized):

   ❑ Heart
   ❑ Vascular
   ❑ Hematopoietic
   ❑ Respiratory
   ❑ Eyes, Ears, Nose, Throat and Larynx
   ❑ Upper Gastrointestinal
   ❑ Lower Gastrointestinal
   ❑ Liver
   ❑ Renal
   ❑ Genitourinary
   ❑ Musculoskeletal/Integument
   ❑ Neurological
   ❑ Endocrine/Metabolic and Breast
   ❑ Psychiatric Illness
   ❑ Other (specify): _____

7. Incontinent?

❑ Yes ❑ No

↓

If yes,

Urine:	❑ Yes	❑ No
Feces:	❑ Yes	❑ No

8. Previous history of pressure ulcers?

❑ Yes ❑ No ❑ Unknown

↓

If yes, locations if known:

❑ Yes	❑ No	Ischials	If yes,	❑ Right	❑ Left	❑ Both
❑ Yes	❑ No	Sacrum				
❑ Yes	❑ No	Coccyx				
❑ Yes	❑ No	Heel	If yes,	❑ Right	❑ Left	❑ Both
❑ Yes	❑ No	Malleolus	If yes,	❑ Right	❑ Left	❑ Both
❑ Yes	❑ No	Knee	If yes,	❑ Right	❑ Left	❑ Both
❑ Yes	❑ No	Trochanter	If yes,	❑ Right	❑ Left	❑ Both
❑ Yes	❑ No	Spinous process				
❑ Yes	❑ No	Elbow	If yes,	❑ Right	❑ Left	❑ Both
❑ Yes	❑ No	Scapula	If yes,	❑ Right	❑ Left	❑ Both
❑ Yes	❑ No	Head				

9. Number of medications currently administered: ____ ____

10. Means of mobility used most often within nursing home (check one):

- ❑ Ambulation
- ❑ Manual wheelchair
- ❑ Other (specify): _____

11. Ambulation

a. Distance:
- ❑ 0 ft **(skip to Q12)**
- ❑ <= 10ft
- ❑ > 10ft

Uses Device? ❑ Yes ❑ No
↓ (check all that apply)
- ❑ Wheeled Walker
- ❑ Standard Walker
- ❑ Crutches
- ❑ Cane
- ❑ Other, specify _____
  _____

b. Assistance with ambulation:
- ❑ None
- ❑ Supervision
- ❑ Minimal
- ❑ Moderate
- ❑ Maximum

- ❑ 1 person
- ❑ 2 persons
- ❑ >2 persons

12. Weight Bearing (WB) Status (check one per extremity)

Extremity	Full (FWB)	As Tolerated (WBAT)	Partial (PWB)	Non-WB (NWB)	Not Specified in Chart (NIC)
Right Lower	❑	❑	❑ ___% body wt.	❑	❑
Left Lower	❑	❑	❑ ___% body wt.	❑	❑
Right Upper	❑	❑	❑ ___% body wt.	❑	❑
Left Upper	❑	❑	❑ % body wt.	❑	❑

13. Transfers

a. Sit↔Stand (Movement from a seated position at edge of bed or wheelchair to a standing position and vice versa.)

i. Assistance (check one)
- ❑ None
- ❑ Supervision
- ❑ Minimal
- ❑ Moderate
- ❑ Maximum
- ❑ Unable to do
- ❑ Mechanical lift

- ❑ 1 person
- ❑ 2 persons
- ❑ > 2 persons

b. Bed↔Chair (Movement from a seated position in a wheelchair to a seated position at the edge of the bed and vice versa.)

i. Assistance (check one)

- ❑ None
- ❑ Supervision
- ❑ Minimal
- ❑ Moderate
- ❑ Maximum
- ❑ Mechanical lift

(Minimal, Moderate, Maximum) →
- ❑ 1 person
- ❑ 2 persons
- ❑ > 2 persons

ii. Technique (check one)

- ❑ Stand turn →
- ❑ Stand pivot
- ❑ Lateral scoot without sliding board
- ❑ Lateral scoot with sliding board
- ❑ Dependent pivot
- ❑ Mechanical lift

Specify Assistive Device (check all that apply)
- ❑ Wheeled Walker
- ❑ Standard Walker
- ❑ Crutches
- ❑ Cane
- ❑ Other, specify _____

c. Sit↔Supine (Movement from a seated position at the edge of the bed to a supine position in bed and vice versa.)

i. Assistance (check one)

- ❑ None
- ❑ Supervision
- ❑ Minimal
- ❑ Moderate
- ❑ Maximum

(Minimal, Moderate, Maximum) →
- ❑ 1 person
- ❑ 2 persons
- ❑ > 2 persons

14. History of hip surgery within past 2 years?

❑ Yes ❑ No

a. Surgery on right side? ❑ Yes ❑ No

Type (check all that apply):
- ❑ Hip replacement, date: __ __/ __ __/ __ __ __ __
- ❑ Fixation following fracture, date: __ __/ __ __/ __ __ __ __
- ❑ Other, specify: _____

Precautions (check all that apply):
- ❑ No hip adduction past midline
- ❑ No hip flexion beyond 90 degrees
- ❑ No internal rotation past neutral
- ❑ Other hip precautions (specify): _____
- ❑ No known precautions

b. Surgery on left side? ❑ Yes ❑ No

Type (check all that apply):
- ❑ Hip replacement, date: __ __/ __ __/ __ __ __ __
- ❑ Fixation following fracture, date: __ __/ __ __/ __ __ __ __
- ❑ Other, specify: _____

Precautions (check all that apply):
- ❑ No hip adduction past midline
- ❑ No hip flexion beyond 90 degrees
- ❑ No internal rotation past neutral
- ❑ Other hip precautions (specify): _____
- ❑ No known precautions

15. Other Precautions (check all that apply)

- ❑ Latex allergy
- ❑ Aspiration precautions
- ❑ Anticoagulant therapy
- ❑ Osteoporosis
- ❑ Other (specify): _____
- ❑ No other known precautions

APPENDIX B

SEATING NEEDS ASSESSMENT

Stage III - Seating Needs Assessment Screening Form

Date __ __ / __ __ / __ __ __ __ Time __ __ : __ __ (military time)

CARDIOPULM	Normal	Precautions:	Limits Function	Assisted: O2 vent suction monitor
VISION HEARING	Normal	Wears glasses/aids	Visual loss Hearing loss	Vision absent Hearing absent
SEIZURE ACTIV	Normal	Precautions	Limits Function	Type:
BLADDER CONT	Normal	Occ. Incontinent	Bladder Program	Diapered
BOWEL CONT	Normal	Occ. Incontinent	Bowel Program	Diapered
SENSATION	Normal	Diminished Questionable	Absent	Level: Area:
RESPONSES	Seeks out/enjoys	Tolerates	Resists/Withdraws	Tactile Propriocep Vestibular Oral
PAIN	None	Intermittent	Constant	Inteferes with Fxn
ABNL REFLEXES	Integrated	Present	Dominant	Type:
MUSCLE TONE	Normal	UE: hi/lo flex/ext	LE: hi/lo flex/ext	Trunk: hi/lo flex/ext variable
STRENGTH	Normal	Reduced	Absent	UE LE Trunk
SCOLIOSIS	Neutral	Flex deformity	Fixed deformity	R/L Thoracic Mild Mod Severe R/L Lumbar Mild Mod Severe
KYPHOSIS LORDOSIS	Neutral	Flex deformity	Fixed deformity	Kyphosis/Lordosis Mild Mod Severe
PELVIC TILT	Neutral	Flex deformity	Fixed deformity	Ant/Post Mild Mod Severe
PELVIC RTN PELVIC OBLIQ	Neutral	Flex deformity	Fixed deformity	R/L R/L
COMMUNICATN	Indep. w/o device	Assisted	Dependent	Method
FEEDING	Independent	Assisted	Dependent	Oral/ G-tube
DRESSING	Independent	Assisted	Dependent	Aids:
HYGIENE	Independent	Assisted	Dependent	Aids:
SITTING BALANCE	Independent	Limited	Dependent	Comments:
TRANSFERS	Independent	Assisted	Dependent	Type:
AMBULATION	Indep. w/o device	Assisted	Dependent/none	Aids:
WC PROPULSN	Independent	Assisted	Dependent	Arm Foot Both
COGNITION	A&O x 3 Follow > 2 step cd	A&O x 2 Follows 2 step cmd	A&O x 1 Follows 1 step cmd	Confused ST Memory Loss
BEHAVIOR/ JUDGEMENT	Age appropriate	Safety risk: self	Safety risk: others	Comments:
THERAPY: current	PT	OT	SPEECH	Comments:

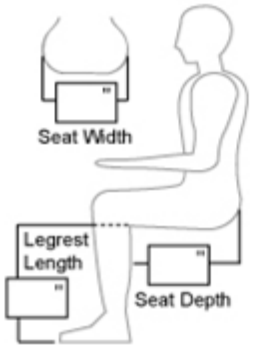
Problems:

_____

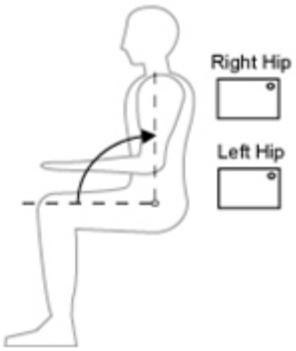
_____

Body Measurements:

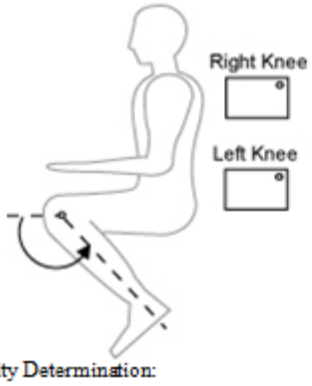
Linear Measures



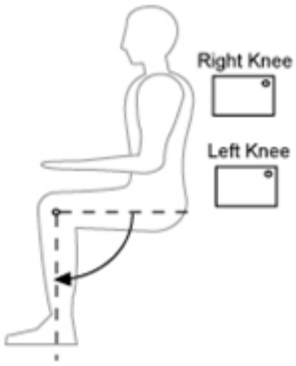
Hip Flexion Angle



Knee Flexion Angle



Knee Extension Angle



Eligibility Determination:

❑ ***Subject Seating Needs will not be met in the study; Subject is EXCLUDED***

❑ ***Subject Seating Needs*** **will be met in the study; Subject is eligible for randomization. After randomization, complete Cushion Selection Evaluation (if PRC Group) and Equipment Issued forms.**

Subject ID: ___ - ____ - _____

Study Group: ❑ Pressure-Reducing Cushion (PRC) ❑ Segmented Foam Cushion (SFC)

Evaluation Order: (1= Infinity, 2 = Jay, 3 = ROHO) ____ ____ ____

APPENDIX C

CUSHION SELECTION EVALUATION

Cushion Selection Evaluation (CSE)

Date: __ __ / __ __ / __ __ __ __ Time __ __ : __ __

Adapted from Functioning Everyday with a Wheelchair (FEW).

Comfort Needs (Skip for SFC group subjects)	Infinity	Jay	ROHO	NA	UTD
Which of the 3 cushions did the study participant report was most comfortable?	❑	❑	❑	❑	❑
Additional Comments:					

Pressure Relief (Skip for SFC group subjects)	Infinity	Jay	ROHO	NA	UTD
Which of the 3 cushions provided the lowest peak and average pressures based on pressure mapping findings?	❑	❑	❑	❑	❑
Additional Comments:					

Cushion Provided	SFC	Infinity	Jay	ROHO
Rationale:	❑	❑	❑	❑

Transfers	IND	PA	VC	UN
OBSERVE the level of independence as the study participant transfers from a bed, toilet, or a different chair to the NEW chair.	❑	❑	❑	❑
Additional Comments:				

Reach and carry out tasks at different surface heights	IND	PA	VC	UN
Study participant accesses tape measure on table/counter [push chair to table – place tape measure directly in front of resident – just beyond fingertip reach] . Say "I NEED YOU TO SHOW ME HOW YOU REACH FORWARD IN YOUR NEW CHAIR – PLEASE HAND ME THE TAPE MEASURE."	❑	❑	❑	❑
Study participant accesses tape measure at shelf height [stand to left of resident – just beyond fingertip reach with measure on palm]. Have resident return tape measure to you as you stand on the right of resident – just beyond fingertip reach]. Say "I NEED TO SEE HOW YOU REACH SIDE TO SIDE IN YOUR NEW CHAIR. PLEASE TAKE THE TAPE FROM ME AND HAND IT BACK WHEN I REACH YOUR OTHER SIDE."	❑	❑	❑	❑
Additional Comments:				

Operate/propel	IND	PA	VC	UN
Study participant propels the wheelchair axle 5 feet. (Place tape measure on floor – 5 ft extended – next to axle for starting position. Say "SHOW ME HOW YOU CAN PUSH THE CHAIR TO THE END OF THE TAPE [POINT]."	❑	❑	❑	❑
Additional Comments:				

Start Date	YES	NO	If No, Date of Start
Did the participant begin using the chair and cushion on the day this evaluation was completed?	❑	❑	__ __ / __ __ / __ __ __ __

KEY:
IND = Independent – NO hands-on assists or verbal cueing.
PA = Physical Assistance – You touched the subject (can include verbal cueing)
VC = Verbal Cueing - No hands-on -- ONLY VERBAL CUES
UN = Unable to accomplish task with PA or VC – staff does for subject.
SFC = Segmented Foam Cushion
NA = Not Assessed
UTD = Unable to Determine

APPENDIX D

BRADEN SCALE

Stage I – Braden Risk Assessment Scale

Date: __ __ / __ __ / __ __ __ __ Time __ __ : __ __

Sensory Perception	1. Completely Limited	2. Very Limited	3. Slightly Limited	4. No Impairment	*Indicate Appropriate Numbers Below*
ability to respond meaningfully to pressure-related discomfort	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	Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	Responds to verbal commands, but cannot always communicate discomfort or the need to be turned OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.	
Moisture	**1. Constantly Moist**	**2. Very Moist**	**3. Occasionally Moist**	**4. Rarely Moist**	
degree to which skin is exposed to moisture	Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	Skin is often, but not always moist. Linen must be changed at least once a shift.	Skin is occasionally moist, requiring an extra linen change approximately once a day.	Skin is usually dry, linen only requires changing at routine intervals	
Activity	**1. Bedfast**	**2. Chairfast**	**3. Walks Occasionally**	**4. Walks Frequently**	
degree of physical activity	Confined to bed.	Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	Walks outside room at least twice a day and inside room at least once every two hours during waking hours	
Mobility	**1. Completely Immobile**	**2. Very Limited**	**3. Slightly Limited**	**4. No Limitations**	
ability to change and control body position	Does not make even slight changes in body or extremity position without assistance	Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	Makes frequent though slight changes in body or extremity position independently.	Makes major and frequent changes in position without assistance.	
Nutrition	**1. Very Poor**	**2. Probably Inadequate**	**3. Adequate**	**4. Excellent**	
usual food intake pattern	Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding	Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	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.	
Friction and Shear	**1. Problem**	**2. Potential Problem**	**3. No Apparent 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 w/maximum assistance. Spasticity, contractures or agitation leads to almost constant friction	Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.		
				Activity/Mobility Score:	
				Total Score:	

Research Staff signature:_____ Date: __ __ / __ __ / __ __ __ __

APPENDIX E

SKIN CHECK

Stage II – Skin Inspection Screening Form

Date __ __ / __ __ / __ __ __ __ Time ___ ___ : ___ ___ (military time)

1. Skin color: ❑ Light (blanch response observed with finger pressure)
   ❑ Dark (no blanch response observed)

2. Indicate skin status below. "Seated surface" locations are marked with an asterisk (*). "Pelvic" locations are listed in *italics*. For possible pressure ulcers and stage I pressure ulcers, check all applicable indicators.

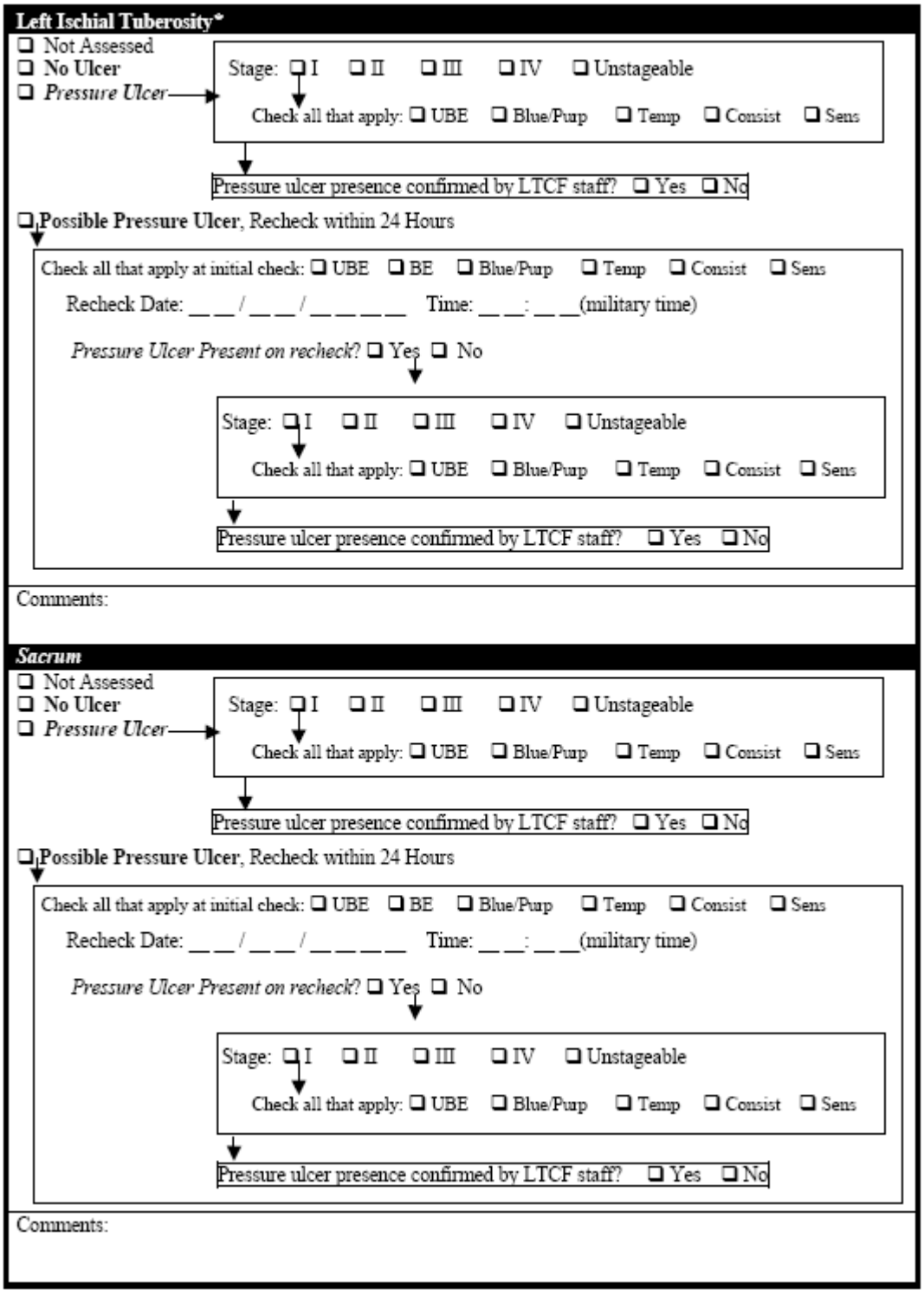
KEY: **LTCF** = Long term care facility; **BE** = Blanchable Erythema **UBE** = Unblanchable erythema; **Blue/Purp** =Blue or purple skin discoloration; **Temp** = Temperature different from contralateral side or adjacent skin; **Consist** = Firm or boggy tissue consistency compared to contralateral side or adjacent skin; **Sens** = Sensation change (pain, itching, etc.); **N/A** = Not applicable

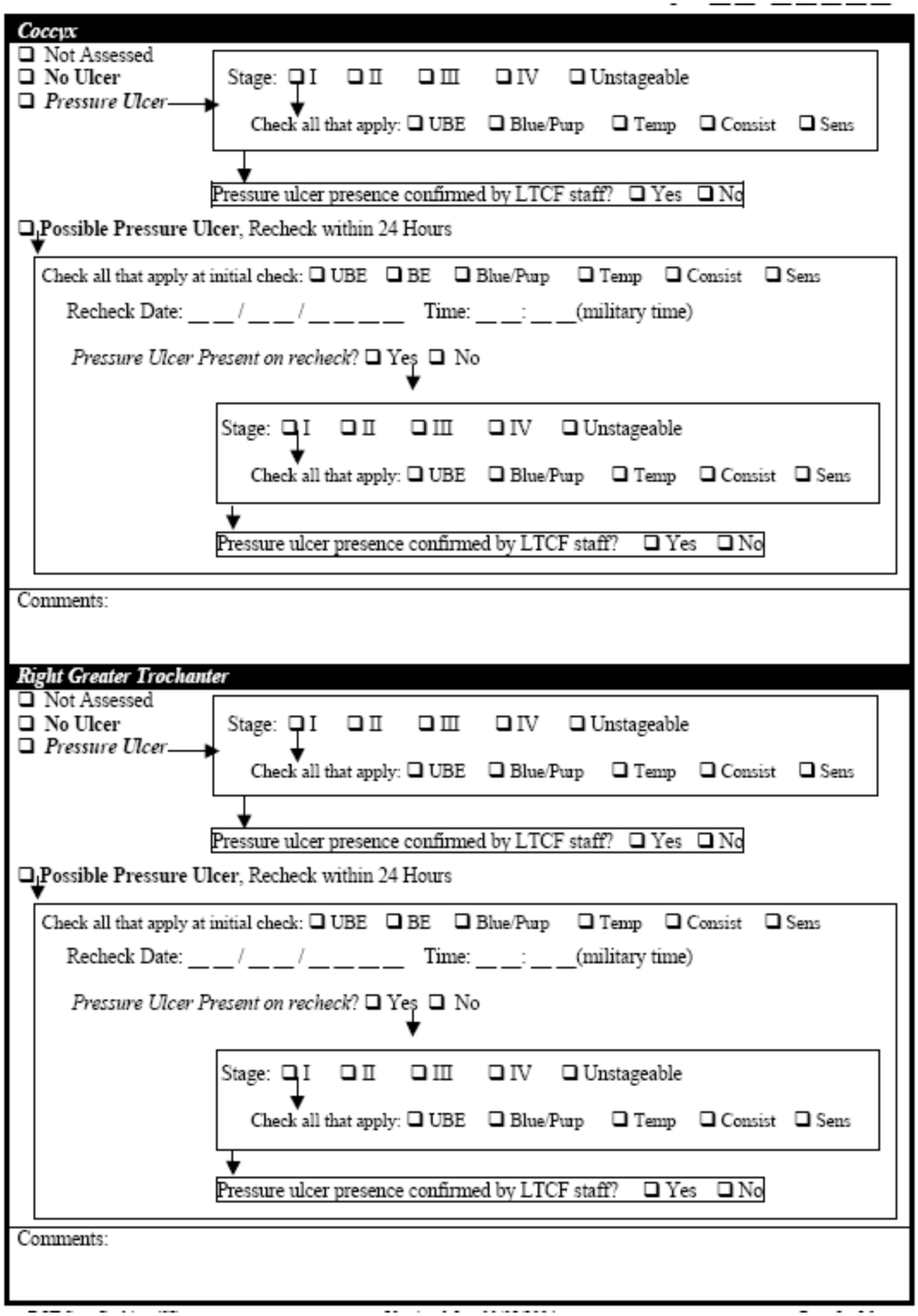
Right Ischial Tuberosity*

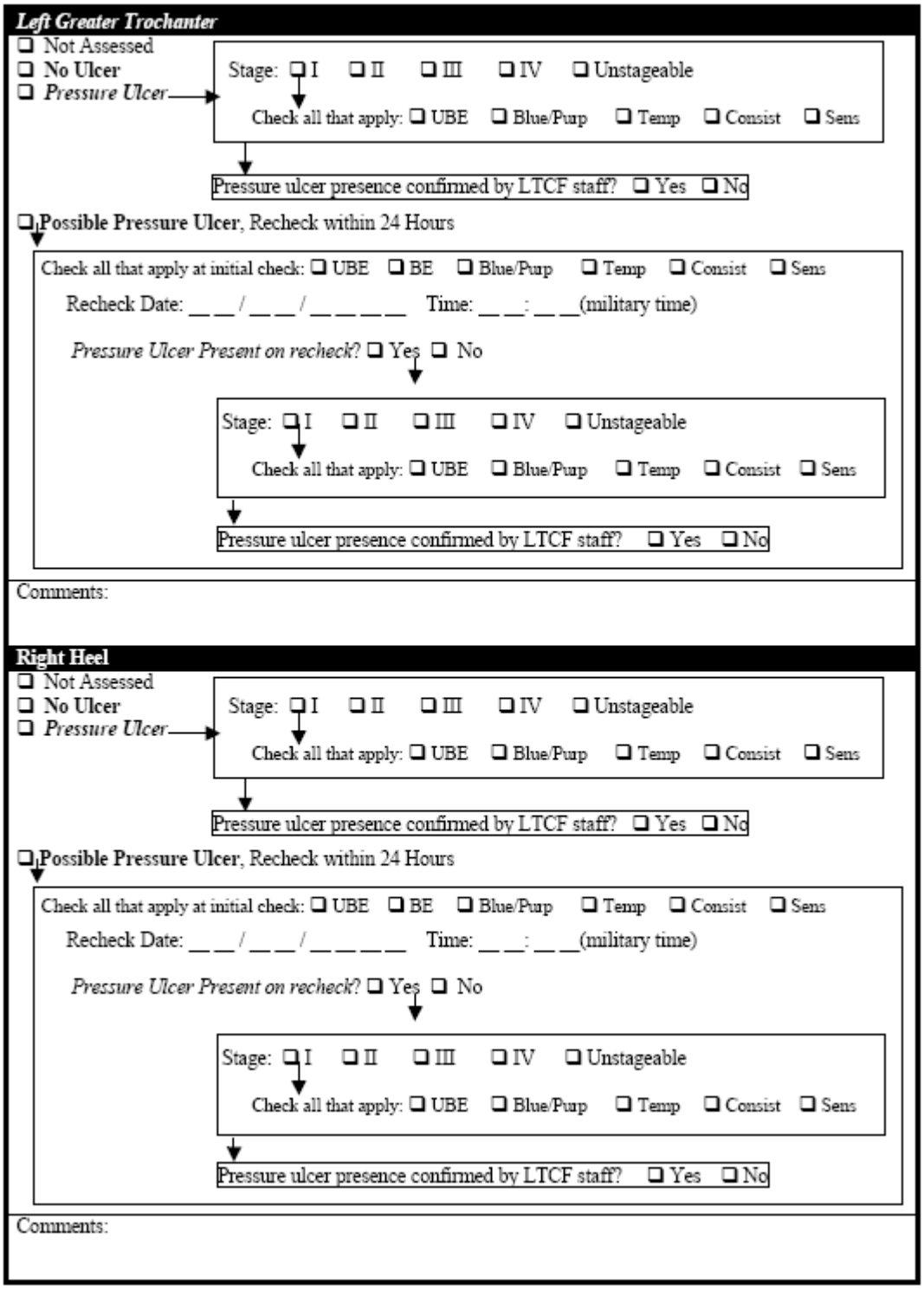
❑ Not Assessed
❑ **No Ulcer**
❑ *Pressure Ulcer* → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

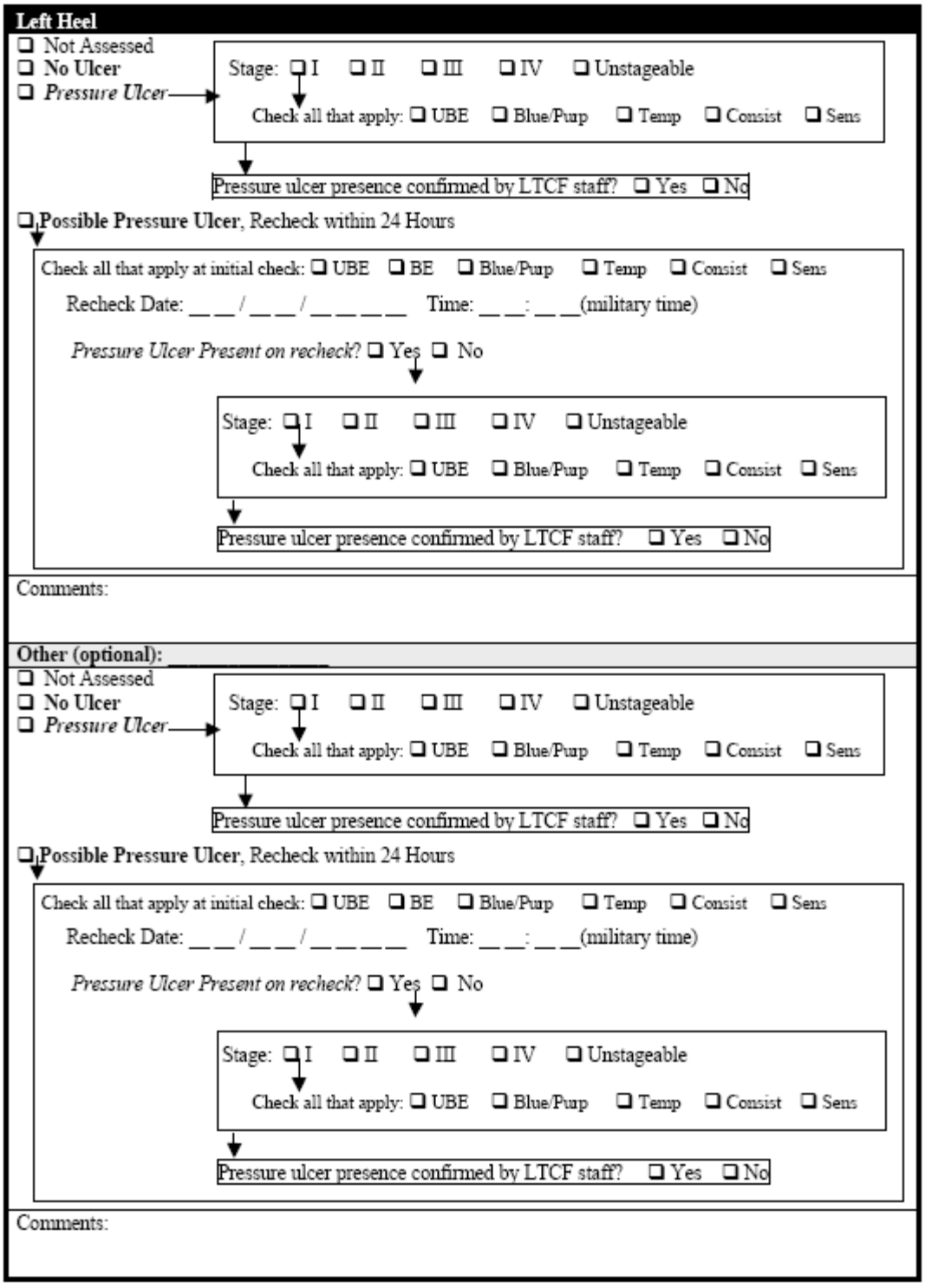
❑ **Possible Pressure Ulcer**, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __ : __ __ (military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:


Left Ischial Tuberosity*
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:
Sacrum
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:

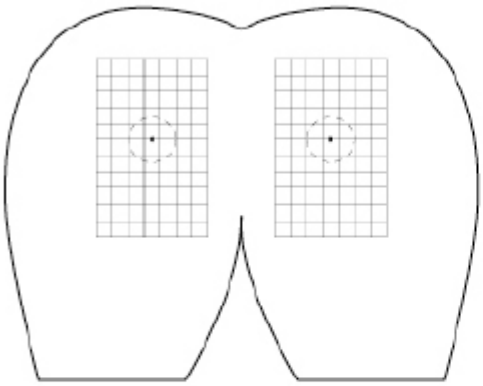

Coccyx
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:
Right Greater Trochanter
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:


Left Greater Trochanter
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:
Right Heel
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:

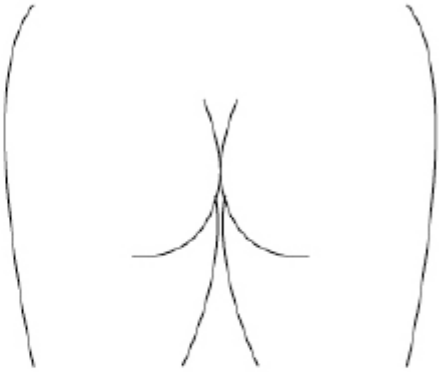

Left Heel
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:
Other (optional): _____
❑ Not Assessed
❑ No Ulcer
❑ Pressure Ulcer
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
❑ Possible Pressure Ulcer, Recheck within 24 Hours
Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
Pressure Ulcer Present on recheck? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No
Comments:

3. Sketch the location and approximate size of confirmed or possible pressure ulcers below.

SEATED VIEW



PRONE VIEW



****Recheck all possible pressure ulcers before completing items below****

4. Is a pressure ulcer present at any seated surface site (marked with an asterisk)?

❑ ***Yes, subject is EXCLUDED from study***

↓

LTCF staff notified of patient's skin status?

❑ Yes ❑ No

❑ No, subject is eligible for seating evaluation

↓

Seating specialist notified?

❑ Yes ❑ No

APPENDIX F

EQUIPMENT ISSUED FORM

Equipment Issued Form (EI)

Date __ __ / __ __ / __ __ __ __ Time ___ ___ : ___ ___ (military time)

DIRECTIONS: Please complete this form when equipment is issued to the subject following randomization and cushion selection.

Component	Specifications		Comments
❑ Guardian Escort Manual Wheelchair ❑ Breezy Manual Wheelchair	(Width x Depth) ❑ 16" x 16" ❑ 18" x 16" ❑ 20" x 16" ❑ Other: _____ x _____		
Back Support	❑ Standard flat ❑ Adjustable tension		
Armrests	Desk Length ❑ Right ❑ Left	Full Length ❑ Right ❑ Left	
Legrests	Non-elevating ❑ Right ❑ Left	Elevating ❑ Right ❑ Left	
Anti-tippers	❑ Issued	❑ Not Issued	
Cushion	Type ❑ Segmented Foam ❑ Roho Quattro ❑ Jay 2 Deep Contour ❑ Infinity Flo-Gel	Size ❑ 16" x 16" ❑ 18" x 16" ❑ 20" x 16" ❑ 20" x 18"	
Solid Seat Insert	❑ Issued	❑ Not Issued	
Escort Owner's Manual	❑ Issued	❑ Not Issued	
Cushion Owner's Manual	❑ Issued	❑ Not Issued	
Other	Please describe:		

APPENDIX G

WEEKLY MONITORING FORM

Weekly Monitoring Form (WM)

Date __ __ / __ __ / __ __ __ __

1. Braden Scale Score Assessed?

   ❑ Yes, enter data from Braden Scale Risk Assessment
   Total of Activity and Mobility Subscales: _____
   Overall score (all subscales): _____

   ❑ No, indicate reason for missed assessment (check one)
   - ❑ Subject unavailable for medical reasons (illness, testing, hospitalization, etc.)
   - ❑ Subject unavailable for non-medical reasons (family visit, etc.)
   - ❑ Subject declined assessment
   - ❑ Research staff unavailable
   - ❑ Other, specify: _____

2. Skin Inspection Performed?

   ❑ Yes, enter data from Skin Inspection – Weekly and PRN form below (check one)
   - ❑ Seated surface pressure ulcer (PU) present, subject exits study, complete endpoint form
   - ❑ No pelvic or seated surface PU present, subject continues in study
   - ❑ Pelvic PU present, subject continues in study, continue to monitor
   - ❑ Both seated surface and pelvic PU present, subject exits study, complete endpoint form
   - ❑ Other, specify: _____

   ❑ No, indicate reason for missed assessment below (check one)
   - ❑ Subject unavailable for medical reasons (illness, testing, hospitalization, etc.)
   - ❑ Subject unavailable for non-medical reasons (family visit, etc.)
   - ❑ Subject declined skin inspection
   - ❑ Research staff unavailable
   - ❑ Other, specify: _____

3. Sitting Time:

   a. Did LTCF staff report exceptions to 6-hour minimum sitting time (check)?

   ❑ Yes ❑ No ❑ Not sampled this week

   ↓

   Reason given (check all that apply):

   - ❑ Illness requiring bed rest
   - ❑ Hospitalization
   - ❑ Medical testing/Special Procedures
   - ❑ Off-campus for non-medical reasons (i.e. family visit)
   - ❑ Other, specify: _____

b. Number of sitting time sampling events this week (check one): ❑ 0 ❑ 1 ❑ 2 ❑ 3

Hours of sitting time at sampling event 1: ____ hours
❑ Sampling day, data missing
❑ N/A: Not a sampling day

Hours of sitting time at sampling event 2: ____ hours
❑ Sampling day, data missing
❑ N/A: Not a sampling day

Hours of sitting time at sampling event 3: ____ hours
❑ Sampling day, data missing
❑ N/A: Not a sampling day

4. Did LTCF staff report a change in the subject's medical or functional status?

❑ Yes ❑ No

If yes, describe: _____

_____

_____

5. Were any adjustments made to the cushion or seating system?

❑ Yes ❑ No

If yes, describe: _____

_____

_____

6. Other comments?

❑ Yes ❑ No

If yes: _____

_____

APPENDIX H

END POINT FORM

Endpoint Form (END)

Date __ __ / __ __ / __ __ __ __

1. Date Endpoint Reached: __ __ / __ __ / __ __ __ __

2. Number of Study Weeks Completed: ____ ____

3. Number of Study Days Completed: ____ ____ ____

4. Endpoint Type

   - ❑ Development of Seated Surface Pressure Ulcer (ischial tuberosity region)
   - ❑ Six months since initiation of seating intervention
   - ❑ Discharged from long-term care facility
   - ❑ Voluntary withdrawal
   - ❑ Death
   - ❑ Other, specify: _____

5. LTCF staff notified that subject has reached study endpoint? ❑ Yes ❑ No

6. Endpoint seating evaluation completed? ❑ Yes ❑ No

   ↓

   Indicate reason:
   - ❑ Subject is deceased
   - ❑ Subject left facility before evaluation could be completed
   - ❑ Subject declined endpoint seating evaluation
   - ❑ Other, specify: _____

7. Other comments? ❑ Yes ❑ No

   If yes: _____

   _____

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