

PHYSIOLOGIC RESPONSES TO SIMULATED CARE
ACTIVITIES IN OLDER SURGICAL PATIENTS

By

Colleen M. Casey

A Dissertation

Presented to
Oregon Health & Science University
School of Nursing
in partial fulfillment of the requirements for the degree of
Doctor of Philosophy

April 28, 2009

APPROVED:

Jill A. Bennett, PhD, RN, Committee Member, Dissertation Chair

Gail Houck, PhD, RN, Committee Member

Heather M. Young, PhD, RN, Committee Member

Kerri Winters-Stone, PhD, Committee Member

George Knafl, PhD, Committee Member

Michael R. Bleich, PhD, RN, MPH, FAAN, Dean, School of Nursing

ACKNOWLEDGMENTS

Funding

American Association of Critical Care Nurses:

Educational Advancement Scholarship

Mary Fran Tracey Educational Advancement Scholarship

John A. Hartford Foundation:

OHSU Center for Geriatric Nursing Excellence Institutional Award

Hartford Senior Nursing Student Scholarship

John A. Hartford Foundation:

Building Academic Geriatric Nursing Capacity Predoctoral Scholarship

National Institutes of Health:

National Institute of Nursing Research

Institutional Traineeship, Research Training 5T32 NR007048-15

National Institutes of Health:

National Institute of Nursing Research

Individual National Research Service Award F31-NR010424-01

Hearst Foundation Endowed Scholarship

Oregon Health & Science University School of Nursing Dean's Dissertation Award

Sigma Theta Tau, Beta Psi Chapter Research Award

Touchmark Foundation Award

ACKNOWLEDGMENTS

I am so grateful for the support I have received during my doctoral study at Oregon Health & Science University (OHSU) School of Nursing (SON). Special thanks to the members of my dissertation committee who so enthusiastically shared their intellect, time, and talent with me, especially Drs. Jill Bennett and Heather Young. Many other SON faculty and staff, too numerous to mention by name, also gifted me with their interest and help. I am privileged to have studied alongside many brilliant student colleagues as well who made the journey more fulfilling. The generous financial support I received not only made my education possible, it introduced me to incredible opportunities and to an invaluable national community of scholars, in particular Dr. Mary Beth Happ of the University of Pittsburgh.

I am especially thankful to the OHSU Hospital staff who worked diligently to support this study, particularly the Pre-Admission Testing clinic and the Cardiac-Surgical ICU. Nurse Managers, Pat Michels and Cyndi Perez, respectively, demonstrated their dedication to the study by contributing staff, materials, and space. Thanks also to my three research assistants who helped in data collection. Of course, the study could not have occurred without the older adults who gave of themselves during a vulnerable and busy time in their lives.

I dedicate this study to my late parents, Edward and Rosemarie Casey. My mom saw me become a nurse and was part of the beginning of my doctoral journey; her spirit of tenacity and perseverance remains with me. As a nurse herself (1947), there would have been no prouder mother.

I have been blessed by the support of a great many family and friends. Finally, I am forever indebted to my husband, Steve, for his love, patience, and commitment to my scholarly pursuits. The road to a PhD would have been much less rewarding, grounded, and fun without him as my companion. And to our son, Will, who always helps provide the light-hearted perspective only a child can.

ABSTRACT

Physiologic Responses to Simulated Care Activities in Older Surgical Patients

Older adults often experience loss of function during hospitalization, thus clinical care activities, like transferring, are part of routine hospital care to prevent functional decline. A paucity of research exists to measure this type of activity objectively. This instrument feasibility study evaluated the utility of the Actiheart™ to measure heart rate and motion responses to five activities, turning, dangling, transferring, sitting, and walking. Fifty-four adults aged 65 and older ($M=72$), scheduled for surgery, participated in a simulation of the five clinical care activities. The study's major findings indicate that the Actiheart™: 1) successfully measured motion and heart rate during various activities; 2) worked well to measure activities that may not show much change in motion alone (like sitting) or heart rate alone (like transferring); 3) discriminated between different clinical care activities, some more consistently than others; 4) discriminated heart rate and motion differences within each clinical care activity; and 5) can reasonably measure heart rate and motion even in the presence of covariates such as gender and BMI. This study was the first to explore the utility and feasibility of the Actiheart™ in a cohort of older adults in a hospital-like environment. It should next be used in an inpatient setting to examine activity patterns of older adults during hospitalization.

Author: Colleen M. Casey

Approved:

Jill A. Bennett, PhD, RN

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CHAPTER 1

INTRODUCTION

The aging of Americans presents many challenges to the United States (US) health care system. In comparison to the overall population, older adults are hospitalized more frequently and have longer hospital lengths of stay than any other age group, accounting for over half of the nation's hospital bill (Centers for Disease Control, 2002; Russo & Elixhauser, 2006). Hospitalization, itself, is a major risk for older persons, particularly for the very old, who often suffer an irreversible decline in functional status (Creditor, 1993). Bed rest often accompanies hospitalization, leading to reduced exercise capacity, often independent of a patient's primary disease (Convertino, Bloomfield, & Greenleaf, 1997). This deconditioning, including loss of mobility, can debilitate older patients as they attempt to recover from their illnesses. Multiple studies have confirmed that many older patients experience some loss in function during hospitalization that can persist for months or years beyond the hospital stay (Chen, Wang, & Huang, 2008; Covinsky et al., 2003; Wu et al., 2000) and puts this population at increased risk for subsequent illness and mortality (Boyd et al., 2008; Carey et al., 2008). The resultant functional limitations and related disability can translate into significant personal and societal costs that may include nursing home placement (He, Sengupta, Velkoff, & DeBarros, 2005), increased demands on family caregivers (Desbiens, Mueller-Rizner, Virnig, & Lynn, 2001), and the potential for a decreased quality of life (Carson, 2003). A critical illness, requiring an intensive care unit (ICU) stay, further exacerbates these risks and associated losses.

By intervening early in an older adult's hospitalization, the potential exists to prevent a loss in function for older adults recovering from an acute illness and improve their prospects for rehabilitation. This focus on the restoration of function represents a core value of nursing, positioning nurses as key players in a hospitalized older adult's recovery trajectory. However, despite the importance of these nursing therapeutics, including the use of clinical care activities like turning, dangling, transferring, sitting, and walking, in the recovery of older adults, little progress has been made in developing measures that can capture these activities with fidelity and integrity. This study proposed to better quantify the patterns of these clinical care activities during a simulation of these activities in a population of older surgical patients. Existing technology that had not yet been tested in an older or clinical population was used to measure motion and heart rate simultaneously during these simulated activities.

The Older Hospitalized Patient

Currently, older adults (age 65 years and older) comprise only 12% of the US population, but this increasingly influential group is expected to swell to 19% by 2030, with the fastest growing segment being those over 85 years of age (He et al., 2005). This oldest-old cohort was 7.5% of the total aged population in 1970 but is projected to comprise 14.5% by 2010 (National Center for Health Statistics, 2004) and even includes over 50,000 centenarians currently living in the US (U.S. Census Bureau, 2005).

Patients aged 65 and older make up a substantial portion of patients in ICUs, are frequent users of critical care services, and have an increased risk of becoming chronically critically ill, defined as patients who require continued ICU care for weeks to months (Carson & Bach, 2002). Estimates of the older population in the ICU setting

range from 48% (Knaus et al., 1991) to 58% and they make up over half of the chronically critically ill (Carson & Bach, 2002; Groeger et al., 1993). In 1999, over 4.4 million adults were cared for in ICUs, with approximately 2.2 million of those patients 65 years and older (Young & Birkmeyer, 2000). Approximately 500,000 critically ill patients died, with mortality rates varying between 20% to 50% for older ICU patients (Chelluri, Grenvik, & Silverman, 1995).

Most important to this study are the 400,000 to 750,000 older adults in the US who survive a critical illness each year and are at risk for post-ICU morbidity (Young & Birkmeyer, 2000). Of these older adults who survive a critical illness, between 23% and 33% suffer from increased disability (Ip, Leung, Ip, & Mak, 1999; Kass, Castriotta, & Malakoff, 1992). Older survivors of chronic critical illness, for example, after weeks or months of ICU care, often have significant functional limitations that require higher and more costly levels of care post discharge (Carson & Bach, 2002). Furthermore, interventions that incorporate and promote activity in the general hospitalized older adult have been shown to reduce mortality and morbidity (Inouye, Bogardus, Baker, Leo-Summers, & Cooney, 2000; Siebens, Aronow, Edwards, & Ghasemi, 2000), but research is only beginning to be conducted on maintaining physical function in ICU patients (Morris et al., 2008; Needham, 2008). These links among pre-hospital functional status, hospitalization, and post-hospital outcomes point toward reducing post-hospitalization morbidity and disability as a clinical and financial priority.

The Costs of Caring for the Older Hospitalized Patient

With older adults being hospitalized more frequently and staying longer than younger adults, older adults account for over \$300 billion in hospital charges annually,

almost half of the nation's hospital bill (DeFrances & Podgornik, 2006; Russo & Elixhauser, 2006). This distribution of costs weighted heavily on the side of older adults also applies to the non-acute end of the care continuum. Since Medicare began in 1966, Medicare spending has risen from 0.6% of the nation's gross domestic product to 2.3% in 1999 and is expected to reach 4% by 2025 (Lubitz, Greenberg, Gorina, Wartzman, & Gibson, 2001). Moreover, the medical costs for disabled older people, defined as those persons with difficulties in physical function, are three times that for nondisabled older people (Trupin, Rice, & Max, 1995).

Certainly, a relationship exists between advancing age and increased costs. Cost analyses have shown that nearly half of lifetime health care expenditures are incurred from age 65 and beyond. Of those patients aged 65 years and older, patients aged 75 years and older account for the majority of health care costs (Federal Interagency Forum on Aging Related [Forum], 2004). The oldest-old, defined as 85 years of age and older, consumes three times as much health care as persons 65 to 74 years old, and nearly twice as much as those adults age 75 to 84 (Alemayehu & Warner, 2004).

On an individual basis, the highest per capita expenditures on health care are in older adults. In 1999, \$11,089 per adult was spent for adults 65 and older (with Medicare covering almost half and Medicaid financing over 15% of these costs), while only \$3,352 was spent for adults aged 19 to 64 (Keehan, Lazeby, Zezza, & Catlin, 2004). Advancing age heightens this disparity, with \$20,001 spent annually per capita by the oldest-old (age 85 and over), who use even more acute care services than younger seniors (Keehan et al., 2004). The outcomes related to these costs also become an issue since on average, 27% of each year's total Medicare expenditures were incurred by the 5% of Medicare

enrollees who died that year (Lunney, Lynn, & Hogan, 2002). Clearly, the hospitalization of older adults has significant financial implications, both related to the actual acute event and during an older adult's rehabilitation subsequent to hospitalization. Improving older adults' recovery in physical function during and after hospitalization offers the opportunity for potential cost savings in terms of fewer discharges to higher levels of care, likely because of a decreased need in personal assistance.

Inactivity in the Hospital and ICU Setting

The importance of preserving physical function during hospitalization, especially for adults aged 65 and older, is so well acknowledged that clinical care activities such as turning, sitting up, transferring, and ambulating are part of routine hospital ward care for all patients. However, this promotion of physical functioning is often not encouraged as much in the ICU. Critical care nurses anecdotally cite several reasons for this difference, including patients' severity of illness, the presence of numerous interventions and devices required for patients' conditions, concerns for patient safety, and patients' relatively short stay in the ICU. Regardless of the patient's primary disease, even short periods of bed rest can reduce functional capacity and lead to post-hospital functional decline (Hirsch, Sommers, Olsen, Mullen, & Winograd, 1990; Kasper, 2001). Consequently, clinical care activities that offer the potential to maintain physical function should be a priority throughout hospitalization, even in the ICU. The chronically critically ill represent a group particularly vulnerable to physical deconditioning. They are often older, frequently postoperative, and are at high risk for mortality, morbidity, and hospital readmissions (Carson & Bach, 2002; Daly, Douglas, Kelley, O'Toole, & Montenegro, 2005).

Gaps in Knowledge

Currently, tools do not exist to systematically and objectively assess activity levels of hospitalized adults even though these activities have been shown to significantly influence a variety of parameters, like length of stay and days until first activity, that can potentially affect physical functioning beyond hospitalization (Morris et al., 2008; Nielsen, Holte, & Kehlet, 2003). Clinical care activities, in particular, have not been quantified in terms of duration or intensity and most often invasive devices have been used to measure patient response to these types of activities (Gawlinski & Dracup, 1998; Lewis et al., 1997; Price, 2006; Verderber & Gallagher, 1994; Weissman & Kemper, 1991; Zafiropoulous, Alison, & McCarren, 2004). Past studies have relied upon observation, nurse recall, or chart review to measure activity levels (Bernhardt, Dewey, Thrift, & Donnan, 2004; Brown, Friedkin, & Inouye, 2004; Siu et al., 2006). A valid and reliable noninvasive measure of activity level, especially clinical care activities, is lacking.

Significance to Nursing

Overall, the problem of inactivity in older hospitalized patients, and the adverse personal, functional, and social consequences are well established. However, little progress has been made in developing standardized, reliable measures of activity and inactivity in critically ill patients. Nurses play a key role in promoting activity through their routine clinical care activities. To advance the nursing science of activity therapeutics for older critically ill adults, in particular the effect of these routine nursing clinical care activities on the trajectory of acute and critical illness and rehabilitation, these types of activities must be measured and quantified. The need persists for an

instrument to capture, quantify, and differentiate various clinical care activities. Only then can progress be made to describe particularly vulnerable periods of inactivity and determine the most effective interventions and their dosages. Increasing older adults' prospects for rehabilitation during their recovery and reducing their physical deconditioning and associated morbidity would mitigate the consequences of post-illness functional decline.

By quantifying different types of clinical care activities, this study serves as a foundation for future studies to describe the relationship between clinical care activities and physical deconditioning, including the identification of the optimal dosing of such activities. The long-term goal of this research is to optimize physical function in hospitalized older adults by using objective measures of activity to ultimately create appropriate physical activity interventions during hospitalization that are tailored to this cohort. This study addressed three of the National Institute of Nursing Research (NINR) strategic objectives: integrating biological and behavioral science, adopting and adapting new technologies, and improving nursing science methods (National Institute of Nursing Research, 2006). This focus on health promotion and disease prevention, increasing the potential for recovery and limiting disability in older ICU patients, represents a core value of nursing and public health, identified as one of NINR's four research areas of opportunity (National Institute of Nursing Research, 2006).

Purpose of the Study

This descriptive feasibility study applied an innovative, clinically relevant, noninvasive approach to measure simulated clinical care activities using existing technology with a population of older surgical patients as a first step towards

systematically evaluating activity patterns commonly used in hospital nursing care.

Accelerometry, using a noninvasive monitoring device that measures the occurrence and intensity of motion, has primarily been used to measure activity levels of healthy or sleeping subjects; though some researchers have begun to use it to study hospitalized adults (Grap, Borchers, Munro, Elswick, & Sessler, 2005; Winkelman, Higgins, & Chen, 2005). This study used the Actiheart™, an enhanced, modified accelerometer that simultaneously measures motion and heart rate during activity to measure simulated activities in older patients prior to surgery.

This study evaluated the utility of the Actiheart™ to measure clinical care activities in a simulated ICU setting with older adults prior to their hospitalization for elective surgical procedures. This population of older adults has been targeted because surgical patients represent a significant proportion of older ICU patients and they are at high risk for both bed rest and chronic critical illness during hospitalization (Carson & Bach, 2002; Casey, Perez, Bennett, & Eldredge, 2006; Hamel, Henderson, Khuri, & Daley, 2005; Pofahl & Pories, 2003). Age, gender, BMI, pain, functional performance and status, comorbidity, beta-blocker use, and assistive device used during activity were analyzed as potential covariates since these characteristics have been shown to influence both activity and heart rate levels and post-hospitalization outcomes in older adults (Guralnik, Ferrucci, Simonsick, Salive, & Wallace, 1995; Guralnik, Simonsick et al., 1994; Hirsch et al., 1990; Kasper, 2001; Roche, Kramer, Hester, & Welsh, 1999; Wu et al., 1995).

Specific Aims

The specific aims of this study of simulated clinical care activities in older pre-surgical patients were to:

- 1) Describe the patterns of motion and heart rate during five different clinical care activities (turning, dangling, transferring, chair sitting, and walking);
- 2) Compare clinical care activities using continuous motion and heart rate data to discriminate motion and heart rate both across and within five different clinical care activities; and
- 3) Measure the effects of covariates (age, gender, BMI, pain, functional performance, functional status, comorbidity, beta-blocker use, and assistive device used during activity) on the ability of the Actiheart™ to measure motion and heart rate data during the simulation of clinical care activities.

CHAPTER 2

BACKGROUND AND SIGNIFICANCE

The Older Hospitalized Patient

Older persons, especially those who are critically ill, are hospitalized more frequently and have longer lengths of stay than any other age group (Carson & Bach, 2002; Centers for Disease Control, 2002). This older population often uses a disproportionate amount of intensive care unit (ICU) care as compared to younger patients, with more than half of all ICU days occupied by patients older than 65 (Angus et al., 2000). Older adults also represent more than half of the average general surgical practice (Pofahl & Pories, 2003), who often can go on to need post-surgical critical care. Studies have shown that older adults may be especially susceptible to lengthy critical illness related to such complications as acute respiratory distress syndrome (ARDS), a severe respiratory illness often requiring prolonged mechanical ventilation (Carson, 2003; Cox et al., 2007; Eachempati, Hydo, Shou, & Barie, 2007). These chronically critically ill are a group particularly vulnerable to physical deconditioning during their lengthy hospitalizations since they are often older, frequently postoperative, and are at high risk for mortality, morbidity, and hospital readmissions (Carson & Bach, 2002; Daly et al., 2005).

However, critical care research indicates that severity of illness, not age, is the strongest predictor of mortality for critically ill patients, even in the oldest-old population of 85 years and older (Chelluri et al., 1995; Demoule et al., 2005; Roche et al., 1999; Van Den Noortgate, Vogelaers, Afschrift, & Colardyn, 1999). Studies show that older adults admitted to the ICU after elective surgery, including those aged 80 and older, are likely to

successfully recover physical function, although age is associated with more complications (de Rooij et al., 2008; Hamel et al., 2005; Pofahl & Pories, 2003). The fact that so many older adults survive their critical illness has warranted study of post-ICU outcomes, with studies demonstrating significant relationships between pre-admission functional status and morbidity post-ICU discharge (Mayer-Oakes, Oye, & Leake, 1991; Nierman, Schechter, Cannon, & Meier, 2001; Richmond, Kauder, Strumpf, & Meredith, 2002; Roche et al., 1999). These studies suggest that pre-admission functional status is related to recovery and subsequent illness and disability. However, fewer studies have focused on how losses in physical functioning that occur during hospitalization impact post-hospital functioning.

Independent of any condition requiring hospitalization or ICU care, older adults tend to be more disabled than the general population. Disability, as defined by Nagi (1965, 1991), is defined as the physical or mental limitations in ability to function in a social context. Disability is commonly measured as deficits in performing activities of daily living (ADLs) (Katz, 1963), with increased disability associated with increased dependency and costs of care (He et al., 2005). For example, loss of ability to perform ADLs is a common reason for entry into costly nursing home care; more than 75% of nursing home residents need assistance in three or more ADLs (Gabrel, 2000). Furthermore, national Nursing Home Survey data report that 45% of residents admitted to nursing homes come from a hospital (Decker, 2005), suggesting that functional decline during hospitalization may have reduced physical functioning to the point of having increased ADL needs. Between one-third and three-quarters of hospitalized older adults have reported declines in their ability to perform ADLs, with only half recovering by 3

months and 6 months postdischarge (Chen et al., 2008; Sager et al., 1996), further evidence that functional decline during hospitalization reduces physical functioning. With the medical costs for disabled older people three times that for nondisabled older people (Trupin et al., 1995), the prevalence of baseline disability upon hospital admission and the acquisition of disability during hospitalization heightens the need to address this disability and mitigate further impairment, especially in high risk patients like the older critically ill.

Conceptual Framework

The concept of disability is pivotal to this study. Even *Taber's Cyclopedic Medical Dictionary* acknowledges in its definition of disability as “any physical, mental, or functional impairment that limits a major activity,” that its definition is controversial among scientists (Venes, 2001). While some experts and researchers consider disability mainly in the context of an inability to perform tasks that had been considered normal for a person in the past, others discuss the concept in a much broader manner that includes the socially-defined roles and context in which a disability occurs. Disability research typically focuses on the epidemiological pathways by which disease, injury, and other conditions can lead to disability and on the surveillance of population levels of disability (Stewart, 2003). The Disablement Process, with multiple adaptations, has served as a guiding framework for researchers from both the disciplines of physical activity and disability (Jette & Keysor, 2003; Stewart, 2003; Verbrugge & Jette, 1994).

The conceptual framework for this study is based on this model, the Disablement Process, an elaboration of Nagi's Disablement Model (1965; Verbrugge & Jette, 1994). The original Nagi framework drew on the concepts of *pathology*, *impairment*, *functional*

limitation, and *disability* (Nagi, 1965); the Disablement Process extends this model with the additional concepts of *risk factors*, *extraindividual* and *intraindividual factors* (see Figure 1) (Verbrugge & Jette, 1994). The use of this framework for this study is appropriate given that bed rest and inactivity have been discussed as a major outcome of hospitalization for older adults, especially those that include ICU stays, and as a major contributor to muscle atrophy and subsequent functional limitations.

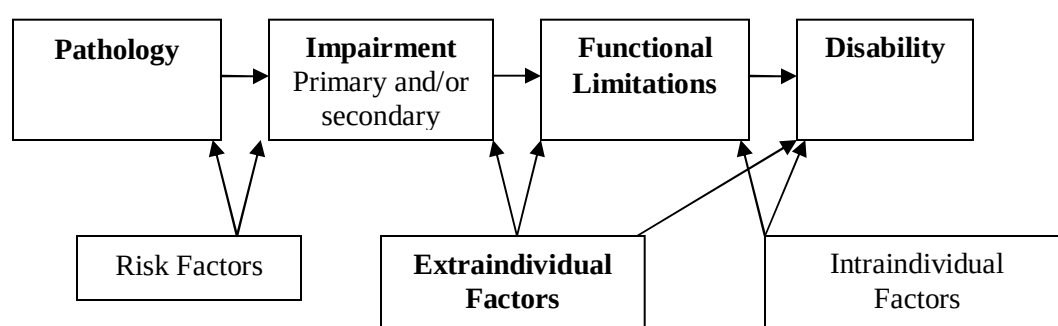


Figure 1. The Disablement Process. Adapted from Verbrugge and Jette (1994)

The International Classification of Functioning, Disability, and Health (ICF) model, developed by the World Health Organization (WHO, 2001), and Creditor's Hazards of Hospitalization framework (Creditor, 1993) were also considered as potential guiding frameworks for this study. The ICF model, a revision by the WHO of their original International Classification of Impairments, Disabilities, and Handicap, was originally developed as a model for coding and analyzing data on the consequences of health conditions (WHO, 2003; 1980). The ICF model consists of two parts, Functioning and Disability (made up of body functions and structures, and activity and participation) and Contextual Factors (including environmental and personal factors). Its structure focuses less on the process or progression of disability, nor on the dynamic, complex nature of the disablement process. For purposes of this study, the ICF model could not

adequately portray the complexity of hospital-related losses in function, particularly in older adults.

Although the Creditor model (1993) offers a unique focus on the hospitalized older adult and acknowledges the important decline that cannot necessarily be “attributed to the progression of the acute problem for which they are hospitalized,” the model assumes a ‘cascade to dependency’ that results in nursing home placement. Furthermore, the model includes additional hazards, such as sensory deprivation, restraints, and diet; while important to consider in an older adult’s overall hospital course, these elements are beyond the scope of this study’s topic of activity and its relationship to physical deconditioning. Hence, neither model provides a balance of adequate breadth and depth for this topic (Pope & Tarlov, 1991). Moreover, the Disablement Process offers a more dynamic framework from which to extend the study’s findings into outcomes and intervention research.

Before outlining the elaborated Disablement Process by Verbrugge and Jette (1994), it is important to briefly discuss the original Nagi framework and apply it to this study (see Table 1)(Nagi, 1965). As part of Nagi’s original framework (1965), *active pathology* involves the disruption of normal cellular processes and a person’s efforts to regain a homeostatic state; in this study, the health problem and any cellular sequelae that requires surgery. *Impairment* refers to a loss or abnormality in a tissue, organ, or body system at the primary site of pathology and sometimes at a secondary site (Nagi, 1965; Pope & Tarlov, 1991). For this study, primary impairment occurs at the affected organ system(s), while secondary impairment might occur as symptoms related to the pathology or primary impairment. *Functional limitations* describe the consequences of pathology

and impairment, representing restrictions in a person's performance, such as difficulty in a person's basic performance, like difficulty in performing locomotor tasks and basic mobility. *Disability* represents any restriction or inability to perform socially defined roles, with an emphasis on social, rather than individual, functioning. Types of activities that may be impacted after a major surgery include basic ADLs, instrumental ADLs, and role and social activities (Jette, 1997; Nagi, 1965).

Verbrugge and Jette (1994) extended Nagi's model by including factors hypothesized or known to influence the ongoing process of disablement: *predisposing risk factors*, *intraindividual factors*, and *extraindividual factors*. These factors become especially important to consider for an older surgical patient (see Table 1). *Risk factors* are present prior to the disabling event (in this case, surgery) and can influence the presence and severity of the process, including sociodemographic background, lifestyle choices, biological factors, and other illnesses. These risk factors might also include the physiologic aging and physiologic reserve of the person. *Intraindividual factors* occur within the person and include lifestyle and behavioral changes, as well as psychosocial and physiologic attributes and coping skills, such as the heart rate measured in this study. *Extraindividual factors* occur outside or external to the person. These factors involve both the physical and social contexts in which the disablement process occurs, including medical and rehabilitation services, medications, other therapeutic regimens, external social supports, and the physical environment. This study focuses on systematically measuring simulated clinical care activities as *extraindividual factors*.

Table 1. *Disablement Process as Applied to Current Study*

Disablement Process Terms/Factors	Related Concepts Measured in Proposed Study
Active Pathology	Etiology of condition requiring surgery (aneurysm, osteoarthritis, e.g.)
Impairment	Symptoms, including those related to active pathology
Functional limitations	Upper body strength Lower body strength
Disability	Functional status
Risk Factors	Sociodemographics, Morbidity/Disease, Age, BMI
Extraindividual Factors	Clinical care activities
Intraindividual Factors	Physiologic responses to clinical care activities

Note. BMI = Body Mass Index

Although this study measured clinical care activities commonly performed in the ICU setting, in part so that it may better measure activity and inactivity in future inpatient studies, especially in the ICU, this aspect of disuse is not an explicit part of the model. In fact, Stewart (2003) discussed the merits of including both disuse and physiologic aging as separate entry points into the model in addition to the originating *pathology* pathway conceptualized in Nagi's model, arguing that these two key mechanisms represent how disablement begins. However, this study retained the use of a single entry point, *pathology*, and considered disuse and deconditioning as either a *risk factor*, in the case of physiologic aging, or *impairment*, in the case of deconditioning. Because this study relates to disability acquired in relationship and subsequent to an acute event, this focus remains appropriate, but deconditioning prior to hospitalization must be accounted for as a covariate.

The Disablement Process provides for disability prevention efforts to be directed at any of the three stages that precede disability, and also at the disability itself. Jette

(1997) called for a more “systematic investigation of factors that influence the occurrence, progression, and recovery patterns of disability in patients with different diseases and impairments.” This study responds to this call by further defining aspects of the environment (clinical care activities) as extraindividual factors that can influence a critically ill older adult’s disablement process at the stages of Impairment or Functional Limitations. Ultimately, intervention efforts can focus on the reversal of disability, the prevention of complications or secondary conditions, such as physical deconditioning, and the restoration of function.

The Phenomenon of Bed Rest

This acquisition of disability during hospitalization presents a major risk for the older person, particularly for the very old, who often suffer an irreversible decline in functional status (Chen et al., 2008; Creditor, 1993; Sager et al., 1996; Wu et al., 2000). Although the advances of modern medicine have meant saving many people from life-threatening diseases and injuries, their survival often comes with the loss of at least some functional capacity (de Rooij et al., 2008; Gaudino et al., 2007; Sager & Rudberg, 1998). Bed rest typically accompanies hospitalization, leading to reduced exercise capacity and functional ability, often independent of a patient’s primary disease (Convertino et al., 1997; Hirsch et al., 1990). Although mobilization is promoted as a clinical goal and part of recovery, studies have shown that patients are likely to spend much of their time in the hospital in bed (Brown et al., 2004; Callen, Mahoney, Grieves, Wells, & Enloe, 2004).

In one study, spontaneous physical activity decreased by 50% in all patients following hospital admission as compared to activity at home (Despond, Buchser, Sprunger, & Sloutkis, 1999). In a study of abdominal surgical patients across middle and

older age groups, the degree of surgical intervention also greatly influenced mobility restoration. For those patients who had more significant surgical procedures, but without complications, postoperative recovery in physical activity was less than 60% of their preoperative level one week postoperatively (Inoue et al., 2003). In the ICU setting, the duration of inactivity—with likely associated physical function declines—is lengthy, especially for patients requiring mechanical ventilation for greater than four days. The time to activity from initial ICU admission to activity was 6.6 days ($SD = 5.5$) to sit on the edge of the bed, 8.8 days ($SD = 7.6$) to sit in a chair, and 11.3 days ($SD = 10.1$) to walk (Bailey et al., 2007). Similarly, Morris (2008) reported that even for ICU patients assigned to a mobility protocol, it took 5 days ($SD = 0.9$) to touch their feet to the floor as compared to 11.3 days ($SD = 2.1$) for a control group of ICU patients receiving usual care. Needham and colleagues' (2007) study of patients with ARDS revealed that patients received activity beyond bed rest in only 11% of 2,470 ICU days observed. In the older adult, this type of delay in activity and mobilization, regardless of the reason, is especially likely to lead to reductions in functional ability.

The reasons for such immobility during general hospitalization, in addition to physiologic instability of the patient, are complex. Studies have shown that bed rest orders are often the default activity order upon admission, are sometimes not revised during the course of hospitalization, and may not have documented medical indications for such bed rest (Brown et al., 2004; Needham, 2008). Morris (2008) found that only 6% of 135 mechanically ventilated patients received physical therapy in the ICU, although it was unclear whether this resulted from staffing issues, the way orders were specified, or other reasons. Furthermore, despite commonly accepted standards of care for even minor

activities, like turning, to occur every two hours, research has shown that such activities may happen as infrequently as every 5 hours (Goldhill, Badacsonyi, Goldhill, & Waldmann, 2008; Krishnagopalan, Johnson, Low, & Kaufman, 2002), putting the ICU patient at increased risk for the musculoskeletal, cardiovascular, respiratory, and integumentary sequelae of immobilization. Safety concerns, multiple device access, sedation, time constraints, staffing, and cost have all been discussed as influencing the lack of progressive activity in the ICU, but a paucity of research exploring these influences exist (Morris, 2007).

Physiologic Consequences of Bed Rest

The inactivity described above, along with the inflammation of critical illness, and age all conspire to promote muscle breakdown and losses in physical function in the older hospitalized patient (Figure 2). Muscle breakdown has been shown to occur as early as several hours from the onset of immobility or disuse, independent of any injury or illness (Hirsch et al., 1990; Kasper, 2001). This breakdown includes altered muscle morphology, with decreases in muscle mass, muscle fiber diameter, and number of fibers per muscle. Cellular-level damage can include rupture of the sarcolemmal membrane of muscle cells, streaming of Z-bands, and torn sarcomeres, all necessary components for effective muscle functioning (Kasper, Talbot, & Gaines, 2002).

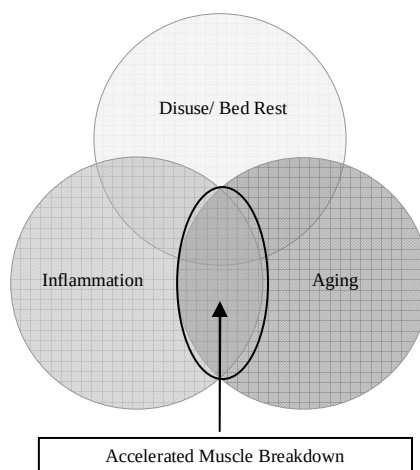


Figure 2. Factors Leading to Muscle Breakdown in Older Hospitalized Patients

This process of muscle breakdown related to inactivity is further compounded by the inflammation characteristic of critical illness. This inflammation leads to the production of reactive oxygen species that mediate a cascade of events promoting oxidative injury to muscle cells. During critical illness, an increased release and action of proinflammatory cytokines promote further muscular atrophy through several complex, interrelated pathways (Winkelman, 2004). Cytokines are small, peptide factors released by immune cells that play a key role as inflammatory mediators during an immune response (Copstead & Banasik, 2000). Cytokine-mediated disturbances in insulin receptors, as well as electrolyte and calcium gradients, have been implicated as the major causes of the loss of muscle contractility (Wagenmakers, 2001). Increased proteosomal proteolytic activity, such as occurs in sepsis, has also been implicated as a major cause of protein degradation and muscle loss in critically ill patients (Klaude et al., 2007).

Pharmacologic interventions and other treatments common in the ICU setting, such as the use of exogenous corticosteroids, can be toxic to nerves and muscles, further

exacerbating skeletal muscle atrophy (Kasper, 2001). One study found that patients with ARDS who had prolonged ICU stays lost, on average, 18% of their body weight in the ICU (Herridge et al., 2003). Similarly, Wagenmakers (2001) found that ICU patients can lose more than 1.5 kg of skeletal muscle mass per day, with up to a 50% loss in total muscle mass in 2 weeks. Clinically, these losses can result in global muscle wasting, foot drop, joint immobility, dyspnea, and weakness leading to reduced physical functioning (Clavet, Hebert, Fergusson, Doucette, & Trudel, 2008; Needham, 2008).

An increasingly recognized phenomenon specific to ICU patients relates to the acquisition of neuromuscular pathologies caused by and acquired during critical illness (Hough & Needham, 2007). These pathologic changes, termed critical illness polyneuropathy (CIP) and critical illness myopathy (CIM) (Hough & Needham, 2007), are often overlooked or misdiagnosed and delay patient recovery even further (Stevens et al., 2007). While the occurrence of CIP and CIM are extreme manifestations of illness-related muscular dysfunction, recent research attention has been paid to the prevalence, risk factors, and outcomes related to this type of neuromuscular compromise unique to the ICU setting (Stevens et al., 2007).

For the older ICU patient, the muscle wasting induced by critical illness, even if not CIP nor CIM, compounds the 40% reduction in muscle cross-sectional area that occurs as part of the natural aging process between the ages of 20 and 80, leaving the older ICU patient less protein reserve with which to recover muscle strength and physical functioning (Griffiths, 1996; Winkelman, 2004). During the process of normal aging, a progressive loss of lean body mass results from the gradual loss of total muscle fibers. The rate of atrophy resulting from inactivity or critical illness is even more rapid than that

of aging. Moreover, the ability of specialized muscle cells that are normally responsible for regenerating muscle to divide and proliferate is finite, decreasing with age (Kasper, 2001). Clearly, the structural and functional changes of muscle cells during the normal aging process put inactive and critically ill elders at high risk for compromised recovery and physical function.

Activity Interventions to Address Hospital-Related Functional Decline

Muscle weakness resulting from hospital-related inactivity has been clearly linked to impaired functional status, but has been shown to be responsive to activity interventions during hospitalization (Henriksen et al., 2002; Kasper, 2001; Suetta et al., 2004). Although early mobilization interventions have been designed to abate functional decline in older adults who are hospitalized (Inouye, 2004; Siebens et al., 2000; Suetta et al., 2004), such interventions have only recently begun to be tested in an ICU setting and have not been directed specifically at older ICU patients (Bailey et al., 2007; Chiang, Wang, Wu, Wu, & Wu, 2006; Martin, Hincapie, Nimchuk, Gaughan, & Criner, 2005; Morris et al., 2008; Needham, 2008). In many of the studies of older non-ICU hospital patients, the activity intervention itself and any associated outcomes have been evaluated using primarily self-report measures, rather than objective measures of the utility of specific activities to prevent functional decline.

For example, Siebens and colleagues (2000) conducted a randomized controlled trial of 300 older patients to test a hospital-based general exercise program that continued for one month post-discharge. To document the intervention, the number of repetitions of flexibility and strengthening exercises and whether patients walked were recorded by staff during hospitalization and reported by patients after discharge. In another study,

patient activity levels were subjectively reported by intervention specialists using patient adherence as the outcome measure. For those patients assigned to the early mobilization intervention, interventionists reported 46% patients as completely adherent, 42% as partially adherent, and 12% as nonadherent (Inouye et al., 2000). Chiang (2006) incorporated the Borg Rating of Perceived Exertion to evaluate and respond to subjects' tolerance during the intervention itself and used the Functional Independence Measure to measure functional outcomes from the intervention, but did not objectively measure the activity intervention itself other than the type and frequency of the activity performed.

At least one study has used objective measures of activity to measure the effect of an intervention. Suetta and colleagues (2004) found postoperative resistance training in older hip surgery patients significantly increased muscle mass, strength, and function, while reducing length of stay. Although measurement of the home-based standard rehabilitation that served as a control was based on self-report, the training load and duration of the resistance intervention was measured by a repetition maximum standard to quantify the intensity of the activity.

The recent ICU activity intervention studies come amidst a transition away from a culture of deep sedation and bed rest that has persisted despite historical evidence of the physical and psychological benefits of early mobilization of both hospitalized and ICU patients (Needham, 2008). Separate studies of daily sedation interruption increasingly have shown the benefit of sedation tapering paired with spontaneous breathing trials (Girard et al., 2008; Jacobi et al., 2002), both elements of which would also promote increased activity levels. Recent studies have pointed to higher-intensity rehabilitation leading to greater benefit, but have not objectively measured the activity itself except to

describe the activity (sitting, walking) and document the distance of walking and duration of activity (Bailey et al., 2007; Chiang et al., 2006; Martin et al., 2005; Needham, 2008; Thomsen, Snow, Rodriguez, & Hopkins, 2008). Despite the positive findings that activity in the ICU setting is feasible and safe, evidence remains preliminary and has not been confirmed by any large, multicenter, randomized controlled trial (Morris & Herridge, 2007), nor by studies using objective measurement of activity.

Many of the ICU activity interventions occurred in the context of special respiratory care units and involved patients who were mechanically ventilated (Bailey et al., 2007; Chiang et al., 2006; Martin et al., 2005; Nava, 1998; Needham, 2008), with only a single study occurring in the context of a medical ICU (Morris et al., 2008). While some of the studies reported mean ages of ≥ 65 years in their sample (Chiang et al., 2006; Nava, 1998), most of the studies had younger patients with the mean age of patients in their 50s (Martin et al., 2005; Morris et al., 2008; Thomsen et al., 2008). None of the studies explored age as a covariate to their findings. Although the studies reported the frequency of rehabilitation offered to patients in the intervention groups, which ranged from 3 times daily passive range of motion to daily or twice daily physical therapy, duration of non-walking activities was not reported, making it difficult to assess the dosage and intensity of such activities to determine their effectiveness in maintaining physical functioning in ICU patients. Each study's definition of activity also was slightly different. In one study, activity only included sitting on the bed, sitting in a chair, and ambulating (Bailey et al., 2007), whereas in another study, even passive range of motion was included in the activity intervention protocol (Morris et al., 2008). Patient movement to a chair position in bed, to a 'cardiac' chair, and passive range of motion were often not

considered activities in these studies, though these activities are traditionally considered rehabilitative activities for ICU patients and could also be important in preserving physical function in the ICU setting.

Overall, the ICU-based studies did not specifically examine activity in older ICU patients, known to be at high risk for complications and decreased functional outcomes related to their critical illness. Moreover, many of the studies, by conducting their interventions in special respiratory care units did not include non-mechanically ventilated, but critically ill, patients; did not include broader critically ill patient populations, such as surgical or trauma patients; and did not conduct interventions in non-respiratory care units that may have different unit cultures around mobilizing patients and different staffing and interdisciplinary structures that influence the delivery of physical therapy to patients. These studies also did not continue the interventions beyond the ICU into the general hospital setting upon the patient's discharge from the ICU. Yet, research has confirmed that even the general hospital setting presents risks for disuse and inactivity, especially to older patients. Most importantly, these studies of activity interventions in the ICU measured the frequency and duration of some interventions, but did not objectively measure the activities, for example, with an accelerometer.

Most intervention research specifically aimed at preserving muscle function during hospitalization involves resistance training and active participation by participants. Such interventions are not possible for all ICU patients because of their cognitive or physiologic status. However, all ICU patients receive clinical care that includes activities such as being turned in bed that may help maintain physical functioning even in the absence of more intense functional interventions, such as resistance exercises, but have

not been formally studied for any rehabilitative effect. Although other studies have linked these clinical care activities to individual physiologic parameters (see Measurement of Activity and Inactivity in the Hospital Setting below), they have not addressed how these activities, such as turning and transferring, influence more global measures, such as physical deconditioning and functional decline.

In contrast to these earlier studies that do not provide sufficient data to assess the dosage and intensity of activities that might preserve physical functioning, the use of accelerometry in this study offers a potential way to more objectively measure the activity of an intervention itself. Being able to measure activity more precisely, particularly as part of intervention studies, is critical to advance the science in this arena. This study is one of the first to test the sensitivity of an accelerometer as an objective measure of a range of simulated clinical care activities common in the ICU. The Actiheart™, an accelerometer combined with a physiological sensor to measure heart rate at the same time, was optimal for this study, allowing for the simultaneous measurement of motion during activity, as well as the physiologic response (heart rate) to that motion. In this way, the Actiheart™ offered a multimodal, non-invasive assessment of low-level clinical care activities that have not previously been studied in this setting or population.

Non-Intervention Measurements of Activity in the Hospital Setting

A number of studies have examined the influence of ICU clinical care activities, such as position changes, bathing, ambulating, and range of motion exercises, on a variety of physiological parameters, such as SvO₂, heart rate, and blood pressure, but have not focused on the measurement of the activities themselves nor on the effect of activities on the maintenance of physical functioning (Gawlinski & Dracup, 1998; Lewis

et al., 1997; Nielsen et al., 2003; Price, 2006; Verderber & Gallagher, 1994; Zafropoulous et al., 2004). This attention stems from the important role activity plays in the relationship between oxygen delivery and consumption, especially during a critical illness (Weissman & Kemper, 1991). Moreover, other non-ICU, hospital-based studies have relied upon chart review, observation, or nurse recall to measure activity level (Bernhardt et al., 2004; Brown et al., 2004; Henriksen et al., 2002; Inouye et al., 2000; Siu et al., 2006). Observation methods suffer from subjectivity, expense, and the potential for a testing effect. Chart review is problematic as a research method because of the lack of standardized documentation for activity and a lack of uniform protocols outlining activity orders. These methods also cannot capture the variation in activity levels that occurs based on a patient's severity of illness and his or her ability to participate (level of consciousness or strength, e.g.).

Some recent efforts have been made in quantifying activity in the critical care setting through the use of accelerometry, which measures motion noninvasively. Grap and colleagues (2005) found accelerometry to correlate well with observed activity levels and with subjective reports of agitation and sedation in 20 ICU patients (mean age of 50.5 years; $SD = 16$). However, the study only included a two-hour time period and measured associated physiologic parameters, like blood pressure, invasively and separately from the accelerometry. Winkelman, Higgins, and Chen (2005) also found acceptable agreement between accelerometry and observation but did not find accelerometry could differentiate the type of activity. However, based on limited observation periods, only turning and range of motion were actually observed as activities (mean age of 59.8; $SD = 16$) (Winkelman et al., 2005), underscoring the need for a clear definition of what

constitutes therapeutic activity in the ICU study. Bailey and colleagues (2007), for example, excluded turning and range of motion as part of their definition of activities. In a study by Browning (2007), researchers used a positional activity device, worn on the leg, to study ‘uptime’ spent in a post-surgical population (mean age of 61 years; $SD = 12$) across hospital and ICU settings. Despite finding that daily uptime predicted length of stay and an overall low duration of uptime (30 minutes on post-operative day 4), the device was not able to discriminate between time spent sitting out of bed, nor between standing and walking.

Nurses use clinical care activities in the ICU and hospital to maintain and advance patients’ activity tolerance, the physiological or psychological energy needed to endure or complete an activity (Urden, Stacy, & Lough, 2002). These types of activities help patients maintain or regain strength while not overtaxing them. Most studies investigating the outcomes of such activities in the hospital or ICU setting have not evaluated multiple measures of activities that were easily synchronized (like the motion and heart rate recorded by the Actiheart™), have relied upon invasive monitoring devices, such as pulmonary artery catheters, to measure patient response, or have only subjectively described the actual activities.

This study extended findings from these initial studies of accelerometry in the ICU by measuring multiple clinical care activities as part of a protocol simulating the ICU environment in a sample of older adults. Activities were standardized across patients so they were dosed similarly and measured objectively. This study is the first to use multiple objective measures of activities to discriminate between a broader range of standard clinical care activities than has previously been studied.

Measurement of Activity Using Accelerometry and Heart Rate

Physical activity is typically described by measuring the intensity, type, duration, and frequency of activity. Numerous methods to describe physical activity are generally grouped into three classes: subjective reports and observations, indirect calorimetry, and other objective measures such as portable motion sensors, like accelerometers and pedometers (Chen & Bassett, 2005). When considering physical activity as a naturally occurring behavior, observation has been considered the gold standard of its measurement despite its sometimes prohibitive cost and potential for Hawthorne effect (Montoye, Kemper, Saris, & Washburn, 1996). However, when evaluating physical activity from a more biomechanical or physiologic perspective, indirect calorimetry, particularly doubly-labeled water (DLW) is used as the gold standard to assess energy expenditure. Portable motion sensors are usually used to study physical activity in groups of subjects and has been studied extensively in both adults and children, with pedometers especially used in community-based walking intervention studies (Freedson & Miller, 2000; Tudor-Locke & Myers, 2001).

Both indirect calorimetry and accelerometers are often utilized not only to describe aspects of physical activity in non-hospitalized persons, but also to predict energy expenditure (EE) related to physical activity. The components of an individual's EE, the amount of energy spent in a day, include the resting metabolic rate, the thermic effect of food, and physical activity, the latter of which provides the greatest variability depending on a person's activity patterns (Whitney, Cataldo, & Rolfes, 1998). This variability makes the physical activity component of EE a natural target for study, measurement, and potential intervention. Energy expenditure is often expressed as

kcal/min or kJ/min and can be more specifically partitioned into total daily EE, activity-related EE, and resting EE (REE); indices based on EE include physical activity level EE, metabolic EE, and the physical activity ratio, defined as the per-minute energy cost of specific activity relative to per-minute REE (Schutz, Weinsier, & Hunter, 2001).

Energy expenditure can be measured by direct or indirect calorimetry, from which the rate of EE is calculated by standard predictive models (Whitney et al., 1998). Indirect calorimetry, which measures gas exchange associated with the oxidation of energy substrates (O_2 consumption and CO_2 production primarily), is the most common method for validation of accelerometric data (Westerterp, 1999). Indirect calorimetry methods include breathing through a mouthpiece, mask or hood into a gas analyzer, a respiration chamber, and DLW. Specifically, DLW is based on the difference in the rates of turnover of hydrogen (H) and oxygen (O) in body water, as measured by CO_2 production and the disappearance rates of isotopes (^2H and ^{18}O) in urine, blood, or saliva (Montoye et al., 1996). DLW provides a reliable measure of EE associated with physical activity over a period of one to three weeks. However, indirect calorimetry methods typically require well-controlled laboratory environments and do not necessarily assess all activities of daily living, particularly those that are considered to be low-intensity (Montoye et al., 1996). Furthermore, DLW only reflects the average level of daily physical activity and cannot elucidate activity patterns over time (Bouten, Verboeket-van de Venne, Westerterp, Verduin, & Janssen, 1996).

Care must be taken not to equate physical activity with energy expenditure. Although they are related concepts, they are not synonymous. While physical activity measurement focuses on documenting naturally occurring activity from a behavioral

perspective, energy expenditure measurement focuses more on the physiologic consequences on measured doses of such behavior. This latter measurement has been more easily quantifiable, while measures of the behavioral aspects of activity have typically taken the form of the self-report method, which has been criticized for issues that include a multitude of measures, various scoring procedures, recall bias, and floor effects (Shephard, 2003; Tudor-Locke & Myers, 2001). Luckily, the accelerometer has been shown to be able to measure both behavioral aspects of activity (patterns, duration, intensity) as well as indirectly measure physiologic-related parameters such as EE. Although this study's purpose was to identify patterns related to clinical care activities, the following discussion of accelerometry will include both the behavioral and physiologic aspects of the measure, particularly since most of the validity and reliability research on the accelerometric approach has been more physiologically focused.

Principles Underlying Accelerometry

Accelerometers are devices that measure body movements in terms of acceleration, a change in speed with respect to time (Mish, 1989), usually measured in gravitational acceleration units (g ; $1\ g = 9.8\ \text{m}\cdot\text{s}^{-2}$). Most accelerometers consist of piezoelectric sensor(s) that detect acceleration in one to three orthogonal places (anteroposterior, mediolateral, and/or vertical). The sensor, a variation of the spring mass system, measures the stretching or compression of the transducer when movement occurs in order to calculate the applied acceleration (Mathie, Coster, Lovell, & Celler, 2004). An output voltage signal is generated that is proportional to the applied acceleration; an area under an acceleration-deceleration wave from is integrated and summed (Chen & Bassett,

2005; Montoye et al., 1996). The measured acceleration depends on both the movement and the orientation of the instrument relative to the gravitational field (see Figure 3).

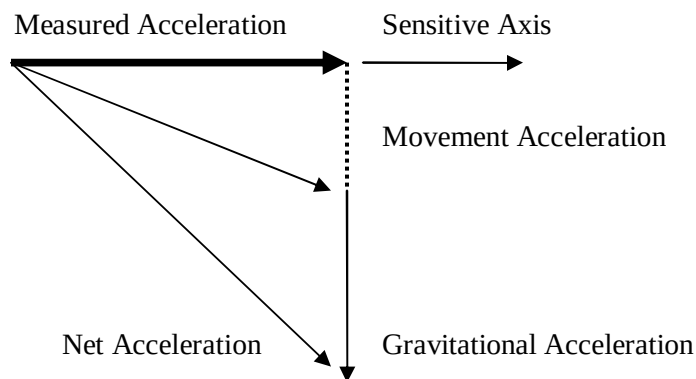


Figure 3. Measurement of Acceleration by Accelerometers. Piezoelectric accelerometers measure the sum of the acceleration due to movement and gravitational acceleration acting along the sensitive axis. Courtesy of Mathie, 2004

The output of accelerometers are called counts. Counts result from the conversion of the analog voltage signal to a digital series of numbers that are called “raw counts.” These counts are then processed by the accelerometry software using a variety of analytic approaches, depending on the device and manufacturer to become the physical activity counts. These analytic approaches include the zero-crossing method, the maximum value algorithm method, and the integration algorithm, the latter of which is the most commonly applied method (Chen & Bassett, 2005).

Properties characteristic of accelerometers include the determination of sampling frequency to ensure that the full range of human motions are captured and the use of band pass filtering that allows frequencies between predetermined low- and high-frequency limits to pass while attenuating all other frequencies, limiting artifact and noise (Chen & Bassett, 2005). The time period over which the accelerometer counts are averaged, called an ‘epoch,’ also influences the interpretation of data. For most adult applications, a 1-minute epoch provides a good time frame for assessing activity (Chen & Bassett, 2005).

Shorter epochs yield higher resolution, especially if physical activity is examined in shorter durations. However, these shorter timeframes can make meaningful interpretation of physiologic value difficult. Longer epochs provide the advantage of time averaging, with the main disadvantage that it can distort the interpretation of two activities of differing intensities, incorrectly reflecting an activity of intermediate intensity.

Evolution of Accelerometers

The first generation of accelerometers consisted of single devices placed on the waist, chosen because it is the closest placement to the center of body mass. Technology development in this area has included the creation of more portable accelerometers, a combination of accelerometers with physiological sensors (such as heart rate and temperature), and multisite assessment of accelerometry. While the initial generation of accelerometers consisted mainly of uniaxial devices, measuring movement only in the vertical plane, newer devices can measure accelerations in multiple directions and are considered multiaxial or omnidirectional. Furthermore, many accelerometers have been limited by only being able to detect acceleration related to dynamic (e.g. vibration) movement such as walking or running (Leenders, Sherman, & Nagaraja, 2006). In the past, it has been assumed that the effect of static exercise on total level of physical activity is negligible (Westerterp, 1999). Newer models, however, are beginning to incorporate technology that can also detect more static (e.g. gravity) movement that expends energy but is not associated with much physical motion, like position changes, carrying loads, or even household chores (Culhane, O'Connor, Lyons, & Lyons, 2005; Matthews, 2005). These types of activities have been shown to comprise a larger

proportion of energy expended than previously thought (Thompson, Batterham, Bock, Robson, & Stokes, 2006).

Applications of Accelerometry

In terms of monitoring human movement, accelerometers can be used for the objective assessment of particular movements, general clinical surveillance, to monitor for adverse events, and to allow for longitudinal tracking of important movements (Mathie, Coster et al., 2004). Specifically, accelerometers have been used to evaluate gait analysis, balance, falls risk, and mobility, especially in older adults (Culhane et al., 2005). In addition to the limited use of accelerometry in the ICU setting discussed previously, accelerometers have been used in a clinical capacity to monitor physical activity patterns of cardiac rehabilitation patients (Ayabe et al., 2004), patients with spinal cord injury (Dearwater, LaPorte, Cauley, & Brenes, 1985; Warmes & Belza, 2004), and chronic obstructive pulmonary disease (Pitta, Troosters, Spruit, Decramer, & Gosselink, 2005; Steele et al., 2003; Steele et al., 2000), patients after stroke (Haeuber, Shaughnessy, Forrester, Coleman, & Macko, 2004), and postoperative patients in the hospital setting (Despond et al., 1999; Inoue et al., 2003).

A number of sophisticated analytic approaches have been proposed to help classify basic movements detected by accelerometers (Allen, Ambikairajah, Lovell, & Celler, 2006; Karantonis, Narayanan, Mathie, Lovell, & Celler, 2006; Mathie, Coster et al., 2004; Veltink, Bussmann, de Vries, Martens, & Van Lummel, 1996). Activity count cut points have also been developed to translate field data into specific activity-intensity categories. Although the definition of the cut points and their validity have been debated, these boundaries have been examined to distinguish between inactive/light, moderate,

and vigorous activities using metabolic equivalents (METs) to more precisely profile the quality and nature of various physical activities (Freedson, Melanson, & Sirard, 1998; Matthews, 2005).

Limitations and Advantages of Accelerometry

Different decision rules can influence important outcome variables when using accelerometry, such as the wearing period, number of days worn, and even device placement (Masse et al., 2005; Welk, 2005). Uniaxial accelerometers have been criticized for not being able to capture more complex movement patterns (Bouten et al., 1996). However, research of multiaxial accelerometers reveals that even collecting additional vectors of information does not completely remedy the problem of underestimating low-intensity or more static activities (Hendelman, Miller, Baggett, Debold, & Freedson, 2000). Multiple studies have concluded that uniaxial and multiaxial accelerometers provide comparable physical activity information, with high correlations between the two types of accelerometers ($r = 0.84-0.93$; $r = 0.77$; $r = 0.77-0.86$) across activities (Kochersberger, McConnell, Kuchibhatla, & Pieper, 1996; Leenders, Sherman, Nagaraja, & Kien, 2001; Welk, Blair, Wood, Jones, & Thompson, 2000, respectively).

Although the use of DLW has become the common criterion measure, the accuracy of accelerometry's ability to estimate EE has been questioned based on validations with DLW. Because the DLW data cannot be parsed by time in the same way accelerometry data can, DLW can underestimate low-intensity activities as compared to accelerometry (Mathie, Celler, Lovell, & Coster, 2004; Tudor-Locke & Myers, 2001; Welk et al., 2000). Moreover, the use of a wide range of activity types and intensities across studies has produced a great deal of variation in the resultant prediction equations

and activity intensity cut points, even when using the same accelerometer (Matthews, 2005). Additional study is needed in order to identify optimal cut points that may differentiate physical inactivity from light-intensity activities. Accelerometers have also been shown to be susceptible to external vibration artifacts, such as in a vehicle. The development of filters to eliminate constant mechanical vibration frequencies has addressed this issue (Bouten et al., 1996; Patterson et al., 1993).

Despite these limitations, accelerometry offers a more objective assessment of physical activity than self-report and observation and is less costly, time consuming, equipment intensive, and invasive than indirect calorimetry, including DLW. Furthermore, the development of mathematical algorithms, typically based on regression equations, has provided for the indirect calculation of EE estimates from accelerometry data based on a demonstrated linear relationships between accelerometry counts and EE during physical activities such as walking and running, although none have been specifically developed for older adults (Leenders et al., 2006; Matthews, 2005). Proponents of the accelerometer argue that its objectivity, physical portability, and scientific applicability make it better suited to the clinical setting than other methods of physical activity assessment. Accelerometry advocates state a need for increased use of accelerometers in older populations in order to better determine whether separate approaches, such as calibration equations, should be made based on age, body composition, or function, for example (Welk, 2005).

Incorporating Heart Rate Monitoring with Accelerometry

A long history exists of research exploring the relationship between heart rate and energy expenditure, particularly during exercise. A linear relationship has been

demonstrated between HR and oxygen uptake (VO_2) over a range of exercise intensities that is based on the Fick equation: $\text{VO}_2 = \text{HR} * \text{Stroke Volume}$ (Montoye et al., 1996). Various methods to monitor heart rate have been proposed and tested, including use of a portable indirect calorimetry system that also measures heart rate (Strath et al., 2000) and the more common use of a Holter electrocardiography monitoring device dedicated to measuring heart rate (Buchheit et al., 2004; Stein, Ehsani, Domitrovich, Kleiger, & Rottman, 1999; Umetani, Singer, McCraty, & Atkinson, 1998).

Integrating physiological measures, such as heart rate monitoring with accelerometry, has been more recently examined as a method to improve precision of activity measurement. Past studies combining the methodologies have aimed to mitigate the weaknesses of each individual device; namely that heart rate can be elevated related to non-activity stressors and that accelerometry cannot account for all bodily movement and work performed (Bassett, 2000). Initial work employed the simultaneous measurement using multiple devices for each physiologic parameter. More recent technology has allowed for a single sensor to record both measures.

Studies have shown a combined sensor demonstrates a lower level of systematic error than single-measure devices (Corder, Brage, Wareham, & Ekelund, 2005). One such device, the Actiheart™, a combined motion and heart rate monitor, has been described as being more precise than either accelerometry or heart rate monitoring alone (Brage, Brage, Franks, Ekelund, & Wareham, 2005). The Actiheart™, has been validated against indirect calorimetry, self-reported physical activity, and pedometer, demonstrating the strongest correlation to energy expenditure as measured by indirect calorimetry, even during low-to-moderate intensity activities (Brage et al., 2004; Crouter,

Churilla, & Bassett, 2008; Haskell, Yee, Evans, & Irby, 1993; Strath, Brage, & Ekelund, 2005; Thompson et al., 2006). A combined sensor offers the opportunity to more thoroughly examine patterns of physical activities, such as the amount of energy or the time of an activity above critical intensity thresholds.

Reliability and validity of the combined heart rate and motion sensor has been tested in the laboratory and during activities such as treadmill walking and running (Brage et al., 2005; Strath et al., 2005). Activities evaluated by the sensor have even been tested in the context of the free-living environment, including low- and moderate-intensity activities (Crouter et al., 2008; Thompson et al., 2006). However, low-level clinical activities have not yet been evaluated using such a device, nor have most activities in older samples. This study proposed to use a combined accelerometer and heart rate monitor to more objectively measure such low-level clinical care activities in a sample of older adults.

State of the Science: Gaps to be Addressed by this Study

The problems and costs of inactivity in older hospitalized patients are well documented. Clinical care activities are a hallmark of nursing and rehabilitation, especially in the ICU. However, little progress has been made in developing standardized, reliable measures of these types of activities and of patient activity levels, especially for patients who are particularly vulnerable like the older critically ill. Studies of activity and inactivity in the hospital rely mostly on subjective measures of activity such as observation, recall, self-report, and chart review. In the ICU setting, studies have often used invasive measures of physiologic responses to activity, but have not measured or quantified the activity itself. Even as part of more recent activity intervention studies

in the ICU setting, the interventions have been only generally described in terms of duration of an activity or frequency of physical therapy, and activity has not been studied in broader non-intubated ICU populations or specifically in older adults. More objective measures of activity are often invasive and resource intensive (DLW) or have not been sufficiently validated in an older clinical population.

Nurses, through many of their routine clinical care activities, are poised to help promote function in this population, but a reliable and valid measure of activity is needed to safely quantify and differentiate various clinical activities. Only then can progress be made to describe particularly vulnerable periods of inactivity, develop interventions to mitigate inactivity, describe the activities that provide the most benefit, and identify appropriate dosing and tailoring of activity. This study built on the findings from initial studies of accelerometry in the ICU setting by studying older pre-surgical adults, measuring multiple clinical care activities as part of a simulation protocol, and using the Actiheart™, a modified, enhanced accelerometer that measured motion and a physiologic response to motion (heart rate) simultaneously in a single, noninvasive device. Because this device has not yet been tested in a more clinical environment, nor in older adults, the study tested the device in a hospital-like setting using simulated clinical care activities with older adults so that findings could later be extended into an actual clinical research environment of the hospital or ICU.

Specific Aims

The specific aims of this study of simulated clinical care activities in older pre-surgical patients were to:

Aim 1: Describe the patterns of motion and heart rate during five different clinical care activities (turning, dangling, transferring, chair sitting, and walking).

Patterns were described and evaluated, including the identification of pre-activity (resting) motion and heart rate levels, as well as minimum, maximum, and total motion and average and maximal heart rate levels, within each activity.

Aim 2: Compare clinical care activities using continuous motion and heart rate data to discriminate motion and heart rate both across and within five different clinical care activities.

Hypothesis: Measurements of motion and heart rate will differentiate between clinical care activities.

Aim 3: Measure the effects of covariates (age, gender, BMI, pain, functional performance, functional status, and comorbidity, beta-blocker use, and assistive device used during activity) on the ability of the Actiheart™ to measure motion and heart rate data during the simulation of clinical care activities.

Hypothesis: Some of these covariates may influence the ability of the Actiheart™ to discriminate motion and heart rate data between the five different types of clinical care activities.

CHAPTER 3

RESEARCH DESIGN AND METHODS

Overview & Rationale

In a sample of older pre-surgical patients, the primary purpose of this study was to describe patterns of five simulated clinical care activities using motion and heart rate data recorded by an instrument, the Actiheart™, that collects both types of data simultaneously (Aim 1). Secondly, the study sought to determine whether the Actiheart™ could discriminate motion and heart rate data across activities of different types and intensities and also could discriminate heart rate and motion data within each activity (Aim 2). In addition, the influences of age, gender, body mass index (BMI), pain, pre-hospital functional performance and status, comorbidities, beta-blocker use, and the use of an assistive device during the simulation of activities were explored as covariates of the ability of the Actiheart™ to measure heart rate and motion (Aim 3).

A cross-sectional descriptive design was used to quantify and differentiate various clinical care activities and test the above hypotheses. Because the study evaluated the feasibility and effectiveness of an instrument that simultaneously measures motion and heart rate, Measurement Theory, used to assess quantitative measurement error (Carmines & Zeller, 1979), guided the development of the study's design and methods. This theory is typically discussed in terms of reliability, the accuracy or consistency of a test, and validity, the ability of a test to adequately measure the construct under study, in this case, activity (Carmines & Zeller, 1979). Two types of error affect empirical measurement: random errors occur by chance to influence the reliability of a measure, while systematic errors threaten a measure's validity (Carmines & Zeller, 1979). The

study evaluated content, criterion, and construct validity to minimize both types of error. As random error is minimized, a measure's validity increases. The study also used stability, internal consistency, and equivalence to evaluate reliability. Please refer to the Reliability and Validity of the Actiheart™ in a Clinical Setting section below for a full description of the reliability and validity of the study's methodological approaches.

Sample and Setting

Sample

The target sample was adults age 65 and over with a planned major surgery and hospitalization. This sample was selected because they were identifiable prior to their hospital admission and represented older adults whose hospitalization might include an intensive care unit (ICU) stay. They were recruited through the Oregon Health & Science University (OHSU) Pre-Admission Testing (PAT) Clinics, where they had scheduled appointments prior to surgery. A convenience sample who met the following inclusion criteria were eligible to participate in the study: a) planned major surgical admission to OHSU requiring PAT appointment; b) age 65 or older; c) oriented to person, time, and place; d) able to speak English; e) ambulatory or able to physically participate in the study; and f) MD approval. Exclusion criteria included: a) other major illnesses with a terminal prognosis; b) diagnosed major psychiatric illness, Axis IV, such as personality disorder; and c) diagnosed cognitive impairment.

Power Analysis

Sample size was determined with a power analysis using published heart rate data since heart rate changes are less detectable than motion changes. It was also based on turning, the activity likely to cause the least amount of heart rate change, making it the

most difficult to detect. Published evidence supported the assumption of a standard deviation for heart rate of 9 to 10 beats per minute (bpm) (Katz-Leurer, Shochina, Carmeli, & Freidlander, 2003; Stein et al., 1999; Umetani et al., 1998). However, the only study to explore heart rate responses to staged activity progression in ICU patients found larger standard deviations for heart rate of between 12 and 15 bpm, though the sample size in that study was small with only 17 ICU patients (Zafiropoulos et al., 2004). Using a standard deviation of 12, an intermediate value across these studies, for power analysis, the proposed study required a sample of 53 participants for 80% power at the 0.05 level of significance for Aim #2 (Dixon & Massey, 1983). Therefore, a proposed sample of 60 adequately addressed both the outcome (heart rate) expected to be least variable and the activity (turning) likely to cause the smallest variation in motion and heart rate response, while also accounting for attrition.

This power calculation assumed a correlation between heart rate measurements within each activity of 0.50 and assumed these correlations were constant as is assumed in the repeated measures ANOVA model used in the analysis of Aim #2. Correlations for the majority of heart rate measurements within each activity were significant, greater than 0.50, and positive ($p < 0.001$), except for the correlation of the pre-activity heart rate before dangling and the maximal heart rate during dangling activity ($r = 0.47$, $p < 0.001$). Motion counts were not as consistently correlated within each activity, particularly for correlations involving pre-activity counts, since often these counts were 0. However, correlation coefficients between total motion and maximum motion were consistently significant ($p < 0.001$) and greater than 0.80.

Setting

All data collection took place in a dedicated study space at OHSU, first on 7A, a trauma ICU, and later in a converted office in Multnomah Pavilion. To save the participant time during the study visit, self-report data was collected prior to the appointment using mailed surveys. A single study visit was planned, involving clinical data collection and the simulation protocol to coordinate with each participant's scheduled PAT clinic appointment, avoiding a separate trip for the participant.

Feasibility of Recruiting Sample

Utilization Data

Findings from the Principal Investigator's (PI) Master's Research Project supported this study's proposal; specifically, 34% of the ICU population 75 years of age and older had a planned admission over the prior study's three-month period and 50% of these patients were surgical patients. Of this critically ill older surgical population, 65% were planned admissions (Casey et al., 2006), supporting the current study's strategy of accessing older adults with planned surgical procedures.

Furthermore, PAT clinic utilization data prior to the study also reflected significant utilization by the 65 and older population. In 2006, the year prior to this study's commencement, the PAT had 9,307 patients, with 2,101 (22.6%) aged 65 years and older (excluding same-day surgery patients). Of these patients, 1,131 patients age 65 and older had major elective surgery with hospital admission, with 837 patients visiting the PAT clinic prior to the day of their surgery (a timeframe necessary in this study to allow for data collection) (University HealthSystem Consortium, 2006). Based on these figures, the number of potentially eligible older adults admitted for major elective surgery

was predicted to be approximately 70 per month. This older pre-surgical sample adequately represented the older ICU population since the hospitalization of approximately 38% of the older surgical patients included an ICU stay (University HealthSystem Consortium, 2006). Based on an expected 30% to 60% participation rate, with recruitment and enrollment of approximately 5 to 10 participants per week, respectively, enrollment and data collection was predicted to take 6 to 12 weeks to meet the sampling goal. In reality, enrollment and data collection took between 6 and 7 months as a result of a number of influences. Please see the Screening and Recruitment section for more information and a monthly breakdown of participants (Table 4).

Gender and Minority Considerations

Both men and women age 65 years and older were included in this study. In 2006, approximately 53% of the hospitalized 65 and older population at OHSU were women. This proportion is slightly lower in the ICU setting, with only 46% of the OHSU ICU population age 65 being older women (University HealthSystem Consortium, 2006). However, in an earlier study by the PI of the OHSU ICU population age 75 and older, this proportion shifted with 52% females versus 49% for males (Casey et al., 2006). Based on these data, enrollment was expected to consist of roughly equal numbers of men and women.

Every effort was made to include minority elders. Based on OHSU utilization rates across all inpatient age groups, the OHSU hospital primarily treats a Caucasian population (75%), reflective of the ethnicity in the Portland area (U.S. Census Bureau, 2005; University HealthSystem Consortium, 2006). The Portland area is relatively

racially homogeneous, with 80% Caucasian, 6% Black/African-American, 8% Hispanic, 7% Asian, and less than 1% American Indian/Alaska Native (U.S. Census Bureau, 2005).

The utilization of OHSU hospital by minorities mostly mirrors this demographic, with 3% of patients describing themselves as Black/African-American, 14% Hispanic, 3% Asian, less than 1% Native American/Alaska Native, 5% reported as other/unknown, and 75% white. The 65 and older population served by the hospital reflects an even less diverse group, with 87% of all inpatients 65 and older reported as white, 2% describing themselves as Black/African Americans, 2% Hispanic, 3% Asian, less than 0.5% Native Americans/Alaska Native, and 5% as other/unknown (University HealthSystem Consortium, 2006). Based on these considerations, the study recruitment plan was to enroll 10% or more non-white participants (6 participants), including roughly equal numbers of Black/African-American, Hispanic, and Asian participants. Recruitment of minority participants was prioritized, in that all minority patients age 65 and older who were identified as potentially eligible were called by the recruiter provided they were English speaking.

Procedures

Screening and Recruitment

All aspects of the study were approved by the OHSU institutional review board (IRB). Recruitment procedures adhered to the guidelines that protect the privacy of hospitalized (in this case, pre-hospitalized) patients as potential research participants. Please see Figure 4 for the Study Protocol.

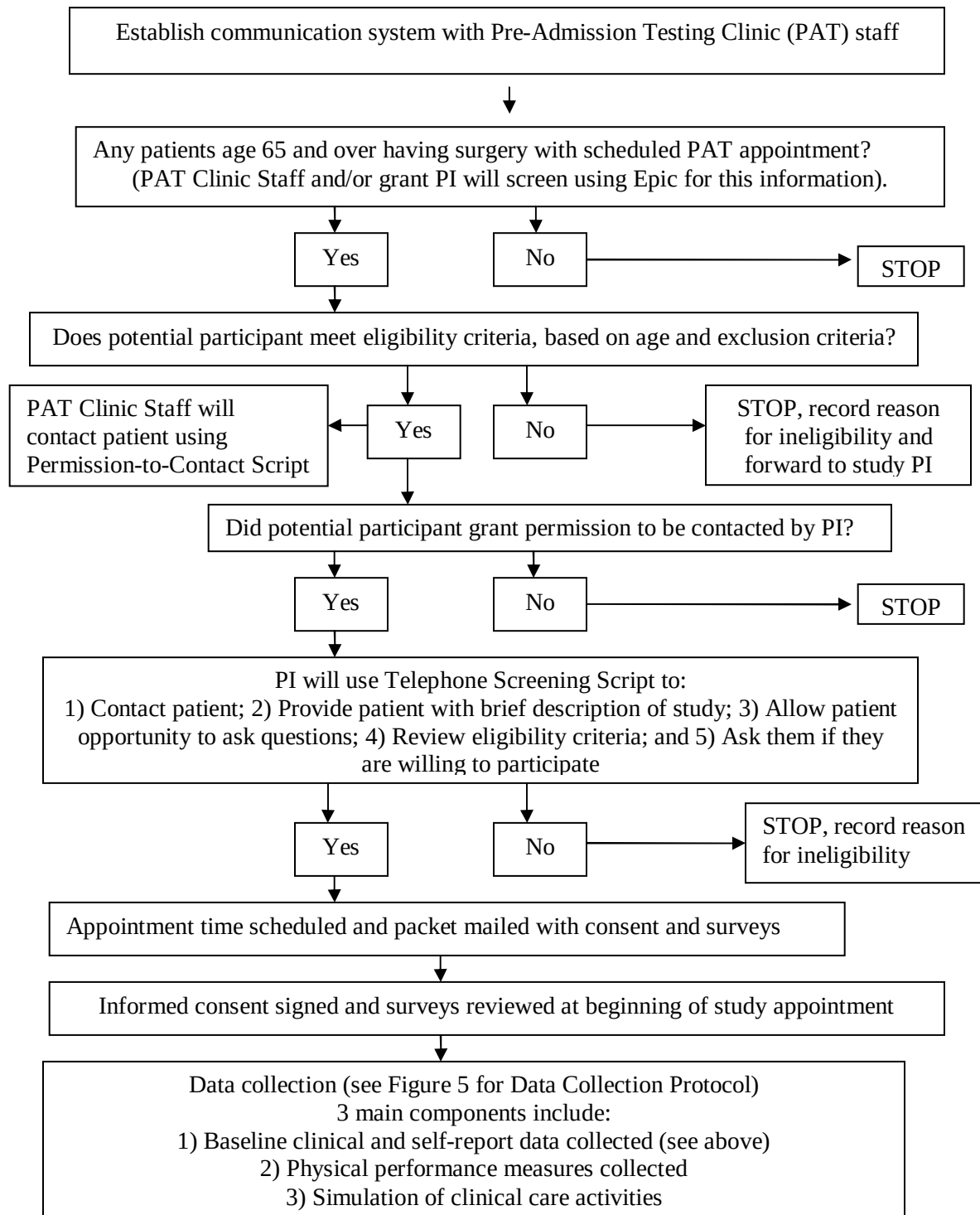


Figure 4. Study Protocol

Prior to beginning recruitment, all OHSU surgeons were identified through the Department of Surgery roster; 86 surgeons were sent an opt-out letter seeking permission to provide information about enrollment in the study to all their patients 65 and older who were scheduled for a major surgery and a PAT appointment. During the study, an additional four surgeons were identified and contacted individually because potentially-eligible patients of theirs were identified through the PAT clinic schedule. These additional surgeons provided consent for their patients to participate prior to data collection.

Recruitment began March 1, 2008. A variety of strategies were employed to screen and recruit eligible participants. Initially, the PI worked with the PAT Clinic Manager and a hospital Case Manager, both nurses, to develop a Recruitment Protocol in which one or both (called PAT RNs) would screen the upcoming surgery schedule at least weekly for potentially eligible patients age 65 and over who had an upcoming surgery in two to three weeks. The PAT RNs used a Permission-to-Contact Script to telephone potentially eligible patients and ask permission of the patient for the PI to call them about participating in the study. If given permission to contact the patient, the PI then used the Telephone Screening Script to further describe the study and determine the patient's eligibility. However, because of PAT clinic staffing changes, hospital reallocation of resources affecting the PAT clinic, and the introduction of a computerized charting system to the entire hospital network (Epic), this screening protocol became impractical because of competing demands on the time of the PAT RNs.

Rather than solely rely on recruitment through the PAT RNs, in March/April 2008, the PI also approached the nurse managers and/or surgeons of the surgical clinics

with the highest volume of patients 65 and older about recruiting patients for the study—orthopedic, neurosurgery, general, vascular, and cardiothoracic surgery (University HealthSystem Consortium, 2006). Tear flyers describing the study and providing the PI's contact information—intended to recruit patients directly—were posted in bathrooms of the Physicians' Pavilion (housing several surgical clinics), the PAT clinic, and waiting rooms of multiple surgical clinics at Physicians' Pavilion and the Center for Health and Healing. The PI also approached clinic management of multiple surgical services about working through clinic nursing staff or clinic schedulers to identify potentially eligible patients. Brochures were distributed to clinic management describing the study. Most clinics indicated that, despite theoretically supporting the study, the workload of clinic staff, the perceived inability of non-clinical staff to determine potential eligibility, and the priority of each clinic's own research screening and enrollment prevented them from actively participating in recruitment for the study. Only the Digestive Health clinic agreed to use their clinical nurse coordinators to screen for eligible patients. However, none of these clinic-oriented strategies yielded any referrals. Ultimately, the same group of patients, surgical patients 65 years and older, were attempted to be recruited as potential participants in three ways—indirectly through tear flyers, through their surgeon's clinic practice, and through the PAT clinic.

Because of the difficulties recruiting through the PAT clinic, the PI met regularly with the PAT Clinic Manager to identify new potential approaches to screening. In May 2008, the study received IRB approval for the PI to screen for potentially eligible patients using the new Epic computerized charting system. The Recruitment Protocol was revised, providing a system for weekly updates of a screening list to be shared by the PI with the

PAT RNs, reversing the original strategy and giving the PI responsibility for the screening process. The use of the Permission-to-Contact script by the PAT RNs and the Telephone Screening Script by the PI remained the same. Again, follow-up with potentially eligible participants by the PAT RNs continued to be irregular and difficult, resulting in zero contacts or referrals back to the PI for a period of six weeks, beginning June 2008, and a decrease in study appointments during July and August (Table 2).

In August 2008, the PAT Clinic Manager agreed to utilize a designated nurse practitioner (NP) within the PAT Clinic as a recruiter (PAT NP), rather than the manager or case manager, to make weekly follow-up calls of patients identified by the PI as potentially eligible. The PAT NP made these calls in between seeing clinic patients or during clinic downtime. In a span of 8 weeks, 50 potentially eligible patients were contacted and referred to the PI for potential enrollment, yielding 38 enrolled participants. This recruitment strategy using the PAT NP was sufficient to complete enrollment, which ended during the first week of October 2008.

Table 2. *Completed Study Appointments by Month*

2008	April	May	June	July	August	September	October
Completed Appointments	3	5	13	5	7	26	1

A total of 799 patients 65 years and older were screened by the PI using the Epic computerized system to evaluate the PAT clinic schedule each week. Of these patients, 524 were ineligible. See Table 3 for reasons for ineligibility upon screening. Of the

Table 3. *Reasons for Ineligibility upon Screening*

Reason for Ineligibility	Relationship to Eligibility Criteria	Number Ineligible
Short Stay	No hospital admission or overnight stay	219
CEI (Eye Surgery)	No hospital admission or overnight stay	133
First-time consult or inpatient surgery not yet determined	Surgery requiring hospital admission not yet decided	47
Metastases or recurrent cancer	Too burdensome for patient	23
Multiple appointments on one day	Too burdensome for patient	15
Altered mental status	Unable to cognitively participate in study	8
Too disabled	Unable to physically participate in study	7
Non-English speaking	Unable to listen, read and understand study surveys and instructions	5
Communicable disease	Study room unable to accommodate	4
Parkinson's Disease	Involuntary movements could influence primary study measures	3
Previously determined ineligible/declined	On PAT clinic schedule for 2 nd time after already having been determined ineligible or previously declining study	3
In hospital already	Unable to physically participate in study	2
Multiple reasons for ineligibility		6
Unknown		49
Total Ineligible upon Initial Screening		524

remaining 275 potentially eligible patients, 101 did not receive follow-up from the recruiter (PAT RNs or PAT NP) because of a lack of recruiter time for the reasons described above. Recruiters contacted 82 patients who did not enroll, 61 of whom were not interested in participating in the study or were deemed ineligible by the recruiter. The PI followed up with the other 21 of these patients, at which time they were determined to be ineligible or they were no longer interested.

A total of 157 patients were contacted by the recruiter and 96 agreed to be contacted by the PI to learn more about the study. Seventy-five patients were enrolled with 60 completing their study appointments (Table 4). Thirty-six participants completed the study appointment on the same day as their PAT appointment, with the remainder scheduling the study appointment on a separate day. Reasons for the 15 study appointment cancellations included emergent hospital admissions after enrollment (2), clinic appointments running late (6), travel delays (1), physically unable to complete the study appointment (2), or persons who changed their minds (4).

Table 4. *Summary of Screening and Enrollment*

Screening or Enrollment Activity	Number of Patients
Screened, but not eligible	524
Screened and potentially eligible	275
Screened, not called by recruiter	118 (includes 17 after study closed to enrollment but who had been screened)
Total Screened	799
Screened, called by recruiter, but not eligible (5) or not interested (56)	61
Screened, called by recruiter, called by PI and not eligible or interested	21
Enrolled and cancelled	15
Enrolled and appointment completed	60
Total Enrolled	75

Consent and Enrollment

For the 96 patients who agreed to be contacted about the study, the PI telephoned each patient to explain the study's purpose, procedures, risks, and benefits. If the patient remained interested in participating, then the PI determined the patient's eligibility by asking questions regarding the inclusion and exclusion criteria. If the patient was eligible and agreed to be in the study, the PI obtained contact information to mail a cover letter, directions, consent form, and study surveys to complete before the study visit in an effort to most fully respect participants' time. Moreover, to decrease participant burden of traveling to OHSU, the PI coordinated the study appointment time in conjunction with the patient's surgical and PAT appointments on the same day. Participants were given an option to schedule a study appointment on a day separate from these appointments if they desired. At the end of each call, the PI provided her contact information for questions or issues that might arise prior to the scheduled PAT appointment.

The participant was directed to review the consent form (Appendix A) when he or she received it by mail, but to wait to sign it until the beginning of the study appointment. A separate media consent (Appendix B) was not mailed. The participant read the media consent at the beginning of the study visit. It described how the video taken during the study visit could be used as part of research or clinical training or for the dissemination of study results. The PI then reviewed both consents with participants before having them sign each one. Each participant received a signed copy of the primary and media consents.

Data Collection

The research team consisted of the PI and three RNs with hospital experience who were enrolled in graduate nursing programs and served as research assistants (RAs). The RAs received training by the PI at OHSU in the conduct of research, completed all necessary paperwork required of the OHSU IRB, and were trained on the administration of the physical performance and other data collection measures. The RAs completed approximately 20 hours of training, which included completing study visits with 10 pilot participants (see below), with each RA collecting data on several pilot participants.

A data collection protocol, including a detailed description of the order of the simulation, was developed and tested before beginning the study (Figure 5). In February 2008, the study received IRB approval for a pilot study of 10 adults age 60 and older, recruited by convenience from the community, and not going to have surgery at OHSU. The pilot study's purpose was to trial the data collection protocol before beginning the official study and to train the three RAs on the protocol. The pilot data were not entered electronically nor analyzed in this study. Pilot participants received the same gift certificate as official study participants upon completion of their study visit.

The average total study appointment was 60 to 90 minutes. Breaks were provided to participants as needed. Enough time was allowed during the study appointment for review and signing of the mailed consent form and the media consent form and data collection. After consent documents were signed, the mailed self-report surveys, including the Sociodemographic Questionnaire, the Brief Co-Morbidity Questionnaire (BCM-Q), and the Brief Pain Inventory (BPI) were reviewed for completeness. A fourth

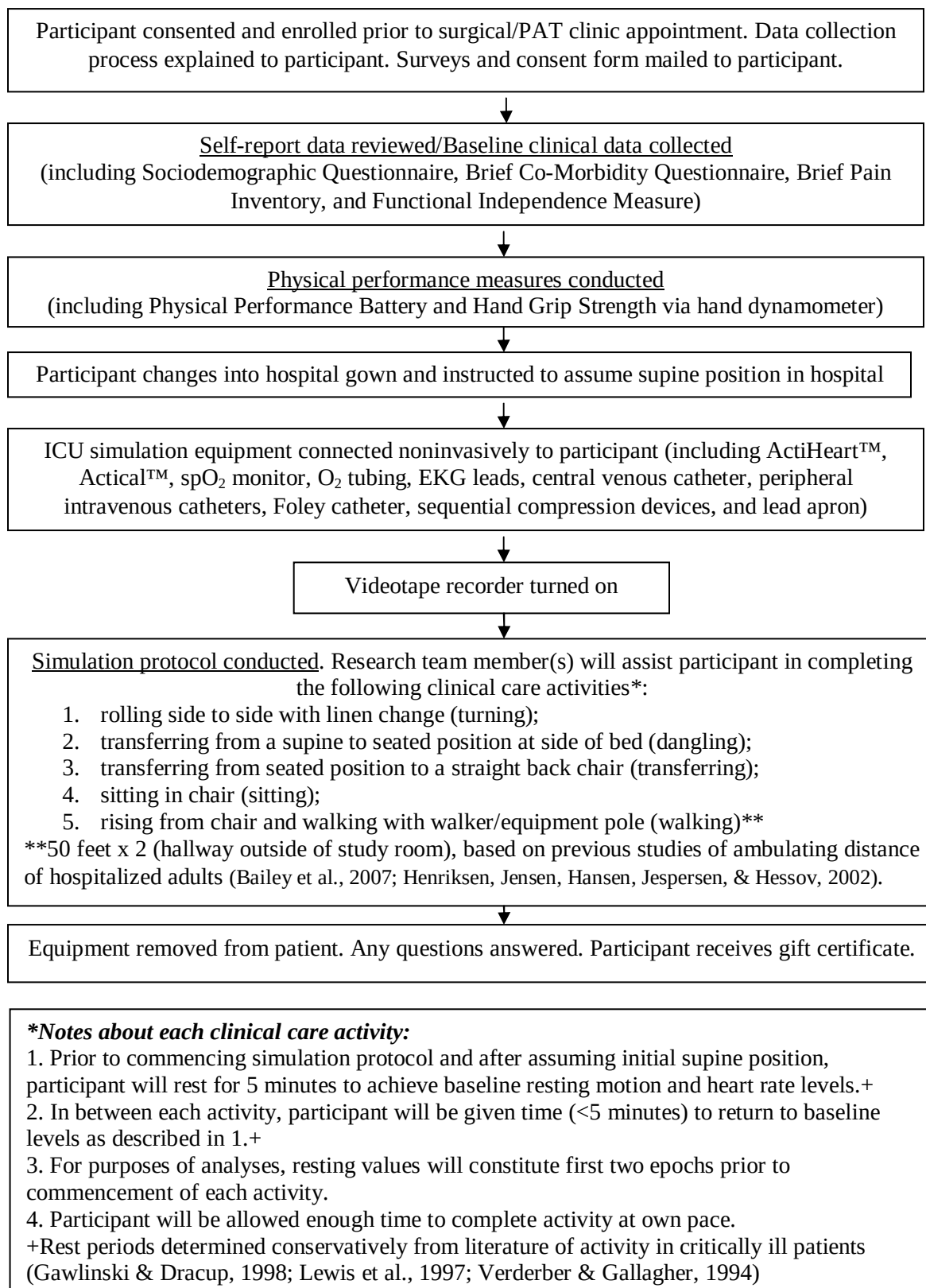


Figure 5. Data Collection Protocol

survey, the Functional Independence Measure (FIM), was completed during the study appointment. Participants were assisted in completing any forms (e.g., reading items to them) as needed. Baseline clinical data were collected and participants then completed the physical performance measures, including the Standing Balance test, Walking Speed test, and Chair Stand test, as well as a test of grip strength using a handheld dynamometer. After the physical performance measures were completed, the participant changed into a hospital gown for the simulation portion of the protocol.

The simulation protocol consisted of five simulated clinical care activities (turning, dangling, transferring, sitting, and walking) and lasted approximately 30 minutes. The participant assumed an initial supine position in a hospital bed. After the relocation to new study space, an automated hospital stretcher, versus hospital bed, was used for the remainder of the study. For the walk activity, an IV pole was used, since most ICU patients ambulate only while connected to continuous monitoring and intravenous infusions attached to an IV pole. If a participant used a walker or other assistive device normally, they were invited to use the device for any of the activities. The two leads with electrodes of the Actiheart™ were attached noninvasively in the manner specified by the protocol and the manufacturer to measure motion and heart rate. The Actical®, a wristwatch-like accelerometer, was fastened around the participant's nondominant wrist per manufacturer's protocol. It measures only motion, which was not analyzed for purposes of this study. The Actical® was used only for its time stamp, which marked the beginning and end of each activity to help interpret the Actiheart™ data during analysis.

Additional equipment characteristic of standard ICU monitoring was also attached noninvasively (with tape) to more fully simulate the hospital environment, including an spO_2 monitor, O_2 tubing, EKG leads, a central venous catheter, peripheral intravenous catheters connected to an infusion pump, Foley catheter, and sequential compression devices placed to the bilateral lower extremities. Participants also wore a weighted lead vest with $\frac{1}{2}$ pound weights totaling approximately 5% of their body weight. Weights were placed in pockets on the front of the vest and helped to simulate both the restricted motion characteristic of being in a hospital environment with equipment attached as well as the gain of water weight typical after major surgical procedures (Metheny, 1983).

Once the equipment was connected, the videotape recorder was turned on and the following positions were assumed: 1. rolling side to side with a linen change (turning); 2. transferring from a supine to a seated position at the side of bed (dangling); 3. transferring from a seated position to a straight back chair (transferring); 4. sitting in a chair (sitting); and 5. rising from the chair and walking, with walker/equipment pole if necessary (walking). Every participant performed the activities in this predetermined order to most closely simulate the natural progression of postoperative activity. A five-minute rest period occurred in between each activity, with the exception of the sitting activity, which began immediately upon transfer from the bed to the chair. Each activity was monitored using the Actiheart™, the Actical®, and videography, in order to closely synchronize the collection of motion and heart rate data, ensuring the accurate interpretation of the Actiheart™ data during each activity. Data were also collected on such variables as whether an assistive device was used or if any unusual events occurred

during the study appointment. At the end of the appointment, participants received a \$40 gift certificate to a local grocery store chain with unrestricted use and no expiration date.

Measures

This study used a variety of instruments to collect data regarding the participants' preadmission health, pain, physical performance, and functional ability, as well as their motion and heart rate response to the activities of the simulation protocol. Table 5 presents each measure in relationship to the concepts examined in the study and guided

Table 5. *Study Measures Related to Concepts within Disablement Process Model*

Disablement Process Terms/Factors	Related Concepts of Proposed Study	Measures/Indicator
Pathology	Etiology of condition requiring surgery (aneurysm, osteoarthritis, e.g.)	Data Collection Form, Surgery Type question
Impairment	Symptoms, including those related to active pathology	Brief Pain Inventory BCMQ Symptom Checklist
Functional Limitations	Upper body strength	Hand grip strength via hand dynamometer
	Lower body strength	Physical Performance Battery
Disability	Functional status	Functional Independence Measure
Risk Factors	Sociodemographics	Sociodemographic Questionnaire
	Morbidity/Disease	BCMQ Medical Condition Checklist
	Age, BMI	Sociodemographic Questionnaire (Age) Data Collection Form (height, weight)
Extraindividual Factors	Clinical care activities	Motion counts via the Actiheart™
Intraindividual Factors	Physiologic responses to clinical care activities	Heart rate via the Actiheart™

by the Disablement Process conceptual framework (Nagi, 1965; Verbrugge & Jette, 1994). These tools used to assess active pathology, impairment, functional limitations, disability, and other factors in the model have all been used previously in studies of older adults. The use of accelerometry has also, though not extensively, been tested in older adult populations. A copy of all the instruments that were used in this study is provided in Appendices C through G.

Primary Outcome Measures

Accelerometry and Heart Rate

Participant motion and heart rate response to clinical care activity was measured using a combined heart rate and motion sensor, the Actiheart™ (model 910-0023-01, Mini Mitter, Bend, OR). A traditional uniaxial accelerometer is a computerized wristwatch-like device worn on the wrist or ankle to collect data generated by body movements in a single vertical plane, integrating degree and intensity of motion (Tyron, 1991). A variation of the accelerometer, the Actiheart™, uses a piezoelectric element to record both motion in the vertical plane and heart rate data simultaneously, and was used for this study. The Actiheart™ consists of a two-lead sensor system placed using electrodes near the center of the sternum and then parallel along the mid-clavicular line. See Appendix H for a photograph of Actiheart™ placement. The Actiheart™ has been shown to be more sensitive to low-intensity activities than an accelerometer alone, improving the accuracy of low-level activity assessment (Brage et al., 2005; Strath et al., 2005). Participants wore the device only during the simulation protocol and data were downloaded to an IBM-compatible computer using a reader/charger and the device's application program.

Data from the Actiheart™ was scored internally based on predetermined computer algorithms, with motion recorded in counts per minute (cpm). Parameters for frequency, sensitivity, and threshold are typically adjustable. For this study, 15-second intervals (the instrument's most frequent epoch level) were used for greatest accuracy in detecting movement, similar to intervals used in other studies that used accelerometry to measure activity in critically ill patients (Grap et al., 2005; Weinbroom, Ben Abraham, Ezri, & Zomer, 2001). Data results in 256 distinct levels of acceleration (128 positive and 128 negative), reflecting a range from no activity to vigorous movement. The monitor is designed to detect accelerations up to a magnitude of 2 *g* with a frequency response between 1 and 7 Hz. Heart rate is measured when the Actiheart™ detects the QRS complex through identification of the R-wave line of steepest descent, with a range of 35 to 255 bpm, a sampling frequency of 128 Hz, and an input impedance of 10 MΩ.

Reliability and Validity of Actiheart™ in a Clinical Setting

The Actiheart™ has demonstrated reliability and validity in participants in laboratory settings (Brage et al., 2005; Thompson et al., 2006). What was not yet known prior to this study is whether it is sufficiently sensitive to detect activity patterns in clinical settings and in older adults. Thus, this feasibility study provided an in-depth examination of the Actiheart™ during five simulated clinical care activities. Although not explicated as a specific aim of this study, aspects of the Actiheart's™ reliability and validity were also evaluated as part of the study's three aims.

Measurements of **reliability**, the lack of distortion or the precision of the measuring instrument, typically include an evaluation of **stability**, **internal consistency**, and **equivalence** (Kerlinger & Lee, 2000) to evaluate the extent of random error (Burns

& Grove, 2001). For **stability**, each Actiheart™ is calibrated by the manufacturer and only one device was used in this study. Correlation analyses evaluated the relationship between heart rates across activity and motion counts across activity to address issues of the **internal consistency** of the Actiheart™, the extent to which all of an instrument's subparts measure the same characteristic. Internal consistency and **equivalence** (comparing two versions of the same instrument or two observers measuring the same event) (Stangor, 2004) was enhanced by the use of one device, the Actiheart™, on all participants that simultaneously measured heart rate and motion. Moreover, two additional devices, a videotape recorder and another type of accelerometer, the Actical®, were used to enhance the reliability of the Actiheart™ by verifying the occurrence of each activity period.

The study used the Actical®, a triaxial accelerometer worn on the participant's nondominant wrist, to help triangulate and interpret the Actiheart™ data. The Actical® features a time stamp, which allows the user to mark certain activities or time periods of interest. In this case, while the motion data from the Actical® was not used for purposes of analysis, the Actical® time stamp was pressed by the data collector at the beginning and end of every activity. The two devices, the Actical® and Actiheart™, were synchronized during calibration before being applied to each participant. This allowed the time stamp information of the Actical® to inform the interpretation of the Actiheart™ data during data analysis. See Preliminary data management and analysis in the Data Analysis Plan section.

Furthermore, the videotape recording of each participant's clinical care activity simulation was viewed as part of the analysis of the motion and heart rate data recorded

by the Actiheart™. Reliability was also optimized by consistent placement of the device, consistent time provided between activities for participants to return to baseline levels as described above, well-defined protocols for set up and administration of the protocol, and consistent administration of the protocol resulting from data collector training. Participants performed the activities in a predetermined order to most closely simulate the natural progression of postoperative activity.

Content validity examines the extent to which the measures include all major elements of a construct and usually involves verification by content experts and the literature (Kerlinger & Lee, 2000). In this study, content validity included the use of an expert panel to evaluate the procedures used for data collection, analysis, and scoring, and during analysis to evaluate the motion and heart rate patterns. Expert consultation was received primarily through e-mail and telephone exchanges with an exercise physiologist, several geriatric nurse researchers, and a health sciences statistician. An extensive literature review, in addition to clinical knowledge, informed the study's development, including the selection of clinical care activities and the selection of the Actiheart™ to evaluate the construct of activity.

Criterion validity compares scores of the identified construct with one or more external variables (Kerlinger & Lee, 2000). *Concurrent validity* measures the construct at the same time with two measures of the construct, usually with one as a gold standard (Kerlinger & Lee, 2000). This study used heart rate and motion to measure activity simultaneously. In the ICU setting, the measurement of SvO₂, using a pulmonary artery catheter, to evaluate patients' physiologic response to activity is considered the gold standard; however, heart rate was used in this study since these catheters are invasive,

expensive, and not used for all ICU patients. In activity studies, the use of doubly-labeled water to measure energy expenditure is often considered the gold standard criterion against which accelerometry is evaluated. However, its expense, invasiveness, and requirement for a laboratory setting made its use unfeasible for this clinical application study.

Construct validity, the most important type of validity, aims to validate not just a measure or test, but the theory behind the test (Carmines & Zeller, 1979). It includes aspects of content and criterion validity, but also requires convergence and discriminability. *Convergent validity* means that evidence from different sources gathered in different ways indicate the same or similar meaning of the construct (Kerlinger & Lee, 2000). In this case, heart rate, motion, and videography were all used to simultaneously measure activity during the simulated activities. Use of the Actiheart™ has been validated to discriminate between different types of activity, including low-intensity activities, but has not been tested in older adults or for clinical care activities (Brage et al., 2005; Strath et al., 2005; Thompson et al., 2006). Videography and the Actical® were used to validate motion and heart rate data to ensure that the Actiheart™ data were appropriately synchronized to the actual simulated activities. The use of videography to validate activity data has been used in past studies (Mann et al., 1994; Roberts, Srouf, & Winkelman, 1996; Tamura, Miyasako, Ogawa, Togawa, & Fujimoto, 1999). The study enhanced *discriminant validity*, that the device could empirically differentiate a construct from other similar constructs (Kerlinger & Lee, 2000), by measuring and statistically controlling for a number of covariates (for example, pain), which might influence the participant's movement and/or heart rate, and by simulating the ICU environment as an

element of control. Moreover, participants were provided with adequate time for their activity and heart rate levels to return to baseline to more purely discriminate across and within the five different types of activity, also adding to construct validity.

Covariate Measures

Sociodemographics

Sociodemographic data included: age; gender; ethnicity and race; years of education; household income; marital status; and employment status. These data were collected using the Sociodemographic Questionnaire, developed by Center for Research in Chronic Disorders (CRCD) at the University of Pittsburgh School of Nursing. It was adapted from income and education questions used in the 2000 United States (US) Census (Bender et al., 2008).

Health Assessment

The Brief Co-Morbidity Questionnaire (BCMQR) assessed for past medical history and current disease comorbidities of 49 specific conditions. The BCMQR, also developed by the CRCD, was adapted as a questionnaire from the Charlson Index of Comorbidity. The Charlson Index has been used extensively in older adults as a reliable and valid measure of comorbid conditions, with each category weighted and scored according to an established algorithm (Charlson, Pompei, Ales, & MacKenzie, 1987). The BCMQR is not weighted and is calculated as a summary score, from 0 to 51, with higher numbers reflecting the presence of more comorbid conditions. Though no formal reliability and validity for the BCMQR has been published, studies have shown that the BCMQR is practical in samples that include older adults (Bender et al., 2008; Sereika, 2006). Anthropometric data was assessed, with height and weight measured in inches and

pounds using a calibrated standing scale (7530, Taylor Precision Products, Las Cruces, NM). Body mass index was calculated from height and weight using the commonly accepted conversion of kilogram (kg)/meter (m)².

Pain

The Brief Pain Inventory (BPI) was used to obtain self-report of pain symptoms. The BPI (Daut, Cleeland, & Flanery, 1983), originally constructed to assess cancer-related pain and the impact of pain on daily function, has become widely used to evaluate pain from other diseases (Keller et al., 2004; Mendoza et al., 2004). The BPI includes 15 items that address pain history, etiology, intensity, location, quality, and interference with activities and has been validated for use with older adults, with higher scores indicating worse pain or interference caused by pain (Kemp, Ersek, & Turner, 2005; McDonald, Thomas, Livingston, & Severson, 2005).

The BPI includes ratings of average, current, least, and worst pain during the past week on a scale of 0 (no pain) to 10 (pain as bad as you can imagine) that create a single pain severity score, with a range of 0 to 10. Pain-related interference is rated as 0 (does not interfere) to 10 (completely interferes) for general activity, mood, walking, work, relationships, sleep, and enjoyment of life. The calculated pain interference score includes these 7 activities, with a range of 0 to 10. In older adult populations, Cronbach's alpha for the BPI has ranged from 0.77 to 0.95 (Kemp et al., 2005; McDonald et al., 2005; Zalon, 2004).

Physical Performance

Upper body strength. Handgrip strength was measured in kilograms (kg) using a hand dynamometer (Grip-D, Takei, Japan) in a standing position with the arm and hand straight and at the hip as described in the manufacturer's instructions. This test has been shown to correlate with elbow flexion strength, knee extension strength, and trunk extension strength, reflective of total body muscle strength (Rantanen, Era, & Heikkinen, 1994) and to be a robust predictor of mortality and disability (Rantanen et al., 1999; Rantanen et al., 2000). Two trials were conducted, one on each arm, with four values recorded. For purposes of analysis, a mean of the four measurements of both arms were used, with higher scores indicating greater arm strength.

Lower extremity function. Lower extremity function was measured by the Physical Performance Battery (PPB), which has been shown to reveal physical difficulties earlier than self-report of ADL difficulties and to prevent future hospitalizations when used as a screening tool (Guralnik et al., 1995; Guralnik, Simonsick et al., 1994; Penninx et al., 2000; Sager et al., 1992). The PPB includes three tests, a standing balance test, gait speed over 4 meters, and five chair stands. The PPB's reliability and validity is well established in older outpatient populations (Guralnik, Seeman, Tinetti, Nevitt, & Berkman, 1994; Penninx et al., 2000) and more recently has been successfully used in older hospitalized populations as well (Denkinger et al., 2009; Morrison, Flanagan, Fischberg, Cintron, & Siu, 2009).

The PPB tests were conducted using standard protocols. For the standing balance test, participants were shown and then asked to stand in a semi-tandem stance, with the heel of one foot placed to the side of the first toe of the other foot. If the participant was

able to hold this position for at least 10 seconds, they were then asked to stand in a full-tandem stance, with the heel of one foot directly in front of the toes of the other foot. Again, this position was timed and recorded. If the participant was unable to complete the semi-tandem test for 10 seconds then they were instructed to do a side-by-side test, with the feet together, next to one another. This test is scored on a 0 to 4 scale, with 4 reflecting completion of both the semi-tandem and full tandem for 10 seconds each.

For the walking speed test, the participant began walking from a standing start, walked along a straight path that was measured to be 4 meters and marked at both ends of the course. They were instructed to walk at their usual speed two times, starting from the same location each time, with the faster of the two scores used for scoring. The score of 0 to 4 reflects the quartiles published by Guralnik (2000), with the quartiles determined by dividing the meters walked by the number of seconds to equal meters per second.

In the chair stand test, the participant sat on a straight-back chair next to a wall. With arms folded across the chest, they were asked to stand up from the chair one time. If they were able to complete this attempt, they were instructed to stand up and sit down five times as quickly, but as safely, as possible. The data collector timed the activity from the initial sitting position to the final standing position at the end of the fifth stand. Scores of 0 to 4 reflect the number of seconds required to perform the five stands (Guralnik, Simonsick et al., 1994). The PPB total score for the three tests ranges from 0 to 12; higher scores reflect better lower extremity function (Guralnik et al., 1995; Guralnik, Seeman et al., 1994).

Functional Status

The Functional Independence Measure (FIM) measured functional status using an 18-item, 7-level scale (1 being completely dependent to 7 being independent without device) of independent performance in self-care, sphincter control, transfers, locomotion, communication, and social cognition (Fiedler, Granger, & Post, 2000). The FIM includes motor (13 items) and cognitive (5 items) components. Although originally developed for use in stroke rehabilitation, it has been validated for use in other settings and populations. For example, Dodds and colleagues (1993) found the FIM to have high internal consistency (0.93) for inpatient rehabilitation patients. The FIM has also been shown to be reliable and valid in the oldest-old, aged 80 years and above and across settings (Pollak, Rheault, & Stoecker, 1996). Total possible scores range from 18 (lowest) to 126 (highest level of independence).

Additional Covariates

Additional covariates included whether the participant was currently using a beta-blocker, known to blunt the response of heart rate to physical activity and identified as a potential confounder to the study's heart rate outcomes (Lehne, 2001). Whether the participant used any assistive device during any of the activities was also considered a covariate. Using a walker, IV pole, or cane, for example, presented a potential influence to the measurement of motion since arms in a semi-fixed position holding such a device could alter the body's natural gait. Table 6 summarizes the primary covariate measures.

Table 6. *Summary of Primary Covariate Measures*

Covariate Measure	Measure/Indicator	Scale of Measure	Variable Type
Age	Sociodemographic Questionnaire	Age $\geq$ 65	Continuous
Gender	Sociodemographic Questionnaire	Male/Female	Dichotomous
BMI	Data Collection Form	kg/m ²	Objective Continuous
Pain	Brief Pain Inventory	0-10 Pain severity	Self-report Continuous
Upper body strength	Hand grip strength via hand dynamometer	kg	Objective Continuous
Lower body strength	Physical Performance Battery	Score 0-12	Objective Continuous
Functional Status	Functional Independence Measure	Score 18-136	Self-report Continuous
Morbidity	Brief Co-Morbidity Questionnaire	Score 0 to 51	Self-report Continuous
Beta-Blocker Use	Brief Co-Morbidity Questionnaire	Yes/No	Self-report
Assistive Device Use	Data Collection Form	Yes/No	Objective

Data Analysis Plan

Preliminary Data Management and Analysis

Non-accelerometry data were entered into a secure, web-based data management software program called Research Electronic Data Capture (REDCap). This application was designed to collect and report data for specific research projects and is hosted at OHSU by the Oregon Clinical and Translational Research Institute (OCTRI) through grant support (1 UL1 RR024140 01). It is accessed using a custom password-protected online data-entry website with data stored on OHSU servers that are compliant with

Secured Socket Layer (SSL) protocol and Health Insurance Portability and Accountability Act (HIPAA) requirements. The study's data entry forms were designed by the PI, with technical assistance provided by OCTRI staff. Data entry was completed by entering data into web forms. Data were entered by four doctoral candidates, with 100% verification conducted by the PI. Once data entry and cleaning were completed, the REDCap-housed study data were exported to Statistical Program for Social Sciences (SPSS) 16.0 Graduate Pack (GP) for analysis.

For the accelerometry data, an expert panel guided the PI in various aspects of data analysis, including Drs. Kerri Winters-Stone, an expert in collection, analysis, and interpretation of accelerometry data, and George Knafl, a statistical expert in electronic monitoring device data analysis. For purposes of analysis, the simulation protocol included five clinical care activities: 1. turning; 2. dangling; 3. transferring; 4. sitting; and 5. walking. Please refer to Table 7 for an overview of the analysis plan. Each participant's motion and heart rate data was first exported from the Actiheart™ software program into Microsoft® Excel 2002. Actical® data for each participant was also exported into the same Excel spreadsheet so that every participant had a single Excel data file with both Actiheart™ and Actical® data in it. Prior to exporting the motion data to SPSS for statistical analysis, the Actiheart™ motion and heart rate data were analyzed using a detailed Accelerometry Analysis Protocol (see Appendix I) developed by the PI and validated by members of the PI's dissertation committee. These analyses included a review of the videotape recordings to interpret and validate the Actiheart™ data for each participant.

Table 7. *Overview of Analysis Plan*

Aim	Aim Description	Variable	Measure/Indicator	Analysis
1	Patterns of motion and heart rate (HR) during 5 clinical care activities	Motion Heart Rate	Actiheart™	Descriptive; calculation of pre-activity, total, minimum, and maximum motion Descriptive; Calculation of pre-activity, average, and maximal HR
2	Compare motion and HR <u>across</u> 5 clinical care activities	Motion HR	Actiheart™	7 repeated measures analysis of variance (RMANOVAs); 3 for HR (pre-activity, average, and maximal); 4 for motion (pre-activity, total, minimum, and maximum)
2	Compare motion and heart rate <u>within</u> each clinical care activity	Motion HR	Actiheart™	10 RMANOVAs for turning, dangling, transferring, sitting, and walking (5 motion; 5 HR)
3	Explore covariates of Actiheart™'s ability to measure motion and HR	Age Gender BMI Assistive Device Used Pain Functional Performance Functional Status Comorbidity Beta-blocker use	Sociodemographic Questionnaire Data Collection Form Brief Pain Inventory Hand grip strength PPB Functional Independence Measure Brief Co-Morbidity Questionnaire	Repeated measures ANCOVA using motion and HR as dependent variables

Motion and heart rate values for each participant were calculated and included pre-activity motion values (using the first two epochs prior to commencement of each activity), minimum, maximum, and total motion (across all epochs of that activity) for all five activities. Similarly, for heart rate, calculated data for each participant included pre-activity and average heart rates, as well as maximal heart rate for each of the five activities. For purposes of validation, data for six participant records were re-analyzed using the Accelerometry Analysis Protocol, revealing consistency of results on all but 2% of 252 calculated values.

Initial Analysis

Statistical analyses were conducted using SPSS 16.0 GP. A p -value of < 0.05 was the criterion used to determine statistical significance. Prior to the analysis addressing the specific aims, distributions of all variables were examined for normality using descriptive statistics and plots to identify excessive skewness or outliers.

Analysis of Primary Aims

Aim #1

Describe the patterns of motion and heart rate during five different clinical care activities (turning, dangling, transferring, chair sitting, and walking).

Using the motion and heart rate data analyzed for each participant, values were calculated including those for pre-activity, average, and maximal heart rates, as well as pre-activity, minimum, maximum, and total motion counts for each activity. Patterns for motion and heart rate values were plotted for each activity for each participant. Separate plots for motion (cpm) and heart rate (bpm) were generated for each participant that included all five activities on a single plot.

Descriptive statistics were then calculated across all participants for each of the five activities. For motion, summary statistics included pre-activity values, minimum, maximum, and total motion counts. Similarly, for heart rate, summary statistics across all participants included pre-activity, average, and maximal heart rate values. The resultant analyses produced 7 values (4 for motion and 3 for heart rate) for the 5 activities. Additional calculations were done to examine the data without the influence of outliers by eliminating cases with values greater than two standard deviations above the mean.

Aim #2

Compare clinical care activities using continuous motion and heart rate data to discriminate motion and heart rate both across and within five different clinical care activities.

Repeated measures analysis of variance (ANOVA) was used to determine differences across the five activities using the calculated values for motion (pre-activity, minimum, maximum, and total) and heart rate (pre-activity, average, and maximal). Clinical care activity was the within-subjects factor, with five levels (five different activities). Seven repeated measures analyses were conducted: Pre-Activity Motion, Minimum Motion, Maximum Motion, Total Motion, Pre-Activity Heart Rate, Average Heart Rate, and Maximal Heart Rate. For example, the pre-activity heart rate was evaluated across turning, dangling, transferring, chair sitting, and walking.

Repeated measures ANOVA was also used to determine the differences in heart rate and motion within each of the five activities using the calculated values for heart rate and motion. Heart rate and motion were the within-subjects factors, with three levels for heart rate (pre-activity, average, and maximal) and three levels for motion (pre-activity,

minimum, and total). Maximum motion was not included for purposes of the within-activity analyses because in many cases, it was not significantly different than total motion. Ten repeated measures analyses were conducted: Turn Heart Rate, Turn Motion, Dangle Heart Rate, Dangle Motion, Transfer Heart Rate, Transfer Motion, Sit Heart Rate, Sit Motion, and Walk Heart Rate, and Walk Motion.

The assumptions associated with the repeated measures ANOVA were tested, including assumptions of independence, normality, and homogeneity of variances similar to the traditional ANOVA (Turner & Thayer, 2001). Because of the sometimes irregular nature of heart rate and motion data, particularly in older adults, the non-parametric Friedman test was also used to evaluate all analyses to account for any outliers. Results from the Friedman test, which does not require a normal distribution of the data, were compared to results from the repeated measures ANOVA (Gibbons, 1993). For any cases of missing values within the sets of repeated measures data, data were restructured for those analyses and re-analyzed using a univariate analysis, with a random participant effect, with results compared to the original repeated measures ANOVA.

Additionally, repeated-measures tests also require the assumption of compound symmetry. If this assumption is violated, as is often the case in behavioral sciences, and the analysis does not account for this violation, there is a risk of a Type I error, rejecting the null hypothesis and finding a significant difference that does not truly exist (Turner & Thayer, 2001). Compound symmetry was assessed using Mauchley's Test of Sphericity. For cases with a statistically significant Mauchley's (indicating a violation of the assumption of compound symmetry), the multivariate test was used, which does not require this assumption. All analyses in this study used the multivariate tests based on

very significant Mauchley's. Results of one of the most common multivariate tests, the Wilk's lambda, were reported (Muller & Barton, 1989; Turner & Thayer, 2001). For analyses with significant results, differences in the means across and within the activities were assessed using simple (first) and repeated measures contrasts to determine the significant relationships between selected pairs of activities. Multiple pairwise comparisons, corrected by the Bonferroni procedure, were also examined for jointly significant pairs and in relationship to results of the contrasts.

Aim #3

Measure the effects of covariates (age, gender, BMI, pain, functional performance, functional status, comorbidity, beta-blocker use, and assistive device used during activity) on the ability of the Actiheart™ to measure motion and heart rate data during the simulation of clinical care activities.

The influence of these covariates on the results of each of the 17 ANOVA models (7 across-activity and 10 within-activity repeated measures ANOVAs) conducted as part of Aim #2 was assessed using repeated measures analysis of covariance (ANCOVA) with heart rate and motion the dependent variables. Covariates included in the model were age, gender, BMI, pain, functional performance, functional status, comorbidity, use of a beta-blocker, and assistive device used during the simulation of activities. The ANCOVA *F* test evaluated whether the population means on the dependent variable, heart rate and motion, adjusting for differences in the covariate, differed across and within the activities (Green & Salkind, 2005). Each covariate was analyzed separately. If *F* was significant, multiple pairwise comparisons were assessed to determine if and where there were

differences in the jointly significant pairs as compared to the pairwise comparisons from the original 17 models.

Protection of Human Participants

Privacy and Confidentiality

Privacy

Participants were recruited after being identified through the PAT clinic schedule prior to their surgical clinic and PAT appointments. Recruitment procedures were developed with respect to guidelines for protecting the privacy of hospitalized (in this case, pre-hospitalized) patients who are potential research subjects and in accord with IRB approval. Prior to beginning participant enrollment, OHSU surgeons were asked for permission to approach their patients age 65 and older who were scheduled to be admitted for a surgical procedure. Those physicians not included in the initial request were contacted individually by the PI if one of their patients was identified as a potential participant.

The privacy and confidentiality of potential participants was carefully considered in the recruitment procedures described in detail in the Screening and Recruitment in the Procedures section above. The PI did not speak to a potential participant until a PAT RN had asked whether the person was interested in hearing more about the study from the PI. When patients gave their permission for the PI to call them, they were screened by telephone. Those who wished to enroll gave their address for receipt of the mailed packet and consent form.

Confidentiality

The main risk of loss of confidentiality was the videotape recordings because participants could be identified. This threat was addressed by 1) transporting the recordings from the clinical site to the research office in a locked container; 2) storing the

recordings in a locked cabinet with access limited to the PI; 3) digitizing the tapes and saving the electronic files using a unique identifier and password protection; and 4) viewing/analyzing tapes behind closed doors so that they were not inadvertently seen by those not involved in the research. All RAs and the PI completed OHSU's required Human Subjects training before the beginning of the study. A media consent to use the videotape recordings for educational/training purposes only was signed by participants. For the confidentiality of the completed paper surveys and electronic data, see the Managing and Storing Data section below.

Managing and Storing Data

Each participant was assigned a unique code number. No one other than the PI had access to the master list with names and code numbers; this master list file was electronically password-protected and encrypted. Data collection forms and surveys contained only the code number, and identifying information such as name or address was separated from the rest of the forms. All informed consents, questionnaires, and data obtained from the simulation protocol were placed in a locked case and transported to the PI's work area where they were stored in a locked file. Data were housed in locked cabinets, with surveys and data forms separated from identifying documents, such as consent forms.

All data were entered into REDCap and analyzed by code number. Videotapes were kept in separate locked files. Electronic data were password protected, with backup files stored on a secure server in the OHSU computer system. Data will be kept until deemed no longer usable or until five years, whichever occurs first. It will be destroyed using cross-hatched shredding procedures. All videotapes were erased, with the digitized

video files saved using a unique code number and kept indefinitely for training and dissemination purposes. Accelerometry data were saved using a unique code number.

Study Monitoring, Auditing, and Inspecting

The investigator permitted study-related monitoring, audits, and inspections by the OHSU IRB, government regulatory bodies, and university compliance and quality assurance groups of all study-related documents (source documents, regulatory documents, data collection instruments, study data), although none occurred during the study. Issues in data quality and management were the primary responsibility of Colleen M. Casey (PI). This responsibility included the supervision of data acquisition, data verification, data audits, data cleaning, data management, and administration. When modifications to the study design, protocol, or documents were required, formal modification requests were submitted to the OHSU IRB for their review and approval.

Ethical Considerations

This study was conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations, and institutional research policies and procedures. The study's protocol and any amendments were submitted to the OHSU IRB for formal approval prior to beginning the study or modifying procedures. The decisions of the IRB concerning the conduct of the study were made in writing to the PI and a copy of these decisions kept on file.

Strategies for Ensuring Informed Consent

Enough time was allowed during the study appointment for consent and data

collection (approximately 60 to 90 minutes). The participant was given the option to schedule a study appointment on a day separate from their other appointments if desired. Once they arrived for the study appointment, patients were asked to sign the consent form they had received in the mail to indicate that their participation was voluntary and that they understood the purpose of research. A separate media consent was also explained and presented to them for their signature. By signing the media consent, they agreed that the videotape recording of the simulation part of the protocol could be used as part of research or clinical training or for dissemination of study results. Each participant received a copy of both signed informed consents.

Only after obtaining the consents from participants did data collection begin. The mailed surveys were reviewed for completeness and additional survey information was collected. Participants then completed the physical performance measures before beginning the simulation protocol. Participants were reminded that their participation was voluntary throughout data collection.

Potential Risks

The risks to study participants were low. Risks included fatigue and safety issues related to the simulation of clinical care activities (turning in bed, sitting on side of bed, standing from bed). A possible risk was that a simulated hospital environment might have caused participants some anticipatory anxiety. The primary risk of videotape recording participants was loss of confidentiality, because participants' faces appeared in the recordings. However, the recordings were recorded at a wide angle to depict the simulated activities and the surrounding environment of the room. There were no known

risks involved in completing the surveys or the physical and performance assessments, except for a slight risk of fatigue.

Protections Against Risk

Fatigue. Study inclusion criteria included being ambulatory and able to physically participate in the simulation protocol. These criteria excluded those patients who might not be able to physically tolerate participating in the simulation protocol or physical performance tests. Arrangements were made to take rest periods at the participants' request and to offer participants the option of scheduling the study appointment separately from their other appointments. The total study appointment time did not exceed 90 minutes, and in many cases, was completed in 60 minutes.

Safety. RAs were trained by the PI in correct body mechanics in assisting participants during the simulation protocol. Patients were encouraged and allowed to use any assistive devices that they typically used in their everyday activities. All devices used in the study (accelerometer, hospital bed, sequential compression devices, etc.) were approved by OHSU clinical engineering before use with participants. Each device was cleansed using industrial-strength antimicrobial cleaning wipes between data collection of each participant. The PI would have produced safety reports for the OHSU IRB to list any adverse events, serious adverse events, and deaths after each event were they to have occurred as required by the IRB. None of these occurred during the course of the study.

Anticipatory Anxiety. The research team recognized that the context of the study appointment might be an emotional time and expected that participants might share concerns related to their upcoming surgery that were independent of the study. The research team provided participants an environment in which to express any concerns if

necessary. If a participant's level of distress warranted the need for additional resources, with the participant's permission, the PI was prepared to inform the participant's primary surgical team for further evaluation and referral if necessary. This situation did not occur during the course of the study. In one case, a participant contacted the PI after the study appointment and after discharge from the hospital, with concerns related to her care in the hospital. The PI, with the participant's permission, referred the concerns to appropriate hospital management for follow-up.

Participants were reminded at each data collection point that their participation was voluntary, that they did not need to answer any questions they did not want to, and that they could withdraw from the study at any time without consequences to their medical treatment. Anecdotal, participants most often described the study appointment as beneficial in allowing time to answer basic questions about postoperative care and recovery and provide an orientation to the equipment and activities typically encountered post-surgically.

Confidentiality. See previous discussion of issues related to confidentiality and steps taken to protect against the risk of loss of confidentiality.

Inclusion of Minorities and Children

There were no exclusions for women or minorities. Both women and men of any race who met study inclusion criteria and did not meet any of the exclusion criteria were eligible. Generally, the study's final sample reflected the older surgical population at OHSU with regard to gender and race/ethnicity characteristic of the local area's older population. See a full discussion of Gender and Minority Considerations in the Feasibility of Recruiting Sample section. Children were not enrolled in this study because this study

tested the measurement of activity levels in older adults, age 65 and older, who are particularly vulnerable to the effects of inactivity during hospitalization, because of their chronologically-induced physiological changes and the increased likelihood of multiple, compounding comorbidities.

Ethnicity and race data were collected per National Institutes of Health recommendation. Respondents were asked to answer two separate questions: ethnicity and racial category. Respondents were able to select more than one racial category. Because the simulation protocol involved explicit giving of and following directions in English, only English-speaking participants were included.

Conflict of Interest

The principal investigator did not anticipate any financial gain from the study. Study participants and pilots received a \$40 gift certificate to a local grocery store chain as an acknowledgment of their time participating in the study.

CHAPTER 4

RESULTS

Pilot data collection occurred in February 2008 and helped the research team identify ways in which to improve the data collection protocol. For example, although the original protocol assigned each pilot participant to a randomized order of activities, pilot data collection revealed that this randomization of activity prevented the activities from being dosed similarly and did not simulate the natural progression of post-operative activity. This finding resulted in a protocol revision to use an ordered set of the five activities. Participant data were collected from March 2008 to October 2008, with 799 persons screened for potential enrollment. Of these, 157 were contacted and 75 people enrolled. Study visits were completed for 60 participants, meeting enrollment goals.

Data were primarily of two types: self-report data and physiologic data (heart rate and motion). Sixty persons provided self-report data with minimal (0.18%) missing data. No single case had sufficient missing self-report data to exclude it; all missing self-report data were less than 2% per participant. Heart rate and motion data were missing in two participants due to equipment failure, and another four participants had missing heart rate data to an extent that could not be reasonably estimated. These six participants were removed from the dataset prior to statistical analyses. Some heart rate data were missing for 4 participants (representing 1.1% of all participants' calculated heart rate values). When possible, these missing values were estimated using heart rate data from adjacent 15-second epochs. Missing data ultimately represented only 0.2% of all calculated heart rate values in the 54 participants included in the final analyses. No motion data were missing.

Demographics

Characteristics of the sample of 54 participants are shown in Table 8. The average age of participants was 71 years (range 65-84), with the majority of participants (52%, $n = 28$) between 65 and 70 years old. Only nine percent of the sample ($n = 5$) was over age 80. The sample was primarily female and Caucasian, with nearly half of participants reporting less than a college education. Five minority elders were enrolled, or 9.3% of the sample, similar to the current 8% utilization rate of OHSU Hospital by minorities age 65 and over (University HealthSystem Consortium, 2006).

Most participants were married and retired, although 18.6% still worked at least part-time. In terms of daily caregiving, 16.7% of participants provided daily care to a child, parent, spouse, or other individual. Thirty-five percent of participants lived in the Portland or Portland metropolitan area, which includes 3 counties and 25 cities and extends approximately 25 miles from the clinical study site. The remaining participants came from non-metropolitan Oregon or out of state (California and Hawaii).

Table 8. *Characteristics of the Study Sample (N = 54)*

Variables	Number of Cases (%)
Age (Years)	54 (100%)
$M = 71$ ($SD = 5.28$)	Range 65-84
Gender	
Female	32 (59.3%)
Race/Ethnicity	
Caucasian	49 (90.7%)
Asian	1 (1.9%)
Hispanic or Latino	3 (5.6%)
American Indian/Other	2 (3.8%)
Marital Status	

Currently married	35 (64.8%)
Widowed	13 (24.1%)
Divorced/separated	6 (11.1%)
Education	
Less than bachelor's degree (includes associate/technical degree)	26 (48.1%)
Bachelor's degree	9 (16.7%)
More than bachelor's degree	11 (20.4%)
Other	8 (14.8%)
Employment Status	
Full-time or part-time work	2 (3.8%)
Retired, not working	42 (77.8%)
Retired, working	8 (14.8%)
Other	2 (3.7%)
Total Gross Annual Income	
<\$13,000	7 (13.0%)
\$13,001 to \$20,000	5 (9.3%)
\$20,001 to \$50,000	23 (42.6%)
>\$50,000	17 (31.5%)
Not reported	2 (3.7%)
Geographic Location	
Portland or Metropolitan Portland, OR (includes Vancouver, WA)	19 (35.2%)
Non-Metropolitan OR	23 (42.6%)
Washington (non-Vancouver)	10 (18.5%)
Out of State (non-WA)	2 (3.7%)

Health Status

All 54 participants participated in the study because they were scheduled to have a major surgical procedure requiring at least one night in the hospital. Orthopedic, spinal, abdominal, and urological procedures were the most common surgical type (68.5% of

sample). Twenty-seven surgeons across nine surgical services performed the participants' surgeries. See Table 9 for a description of health-related characteristics of the sample.

Table 9. *Health-Related Characteristics of the Study Sample (N=54)*

Variables	Number of Cases (%)
Surgery Type	54 (100%)
Knee Replacement	10 (18.5%)
Abdominal	8 (14.8%)
Spinal	8 (14.8%)
Urology	7 (13.0%)
Brain	6 (11.1%)
Breast & Female Gynecologic	6 (11.1%)
Orthopedic Other	4 (7.4%)
Vascular	3 (5.6%)
Other	2 (3.7%)
BMI	
Obese (≥ 30 kg/m ²)	27 (50%)
Overweight (25-29.9 kg/m ²)	21 (38.9%)
Normal (18.5-24.9 kg/m ²)	6 (11.1%)
Medical Conditions	
Cardiac	39 (72.2%)
Respiratory	20 (37.0%)
Neurologic	42 (77.8%)
Arthritis	37 (68.5%)
Cancer	27 (50.0%)
Vision problems	36 (66.7%)
Hearing problems	21 (38.9%)

Participants were mostly overweight or obese (88.9%), with a mean body mass index (BMI) of 31.25 kg/m² ($SD = 7.46$). The study used the commonly accepted World Health Organization (WHO, 1998) guidelines to classify persons as underweight, normal,

overweight, and obese based on BMI. Participants reported a mean of 11.20 ($SD = 4.96$) medical conditions, with a range of 3 to 24 conditions. These conditions were reported out of 51 possible medical problems listed on the Brief Co-Morbidity Questionnaire (BCM-Q) and aggregated by body system. Over 70% of participants reported a current or past history of cardiac problems that included heart attack, heart failure, coronary artery disease, irregular heart rate, heart valve disorders, peripheral vascular disease, high blood pressure, or other heart problems. Nearly 30% of all participants ($n = 16$) reported taking a beta-blocker.

Respiratory conditions included chronic bronchitis, asthma or wheezing, emphysema, pneumonia, tuberculosis, or pulmonary fibrosis. Neurologic conditions included non-joint leg pain, headaches, seizures or epilepsy, neuromuscular disorders, sudden arm or leg weakness, numbness, tingling, or paresthesia, slurring or loss of speech, and stroke or transient ischemic attacks.

Functional Status

In terms of functional status, participants scored an average of 123.57 ($SD = 3.93$) on the Functional Independence Measure (FIM), which has a range of 18 to 126. The FIM is divided into motor and cognitive subsections, with the majority of participants (83.3%, $n = 45$) reporting no deficits in cognitive functioning (score of 0 to 35, with 35 indicating no deficits). Additionally 46.3% of participants ($n = 25$) scored 126, reflecting no physical or cognitive deficits or assistance needed. Participants scored a mean of 88.75 ($SD = 3.90$) on the FIM motor subscore, with a range of 70 to 91 reported (91 is the maximum motor score possible). Cronbach's α on the FIM was 0.77. During the course of the study's data collection, approximately 20% of participants ($n = 10$) used some type

of assistance, primarily a cane, walker, or IV pole during the simulation protocol. The use of these devices occurred during the timed walk test, the dangle activity, and the walking activity.

Related to symptoms potentially affecting function, 46.3% of participants ($n = 25$) reported either upper or lower back pain and 64.8% ($n = 35$) reported lower extremity pain. Overall, participants reported a pain severity of 3.20 ($SD = 2.40$) on a scale of 0 to 10. Pain severity reflects the mean of the worst, least, average, and current pain levels reported by participants on the Brief Pain Inventory (BPI). Mean pain interference was reported to be 2.59 ($SD = 2.53$), also on a scale of 0 to 10. Pain interference represents the mean interference reported on general activity levels, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. Cronbach's α on the BPI was 0.94 for both pain severity (four items) and pain interference (seven items).

In terms of other symptoms reported that could potentially influence activities such as walking, participants reported problems with mobility, shortness of breath, and balance most frequently. In fact, 20.4% of the sample ($n = 11$) reported either mobility or balance problems, with 11.1% of the sample ($n = 6$) reporting both of these symptoms. See Table 10 for a listing of selected symptoms.

Table 10. *Symptoms that Could Affect Function Reported by Study Sample (N=54)*

Variables	Number of Cases (%)
Symptoms Reported	
Dizziness or Lightheadedness with Standing	11 (20.4%)
Dizziness or Lightheadedness with Sitting/Lying	3 (5.6%)
Fainting or blackouts	1 (1.9%)
Leg or arm weakness	13 (24.1%)
Leg or arm paralysis	1 (1.9%)
Shortness of breath	16 (29.6%)
Chest palpitations	3 (5.6%)
Mobility (walking problems)	25 (46.3%)
Balance problems	16 (29.6%)

Physical Performance

The Physical Performance Battery (PPB) tested participants' standing balance, gait speed, and leg strength. See Table 11 for a summary of physical performance measures. For some tests, results were significantly different for male and female participants. An independent-samples t test was conducted to evaluate the difference in walk speed between men and women, $t(2.10) = 3.00$, $p = 0.04$. Men completed the task more quickly than women (mean 5.00 seconds, $SD = 1.18$ versus mean 6.13, $SD = 2.34$).

In terms of upper body strength, gender also differentiated the degree of grip strength. An independent-samples t-test, with $t(9.66) = 4.66$, $p < 0.001$, revealed men were significantly stronger than women in grip strength. Nearly 69% of women ($n = 22$) demonstrated grip strength less than 20 kg while 64% of men ($n = 14$) demonstrated grip strength over 35 kg, with the majority of crossover (26% of the sample) between men ($n = 8$) and women ($n = 10$) occurring primarily between 20 and 30 kg.

Table 11. *Summary of Physical Performance Measures*

Variable	N	Overall Mean (SD)	Female Mean (SD)	Male Mean (SD)
Physical Performance Battery				
Standing balance score, 0 to 4	54	3.48 (1.02)		
Timed walk score, 0 to 4	54	3.09 (0.90)	2.88 (0.91)	3.41 (0.80)
Chair stand score, 0 to 4	54	2.20 (1.09)		
Total PPB score, 0 to 12	54	8.62 (2.23)		
Grip Strength	54	25.36 (10.28)	18.44 (5.03)	35.42 (7.11)

Note. Male and female means provided only when significantly different

Motion and Heart Rate Data

Results for Specific Aim #1

Aim 1: Describe the patterns of motion and heart rate during five different clinical care activities (turning, dangling, transferring, chair sitting, and walking).

Calculated Statistics by Participant

Summary statistics for each participant were calculated from the raw motion and heart rate data in order to determine seven calculated variables: Pre-Activity Heart Rate, Maximal Heart Rate, Average Heart Rate, Pre-Activity Motion, Total Motion, Minimum Motion, and Maximum Motion. Each of these variables was computed for five clinical care activities: Turning, Dangling, Transferring, Sitting, and Walking. Videography was used to help interpret when these activities occurred. Designation of specific activity and rest (pre-activity) periods were determined prior to computation of variables. Please see Appendix I for a complete description of the protocol used for analysis of raw heart rate and motion data.

The analysis revealed that the device was sometimes not able to detect enough information during a 15-second epoch to produce a heart rate value for that epoch. In these cases, the data read Not a Number (NaN) for that epoch. As mentioned previously, four participants had missing heart rate data, with multiple readings of NaN, to an extent that their heart rate could not be reasonably estimated and they were excluded from the analysis. For the remaining 54 participants, epochs with readings of NaN during the period of time from the pre-activity period before turning to the end of the walking activity ranged from 0 to 37, with 64.9% of participants ($n = 35$) having 0 to 2 instances of an NaN epoch. In terms of the percentage of simulation epochs occupied by NaN

readings, over 75% of participants ($n = 41$) had a percentage of NaN of their total epochs of no more than 5% and 92.6% of the sample ($n = 50$) had 14% or less of their total heart rate readings as invalid (NaN). For only 4 participants did the percentage of NaN epochs as a proportion of total heart rate epochs exceed 20% (22.1%, 22.7%, 38.9%, and 40%).

The number of weights were thought to be potential influences since all weights were placed in front vest pockets when possible, with more weights potentially causing interference with the Actiheart™ by pressing against it. BMI was also considered a potential influence that could have interfered with appropriate placement of the device or caused insufficient lead attachment. However, correlations of BMI and number of weights in the lead vest with percentage of NaN were not significant. The activity with the highest rate of NaN as a percentage of total epochs for that activity was turning for 68.5% of the sample ($n = 37$). Please see Table 12 for the percentage of participants with NaN epochs for each of the five activities.

Table 12. *Summary of Percentages of Heart Rate NaN Epochs by Activity*

	Turning	Dangling	Transferring	Sitting	Walking
NaN per Activity					
One NaN	40.7%	24.1%	1.9%	1.9%	16.7%
More than One NaN	27.8%	5.6%	3.7%	3.7%	11.1%

Summary Measures by Participant

In general, the pre-activity calculations used the 30-second period (2 15-second epochs) at the end of the 5-minute rest period prior to the commencement of each activity. For the activity of sitting, the recordings of pre-activity heart rate and motion preceding the transfer activity were used since no distinct rest period occurred between

the transfer and sitting activities. In cases of missing data (NaN), data from epochs adjacent to this 30-second period were used. For pre-activity heart rate, a mean was calculated. For pre-activity motion, a sum was calculated since motion counts are typically more meaningful when they are totaled and not averaged (Grap et al., 2005). The other five variables were calculated during the time period the activity occurred: maximal heart rate and motion reflected the highest value during each activity; average heart rate reflected the mean heart rate during that period; total motion reflected the calculated sum of all motion counts during each activity; and minimum motion reflected the lowest non-zero motion count (unless only zeros were recorded in which case zero was recorded). Heart rate and motion plots for all activities for each participant were generated to graphically represent patterns of motion and heart rate across activities.

Although definitive statistical conclusions could not be made based on individual participant data, plots of each participant's motion and heart rate data depicted some general patterns. Data shown in Figures 6 through 8 depict the results from a single participant, Participant #150, as an example of individual participant data. In most participants, heart rate was within a 20-point range for the activities of turning, dangling, transferring, and sitting that varied based on the participant's baseline heart rate. Data revealed that many participants had higher heart rates, outside of their 20-point range, during the walking activity, with turning the second most frequent activity causing an increase in heart rate. In terms of motion, Figure 7, illustrating motion for Participant #150, shows that increases in motion occurred most often during turning, dangling, transferring, or walking, but without any consistent pattern among participants of which activities had higher motion counts. Some participants had higher motion counts only in

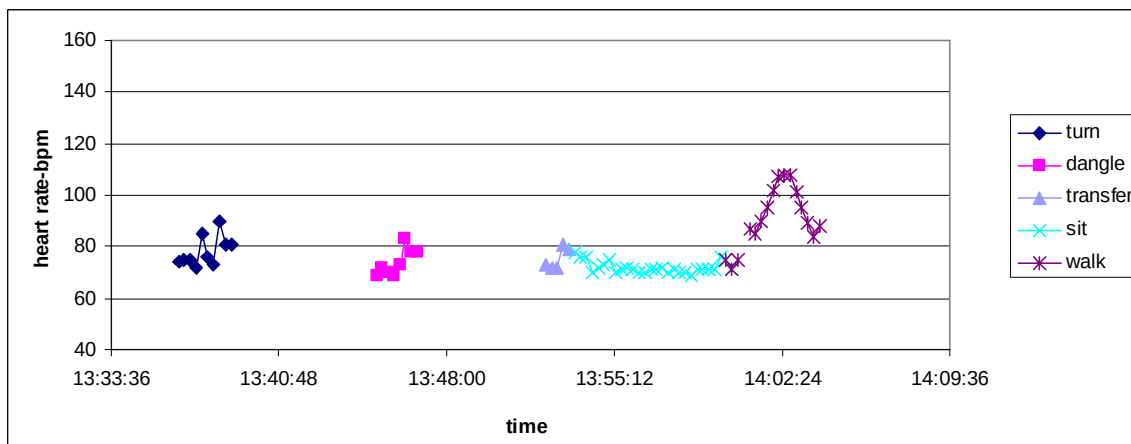


Figure 6. Example of Heart Rate Data Across Activities, ID #150

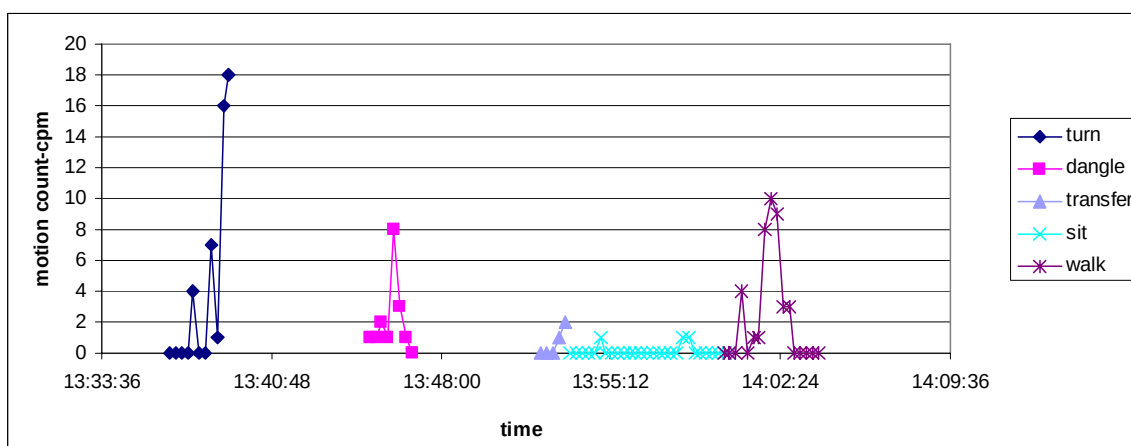


Figure 7. Example of Motion Data Across Activities, ID #150

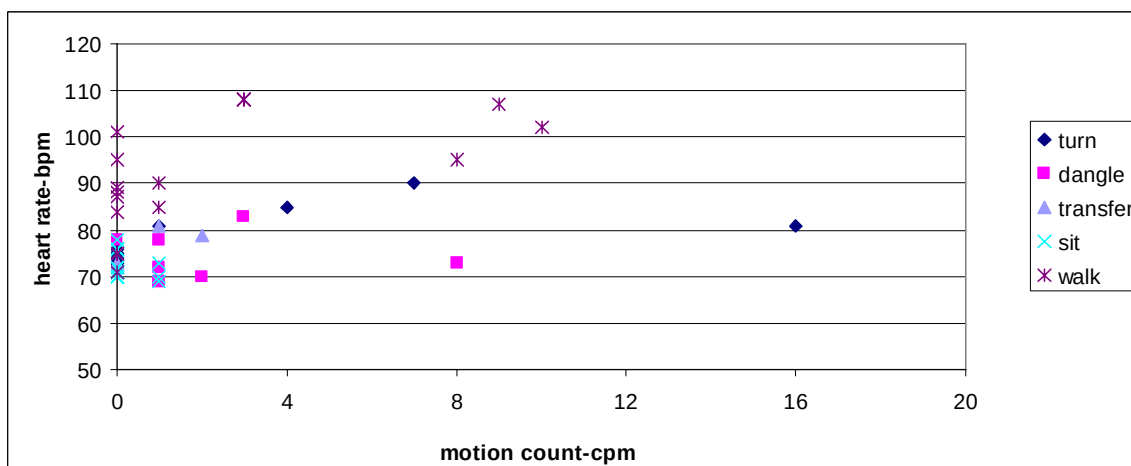


Figure 8. Example of Motion by Heart Rate Plot, ID #150

turning and walking; others only in transferring and walking. Walking was the activity with an increased motion count consistent across all participants. The motion by heart rate plots (Figure 8 illustrates data for Participant #150) generally showed higher motion counts matched with higher heart rates, especially during the walking activity. The other activities did not demonstrate this relationship to the extent walking did, with both higher and lower heart rates associated with lower motion counts.

Summary Measures across Sample

The seven values for each activity were averaged over all participants to obtain summary measures (Tables 13 through 17). The five tables, one for each activity, include the means, standard deviations, minimum and maximums for each of the seven heart rate and motion values within that activity. An adjusted mean was also calculated based on the exclusion of significant outliers. Heart rate outliers were determined by calculating two standard deviations above the mean and then rounding to the nearest whole number in increments of five. Heart rate values greater than that number were considered outliers and eliminated from the calculation of the adjusted means. Adjusted means for total and maximum motion counts that excluded outliers were calculated the same way. Because the range of motion counts was more narrow for pre-activity and minimum motion counts, after calculating two standard deviations above the mean, the value was rounded to the nearest whole number (not in increments of five as above), not less than two. Values greater than that number were considered outliers and eliminated from the calculation of the adjusted means. No more than three cases were deleted for any calculation of a summary measure.

Statistics in Tables 13 through 17 were calculated with and without outliers in order to determine the degree to which data from participants with outlier heart rate and motion values affected the means. Results showed that for pre-activity and average heart rate, adjusted values were no more than 1 to 3 beats per minutes lower than non-adjusted values for all five activities. For maximal heart rate, these differences were greater, ranging between 3 and 7 beats per minute lower for the adjusted values than for non-adjusted values across the five activities. Pre-activity motion only had outliers for the activities of sitting and transferring, with adjusted means slightly lower than non-adjusted means by 0.16 and 0.17 counts per minute, respectively. The greater differences between the adjusted and non-adjusted means of motion occurred for total motion of turning and walking (1.14 and 2.66 counts per minute, respectively). All the other adjusted means for motion were lower, no more than 0.60 and as little as 0.13 counts per minute, compared to non-adjusted means. No adjustments for outliers were needed for maximum motion during dangling, total and maximum motion during transferring, and maximum and minimum motion during sitting.

Table 13. *Summary Statistics for Motion and Heart Rate during Turn across Sample (N=54 unless otherwise indicated)*

	Heart Rate (beats per minutes)			Motion (counts per minute)			
	Pre	Average (n=53)	Max (n=53)	Pre	Total	Maximum	Minimum
Turn							
Mean	71.26	75.08	86.42	0.07	5.35	2.93	1.17
SD	13.37	13.51	31.49	0.26	7.68	3.42	1.23
Minimum	50	51	55	0	0	0	0
Maximum	116	123	217	1	46	18	8
Turn (Adjusted for Outliers)							
Outlier Cutoff (No. of Cases Deleted)	100 (2)	100 (2)	150 (3)	2 (0)	20 (2)	10 (1)	4 (1)
Mean	69.69	73.63	79.98		4.21	2.64	1.04
SD	10.84	11.33	16.16		4.55	2.73	0.78
Maximum	92	97	146		20	10	3

Note. Adjusted for outliers reflects means without the outliers. Outliers defined as greater than 2 SD above the mean.

Table 14. *Summary Statistics for Motion and Heart Rate during Dangle across Sample (N=54)*

	Heart Rate (beats per minutes)			Motion (counts per minute)			
	Pre	Average	Max	Pre	Total	Maximum	Minimum
Dangle							
Mean	69.07	78.98	85.57	0.09	4.81	3.35	2.06
<i>SD</i>	12.28	20.42	30.42	0.35	4.17	2.69	2.07
Minimum	49	52	54	0	0	0	0
Maximum	115	162	224	1	17	8	8
Dangle (Adjusted for Outliers)							
Outlier Cutoff (No. of Cases Deleted)	95 (2)	120 (3)	145 (2)	2 (0)	15 (1)	10 (0)	6 (3)
Mean	67.52	75.27	80.63		4.58		1.71
<i>SD</i>	9.43	13.18	16.92		3.85		1.51
Maximum	90	118	142		15		6

Note. Adjusted for outliers reflects means without the outliers. Outliers defined as greater than 2 *SD* above the mean.

Table 15. *Summary Statistics for Motion and Heart Rate during Transfer across Sample (N=54)*

	Heart Rate (beats per minutes)			Motion (counts per minute)			
	Pre	Average	Max	Pre	Total	Maximum	Minimum
Transfer							
Mean	73.69	76.06	81.37	0.28	3.41	2.72	2.31
<i>SD</i>	15.69	13.81	23.59	1.27	2.51	2.23	2.21
Minimum	51	52	52	0	0	0	0
Maximum	135	142	233	9	10	10	10
Transfer (Adjusted for Outliers)							
Outlier Cutoff (No. of Cases Deleted)	105 (2)	105 (1)	130 (1)	3 (1)	10 (0)	10 (0)	7 (2)
Mean	71.62	74.81	78.51	0.11			2.06
<i>SD</i>	11.64	10.45	10.79	0.38			1.79
Maximum	96	96	100	2			7

Note. Adjusted for outliers reflects means without the outliers. Outliers defined as greater than 2 *SD* above the mean.

Table 16. *Summary Statistics for Motion and Heart Rate during Sit across Sample (N=54)*

	Heart Rate (beats per minutes)			Motion (counts per minute)			
	Pre	Average	Max	Pre	Total	Maximum	Minimum
Sit							
Mean	74.74	72.07	78.13	0.28	1.17	0.56	0.41
<i>SD</i>	20.93	13.69	16.20	1.27	2.22	0.82	0.50
Minimum	51	50	53	0	0	0	0
Maximum	192	120	149	9	10	3	1
Sit (Adjusted for Outliers)							
Outlier Cutoff (No. of Cases Deleted)	115 (2)	100 (2)	110 (2)	3 (1)	5 (3)	5 (0)	2 (0)
Mean	71.62	70.31	75.87	0.11	0.73		
<i>SD</i>	11.64	10.43	11.22	0.38	1.25		
Maximum	96	94	106	2	5		

Note. Adjusted for outliers reflects means without the outliers. Outliers defined as greater than 2 *SD* above the mean.

Table 17. *Summary Statistics for Motion and Heart Rate during Walk across Sample (N=54)*

	Heart Rate (beats per minutes)			Motion (counts per minute)			
	Pre	Average	Max	Pre	Total	Maximum	Minimum
Walk							
Mean	71.28	83.26	95.24	0.02	46.06	15.15	1.61
<i>SD</i>	12.85	15.33	28.69	0.14	25.42	8.92	1.54
Minimum	50	55	60	0	5	2	1
Maximum	121	155	241	1	118	47	9
Walk (Adjusted for Outliers)							
Outlier Cutoff (No. of Cases Deleted)	100 (1)	115 (1)	155 (2)	2 (0)	100 (2)	35 (1)	5 (2)
Mean	70.34	81.91	90.56		43.40	14.55	1.35
<i>SD</i>	10.95	11.77	15.35		21.85	7.83	1.00
Maximum	98	108	127		86	33	3

Note. Adjusted for outliers reflects means without the outliers. Outliers defined as greater than 2 *SD* above the mean.

Results for Specific Aim #2

Aim #2: Compare clinical care activities using continuous motion and heart rate data to discriminate motion and heart rate both across and within five different clinical care activities.

The values computed as part of Aim 1 over all participants were analyzed using one-way repeated measures analysis of variance (ANOVA). In order to evaluate differences in heart rate and motion across activities, clinical care activities was the within-participants factor, with five levels (five different activities). Seven separate analyses were conducted for the three values of heart rate (pre-activity, maximal, and average) and four values of motion (pre-activity, minimum, maximum, and total) across activities. A separate series of analyses, also using repeated measures ANOVA, were conducted to evaluate differences in heart rate and motion within each activity. For these analyses, heart rate and motion were analyzed separately as the within-participants factors, with 3 levels for heart rate (pre-activity, average, and maximal) and 3 levels for motion (pre-activity, minimum, and total). Maximum motion was not included for purposes of the within-activity analyses because in many cases, it was not significantly different than total motion. Ten separate analyses (five for heart rate and five for motion) were conducted for the five types of activities (turning, dangling, transferring, sitting, and walking).

For both the across- and within-activities analyses, contrasts were used to test for differences for each analysis that resulted in significance. Simple contrasts evaluated means based on comparisons to the first activity of turning. In the case of within-activity analyses, means were evaluated based on comparisons to pre-activity heart rate or pre-

activity motion. Repeated measures contrasts were also used to interpret means by comparing data from the preceding activity. In the case of within-activity analyses, repeated measures contrasts compared adjacent heart rate or motion data. Furthermore, pairwise comparisons were also examined since pairwise comparisons offered a more conservative approach to the data by adjusting for multiple pairs using the Bonferroni adjustment. Pairwise comparisons also allowed for later comparisons between these original analyses and the influence of significant covariates.

Because of the non-normal distribution of heart rate and motion data, the Friedman test, also called a non-parametric randomized block analysis of variance, was used to analyze the repeated measures of motion and heart rate across and within activities because it makes no assumptions about the normal distribution of data (Gibbons, 1993). The null hypothesis in the Friedman test is that the distribution of the ranks of each type of activity are the same so a significant p -value indicates that a difference exists between the mean ranks, but it does not indicate the nature of the relationship nor the significance, if any, between various activities.

Across-Activities Analyses

Heart Rate

See Figure 9 for a graph of mean heart rate values for all three analyses that show their relative relationship to one another. A discussion of the three analyses for heart rate across all five activities follows: pre-activity, average, and maximal heart rate.

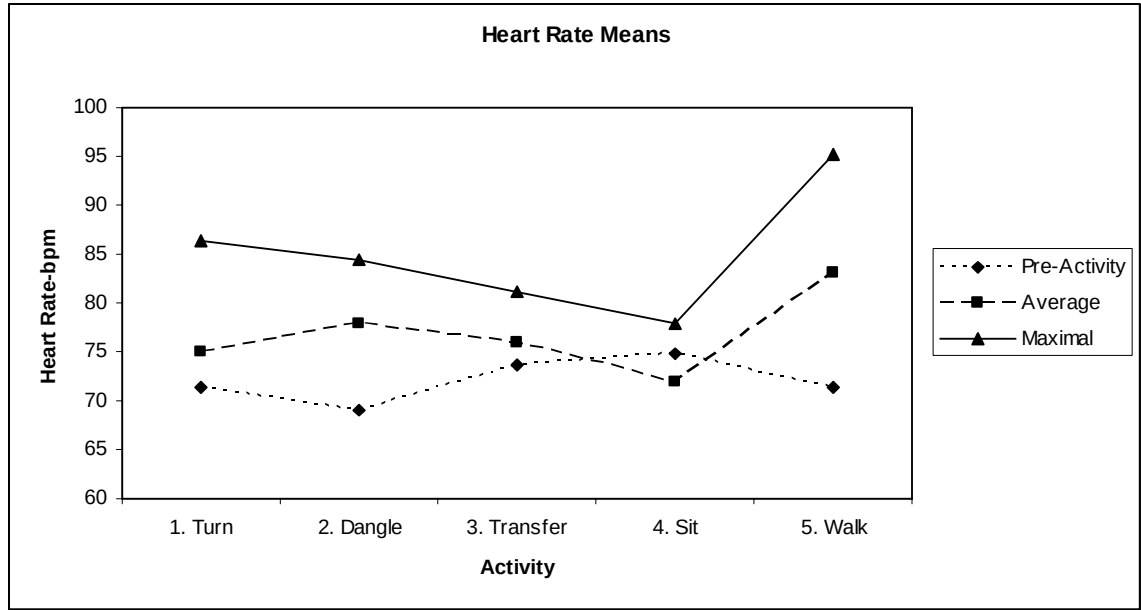


Figure 9. Means of Heart Rate Values across All Activities and Participants

Pre-Activity Heart Rate. A one-way repeated-measures ANOVA showed that mean pre-activity heart rate was significantly different among the five activities, Wilk's $\lambda = 0.58$ ($F_{4,50} = 9.02, p < 0.001$). The means and standard deviations for Pre-Activity Heart Rate are presented in Table 18 below. Follow-up simple contrasts (using comparison to first value) indicated a significant difference in mean pre-activity heart rate between turning and dangling, with the mean heart rate lower for dangling than for turning ($F_{1,53} = 14.35, p < 0.001$). Repeated measures contrasts revealed an additional significant difference between mean heart rates between dangling and transferring ($F_{1,53} = 11.38, p = 0.001$), with pre-activity heart rate for transferring higher than dangling. Multiple pairwise comparisons supported these contrasts as well as revealing an additional jointly significant difference in pre-activity heart rate between dangling and walking ($p = 0.03$), with the mean pre-activity heart rate for walking higher compared to dangling. A Friedman analysis also confirmed that there was a significant difference

between pre-activity heart rates across all activities ($\chi^2(4, N = 54) = 53.56, p < 0.001$). The rank order of pre-activity heart rates (from lowest to highest mean rank) was dangling, walking, turning, transferring, and sitting.

Table 18. *Means and Standard Deviations for Pre-Activity Heart Rate During Five Activities (N=54)*

	Mean	SD
Pre-Turn	71.26	13.37
Pre-Dangle	69.07	12.28
Pre-Transfer	73.69	15.69
Pre-Sit	74.74	20.93
Pre-Walk	71.28	12.85

Note. Activities were performed in the order presented in table.

Average Heart Rate. A one-way repeated-measures ANOVA showed that mean heart rate was significantly different among the five activities, Wilk's $\lambda = 0.21$ ($F_{4, 49} = 45.37, p < 0.001$). For one case, data on this variable were not available and could not be imputed, leaving analysis on 53 cases. The means and standard deviations for Average Heart Rate are presented in Table 19 below. The results for the follow-up simple contrasts (using comparison to first value) indicated a significant difference in mean heart rate during both sitting and walking compared to turning, with the mean heart rate higher for turning compared to sitting ($F_{1, 52} = 10.98, p = 0.002$) and lower for turning compared to walking ($F_{1, 52} = 59.47, p < 0.001$). Repeated measures contrasts revealed additional significant differences between mean heart rates between transferring and sitting ($F_{1, 52} = 10.79, p = 0.002$) and between sitting and walking ($F_{1, 52} = 144.86, p < 0.001$). Average heart rate was higher in transferring compared to sitting and lower during sitting compared to walking. Multiple pairwise comparisons supported these contrasts as well as

revealing additional jointly significant differences in mean heart rate between dangling and sitting ($p = 0.02$) and between transferring and walking ($p < 0.001$). Average heart rate was higher in dangling compared to sitting and lower during transferring compared to walking.

A Friedman analysis also confirmed that there was a significant difference between average heart rates across all activities ($\chi^2 (4, N = 53) = 125.99, p < 0.001$). The rank order of average heart rates (from lowest to highest mean rank) was sitting, turning, dangling, transferring, and walking. In an alternative approach to account for the missing average heart rate data during turning for a single case, all cases were restructured in SPSS so that the average heart rate values for the other four activities for the case with the missing value was retained. In the standard repeated measures ANOVA, the entire case, with all four remaining heart rate values, was excluded because of the single missing average heart rate value. A univariate analysis of variance of the restructured data, with a random participant effect, retained these four heart rate values and confirmed that average heart rate was significantly different across the five activities ($F_{4, 211} = 14.39, p < 0.001$).

Table 19. *Means and Standard Deviations for Average Heart Rate During Five Activities (N=53)*

	Mean	SD
Turn	75.08	13.51
Dangle	77.79	18.63
Transfer	75.91	13.90
Sit	71.87	13.74
Walk	83.11	15.43

Note. Activities were performed in the order presented in table.

Maximal Heart Rate. A one-way repeated-measures ANOVA showed that mean maximal heart rate was significantly different among the five activities, Wilk's $\lambda = 0.54$ ($F_{4, 49} = 10.57, p < 0.001$). The means and standard deviations for Maximal Heart Rate are presented in Table 20 below. Data on this variable during turning was not available and could not be imputed for the same case that had a missing average heart rate value, leaving analysis on 53 cases. Follow-up simple contrasts (using comparison to first value) indicated a significant difference in mean maximal heart rate between both sitting and walking compared to turning, with the mean maximal heart rate higher for turning compared to sitting ($F_{1, 52} = 4.95, p = 0.03$) and lower for turning compared to walking ($F_{1, 52} = 4.50, p = 0.04$). Repeated measures contrasts revealed an additional significant difference in mean maximal heart rates between sitting and walking ($F_{1, 52} = 27.99, p < 0.001$), with maximal heart rate higher for walking compared to sitting. Multiple pairwise comparisons did not support the findings of a significant difference between turning and sitting and turning and walking as was indicated by the simple (first) contrasts. However, multiple pairwise comparisons supported the repeated measures contrast as well as indicating a jointly significant difference in maximal heart rate between transferring and walking ($p < 0.001$), with a higher maximal heart rate during walking compared to transferring.

A Friedman analysis again confirmed that there was a significant difference between mean maximal heart rates across all activities ($\chi^2(4, N = 53) = 85.54, p < 0.001$). The rank order of maximal heart rates (from lowest to highest mean rank) was sitting, transferring, dangling, turning, and walking. Similar to the analysis of average heart rate, all cases were restructured in SPSS to retain the maximal heart rate values for

the other four activities for the case with the missing value. A univariate analysis of variance of the restructured data, with a random participant effect, also confirmed that maximal heart rate was significantly different across the five activities ($F_{4, 211} = 5.70, p < 0.001$).

Table 20. *Means and Standard Deviations for Maximal Heart Rate During Five Activities (N=53)*

	Mean	SD
Turn	86.42	31.49
Dangle	84.51	29.68
Transfer	81.17	23.77
Sit	77.92	16.28
Walk	95.21	28.96

Note. Activities were performed in the order presented in table.

Motion

See Figure 10 for a graph of motion values for all four analyses that show their relative relationship to one another. A discussion of the four analyses for motion follows: pre-activity, minimum, maximum, and total motion.

Pre-Activity Motion. A one-way repeated-measures ANOVA was used to examine the hypothesis that pre-activity motion (the dependent variable) significantly changed over five activities in a sample of 54 older adults. The means and standard deviations for Pre-Activity Motion are presented in Table 21 below. The results for this ANOVA indicated that pre-activity motion did not significantly change over five activities, reflecting a similar baseline of 0 for each activity. A Friedman analysis also confirmed that there was not a significant difference between pre-activity motion counts across activities.

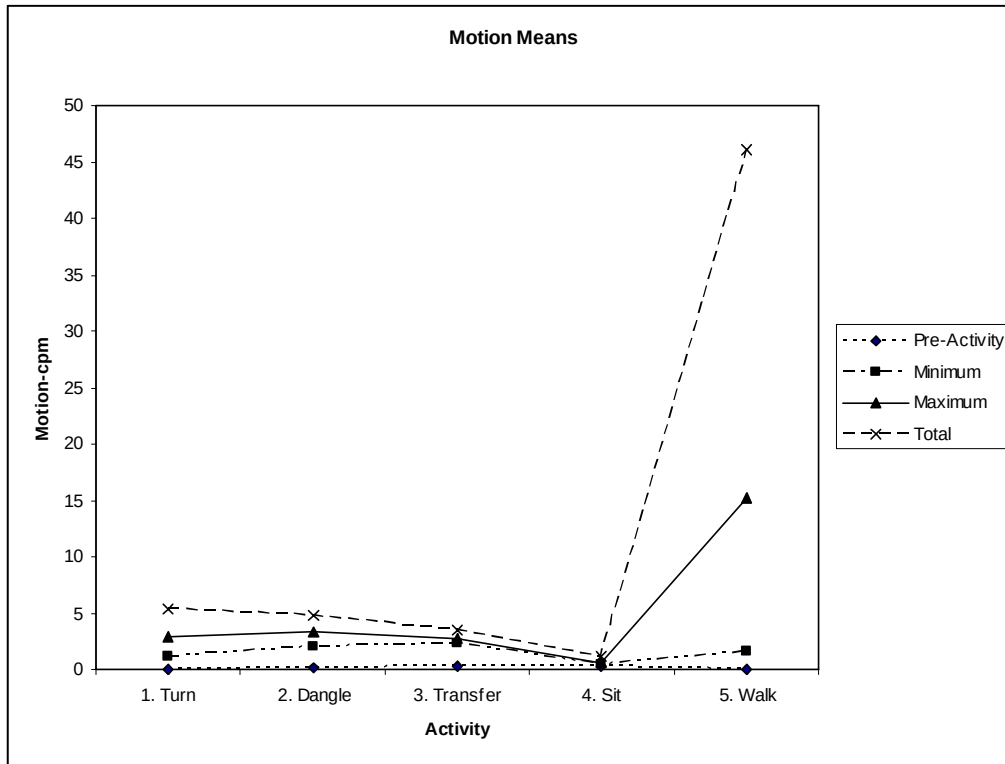


Figure 10. Means of Motion Values across All Activities and Participants

Table 21. Means and Standard Deviations for Pre-Activity Motion Count During Five Activities (N=54)

	Mean	SD
Pre-Turn	0.07	0.26
Pre-Dangle	0.09	0.35
Pre-Transfer	0.28	1.27
Pre-Sit	0.28	1.27
Pre-Walk	0.02	0.14

Note. Activities were performed in the order presented in table.

Minimum Motion. A one-way repeated-measures ANOVA showed that mean minimum motion count was significantly different among five activities, Wilk's $\lambda = 0.40$ ($F_{4, 50} = 18.92, p < 0.001$). The means and standard deviations for Minimum Motion Count are presented in Table 22 below. Follow-up simple contrasts (using comparison to

first value) indicated a significant difference in mean minimum motion between turning and dangling ($F_{1,53} = 9.37, p = 0.003$), turning and transferring ($F_{1,53} = 11.27, p = 0.001$), and turning and sitting ($F_{1,53} = 18.36, p < 0.001$). The mean minimum motion count was lower for turning compared to dangling and to transferring, but was higher for turning compared to sitting. Repeated measures contrasts revealed additional significant effects between mean minimum motion counts for transferring and sitting ($F_{1,53} = 37.38, p < 0.001$) and between sitting and walking ($F_{1,53} = 31.24, p < 0.001$) with minimum motion higher for transferring compared to sitting and lower for sitting compared to walking. Multiple pairwise comparisons supported these contrasts as well as revealing an additional jointly significant difference in minimum motion between dangling and sitting ($p < 0.001$), with dangling higher compared to sitting. A Friedman analysis also confirmed that there was a significant difference between minimum motion counts across all activities ($\chi^2(4, N = 54) = 65.306, p < 0.001$). The rank order of the minimum motion counts (from lowest to highest mean rank) was sitting, turning, walking, dangling, and transferring.

Table 22. *Means and Standard Deviations for Minimum Motion Count During Five Activities (N=54)*

	Mean	SD
Turn	1.17	1.23
Dangle	2.06	2.07
Transfer	2.31	2.21
Sit	0.41	0.50
Walk	1.61	1.54

Note. Activities were performed in the order presented in table.

Maximum Motion. A one-way repeated-measures ANOVA showed that the maximum motion count was significantly different among the five activities, Wilk's $\lambda = 0.22$ ($F_{4, 50} = 43.79$, $p < 0.001$). The means and standard deviations for Maximum Motion Count are presented in Table 23 below. Follow-up simple contrasts (using comparison to first value) indicated a significant difference in mean maximum motion between turning and sitting ($F_{1, 53} = 26.51$, $p < 0.001$) and turning and walking ($F_{1, 53} = 90.36$, $p < 0.001$). The mean maximum motion count was higher for turning compared to sitting and lower for turning compared to walking. Repeated measures contrasts revealed additional significant differences between mean maximum motion between transferring and sitting ($F_{1, 53} = 44.27$, $p < 0.001$) and between sitting and walking ($F_{1, 53} = 136.43$, $p < 0.001$), with maximum motion lower for sitting compared to both transferring and walking. Multiple pairwise comparisons supported these contrasts as well as revealing additional jointly significant differences in maximum motion between dangling and sitting ($p = < 0.001$), dangling and walking ($p = < 0.001$), and transferring and walking ($p = < 0.001$).

Table 23. *Means and Standard Deviations for Maximum Motion Count During Five Activities (N=54)*

	Mean	SD
Turn	2.93	3.42
Dangle	3.35	2.69
Transfer	2.72	2.23
Sit	0.56	0.82
Walk	15.25	8.92

Note. Activities were performed in the order presented in table.

Mean maximum motion was higher for dangling compared to sitting but lower for dangling and transferring as compared to walking. A Friedman analysis also confirmed

that there was a significant difference between maximum motion counts across all activities ($\chi^2(4, N = 54) = 133.23, p < 0.001$). The rank order of maximum motion counts (from lowest to highest mean rank) was sitting, turning, transferring, dangling, and walking.

Total Motion. A one-way repeated-measures ANOVA showed that mean total motion was significantly different among the five activities, Wilk's $\lambda = 0.23$ ($F_{4, 50} = 41.17, p < 0.001$). The means and standard deviations for Total Motion are presented in Table 24 below. Follow-up simple contrasts (using comparison to first value) indicated a significant difference in mean total motion between turning and sitting ($F_{1, 53} = 15.94, p < 0.001$) and turning and walking ($F_{1, 53} = 130.69, p < 0.001$). The mean total motion count was lower for sitting compared to turning and lower for turning compared to walking. Repeated measures contrasts revealed additional significant differences between dangling and transferring ($F_{1, 53} = 4.71, p = 0.034$), between transferring and sitting ($F_{1, 53} = 24.70, p < 0.001$), and between sitting and walking ($F_{1, 53} = 161.85, p < 0.001$). Total motion was higher for dangling compared to transferring, higher for transferring compared to sitting, and higher for walking compared to sitting. Multiple pairwise comparisons did not support the findings of a significant difference between dangling and transferring as was indicated by the repeated measures contrast. However, multiple pairwise comparisons supported the other repeated measures and simple (first) contrasts as well as indicating jointly significant differences in total motion between dangling and sitting ($p < 0.001$), dangling and walking ($p < 0.001$), and transferring and walking ($p < 0.001$). Total motion was higher for dangling compared to sitting, but lower for dangling and transferring compared to walking. A Friedman analysis also confirmed that there was

a significant difference between total motion counts across all activities ($\chi^2(4, N = 54) = 135.13, p < 0.001$). The rank order of total motion counts (from lowest to highest mean rank) was sitting, transferring, turning, dangling, and walking although this order did not match the order of the dangling and turning activity based on their means. However, there was little difference in the mean ranks for these two activities (dangling, 2.98, and turning, 2.81).

Table 24. *Means and Standard Deviations for Total Motion Count During Five Activities (N=54)*

	Mean	SD
Turn	5.35	7.68
Dangle	4.81	4.17
Transfer	3.41	2.51
Sit	1.17	2.22
Walk	46.06	25.42

Note: Activities were performed in the order presented in table.

Summary of Across-Activities Analyses

Except for pre-activity motion, significant differences were found across the five clinical care activities for the six analyses of heart rate (pre-activity, average, and maximal) and motion (minimum, maximum, and total). Friedman analyses confirmed the repeated measures ANOVA findings in all seven analyses (see Table 25). Furthermore, contrasts and pairwise comparisons revealed differences between pairs of activities, with the difference between sitting and walking the most common finding across the seven analyses (see Table 26).

Table 25. *Summary of Parametric and Nonparametric Results for All Heart Rate and Motion Values*

	Repeated Measures ANOVA				Friedman (N=54)		
	N	F	df	p	χ^2	df	p
Heart Rate							
Pre-Activity	54	9.02	4,50	<0.001	53.56	4	<0.001
Maximal	53	10.57	4,49	<0.001	85.54	4	<0.001
Average	53	45.37	4,49	<0.001	125.99	4	<0.001
Motion							
Pre-Activity	54	1.67	3,51	0.19	4.80	4	0.31
Minimum	54	18.92	4,50	<0.001	65.31	4	<0.001
Maximum	54	43.79	4,50	<0.001	133.23	4	<0.001
Total	54	41.17	4,50	<0.001	135.13	4	<0.001

Table 26. *Summary of Statistically Significant Pairwise Comparisons Across Activities (p < 0.05)*

Activities	Turn	Dangle	Transfer	Sit	Walk
Turn (T)	----				
Dangle (D)	PreHR ^T Min Motion ^D	----			
Transfer (X)	Min Motion ^X	PreHR ^X	----		
Sit (S)	Average HR ^T Min Motion ^T Max Motion ^T Total Motion ^T	Average HR ^D Min Motion ^D Max Motion ^D Total Motion ^D	Average HR ^X Min Motion ^X Max Motion ^X Total Motion ^X	----	
Walk (W)	Average HR ^W Max Motion ^W Total Motion ^W	PreHR ^W Max Motion ^W Total Motion ^W	Average HR ^W Max HR ^W Max Motion ^W Total Motion ^W	Average HR ^W Max HR ^W Min Motion ^W Max Motion ^W Total Motion ^W	----

Note. HR = heart rate. Initial in superscript indicates activity with higher value in pairwise comparison

Within-Activities Analyses

Turning

Heart Rate. A one-way repeated-measures ANOVA showed that heart rate was significantly different during the activity of turning, Wilk's $\lambda = 0.71$ ($F_{2, 51} = 10.36$, $p < 0.001$). Data on average and maximal heart rate was not available and could not be imputed for one case, leaving analysis on 53 cases. The means and standard deviations for pre-activity, average, and maximal heart rates are presented in the summary statistics for turning described in Aim #1 (Table 13). Follow-up simple contrasts (using comparison to pre-activity heart rate) indicated a significant difference between pre-activity heart rate and both average and maximal heart rates, with the pre-activity heart rate for turning lower compared to the average heart rate ($F_{1, 52} = 19.62$, $p < 0.001$) and lower compared to the maximal heart rate ($F_{1, 52} = 17.00$, $p < 0.001$). Repeated measures contrasts revealed an additional significant difference between average heart rate and maximal heart rate during turning ($F_{1, 52} = 13.27$, $p < 0.001$), with maximal heart rate higher than average heart rate. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between heart rate across the activity of turning ($\chi^2 (2, N = 53) = 78.39$, $p < 0.001$). The rank order of heart rate during turning (from lowest to highest mean rank) was pre-activity, average, and maximal heart rate.

Motion. A one-way repeated-measures ANOVA showed that motion was significantly different during the activity of turning, Wilk's $\lambda = 0.49$ ($F_{2, 52} = 27.36$, $p < 0.001$). The means and standard deviations for pre-activity, minimum, and total motion are presented in the summary statistics for turning described in Aim #1 (Table 13).

Follow-up simple contrasts (using comparison to pre-activity motion) indicated a significant difference between pre-activity motion and both minimum and total motion, with the pre-activity motion for turning lower compared to the minimum motion ($F_{1,53} = 40.42, p < 0.001$) and lower compared to the total motion for turning ($F_{1,53} = 25.41, p < 0.001$). Repeated measures contrasts revealed an additional significant difference between minimum motion and total motion during turning ($F_{1,53} = 16.56, p < 0.001$), with total motion higher than minimum motion. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between motion across the activity of turning ($\chi^2 (2, N = 54) = 74.71, p < 0.001$). The rank order of motion during turning (from lowest to highest mean rank) was pre-activity, minimum, and total motion.

Dangling

Heart Rate. A one-way repeated-measures ANOVA showed that heart rate was significantly different during the activity of dangling, Wilk's $\lambda = 0.70$ ($F_{2,52} = 10.94, p < 0.001$). The means and standard deviations for pre-activity, average, and maximal heart rates are presented in the summary statistics for dangling described in Aim #1 (Table 14). Follow-up simple contrasts (using comparison to pre-activity heart rate) indicated a significant difference between pre-activity heart rate and both average and maximal heart rates, with the pre-activity heart rate for dangling lower compared to the average heart rate ($F_{1,53} = 22.19, p < 0.001$) and lower compared to the maximal heart rate ($F_{1,53} = 20.20, p < 0.001$). Repeated measures contrasts revealed an additional significant difference between average heart rate and maximal heart rate during dangling ($F_{1,53} = 12.21, p = 0.001$), with maximal heart rate higher than average heart rate. Multiple

pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between heart rate across the activity of dangling (χ^2 (2, $N = 54$) = 98.71, $p < 0.001$). The rank order of heart rate during dangling (from lowest to highest mean rank) was pre-activity, average, and maximal heart rate.

Motion. A one-way repeated-measures ANOVA showed that motion was significantly different during the activity of dangling, Wilk's $\lambda = 0.37$ ($F_{2, 52} = 43.61$, $p < 0.001$). The means and standard deviations for pre-activity, minimum, and total motion are presented in the summary statistics for dangling described in Aim #1 (Table 14). Follow-up simple contrasts (using comparison to pre-activity motion) indicated a significant difference between pre-activity motion and both minimum and total motion, with the pre-activity motion for turning lower compared to the minimum motion ($F_{1, 53} = 47.55$, $p < 0.001$) and lower compared to the total motion for dangling ($F_{1, 53} = 75.54$, $p < 0.001$). Repeated measures contrasts revealed an additional significant difference between minimum motion and total motion during dangling ($F_{1, 53} = 30.52$, $p < 0.001$), with total motion higher than minimum motion. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between motion across the activity of dangling (χ^2 (2, $N = 54$) = 84.51, $p < 0.001$). The rank order of motion during dangling (from lowest to highest mean rank) was pre-activity, minimum, and total motion.

Transferring

Heart Rate. A one-way repeated-measures ANOVA showed that heart rate was significantly different during the activity of transferring, Wilk's $\lambda = 0.83$ ($F_{2, 52} = 5.32$, $p = 0.008$). The means and standard deviations for pre-activity, average, and maximal heart

rates are presented in the summary statistics for transferring described in Aim #1 (Table 15). Follow-up simple contrasts (using comparison to pre-activity heart rate) indicated a significant difference only between pre-activity heart rate and maximal heart rate, with the pre-activity heart rate for transferring lower compared to the maximal heart rate ($F_{1, 53} = 9.68, p = 0.003$). Pre-activity heart rate was not significantly lower than average heart rate for transferring ($p = 0.09$). Repeated measures contrasts revealed an additional significant difference between average heart rate and maximal heart rate during transferring ($F_{1, 53} = 10.33, p = 0.002$), with maximal heart rate higher than average heart rate. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between heart rate across the activity of transferring ($\chi^2(2, N = 54) = 74.28, p < 0.001$). The rank order of heart rate during transferring (from lowest to highest mean rank) was pre-activity, average, and maximal heart rate.

Motion. A one-way repeated-measures ANOVA showed that motion was significantly different during the activity of transferring, Wilk's $\lambda = 0.46$ ($F_{2, 52} = 30.31, p < 0.001$). The means and standard deviations for pre-activity, minimum, and total motion are presented in the summary statistics for transferring described in Aim #1 (Table 15). Follow-up simple contrasts (using comparison to pre-activity motion) indicated a significant difference between pre-activity motion and both minimum and total motion, with the pre-activity motion for transferring lower compared to the minimum motion ($F_{1, 53} = 33.75, p < 0.001$) and lower compared to the total motion for dangling ($F_{1, 53} = 61.19, p < 0.001$). Repeated measures contrasts revealed an additional significant difference between minimum motion and total motion during dangling ($F_{1, 53} = 20.52, p$

< 0.001), with total motion higher than minimum motion. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between motion across the activity of transferring ($\chi^2 (2, N = 54) = 79.44, p < 0.001$). The rank order of motion during transferring (from lowest to highest mean rank) was pre-activity, minimum, and total motion.

Sitting

Heart Rate. A one-way repeated-measures ANOVA showed that heart rate was significantly different during the activity of sitting, Wilk's $\lambda = 0.35$ ($F_{2, 52} = 48.61, p < 0.001$). The means and standard deviations for pre-activity, average, and maximal heart rates are presented in the summary statistics for sitting described in Aim #1 (Table 16). Follow-up simple contrasts (using comparison to pre-activity heart rate) did not show significant differences between pre-activity and average heart rate during sitting ($p = 0.23$) nor between pre-activity and maximal heart rate ($p = 0.16$). Repeated measures contrasts did reveal a significant difference between average heart rate and maximal heart rate during sitting ($F_{1, 53} = 90.72, p < 0.001$), with maximal heart rate higher than average heart rate. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between heart rate across the activity of sitting ($\chi^2 (2, N = 54) = 73.41, p < 0.001$). The rank order of heart rate during sitting (from lowest to highest mean rank) was average, pre-activity, and maximal heart rate.

Motion. A one-way repeated-measures ANOVA showed that motion was significantly different during the activity of sitting, Wilk's $\lambda = 0.86$ ($F_{2, 52} = 4.12, p = 0.02$). The means and standard deviations for pre-activity, minimum, and total motion are

presented in the summary statistics for sitting described in Aim #1 (Table 16). Follow-up simple contrasts (using comparison to pre-activity motion) indicated a significant difference between pre-activity motion and total motion ($F_{1,53} = 7.08, p = 0.01$), with the pre-activity motion for sitting lower compared to the total motion. This contrast revealed no significant difference between pre-activity motion and minimum motion during sitting ($p = 0.45$). Repeated measures contrasts revealed an additional significant difference between minimum motion and total motion during sitting ($F_{1,53} = 8.26, p = 0.006$), with total motion higher than minimum motion. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between motion across the activity of sitting ($\chi^2(2, N = 54) = 22.30, p < 0.001$). The rank order of motion during sitting (from lowest to highest mean rank) was pre-activity, minimum, and total motion.

Walking

Heart Rate. A one-way repeated-measures ANOVA showed that heart rate was significantly different during the activity of walking, Wilk's $\lambda = 0.13$ ($F_{2,52} = 0.017, p < 0.001$). The means and standard deviations for pre-activity, average, and maximal heart rates are presented in the summary statistics for walking described in Aim #1 (Table 17). Follow-up simple contrasts (using comparison to pre-activity heart rate) indicated a significant difference between pre-activity heart rate and both average and maximal heart rates, with the pre-activity heart rate for walking lower compared to the average heart rate ($F_{1,53} = 203.10, p < 0.001$) and lower compared to the maximal heart rate for walking ($F_{1,53} = 60.25, p < 0.001$). Repeated measures contrasts revealed an additional significant difference between average heart rate and maximal heart rate during walking ($F_{1,53} =$

25.85, $p < 0.001$), with maximal heart rate higher than average heart rate. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between heart rate across the activity of walking (χ^2 (2, $N = 54$) = 108.00, $p < 0.001$). The rank order of heart rate during walking (from lowest to highest mean rank) was pre-activity, average, and maximal heart rate.

Motion. A one-way repeated-measures ANOVA showed that motion was significantly different during the activity of walking, Wilk's $\lambda = 0.21$ ($F_{2, 52} = 95.69$, $p < 0.001$). The means and standard deviations for pre-activity, minimum, and total motion are presented in the summary statistics for walking described in Aim #1 (Table 17). Follow-up simple contrasts (using comparison to pre-activity motion) indicated a significant difference between pre-activity motion and both minimum and total motion, with the pre-activity motion for turning lower compared to the minimum motion ($F_{1, 53} = 57.14$, $p < 0.001$) and lower compared to the total motion for walking ($F_{1, 53} = 177.19$, $p < 0.001$). Repeated measures contrasts revealed an additional significant difference between minimum motion and total motion during walking ($F_{1, 53} = 169.92$, $p < 0.001$), with total motion higher than minimum motion. Multiple pairwise comparisons supported these findings. A Friedman analysis also confirmed that there was a significant difference between motion across the activity of walking (χ^2 (2, $N = 54$) = 107.51, $p < 0.001$). The rank order of motion during walking (from lowest to highest mean rank) was pre-activity, minimum, and total motion.

Summary of Within-Activities Analyses

Significant differences were consistently found between pre-activity, average, and maximal heart rates and between pre-activity, minimum, and total motion within every

activity except sitting. Friedman analyses confirmed the repeated measures ANOVA analyses. Furthermore, contrasts and pairwise comparisons of both heart rate and motion revealed multiple differences between pairs of heart rate or motion, with the differences between average and maximal heart rate, pre-activity and total motion, and minimum and total motion the most common findings (see Tables 27 and 28).

Table 27. *Summary of Statistically Significant Pairwise Comparisons Within Activities-Heart Rate ($p < 0.05$)*

Heart Rate	Pre-Activity	Average	Maximal
Pre-Activity (P)	----		
Average (A)	Turn ^A Dangle ^A Walk ^A	----	
Maximal (M)	Turn ^M Dangle ^M Transfer ^M Walk ^M	Turn ^M Dangle ^M Transfer ^M Sit ^M Walk ^M	----

Note. Initial in superscript indicates activity with higher value in pairwise comparison

Table 28. *Summary of Statistically Significant Pairwise Comparisons Within Activities-Motion ($p < 0.05$)*

Motion	Pre-Activity	Minimum	Total
Pre-Activity (P)	----		
Minimum (M)	Turn ^M Dangle ^M Transfer ^M Walk ^M	----	
Total (T)	Turn ^T Dangle ^T Transfer ^T Sit ^T Walk ^T	Turn ^T Dangle ^T Transfer ^T Sit ^T Walk ^T	----

Note. Initial in superscript indicates activity with higher value in pairwise comparison

Results for Specific Aim #3

Aim 3: Measure the effects of covariates (age, gender, BMI, pain, functional performance, functional status, comorbidity, beta-blocker use, and assistive device used during activity) on the ability of the Actiheart™ to measure motion and heart rate data during the simulation of clinical care activities.

The influence of these covariates on the results of each of the seventeen tests (7 across activity and 10 within activity) conducted as part of Aim #2 was assessed using repeated measures analysis of covariance (ANCOVA). In the case of the across-activities analyses, heart rate or motion for every activity were dependent variables and the covariates included measures of age, gender, BMI, pain, functional performance, functional status, comorbidity, use of a beta-blocker, and assistive device used during the activities. Use of a beta-blocker or assistive device were dichotomous variables and were coded as 1 (used) or 0 (not used). For the within activities analyses, heart rate or motion within each activity were the dependent variables with the covariates as described above. Please refer to Table 6 for a list of variables used for each covariate analysis.

To ensure that the 10 covariates were measuring independent constructs, correlation coefficients were computed among the covariates, with only 2 correlations greater than 0.50. These included gender and grip strength ($r = 0.82, p < 0.001$) as well as functional status, as measured by the FIM, and whether an assistive device was used ($r = -0.59, p < 0.001$). These correlations informed later analyses and interpretation.

The ANCOVA F test evaluates whether the population means of the dependent variable differ across the levels of a factor, adjusting for differences in the covariate (Green & Salkind, 2005). Each covariate was analyzed separately with each of the prior

17 analyses of heart rate and motion. If F of the between-subjects effects was significant for the covariate, then pairwise comparisons were examined to determine if the pairs determined to be significant from the original repeated measures ANOVA remained significant under the influence of the covariate. The Bonferroni procedure was used to control for Type I error across the pairwise comparisons (Green & Salkind, 2005).

Covariate Analysis-Across Activities

Covariates with Significant Effects. Analyses indicated statistically significant between-subjects effects of four individual covariates, including gender, grip strength, BMI, and the use of an assistive device during the activity simulation. See Table 29 for summary of significant covariates and the dependent variable affected.

Table 29. *Summary of Significant Covariates-Across Activities*

Covariate	Dependent Variable	df	F	p
Device Use	Total Motion	1,52	5.84	0.02
	Maximal Heart Rate (HR)	1,51	7.45	0.009
Gender	Minimum Motion	1,52	5.33	0.03
	Maximum Motion	1,52	5.96	0.02
Grip Strength	Minimum Motion	1,52	4.72	0.03
	Maximum Motion	1,52	9.14	0.004
BMI	Pre-activity HR	1,52	5.63	0.02
	Maximal HR	1,51	14.73	0.000
	Average HR	1,51	11.49	0.001

Note. Models included covariates age, gender, BMI (body mass index), pain, functional performance, functional status, comorbidity, use of a beta-blocker, and assistive device, all entered separately as covariates

In order to study the effect of these covariates, pairwise comparisons, adjusted for the influence of the covariate, were examined to determine if the covariate influenced the activity pairs found to be significant in the original analysis. Every pair of activities

found to be significant during the original analyses remained significant after adjusting for the significant covariate. For example, device use was found to be a significant covariate for the measure of maximal heart rate across activities. Significant pairwise comparisons after accounting for device use for mean maximal heart rate were between transferring and walking and sitting and walking, the same pairwise comparisons as were revealed in the original analyses for maximal heart rate without covariates.

In order to more fully explore the influence of BMI as a covariate, BMI was centered to improve interpretability. In the resultant multivariate tests, all of the main effects for pre-activity heart rate, average heart rate, and maximal heart rate, which had been nonsignificant when using a continuous BMI, became significant. Furthermore, because 49% of the sample was obese, BMI was also dichotomized to obese or non-obese to explore this effect. Although the between-subjects effect remained significant for average heart rate ($p = 0.04$), pre-activity and maximal heart rate became non-significant and even average heart rate became much less significant. These tests indicate that controlling for a continuous predictor, such as BMI, has more of an effect than dichotomizing the indicator to obese or not and that while BMI may explain part of the differences across activities, it does not necessarily explain all of the differences.

An additional analysis was also conducted to explore the significance of gender and grip strength of covariates of motion. Because of the significant influence of gender on grip strength as previously described, both of these covariates were added together in a separate analysis of maximum motion. When taken together as covariates, the between-subjects effects for each became non-significant, changing from $p = 0.004$ to $p = 0.10$ for grip strength and from $p = 0.02$ to $p = 0.96$ for gender. These covariates also became non-

significant as between-subjects effect when added together in an additional analysis of minimum motion, suggesting that these are overlapping covariate effects rather than distinct ones. This follow-up informs us of the confounding influence of grip strength and gender on one another.

Covariate Analysis-Within Activities

Covariates with Significant Effects. Analyses indicated statistically significant between-subjects effects on some of the within-activity analyses. The seven significant individual covariates included age, gender, BMI, physical performance, functional status, and the use of an assistive device during the activity simulation. See Table 30 for summary of significant covariates and the activity affected.

In order to study the effect of these covariates, pairwise comparisons, adjusted for the influence of the covariate, were examined to determine if the covariate influenced the activity pairs found to be significant in the original analysis. Every pair of activities found to be significant during the original analyses remained significant after adjusting for the significant covariate. For example, device use was a significant covariate for the measure of heart rate during turning. Significant pairwise comparisons of mean heart rates during turning, after accounting for device use, remained between pre-activity and average heart rate, pre-activity and maximal heart rate, and average and maximal heart rate. Separate analyses to explore the effect of centering BMI, dichotomizing BMI, or adding multiple covariates into any of the models was not performed.

Table 30. *Summary of Significant Covariates-Within Activities*

Covariate	Dependent Variable	df	<i>F</i>	<i>p</i>
Device Use	Turn HR	1,51	9.28	0.004
	Walk HR	1,52	7.10	0.01
	Walk Motion	1,52	13.21	0.001
Gender	Transfer Motion	1,52	5.08	0.03
Age	Walk Motion	1,52	8.06	0.006
FIM	Walk Motion	1,51	5.82	0.02
Grip Strength	Transfer Motion	1,52	4.51	0.04
PPB	Turn HR	1,51	4.72	0.03
BMI	Turn HR	1,51	13.53	0.001
	Turn Motion	1,52	11.22	0.002
	Dangle HR	1,52	5.16	0.03
	Transfer HR	1,52	7.13	0.01
	Sit HR	1,52	4.92	0.03
	Walk HR	1,52	12.21	0.001

Note. HR = heart rate; FIM = Functional Independence Measure; PPB = Physical Performance Battery, BMI = body mass index. Models included covariates age, gender, BMI, pain, functional performance, functional status, comorbidity, use of a beta-blocker, and assistive device, all entered separately as covariates

CHAPTER 5

DISCUSSION

This chapter addresses the study's major finding, implications, and limitations and offers suggestions for future research efforts with older, hospitalized patients, specifically older ICU patients. The discussion is organized according to the study's aims.

The purpose of this study was to test whether the Actiheart™, a device that measures motion and heart rate, could effectively measure motion and heart rate during the simulation of clinical care activities in an older surgical population (Aim #1). The study also tested whether the use of the Actiheart™ would be feasible, practical, and comfortable to participants in a more clinically-based research setting. The study sought to determine if the Actiheart™ could discriminate, in terms of heart rate and motion, both across the different types of clinical care activities that commonly occur during a patient's rehabilitation in a hospital and within each of those activities (Aim #2). A secondary aim, Aim #3, was to determine if selected potential covariates significantly influenced the measurement of motion and heart rate.

The major findings of this descriptive study indicate that: 1) the Actiheart™ could successfully measure the motion and heart rate of various clinical care activities in a population of older surgical patients; 2) a combined motion and heart rate monitor works well to monitor clinical care activities that may not show much change in motion, but do cause some change in heart rate (like sitting); 3) a combined motion and heart rate monitor works well to monitor clinical care activities that may not show much change in heart rate, but do cause a change in motion (like transferring); 4) the Actiheart™ could discriminate between different clinical care activities, some more consistently than

others; 5) the Actiheart™ could discriminate heart rate and motion differences within each clinical care activity; and 6) measurements of the Actiheart™ were not confounded by many of the covariates common in an older surgical population. This study was the first to explore the ability of the Actiheart™ to measure motion and heart rate in a cohort of older adults in a hospital-like environment.

Major Findings and Implications

Specific Aim #1

Describe the patterns of motion and heart rate during five different clinical care activities (turning, dangling, transferring, chair sitting, and walking).

This study provides strong evidence that activity can be more objectively measured in older hospitalized patients. The current study showed that for any of the five clinical care activities, the Actiheart™ could satisfactorily measure the heart rate and motion associated with such activities. Logically, the pre-activity heart rate prior to the dangling activity was lowest after a rest period of the participant lying supine. While the average and maximum heart rate were lowest for sitting, as might be expected, the pre-activity heart rate prior to sitting was the highest of the pre-activity heart rates. The sitting pre-activity heart rate was considered to be the same as the pre-transfer heart rate since no separate rest period occurred after transferring, but prior to the sitting activity. This higher heart rate possibly represents the aerobic effort required of participants during the dangling activity that occurred prior to the transfer activity as participants assumed a seated position on the side of the bed from a lying position. This finding may have significant importance because few studies have explored the role of dangling (Dingle, 2003; Lane, Winslow, Woods, & Dixon, 1997) nor have they examined the physiologic

responses, like heart rate and motion, to dangling despite clinical recommendations that have linked dangling with improving patients' ability to tolerate orthostatic stress (Convertino, 2003). Because the Actiheart™ can measure the motion and heart rate associated with dangling, the role and importance of this activity could be further explored.

Despite the activity of sitting being described in the literature (Ahrens, Burns, Phillips, Vollman, & Whitman, 2005; Timmerman, 2007) as a progressive and rehabilitative activity for hospitalized patients, from a motion perspective, little occurs while a patient sits in a chair. Because there is no movement, the Actiheart's™ accelerometer did not recognize sitting on a continuum of activity, registering no more than an average of three counts per minute for even the maximum or total motion counts. Motion counts for sitting were lower than for all four other activities. Thus, the motion portrayed by the Actiheart™ of the sitting activity may not accurately reflect the clinical benefits of assuming an upright position, particularly during a recovery from an illness or surgical procedure. Yet, the cardiovascular, respiratory, and neuromuscular effects of sitting have been touted in studies as being especially important to promote postoperative lung function, counteract orthostatic hypotension, and alleviate muscle atrophy (Convertino, 2003; Malone, 2006; Nielsen et al., 2003). However, this study actually found that maximal and average heart rates were lowest for sitting as compared to the other four activities. While this is not to say there are not clinically beneficial effects of sitting as an activity, in this study, the Actiheart™ did not reflect activity, either through increased motion or heart rate, during sitting in the same magnitude that it did for the other activities. Theoretically, in a combined device such as the Actiheart™, which

measures both motion and heart rate, changes in heart rate during an activity may provide meaningful information despite there not being any motion during that activity. Future studies might identify such types of activities.

The simulated nature of this study ensured that heart rate and motion measurements were taken during all five activities. Because past studies using accelerometry alone have occurred in a naturalistic environment, measurement of specific activities was irregular and could not be anticipated (Grap et al., 2005; Winkelman et al., 2005). Participants in Winkelman's study were observed a total of 8 hours to help analyze the concurrent accelerometry data, during which time all 20 were turned several times, 11 experienced range of motion, 2 sat in a chair, and 1 stood. No dangling, transferring, or walking was observed. The Winkelman (2005) study also revealed that the time required for turning averaged 11 minutes ($SD = 6$) as compared to the average turning time in this study of 1 minute, 45 seconds ($SD = 30$ seconds). In a naturalistic setting, researchers obviously cannot control the occurrence or duration of desired activities. For a measurement study, this lack of systematization can present challenges to analyzing results for common patterns and significant findings.

In the current study, since the focus of the study was to determine the ability of the Actiheart™ to measure clinical care activities, all activities were performed by all participants and generally lasted about the same amount of time with the exception of the walking activity, which ranged from 1.5 minutes to 4 minutes, 45 seconds ($M = 2.5$ minutes; $SD = 0.65$ minutes), longer than the other activities. While this more controlled environment cannot account for all of the realities and potential influences of a more clinical setting, it was a necessary first step since the Actiheart™ had not previously been

used in an older population nor in a more clinical setting. In a clinical research setting, the Actiheart™ may be equally, if not more, effective in measuring activities because the activities would likely last longer and allow the Actiheart™ a greater period of time to record motion and heart rate data.

By measuring both motion and heart rate, using videography to assist in the interpretation of the simulated clinical care activities, and sampling every 15 seconds, the ActiHeart™ offered the opportunity to assess these activities in a sample of older adults in a way that has not been studied before. The time stamp of the Actical®, pressed at the beginning and end of each clinical care activity, was especially important in the analysis of the Actiheart™ data. Without this time stamp feature and the videography, it could have been difficult to define specific beginning and end points of some of the activities. In past studies (Grap et al., 2005; Winkelman et al., 2005) that relied on a wristwatch-type of accelerometer like the Actical®, activity was primarily measured using observation periods that were limited to several hour blocks of time to help correlate the 24-hour accelerometry data. Grap (2005) found that although wrist- and ankle-placed accelerometry were highly correlated, ankle placement indicated decreased levels of activity as might be expected, since the ankle does not move as much as the wrist and can filter out unwanted activity. Although not formally analyzed as part of this study, wrist-worn Actical® readings in this study were never 0 and seemed responsive even to such movements as when participants were talking with their hands, all of which could make discriminating meaningful from unmeaningful activity difficult with this device.

Thus, no single instrument currently offers all the features that would make each one fully useful for an inpatient clinical research application. Actiheart™ data from this

study would have been very difficult to interpret without the corroborating time stamp information of the Actical®. In future studies of longer duration, this difficulty would likely be even more pronounced. While this study did not statistically compare the motion measurements of the Actiheart™ and the Actical®, preliminary examination of the Actical® data indicates that the Actical® might include too much motion data per epoch that is not meaningful (hands moving in the air) and would also not offer the synchronized heart rate information provided by the Actiheart™. Taken together, the ideal device for this study would have been, and for future studies would be, an Actiheart™ device that had a time stamp feature built into the device.

Specific Aim #2

Compare clinical care activities using continuous motion and heart rate data to discriminate motion and heart rate both across and within five different clinical care activities.

For every activity except pre-activity motion, the Actiheart™ distinguished between different clinical care activities for various heart rate and motion parameters. This study found a significant difference in pre-activity heart rate across activities, with the highest pre-activity heart rate for the sitting activity. The preceding activities of dangling and transferring, which would have caused the participants to assume an upright position, likely caused the higher heart rate before the sitting activity, especially since no separate rest period occurred prior to the sitting activity. The purpose of the standardized five-minute rest period was so that all participants had roughly the same opportunity to return to a baseline heart rate. While it is unclear whether a separate pre-sitting rest period would have influenced the pre-activity heart rate for that activity, we would have

expected the pre-activity heart rates of the other activities to not be significantly different. These results reflect an important finding related to the study's methodology. Although the study's rest period duration of 5 minutes was based on past work of adequate rest periods for both ICU patients and healthy adults that ranged between 5 and 15 minutes, respectively (Lewis et al., 1997; Verderber & Gallagher, 1994), these findings show that the 5-minute rest period may not have been long enough in this sample of older adults needing surgery. Although future inpatient studies would not necessarily incorporate a so-called rest period into their methods, determining a participant's baseline heart rate prior to any activity would be important for any study in order to accurately measure that person's response to activity.

Not surprisingly, the activity transition that had the most significant differences across heart rate and motion parameters detectable by the Actiheart™ was between sitting and walking, with sitting and walking representing the low and high ends of the motion and heart rate spectrum. The next most common transitions detectable by the Actiheart™ were between sitting and the activities of turning, dangling, and transferring and between transferring and walking. For only a few of the analyses was the Actiheart™ able to differentiate between the activities of turning and dangling, turning and transferring, and dangling and transferring. This finding provides evidence that the Actiheart™ could be used to study the progressive nature of clinical care activities, although it may not be able to easily differentiate between some of the activities that generate similar motion and heart rate responses, namely turning, dangling, and transferring.

While the analyses of motion and heart rate across activities was less informative for the more subtle activities of turning, dangling, and transferring, the analyses of heart rate and motion within each activity importantly revealed that heart rate and motion changed significantly within these activities. With the exception of no significant difference between pre-activity and average heart rate during transferring, all other differences between pre-activity, average, and maximal heart rates and pre-activity, minimum, and total motion were significant for every activity except for sitting. The finding that heart rate and motion significantly changed during the activity of dangling underscores the importance of further studying this type of clinical care activity, described previously as often overlooked as a therapeutic activity (Dingle, 2003). Moreover, the within-activity analyses further substantiated the questions that have arisen in this study regarding the role of sitting as a clinically meaningful activity. Only one of three potential differences in heart rate pairs was significant for sitting (average and maximal heart rate) and differences between pre-activity and minimum motion were also not significant. The lack of statistically significant differences in heart rate during sitting is likely attributable to the higher pre-activity heart rate as has previously been discussed. However, further study of objective measures of more sedentary activities, such as sitting, must thoughtfully consider how to effectively measure its therapeutic benefit.

This study measured the differences between five clinical care activities in a sample of older surgical patients. Other studies using non-Actiheart™ accelerometry in clinical environments have measured fewer activities or have not been able to discriminate between activities. This study was broader than prior studies using accelerometry in the ICU setting of non-older adults; for example, the Winkelman study

(2005) only observed two different types of activity, turning and range of motion, and did not make comparisons between the two activities. The Grap study (2005) did not measure the nature of activity at all. Browning and colleagues (2007) used the Positional Activity Logger, an alternative to an accelerometer used to measure out of bed activity. The logger measures the quantity of time spent in an upright (uptime) position by detecting when the device, worn on the thigh, is in a position greater than 45 degrees to the horizontal axis. Although used to study postoperative mobilization, the logger was unable to measure time spent out of bed nor to delineate between standing and walking. Culhane (2004) monitored five older adults in a rehabilitation clinic using accelerometry, studied only standing, sitting, and lying, and found some difficulty distinguishing between sitting and lying.

In terms of the sensitivity and specificity of the Actiheart™ in this study, the device was able to detect differences between activities, in a manner more sensitive than instruments in previous studies, but was limited in its ability to detect potentially more subtle activities like turning, dangling, and transferring that, while presumably therapeutic, do not register large differences in heart rate or motion. This finding regarding the potential lack of specificity of the Actiheart™, particularly of these lower intensity activities, corroborates past research that has found that even multiaxial accelerometers can underestimate these types of activities (Hendelman et al., 2000; Thompson et al., 2006). However, the lower-intensity activities of turning, dangling, and transferring also occurred over the shortest period of time during the protocol; shorter epochs and duration of activity have been discussed as influencing the meaningful interpretation of activity (Chen & Bassett, 2005). In a more naturalistic clinical research

setting, as discussed previously, activities such as turning, dangling, and transferring would likely take longer, potentially improving the ability of the Actiheart™ to detect and discriminate these activities from one another. The Actiheart™ was most successful in discriminating walking from the other four activities. This finding is especially important if the Actiheart™ were to be used in clinical research because walking remains a key rehabilitation goal in the hospital setting.

The Actiheart™ offers the potential to be used in research studies, particularly in a hospital setting, in ways that could help define what clinical care activities are, when they occur or do not occur, and then potentially determine which activities are most therapeutic by being able to measure within-activity differences in heart rate and motion. Browning (2007) has argued that there currently is no standard definition of early mobilization. Several of the ICU intervention studies underscore this point. Bailey (2007) defined activity as only sitting on the bed, sitting in a chair, or walking, while Thomsen (2008) also included range of motion, but excluded the activity of turning in bed. The use of a device such as the Actiheart™ might help further define the various clinical care activities and their therapeutic value. Findings from the Actiheart™ in the context of clinically-based research could potentially translate into practice changes affecting clinicians' understanding of the utility of clinical care activities and the use of them early in an older person's hospitalization.

Specific Aim #3

Measure the effects of covariates (age, gender, BMI, pain, functional performance, functional status, and comorbidity, beta-blocker use, and assistive device used during activity) on the ability of the Actiheart™ to measure motion and heart rate data during the simulation of clinical care activities.

This study found that even when select covariates were determined to be significant, as was the case for device use, BMI, gender, and grip strength, the pairwise comparisons of the different activities from the original analysis remained the same and statistical significance was also unchanged after accounting for the covariate. Thus, the results reflect a minimum and inconsequential influence of the covariates on the ability of the Actiheart™ to discriminate the different activities, as well as the heart rate and motion within the activities. The study's findings that grip strength was significantly influenced by gender informed our understanding of the results related to these two covariates. When grip strength and gender were analyzed together as covariates, neither remained a significant covariate. Similarly, the various approaches used to analyze BMI also portray the difficulty in fully understanding the effect of BMI on the measurement of heart rate and motion. The fact that BMI showed significant between-subjects effects primarily for heart rate analyses, both for the across and within-activities analyses, leads us to wonder if the heart rates of persons with higher BMIs are not driving these results. Although not statistically significant, the maximal heart rate for all five activities was higher for persons with BMIs of 30 or more (defined as obese) than for those participants with BMIs less than 30.

These findings are not to say that there may not be covariates that might confound the ability of the Actiheart™ to measure differences between activities. Particularly if the Actiheart™ is used in future studies in an inpatient environment, researchers should anticipate what covariates might be important in the environment and plan for them in the study's design and analysis. For example, maybe a study would stratify enrollment by BMI so that a sample was adequately represented by persons across the BMI range.

Data Characteristics of the Actiheart™

The study also addressed a technical issue related to the measurement of heart rate that has not yet been discussed in the literature. In terms of the mechanics of the Actiheart™ itself, no other Actiheart™ studies have discussed whether, or to what degree, readings of Not a Number (NaN; meaning data were missing) during heart rate epochs occurred, even in the study that used 15-second epochs in a field setting (Crouter et al., 2008). The manufacturer states that output may read NaN when there is device error, out-of-range activity or heart rate, or not enough data to compute an output for an epoch (MiniMitter Company, 2004). Yet, this study had heart rate data from almost half of participants that included either one or two NaNs. While this minor level of NaN data in place of valid heart rate values did not significantly influence subsequent analyses, four participants were excluded from the analysis because of the degree of missing heart rate data caused by NaN. Another 4 participants remained in the analysis but had over 20% of their epochs labeled NaN.

While device error was unlikely in this study since the same Actiheart™ was used across all participants and other higher heart rates, determined later as outliers, were recorded, perhaps the shorter epoch of 15 seconds disallowed sufficient heart rate

information to be recorded at times. The protocol also did not shave participants' chest, as recommended by the manufacturer when appropriate, which could have influenced some Actiheart™ readings. As a result of our study, researchers in an inpatient clinical research study or study of longer duration should consider collecting data across the other longer epochs offered by the device, 30 or 60 seconds, perhaps allowing for fewer instances of NaN epochs. Additional factors may have influenced the heart rate readings in our sample of older adults and these factors should be considered in future data collection using the Actiheart™; for example, older adults have relatively drier skin that may influence electrode conductance, thus different electrodes might improve electrical conductance and adhesive ability. In addition, securing the Actiheart™ with tape over the device itself might reduce the number of NaN epochs (Bell, F., personal communication, May 3, 2009).

Another contributor that might explain that almost 41% of participants had at least a single NaN reading during the activity of turning and 24% during dangling is that both activities require a twisting of the trunk that may interfere with either the chest lead placements of the Actiheart™ sensors or the Actiheart's™ ability to adequately detect heart rate when in a twisting or turning position. However, these activities did not seem to interfere with Actiheart™ measurements of motion during those time periods. Neither BMI nor gender was significantly correlated with percentage of NaN readings as initially suspected by the PI. In general, though overall use of the Actiheart™ was successful in measuring clinical care activities, before any larger scale use of the device occurs, researchers should consider methods, such as longer epochs, choosing electrodes optimized for use in the sample being studied, shaving male chests, exterior securement

of the device, accounting for twisting, or other factors that reduce the proportion of NaN readings.

Characteristics of the Sample

This study differed from past studies of the Actiheart™ in terms of the participants' age, the study setting, and the nature of activities studied. The current study focused on older adults age 65 and older prior to their admission for a surgical procedure whereas most of the studies using the Actiheart™ have used subjects much younger, with mean ages of participants in their 20s (Brage et al., 2006; Strath et al., 2005; Thompson et al., 2006) or 30s (Crouter et al., 2008; Rennie, Rowsell, Jebb, Holburn, & Wareham, 2000). Furthermore, none of the Actiheart™ devices have been studied in a clinical setting. Most Actiheart™ studies have taken place in a laboratory setting (Brage et al., 2006; Strath, Bassett, Thompson, & Swartz, 2002; Thompson et al., 2006), with only recently a study occurring in a field-type setting (Crouter et al., 2008). Although a few studies have begun to examine the use of the Actiheart™ to measure very low intensity activities (Crouter et al., 2008; Thompson et al., 2006), none have examined clinical care activities that typically occur as part of rehabilitation during a hospitalization. Participants in the present study, as a group, were also more likely to have physiologic responses to the simulated activities, such as accelerated heart rates, presumably due in part to their older age. These differences are important because prior studies have not specifically discussed analyzing data with heart rates significantly above the mean heart rates, nor have they discussed how to address such outliers.

The participants in this study were younger than expected (mean age of 71), although similar in age to Gerson's study (1990) of 177 older patients undergoing

elective surgery who had a mean age of 72 (*SD* not provided). Reasons for this relatively young age might be explained by the fact that younger-old (age 65 to 74) patients have more elective surgery than even patients age 75 and older (Barlow et al., 1989). Since oldest-old adults have been found to have fewer elective admissions (Casey et al., 2006), it is logical that by recruiting from a clinic that sees only patients undergoing elective surgery, the study would have recruited younger patients. Epidemiologic studies (Steinmetz, 2006) also suggest that disability increases with age, confirming the study's anecdotal findings that some of the older patients recruited as potential participants were too disabled to participate in the study.

While the female gender composition of the study's sample was slightly higher (60%) than past utilization data or study data from the hospital (Casey et al., 2006; University HealthSystem Consortium, 2006), it mirrors the 58.8% of females as a proportion of the 65 and older population reported from the 2000 census (He et al., 2005) and thus is probably typical of the general population of elective surgical patients. While enrolling 5 minority older adults (9.3% of the sample) out of the 6 projected, the study achieved a study sample that closely reflected the hospital's utilization by minority older adults (University HealthSystem Consortium, 2006). However, in terms of the racial and ethnic composition within the group of five minority participants, the study did not enroll any African American participants, which may limit the generalizability of its findings.

The participants were a relatively independent group of older adults, in terms of activities of daily living, in spite of reporting multiple diseases and symptoms. Although Chen and colleagues (2008) did not use the same instrument to measure comorbidity, they did use a comorbidity checklist with common medical conditions to calculate a total

comorbidity score as this study did. Chen (2008) found a population of 286 older Taiwanese hospitalized patients to have an average of 4.14 ($SD = 1.84$) conditions while this study reported a mean of 11.20 ($SD = 4.96$) medical conditions. While not directly comparable or explainable because of potential differences in comorbidities included in the instruments, the degree of difference calls into questions whether our sample's comorbidity was typical of surgical patients. This question is a potential limitation of our study, but is unlikely to affect the findings related to the study aims.

The study's participants scored 123.57 ($SD = 3.93$) on the Functional Independence Measures (FIM) out of a possible 126, perhaps reflecting a lack of disability because of the younger age of the sample as discussed above. The score might also reflect the exclusion of patients with neuromuscular disorders and cognitive deficits, as well as those patients who were not able to physically participate in the simulation protocol. The sample's FIM score does reveal a potential ceiling effect for this study's participants, although in general, the FIM has been shown to be more responsive to change in populations of older rehabilitation patients and less prone to ceiling effects than other self-report measures of function (de Morton, Keating, Berlowitz, Jackson, & Lim, 2007; Dromerick, Edwards, & Diringer, 2003). Additional study is warranted to determine the effectiveness of the Actiheart™ to measure heart rate and motion response to clinical care activities in another sample of older patients with higher reported disability.

In examining the grip strength of the study's participants as compared to published norms, the study's sample proved weaker than other studies for both males and females. Using published reference values (Gunther, Burger, Rickert, Crispin, & Schulz,

2008) for healthy Caucasian women and men aged 60 to 69 (since the majority of the sample was between 65 and 70), women in the study averaged a grip strength of 18.44 ($SD = 5.04$) as compared to the normative value of 25.5 ($SD = 5$). For men, the study's sample had a grip strength of 35.42 ($SD = 7.11$) while the normative range for men 60-69 was 44 ($SD = 7$). Humphreys (2002) studied handgrip strength as a predictor of loss of functional status in hospitalized patients. Although a younger sample (mean age 55, $SD = 16$), the study found handgrip strengths of 28.7 and 27.0 (right and left, respectively) for patients in whom functional capacity did not decline, but found handgrip strength of 17.3 and 16.2 (right and left, respectively) for patients whose functional capacity declined. Humphreys also found the handgrip strength of the hospitalized participants to be significantly lower than compared to healthy controls, although our study used published reference values of healthy older adults (Gunther et al., 2008). Although participants in this study were not yet hospitalized, the lower grip strength in our participants may indicate that, like those in Humphrey's study, the physical functioning levels were actually lower than the high function indicated by the self-report FIM. All of these findings regarding the characteristics of this study's sample suggest a foundation from which the Actiheart™ could be used in future studies of older hospitalized patients.

Limitations

A limitation of our study was the use of simulated activities in a population of older adults that was not yet hospitalized. However, this approach was a practical way to study activities and test the feasibility of the Actiheart™. A prospective design to evaluate clinical care activities after surgery and after admission to an actual ICU could have sampled from the ultimate target population, critically ill older adults, as well as

measured clinical care activity in its complete clinical context and over the duration of hospitalization. This type of design, however, would have required a longer period of time to conduct at a significantly increased cost. Multiple accelerometers would have been required for use at any one time and recruitment issues would have been more complex in terms of identifying eligible patients, the availability of the patient and/or family to consent during a highly stressful time, and working across multiple inpatient ICU units and staffs. Videography would also have been difficult, requiring the incorporation of its use into the inpatient setting at an increased cost and requiring the buy-in of hospital staff and administration for its use during routine clinical practice. Most importantly, use of the Actiheart™ in an older population and in a non-laboratory population has not been studied until now. Until research was conducted to explore its feasibility in a more clinical setting and in an older population, the expense and complexity of a longitudinal project could not yet have been justified. Therefore, this study was designed to simulate important elements from the actual clinical setting (equipment, positioning, activities) while retaining some aspects of a more controlled laboratory-type environment (standardization of protocol, equipment placement, videography, and calibration of the Actiheart™).

Other methodologic issues that could serve as limitations to the study include not randomizing the order of the simulated activities, as well as potential environmental influences. Though randomization of the activities could have reduced the potential for systematic error, the consistency produced by using the same order of activities was considered to be more important to the study's hypothesis that the device could discriminate between the progressive nature of the activities. For example, we were able

to posit that the high pre-activity heart rate of the sitting activity was likely caused by the previous activity of dangling, a pattern we could not have seen if activities were in random order. Environmental influences included the use of an automated bed and a change in study location at the beginning of the study. Though it was possible that extraneous measurements of motion by the Actiheart™ might occur when the automated hospital bed moved up and down since one study (Patterson et al., 1993) implicated riding in automobiles as introducing the potential for vibrational artifact with accelerometers, data revealed that bed motion was not detected by the Actiheart™, perhaps because only the bed was moving, not the participant. For the majority of participants, the hospital bed was not adjusted during the simulation protocol.

The study location changed after data collection on 13 participants. Except for a change in hospital beds, all other equipment used in the study remained the same after changing study locations. However, differences in mean heart rates and motion counts of participants before and after the change in locations were not significant, minimizing this limitation. The second location also allowed for the permanent setup of all equipment, reducing the potential for errors in equipment setup and calibration.

This study may not have had sufficient power to detect a difference caused by covariates in Aim #3. Without knowing or being able to anticipate the distribution of the sample in terms of the multiple covariates, this aim was an exploratory aim. Based on a thorough literature review, as well as clinical experience, the covariates were chosen to reflect the factors that were hypothesized or shown to influence motion and/or heart rate. Prioritizing a single covariate from which to power this aim would have been speculative. This aim's hypothesis did allow for relationships to be measured between these

covariates and the primary outcome measures, producing information useful for understanding which covariates may influence readings of heart rate and motion by the Actiheart™ and which we have learned do not. Future studies can then account for these potential influences in their study designs and methodologies.

Generalizability of the study's results represents another potential limitation. Participants were recruited and enrolled only from patients seen at OHSU, particularly those who visited the PAT clinic prior to an elective surgery. As a result, this requirement of a PAT clinic appointment did not capture older adults who were admitted urgently nor did it capture older adults who visited a surgical clinic, were informed they needed immediate surgery, and visited the PAT clinic the same day as their surgical clinic appointment. As a result, the study's participants were perhaps less old and less acutely morbid than more emergent older patient populations. Furthermore, the eligibility criteria requiring that participants be ambulatory and able to fully participate in the simulation excluded some more disabled elders who are at even greater risk for inactivity during hospitalization. This limitation was minimized by allowing any participant to use an assistive device during any part of the study visit so as not to exclude older adults using these devices. Despite these limitations, this study provides an important step to beginning to measure clinical care activities, but may only be generalizable to a younger-old, surgical, Caucasian, and relatively functionally independent sample. Future studies can build on this foundation by studying the measurement of clinical care activities in an actual hospital setting with older adults who are more racially diverse, are older, and are more disabled, allowing the Actiheart™ to be tested in an even more heterogeneous sample of hospitalized older adults.

Suggestions for Future Research

The findings of this study add to our understanding of how to effectively approach the objective measurement of activity in studies conducted in the hospital setting. This study, while not the first to propose use of an accelerometer in an ICU or hospital setting, is the first to examine the feasibility of such measurement and to trial the use of a combined heart rate and motion monitor. Findings from this study reveal multiple areas that warrant future investigation. These areas include: 1) the evaluation of activity over the course of an older adult's hospitalization to identify patterns of activity in an actual hospital or ICU setting; 2) the identification of covariates that affect whether an older adult performs or receives clinical care activities and/or the risk factors that might adversely affect heart rate or motion during such activities; 3) whether some clinical care activities might produce benefits in terms of physical functioning as measured by the use of a device, such as an Actiheart™; 4) comparing populations of older hospitalized adults, those who receive activity based on a usual standard of care and those who receive a focused activity intervention, and exploring the effect of the intervention on such hospital outcomes as length of stay, rate of complications, and discharge disposition; and 5) intervention studies to identify optimal dosing of activity and mobility in older hospitalized patients, especially those in the ICU.

Description of Activity in the Hospital Setting

Morris and Herridge (2007) have called for more information on current practice patterns and a description of variability across different types of units and hospitals in order to inform early mobility interventions and protocols. Studies such as this one are a first step in describing clinical care activities in terms of heart rate and motion using the

Actiheart™ as a measure. The Actiheart™ distinguished between several different care activities, suggesting that future studies could use the Actiheart™ to help characterize activity patterns, especially in light of the device's water-resistance, placement on the chest (versus leg, wrist, or ankle), and battery life of just under 2 weeks, though in cases of cardiac surgery, placement of the Actiheart™ would likely be contraindicated.

Descriptive studies related to current activity patterns using a device such as the Actiheart™ could inform important aspects of future intervention studies, by defining what usual care is for activity in the hospital and ICU setting. The clinical rule of thumb says patients, when physiologically stable, should get out of bed three times a day. However, Callen (2004) found that of 118 older patients less than 20% walked once per day. Studying such patterns of activity with a device like the Actiheart™ could highlight the gaps between practice recommendations and actual practice.

Future studies using a device like the Actiheart™ could further define what constitutes meaningful rehabilitative activity. For example, does range of motion count as important activity? Historically, nursing has promoted passive range of motion as a standard of care yet its effectiveness is not well documented. A few studies have described range of motion as effective (Rosenfeld, Seferiadis, Carlsson, & Gunnarsson, 2003; Winters et al., 2004) and the use of the continuous passive motion remains a standard in post-knee replacement orthopedic patients (Milne et al., 2009). However, these activities have not been studied as part of a larger picture of overall physical rehabilitation. Placement of the Actiheart™ during the course of hospitalization as part of a clinical research study could help better define the full range of activity that has become

a part of an older adult's rehabilitation and potentially how these elements relate to one another to ultimately affect the older person's recovery.

Covariates and Risk Factors to Activity and Inactivity

The activity measurements by the Actiheart™ could be collected in addition to other variables shown to influence mobilization in past studies, including an evaluation of bed rest orders and their medical indication (Brown et al., 2004; Needham, 2008), type of therapy received, involvement of physical therapy (Winkelman et al., 2005), severity of illness (Morris et al., 2008), or whether family, nursing, or therapy staff assisted in mobilization (Callen et al., 2004), to name just a few. A separate review of predictors of functional decline in older hospitalized patients did not even mention 'within' hospital factors, such as the amount of physical activity or bed rest, because the 27 studies it included did not discuss such possible predictors (McCusker, Kakuma, & Abrahamowicz, 2002). Yet, hospitalization itself has been implicated as a cause of subsequent disability upon discharge (Thomas, 2002). Research to more objectively and specifically measure activity in older hospitalized patients could help elucidate these relationships.

The need also exists to better define the risk factors for inactivity in older hospitalized adults. While many preadmission variables are often collected as part of a hospital intake (Creditor, 1993), most do not directly inform whether someone is more at risk for inactivity during hospitalization. A clinical tool does not exist that might specifically help identify high-risk patients who would benefit from intensified rehabilitative efforts. This type of assessment often occurs empirically in the inpatient setting, but is not formalized so that resources could be most appropriately targeted.

Future research might be directed at identifying such high risk groups by better defining important covariates and risk factors for inactivity in older hospitalized patients. Studies that would formally evaluate these risk factors for inactivity would be invaluable to then help target interventions aimed at decreasing the frequency and negative outcomes associated with inactivity.

Intervention Studies

If the Actiheart™ can produce good descriptions of the quantity, duration, and intensity of activities in hospitalized patients, both clinical care activities and other mobilization activities, intervention studies that more objectively measure such activity could follow. Overall, the ICU-based intervention studies to date have not specifically examined activity in the older ICU population, known to be at high risk for complications and decreased functional outcomes related to their critical illness. Although prior studies have delineated the frequency and durations of the activity interventions, by not utilizing any objective measure the activities themselves, earlier studies make it difficult to assess the dosage and intensity of such activities as might be possible using an objective measure of activity, such as an accelerometer like the Actiheart™. Thus, further descriptive studies of activities to identify an effective objective measure of activity should precede the design of any intervention studies.

Intervention studies in this area of inactivity would set the stage for beginning to identify optimal dosages of physical activity in older ICU patients. The idea of a dose-response relationship has received increasing attention in the arena of general physical activity within a community-based setting (Church, Earnest, Skinner, & Blair, 2007; Lee, 2007). The use of an accelerometer like the Actiheart™ could add to the measurement of

any intervention's treatment implementation. Additionally, more objective research in this area could potentially enhance the ability to customize activity prescriptions for individuals, contributing to more precise and targeted rehabilitation protocols.

Summary

The fact that ordinary clinical care activities in older adults can be measured more objectively than has previously occurred is especially important in light of our aging society and the increased utilization of hospital services by older adults (Russo & Elixhauser, 2006). This study was the first to investigate the measurement of heart rate and motion during clinical care activities using the Actiheart™ in a cohort of older adults scheduled for surgery. The study offered several advantages to studying the activity patterns of hospitalized older adults. By sampling from a subset of older surgical patients prior to their surgery, the study presented the opportunity to examine the use of Actiheart™ in a sample that better approximated the target sample than standard measurement study samples of young, healthy volunteers, but retained elements of a more controlled setting by using a hospital-type laboratory setting. The use of simulated clinical care activities and equipment characteristic of an ICU setting infused the realities of the clinical setting into a controlled environment. The study highlighted that while the Actiheart™ does have some important limitations, namely the lack of a time stamp on the device, difficulty in detecting and recording some heart rate data, and difficulty in discriminating between lower-intensity activities, it could still serve as an important objective measure of activity in a clinical research setting. Its simultaneous measurement of both motion and heart rate and, as the results of this study demonstrate, its ability to detect significant differences between these measurements both across and within a

number of standard clinical care activities compliments the device's convenient placement, portability, extended battery life, and water resistance.

The study successfully addressed three of the National Institute of Nursing Research (NINR) strategic objectives (2006). The use of the Actiheart™ to measure motion and heart rate in response to simulated clinical care activities achieved the NINR objective of integrating biological and behavioral sciences. The testing of the device in a sample and setting in which it has previously not been studied fulfilled a second NINR objective to adopt and adapt new technologies. The findings from this study may ultimately benefit the hospitalized older adult by demonstrating that the measurement of activities in older hospitalized adults can be accomplished more objectively than has occurred in past studies, satisfying a third NINR objective to improve nursing science methods. This study's findings can lead to future studies of activity during hospitalization that may highlight particular patterns of inactivity and activity in the older hospitalized patient. Ultimately, additional intervention studies to increase rehabilitative activity in a population known to be at risk for functional decline during hospitalization can and should be developed that use a device, such as the Actiheart™, to more objectively measure the activity intervention itself.

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Appendix A

Consent and Authorization Form



Oregon Health & Science University
Consent and Authorization Form

IRB#: 3766

Protocol Approval Date: 7/13/2008

OREGON HEALTH & SCIENCE UNIVERSITY
Consent and Authorization Form

TITLE: Physiological Responses to Simulated Care Activities in Older Surgical Patients

PRINCIPAL INVESTIGATOR: Heather M. Young, PhD, GNP (541) 552-6706

CO-INVESTIGATOR: Colleen M. Casey, MS, RN, (503) 494-4799, pager #16187

RESEARCH STAFF: Ardith Conway, BSN, RN, MPA
Joan Newby, BSN, RN
Jessica Madison, RN

SPONSOR: National Institutes of Health, National Institute of Nursing Research

PURPOSE:

You have been invited to be in this research study because you are 65 years of age or older and will be having surgery at Oregon Health & Science University (OHSU). The purpose of this study is to learn about motion and heart rate patterns during nursing care activities. We will study this activity in older adults before they enter the hospital for surgery. These activities will take place in a lab, not at the time of actual care. The activities will include turning in bed, sitting on the side of the bed, transferring from the bed to a chair, sitting in a chair, and walking.

During this research study you will be videotaped. If you agree to also allow the videotape to be used for educational and research purposes, we will need to obtain your permission in a separate media consent form.

This study requires 1 visit. It will be scheduled to occur before or after your Pre-Admission Testing (PAT) clinic appointment before your surgery. The study will take between 1 1/2 and 2 hours to complete. We will enroll about 60 participants in this study.

PROCEDURES:

You will complete three (3) main parts of the study. These include:

- 1) Questions about your health, any pain you have, what types of physical activity you can complete, and other social and lifestyle questions (called 'Health Data'). We will review your medical record to make sure that the illnesses you report are included in your record as diagnoses.

- 2) Two (2) measures of your physical ability. We will test your balance, walking speed, and ability to stand up from a chair, as well as how strong your grip is (called 'Physical Performance').
- 3) Nursing care activities that are standard in the hospital (called 'Activities'). The order of the nursing care activities will be random. Before each activity and in between the activities, you will be able to rest.

The table below also shows the parts of the study and the time required for each part.

Summary of Procedures:

	Visit 1 Part 1	Visit 1 Part 2	Visit 1 Part 3
Health Data	X		
Pain Questions	X		
Function Questions	X		
Health and Symptom Questions	X		
Social and Lifestyle Questions	X		
Physical Performance		X	
Leg and arm strength tested			
Activities ●Motion and heart rate measured ●Activities including turning, transferring in and out of bed, sitting in chair, and walking			X
Total time	15 minutes	20 minutes	40 minutes

As part of the Activities, we will connect you to equipment that is common in the hospital. All equipment will be attached with tape to your skin temporarily. We will place electrodes on your chest to measure your motion and heart rate during these activities.

If you have any questions regarding this study now or in the future, contact Dr. Heather Young, (541) 552-6706 or Colleen M. Casey, (503) 494-4799, pager #16187.

RISKS AND DISCOMFORTS:

Risks to you will be very low for this study. You may become tired and will be allowed to take rest periods when you need them. You may also schedule the study visit at a different time from your clinic appointment.

To ensure your safety during the study, you will be allowed to use any device (walker, cane) you normally use. All equipment used for the study will be approved by OHSU's safety department and will be cleaned thoroughly in between subjects.

Some of the questions on the questionnaires may seem personal. You may refuse to answer any of the questions that you do not wish to answer. Because this appointment will happen prior to your surgery, you may tell us about worries related to the surgery that are not part of this study. If you are very upset, we will help you contact your surgeon with your permission.

There are no other risks or discomforts we expect in this study.

BENEFITS:

You will not benefit from being in this study. However, by serving as a participant, you may help us learn how to benefit patients in the future.

ALTERNATIVES:

You may choose not to be in this study. You do not have to take part in this study to have surgery and receive treatment.

CONFIDENTIALITY AND PRIVACY OF YOUR PROTECTED HEALTH INFORMATION:

We will not use your name or your identity for publication or publicity purposes. If you sign this form, you are agreeing that OHSU may use and disclose protected health information collected and created in this research study. The specific health information and purpose of each use and disclosure are described in the table below:

Health Information	Purpose(s)
☒ Limited information from your existing health record (specify): Medical Diagnoses	<u>a, c</u>
THE FOLLOWING CHECKED ITEM(S) WILL BE GENERATED/COLLECTED DURING THE COURSE OF THIS STUDY:	
☒ History and physical examinations	<u>a, c</u>
Reports: ☐ Laboratory ☐ Operative ☐ Discharge ☐ Progress	_____
☒ Photographs, videotapes, or digital or other images	<u>a, b, c</u>
☐ Diagnostic Images/X-ray/MRI/CT	_____
☒ Bioelectric Output (EKG)	<u>a</u>
☒ Questionnaires, interview results, focus group survey, psychology survey, behavioral performance tests (e.g., memory & attention)	<u>a, c</u>
☒ Other: <u>Actigraphic data (motion)</u>	<u>a</u>
Purpose Categories	
a. To learn more about the condition/disease being studied	
b. For teaching purposes	
c. Other <u>results may influence measures of motion and heart rate</u>	

The persons who are authorized to use and disclose this information are the OHSU Institutional Review Board and the investigators listed on the first page of this consent form.

The persons who are authorized to receive this information are the Office for Human Research Protection and the study sponsor (National Institutes of Health).

We may continue to use and disclose protected health information that we collect from you in this study until the study is completed and the final study reports are published.

While this study is still in progress, you may not be given access to medical information about you that is related to the study. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study.

You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the Principal Investigator listed on page one of the research consent form. If you do send a letter to the Principal Investigator, the use and disclosure of your protected health information will stop as of the date she receives your request. However, the Principal Investigator is allowed to use and disclose information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with OHSU.

The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law.

If the information to be used or disclosed contains any of the types of records or information listed just below, additional laws relating to use and disclosures of the information may apply. You understand and agree that this information will be used and disclosed only if you place your **INITIALS** in the applicable space next to the type of information.

- _____ Acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) infection information
- _____ Drug/alcohol diagnosis, treatment, or referral information
- _____ Mental or behavioral health or psychiatric care

Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

COSTS:

There are no costs to you for being in this study. You will receive a \$40 gift certificate to a local grocery chain at the end of the study.

LIABILITY:

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact Colleen M. Casey, (503) 494-4799, pager #16187.

You have not waived your legal rights by signing this form. If you are harmed by this research project, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

It is not the policy of the U.S. Department of Health and Human Services to compensate or provide medical treatment for human subjects in the event the research results in physical injury.

PARTICIPATION:

Colleen M. Casey, (503) 494-4799, pager #16187, will answer any questions you may have about this study. If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. You may be removed from the study if the investigator stops the study or you are not able to follow instructions.

We may contact you by mail about other studies being conducted at OHSU that may or may not be related to the current study. Your participation in additional studies is entirely voluntary. If you wish to participate in this study, but do NOT wish to be contacted about additional studies, please place your INITIALS here:_____

We will give you a copy of this consent and authorization form.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

OREGON HEALTH & SCIENCE UNIVERSITY INSTITUTIONAL REVIEW BOARD PHONE NUMBER (503) 494-7887 CONSENT/AUTHORIZATION FORM APPROVAL DATE
July 13, 2008
Do not sign this form after the Expiration date of: <u>7/12/2009</u>

Signature of Subject

Date

Time

Printed Name

Signature of Investigator Obtaining Consent

Date

Time

Appendix B

Media Consent Form



Oregon Health & Science University

Consent Form

IRB#: 3766

Study Approval Date: 7/13/2008

OREGON HEALTH & SCIENCE UNIVERSITY Media Consent Form

TITLE: Physiologic Responses to Simulated Care Activities in Older Surgical Patients

PRINCIPAL INVESTIGATOR: Heather M. Young, PhD, GNP (541) 552-6706

CO-INVESTIGATOR: Colleen M. Casey, MS, RN, (503) 494-4799,
pager #16187

RESEARCH STAFF: Ardith Conway, BSN, RN, MPA
Joan Newby, BSN, RN
Jessica Madison, RN

SPONSOR: National Institutes of Health, National Institute of Nursing Research

PURPOSE:

You have already consented to be in this research study because you are 65 years of age or older and will be having surgery. During this study, you will be videotaped as you complete five (5) nursing care activities. These activities will take place in a lab, not at the time of actual care. The activities will include turning in bed, sitting on the side of the bed, transferring from the bed to a chair, sitting in a chair, and walking. The purpose of this form is to obtain your permission to use the videotapes for educational or research purposes.

PROCEDURES:

We will videotape you one (1) time while you complete the five (5) different nursing activities. A member of the research team will videotape you and will be in the room with the camera. We will start taping after you are in the hospital bed with any equipment connected to you and will end when you complete the last activity. This taping should take no more than 40 minutes in most cases. The videotapes will be stored indefinitely and may be used for other studies in the future.

Because we believe it is important to show any facial expressions during the activities, we will not hide your face.

You will not have the option to review the recordings before they are released.

RISKS AND DISCOMFORTS:

The primary risk of being in this study is that you will be videotaped, your face will be seen, and you could probably be identified on the tapes. You may feel that the taping gets in the way of completing the activities. The research staff will try to stay out of your way as much as possible. If you have other concerns about the taping, you may discuss these with Colleen M. Casey.

Videotaped material will be kept indefinitely for training and research purposes. All videotaped material will be coded with a unique identifier.

BENEFITS:

You will not personally benefit from being in this study. However, by serving as a subject, we may gain new information that benefits patients in the future.

ALTERNATIVES:

You may choose not to allow the videotapes of you to be used for educational or research purposes.

CONFIDENTIALITY:

The videotapes will be used for educational and research purposes. The primary risk of permitting such recordings is the loss of confidentiality as your identity will not be concealed. These videotapes may be presented to any of the following groups: hospital staff, other researchers, other health care disciplines, students, governmental agencies, and associations. Your name will not be recorded on any videotape. Copies of the recordings will not be released to anyone else not affiliated with the research team without your written permission.

Suspected elder abuse must be reported to the appropriate authorities in accordance with Oregon law.

COSTS:

You will not be charged nor will you be paid for allowing us to use the videotapes.

LIABILITY:

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact Colleen M. Casey, (503) 494-4799, pager #16187.

You have not waived your legal rights by signing this form. If you are harmed by the use of your videotapes, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

PARTICIPATION:

Colleen M. Casey, (503) 494-4799, pager #16187, will answer any other questions you may have about this study. If you have any questions regarding your rights as a research subject,

you may contact the OHSU Research Integrity Office at (503) 494-7887. You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

We will give you a copy of this consent form.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to have your videotape used for educational and research purposes.

OREGON HEALTH & SCIENCE UNIVERSITY INSTITUTIONAL REVIEW BOARD PHONE NUMBER (503) 494-7887 CONSENT/AUTHORIZATION FORM APPROVAL DATE July 13, 2008 Do not sign this form after the Expiration date of: 7/12/2009

 Signature of subject _____ Date

 Printed Name

 Signature of Investigator Obtaining Consent _____ Date

Appendix C

Sociodemographic Questionnaire

Participant ID#: _____

Tester ID#: _____

Date (Month, Day, Year)/Time (24hr): ____/____/____ : ____

Sociodemographic Questionnaire

Directions:

The information requested is important to understand more about you and your health. A person's characteristics have been shown to influence health, either through heredity or current and past lifestyle practices. The information you provide will be used for research purposes only and will be held in confidence.

For each question, please select the response that best describes you. If you do not know the information requested, mark "Do Not Know" or "Unknown" as indicated. If you feel that a question does not apply to you, mark "Not Applicable."

1. Today's Date: _____

2. First Name, Middle Initial: _____

3. Last Name: _____

4a. Phone: (____) _____ 4c. Alternate Phone: (____) _____

Please circle one: cell home work cell home work

4e. Best time to call? _____

5. Mailing Address: _____

6. Email address: _____

7. Preferred method of contact: ☐ Phone ☐ Email

8. Alternate contact (name, relationship, and phone number):

Name: _____ Relationship: _____ Phone: _____

9. Date of Birth (mm/dd/yyyy):
Month Day Year

FOR RESEARCHER USE ONLY:

Participant ID#: ____ ____ ____

Tester ID#: ____ ____ ____

Date (Month, Day, Year)/Time (24hr): ____ ____ ____ / ____ : ____

This page intentionally left blank.

15. How many years of formal education have you completed?

(For example, if you completed high school in the USA, you would have had 12 years of education).

(years)

16. What is your educational background?

(Please complete to the highest level of education attained.)

- 1 ☐ Less than high school
- 2 ☐ High school graduate / GED
- 3 ☐ Associate / technical degree
- 4 ☐ Bachelor's degree
- 5 ☐ Graduate school (Master's level)
- 6 ☐ Advanced degree (MD, DVM, JD, PhD, EdD)
- 7 ☐ Other (Please specify): _____

17. What is your current employment status?

- 1 ☐ Full time (working at least 35 hours a week)
- 2 ☐ Part time (working less than 35 hours a week)
- 3 ☐ Unemployed or laid off
- 4 ☐ Retired, not working at all
- 5 ☐ Retired, but working part or full time
- 6 ☐ Disabled, unable to work
- 7 ☐ Full-time Homemaker
- 8 ☐ Student
- 9 ☐ Other (Please specify): _____

18. What is or was your primary occupation?

(where you work/worked the most hours per week)

FOR RESEARCHER USE ONLY:

Participant ID#: ____

Tester ID#: ____

Date (Month, Day, Year)/Time (24hr): ____/____:____

Please specify job title: _____

2 ☐ Do Not Know

3 ☐ Not Applicable

19. How many people presently live in your household including yourself?

a. (Adults)

b. (Children, under age 18; If NONE, enter 00.)

20. To whom do you provide direct, daily care? (Check all that apply)

1. ☐ Child / children

2. ☐ Elderly parent

3. ☐ None

4. ☐ Other (Please specify): _____

The following question concerns family and individual income. We recognize the sensitive nature of these questions. This information is important to understand the economic impact of illness on the family and individual. Your answers will be held in strict confidence.

20. What is the total gross annual income for your household from all sources (before taxes and deductions), including Social Security:

1 ☐ Under \$10,000

2 ☐ \$10,000 to \$13,000

3 ☐ \$13,001 to \$20,000

4 ☐ \$20,001 to \$30,000

5 ☐ \$30,001 to \$50,000

6 ☐ Over \$50,000

FOR RESEARCHER USE ONLY:

Participant ID#: ____ ____ ____

Tester ID#: ____ ____ ____

Date (Month, Day, Year)/Time (24hr): ____ ____ ____/____:____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

**Adapted from and used with permission of the
Center for Research in Chronic Disorders,
University of Pittsburgh School of Nursing**

Appendix D

Brief Co-Morbidity Questionnaire

Brief Co-Morbidity Questionnaire

Some people have more than one health condition.

We are interested in your health history.

The following is a list of conditions you may have experienced.

Please mark either the YES or NO column for each condition.

Please answer the following questions regarding the medical conditions listed below:

Medical Condition		Have you ever had?	
		Yes	No
1	Heart Attack		
2	Heart Failure		
3	Coronary Artery Disease		
4	Irregular Heart Rate		
5	Heart Valve Disorders		
6	Peripheral Vascular Disease		
7	Other Heart Problems		
	Specify Condition(s):		
8	High Blood Pressure		
9	Anemia		
10	High Cholesterol		
11	Other Blood Problems		
	Specify Condition(s):		
12	Chronic Bronchitis		
13	Asthma or Wheezing		
14	Emphysema		
15	Pneumonia		
16	Tuberculosis		
17	Pulmonary Fibrosis ("stiff lungs")		

Medical Condition		Have you ever had?	
		Yes	No
18	Leg Pain (not joint pain)		
19	Headaches		
20	Seizures or Epilepsy		
21	Neuromuscular Disorders (MS, Parkinson Disease)		
	Specify Condition(s):		
22	Sudden Arm or Leg Weakness		
23	Numbness, Tingling, or Loss of Feeling in your Arms, Legs, or Face		
24	Loss, Slurring, or Changes in Speech		
25	Stroke, "Mini Strokes," or "TIAs"		
26	Thyroid or Endocrine Disorders (low thyroid, goiter)		
27	Diabetes or High Blood Sugar (do not include diabetes during pregnancy)		

FOR RESEARCHER USE ONLY:

Participant ID#: ____ _

Tester ID#: ____ _

Date (Month, Day, Year)/Time (24hr): ____/____/____:____:____

Medical Condition		Have you ever had?	
		Yes	No
28	Bladder Problems		
	Specify Condition(s):		
29	Prostate Problems	NA	
	Specify Condition(s):		
30	Kidney Problems		
	Specify Condition(s):		
31	Liver Problems		
	Specify Condition(s):		
32	Cirrhosis		
	33	Digestive Problems (Crohn's Disease, Colitis)	
Specify Condition(s):			
34	Ulcers of Stomach or Intestines		
	35	Cancer	
Specify Type(s):			
36	Arthritis or Rheumatic Disease		
	Specify Type(s):		
37	Osteoporosis		
	38	Bone Fracture	
Specify Type(s):			

Medical Condition		Have you ever had?	
		Yes	No
39	HIV Positive		
	40	Skin Disorders (Acne, Eczema, Ulcers, Pressure Sores, Gangrene)	
Specify Condition(s):			
41	Retinopathy		
	42	Vision Loss	
43		Other Eye Problems requiring treatment by eye doctor	
	Specify Condition(s):		
44	Hearing Loss		
	45	Loss of Leg	
46		Loss of Foot	
	47	Loss of Toe	
48		Depression	
	49	Anxiety	
50		Other Mental Health Problem(s)	
	Specify Condition(s):		
51	Other Health Issue(s)		
	Specify Condition(s):		
52	Do you take a beta-blocker? (Metoprolol, Labetalol, Bisoprolol, Timolol, Carvedilol)		
	Specify Drug(s):		

Symptom Checklist

Please indicate which of the following symptoms currently or frequently apply to you. . .

Symptoms		a. Do you have this symptom?		b. If “Yes,” has this symptom decreased your quality of life?				
		Yes	No	Not at all	Slightly	Moderately	Greatly	Extremely
		1	2	0	1	2	3	4
53	Skin rashes							
54	Itching							
55	Night sweats							
56	Fever							
57	Fatigue							
58	Weight Loss							
59	Weight Gain							
60	Nausea							
61	Vomiting							
62	Diarrhea							
63	Constipation							
64	Loss of Appetite							
65	Over-eating							
66	Vision Problems							
67	Hearing Problems							
68	Dizziness or Lightheadedness (with standing)							
69	Dizziness or Lightheadedness (sitting or lying)							
70	Fainting or Blackouts							
71	Leg or Arm Weakness							

FOR RESEARCHER USE ONLY:

Participant ID#: ____ ____ ____

Tester ID#: ____ ____ ____

Date (Month, Day, Year)/Time (24hr): ____ ____ ____/____:____

Symptom Checklist (continued)

Please indicate which of the following symptoms currently or frequently apply to you. . .

Symptoms		a. Do you have this symptom?		b. If "Yes," has this symptom decreased your quality of life?				
		Yes	No	Not at all	Slightly	Moderately	Greatly	Extremely
		1	2	0	1	2	3	4
72	Leg or Arm Paralysis							
73	Shortness of Breath							
74	Chest Palpitations							
75	Pain (Generalized)							
76	Chest Pain							
77	Abdominal Pain							
78	Back Pain							
79	Joint Pain							
80	Leaking Urine							
81	Frequent Urination							
82	Sleep Problems							
83	Mobility (walking) problems							
84	Balance Problems							
85	Numbness							
86	Leg Pain							
87	Confusion							
88	Changes in Feeling of Feet or Legs							

FOR RESEARCHER USE ONLY:

Participant ID#: ____ ____ ____

Tester ID#: ____ ____ ____

Date (Month, Day, Year)/Time (24hr): ____ ____ ____/____:____

Symptom Checklist (continued)

Please indicate which of the following symptoms currently or frequently apply to you. . .

Symptoms			a. Do you have this symptom?		b. If "Yes," has this symptom decreased your quality of life?				
			Yes	No	Not at all	Slightly	Moderately	Greatly	Extremely
			1	2	0	1	2	3	4
89	Impotence (Difficulty with Erection)	NA							
90	Symptoms of Hypoglycemia								
	(can include shakiness; nervousness; sweating; irritability; chills/clamminess; rapid heartbeat; anxiety; lightheadedness; hunger; blurred vision; sleepiness; headaches; confusion)								
91	Symptoms of Hyperglycemia								
	(can include sleepiness; frequent urination; intense thirst; dry mouth)								

92	What is your weight in pounds?			
----	--------------------------------	--	--	--

(pounds)

93	What is your height ?					
----	-----------------------	--	--	--	--	--

(feet) (inches)

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Adapted from and used with permission of the
Center for Research in Chronic Disorders,
University of Pittsburgh School of Nursing

Appendix E
Brief Pain Inventory



Date: / /
(month) (day) (year)

Time (24hr): :

Study Subject #:

FOR RESEARCHER USE ONLY:
IRB 3766
Tester ID#:

Revision: 07/01/05

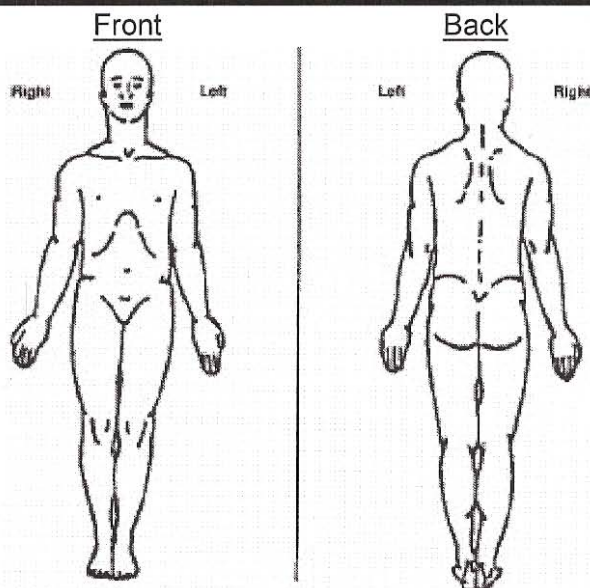
PLEASE USE
BLACK INK PEN

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by marking the box beside the number that best describes your pain at its **worst** in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
No Pain Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its **least** in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
No Pain Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the **average**.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
No Pain Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have **right now**.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
No Pain Pain As Bad As You Can Imagine

Appendix F

Functional Independence Measure

FOR RESEARCHER USE ONLY:
 IRB #3766

Participant ID#: ____ Tester ID#: ____
 Date (Month, Day, Year)/Time (24hr): ____/____/____:____

Functional Independence Measure™ (FIM)

L E V E L S	7	Complete Independence (Timely, Safely)	NO HELPER		
	6	Modified Independence (Device)			
	Modified Dependence			HELPER	
	5	Supervision (Subject = 100%+)			
	4	Minimal Assist (Subject = 75%+)			
	3	Moderate Assist (Subject = 50%+)			
	Complete Dependence				
2	Maximal Assist (Subject = 25%+)				
1	Total Assist (Subject = less than 25%)				
Self-Care			On Admission		
A.	Eating				
B.	Grooming				
C.	Bathing				
D.	Dressing-Upper Body				
E.	Dressing-Lower Body				
F.	Toileting				
Sphincter Control					
G.	Bladder Management				
H.	Bowel Management				
Transfers					
I.	Bed, Chair, Wheelchair				
J.	Toilet				
K.	Tub, Shower				
Locomotion					
L.	Walk/Wheelchair		W-Walk, C-Wheelchair, B-Both	Circle One	
M.	Stairs				
Motor Subtotal					
Communication					
N.	Comprehension		A-Auditory, V-Visual, B-Both	Circle One	
O.	Expression		V-Vocal, N-Nonvocal, B-Both	Circle One	
Social Cognition					
P.	Social Interaction				
Q.	Problem Solving				
R.	Memory				
Cognitive Subtotal					
TOTAL FIM SCORE					

Note: Leave no blanks. Enter 1 if patient not testable due to risk.

Appendix G
Data Collection Form

DATA COLLECTION FORM

Physiologic Responses to Simulated Care Activities in Older Surgical Patients

IRB #3766

TODAY'S DATE: _____ Start Time: _____ Tester Name/ID: _____

ID#:

Clinical/Fitness Measures

TEST	Tester Initials	Data	Remarks
Surveys		☐ FIM ☐ BPI ☐ BCMQ ☐ Socio	
Height & Weight		Height ___ft. ___in. == ___inches (5 ft 3 in == 63 inches) Weight _____lbs.	Lead Vest 5% of Body Weight : _____lbs # of Weights in Vest: _____ (each weight is ½ lb) ☐ Unable to wear ☐ Participant refused ☐ Removed prior to Activity (specify) ☐ Other: _____
Standing Balance (time for at least 10 seconds)		Front Foot: R L Semi-tandem _____s. Side-by-Side _____s. NA If semi-Tandem: Full-tandem _____s. NA	☐ Unable to attempt ☐ Unable to complete ☐ Participant refused ☐ Other _____ NA indicates person did not need to complete per protocol
4-m walk (include ms)		<u>T1</u> Usual Walk _____s <u>T2</u> _____s	☐ Used assistive device. Type(s): _____ ☐ Unable to attempt ☐ Unable to complete ☐ Participant refused ☐ Other _____
Chair Stands (include ms)		Time _____sec. # Completed _____	☐ Unable to attempt ☐ Unable to complete 1 ☐ Unable to complete 5 ☐ Participant refused ☐ Other _____
Grip Strength		<u>T1</u> Left Hand _____kg Right Hand _____kg <u>T2</u> _____kg _____kg	Width Setting Left Hand _____ Width Setting Right Hand _____

APPROVED: July 13, 2008

Physiologic Responses to Simulated Care Activities in Older Surgical Patients
IRB #3766

ID#:

Simulation Measures

TEST	Tester Initials	Data	Remarks
Clinical Equipment Attached		Completed _____ Dominant Hand: Left Right Actical placed on: L wrist R wrist (place on NONDOMINANT wrist) Pacemaker/AICD: Yes No (If yes, circle which one)	_____ If some equipment not attached please list that equipment:
Simulation Resting Heart Rate (RHR) Baseline: _____ (pre-Activity 1) 25 % > baseline: _____		<u>Activity 1: Turning in Bed with Linen Change</u>	_____ Used assistive device. Type(s): _____ _____ Unable to attempt _____ Unable to complete _____ Participant refused _____ Other _____
		RHR pre-2: _____ <u>Activity 2: Dangling</u>	_____ Used assistive device. Type(s): _____ _____ Unable to attempt _____ Unable to complete _____ Participant refused _____ Other _____
		Remove SCDS before Activity 3 RHR pre-3: _____ <u>Activity 3: Transferring to Chair</u>	_____ Used assistive device. Type(s): _____ _____ Unable to attempt _____ Unable to complete _____ Participant refused _____ Other _____
		<u>Activity 4: Sitting in Chair</u>	_____ Used assistive device. Type(s): _____ _____ Unable to attempt _____ Unable to complete _____ Participant refused _____ Other _____
		RHR pre-5: _____ <u>Activity 5: Walking in Hallway WITH MONITOR ATTACHED</u> HR AFTER Activity 5: _____	_____ Used assistive device. Type(s): _____ _____ Unable to attempt _____ Unable to complete _____ Participant refused _____ Other _____
		For ambulation activity (100 ft): If subject does not complete 100 ft Approx distance walked: _____ ft	Other Simulation Notes:

Completion Time: _____ Other Comments: _____

Appendix H

Actiheart™ Placement Photograph

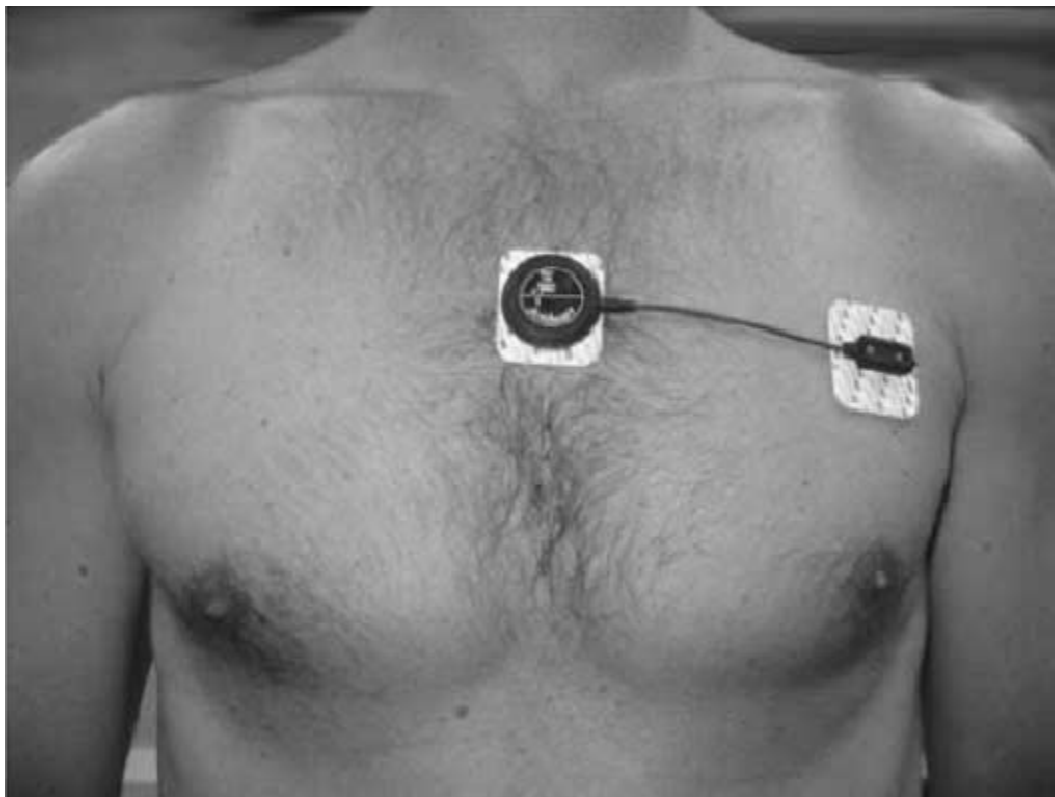


Figure 1H. Actiheart™ Placement on Human Participant.

Brage, S., Brage, N., Franks, P. W., Ekelund, U., & Wareham, N. J. (2005). Reliability and validity of the combined heart rate and movement sensor Actiheart. *European Journal of Clinical Nutrition*, 59(4), 561-570.

Appendix I

Accelerometry Analysis Protocol

Actiheart Data

Open Actiheart, View Data, Pick File, Click on View Chart

Go to Copy, Epoch-by-Epoch List and it will copy it to the clipboard

Open an excel file

Copy into top left-hand corner

Save under ID# and data (111.06.05.08)

This file name is also on 2nd row of pasted text in Excel; make sure they are consistent

Click on View and click Show Invalid Points

Then copy Actiheart Activity Graphic and HR graphic into column T (done as separate copies)

Place the HR graphic just below the Activity Graphic

Actical Data

Open Actical

Click on File Load, then find the matching file to the Actiheart data

C:\Documents and Settings\Staff\My Documents\MSN-OHSU\Dissertation-Post-Award\Data-Accelerometry\Actical\Subject Data

Click Actogram. Click on Markers, Copy and Copy Markers into Column P. Notice the time of the first marker and use it in the next step.

On the Actogram screen, change Start Time to the 15 minute intervals just prior to the first Time Stamped activity (cannot enter own time; forced entry in 15 minute intervals). If you do not modify this time, copy of data will include entire day beginning at 0:00. For example, if first time stamp occurs at 10:18:45, then choose the Start Time as 10:15.

Then click Copy, Raw Data, All Displayed Days, and then copy into Column K of Excel spreadsheet. You will notice that the column with Ms (likely in Column N) is the event marker.

Verify that subject ID, height, and weight match before further analysis

Align the times for Actiheart with Actiwatch (for example, 7:25:00 to 7:25:00), typically by moving Actical data down (do not insert rows, only cut and paste data minus the heading).

Use conditional formatting to highlight all non-zero activity counts (from Actiheart data)

as light yellow for easy visibility. To do this, highlight the whole column F, go to Format, Conditional Formatting. For condition 1, choose Great than, enter 0. Click on Format and choose light yellow under Patterns tab. Click OK.

Highlight the entire row for each M row and highlight it green. Do multiple rows at one time, by holding down CTRL, highlighting row, then click on **Green**.

Label time stamp event marker list (M) with Turn Start, Turn Stop, Dangle Start, Dangle Stop, Transfer Start, Transfer Stop, Walk Start, Walk Stop (if it is obvious). If additional time stamps, or unclear, then defer to video and label with question marks.. Highlight these markers **bright green**.

Copy entire time stamp highlighted area (column R). Then use these to cut and paste into column H, to go with appropriate event marker.

Once you have done this for the Actiheart data, then copy that portion of column H and paste it into the matching Actical column (column O).

View video and enter times of notable activity labels and other pertinent movements/events/comments into Column I.

Use Pinnacle Studio SE software to view digitized video. Choose appropriate file to view.

Label Marked Pushed when video shows time stamp being pushed. When possible align with Actiheart time.

Based on video viewing and activity and heart rate patterns, determine if any shift of the data is necessary. If so, shift the entire block of data (columns H, I, and J) and note the number of rows shifted. This will be documented in seconds (15 seconds) on the data analysis sheet.

For Analysis

Prior to the Start of each activity, highlight in bright Yellow the first two epochs that will be considered the 'rest' epochs for purposes of analysis.

Or highlight any notable activity during rest periods with interpretation in column I as allowable based on video analysis.

Bright Yellow	"Rest" Activity counts (pre-activity) for motion and HR; 2 epochs prior to start row of any activity (except sitting)
Light Yellow	Non-zero activity counts for ease of viewing-Highlight column F, go to Format, Conditional Formatting, If cell value is Greater than 0, color light yellow
Bright Green	Time Stamped time; usually start or stop indicator
Light Green	Un-time stamped start/stop; changed start/stop time; start of walk time

Use Names function to define ranges of cells. 19 names will be assigned.

Names:

PreTurnHR	TransferHR
PreTurnMotion	TransferMotion
TurnHR	SitHR
TurnMotion	SitMotion
PreDangleHR	PreWalkHR
PreDangleMotion	PreWalkMotion
DangleHR	WalkHR
DangleMotion	WalkMotion
PreTransferHR	TotalHR
PreTransferMotion	

Assign names to activities/pre-activities. Use the above names. Make sure you assign names before copying and pasting header rows below.

Go to Names column and make sure you have 19 names before proceeding.

Go to Header Row file and copy and paste into Subject file the template of column headings and formulas (all formulas also have these Names in place of cell ranges).

Right click, and Click on Insert Copied Cells and when it asks, indicate you want to Shift cells down

When it asks you if you want to replace, says Yes (multiple times).

Go to Window, Freeze and move line so that top 3 rows are frozen.

Use frozen screen to roughly verify that data makes sense

In Complete Study File, add a row for your subject's ID. Copy the data from source file and then use Paste Special feature into Complete Study File. When it prompts you, click Link Data. Data will appear.

Explanation of Complete Study File Data Worksheet

Column	Label	Entry	Notes
B, I, P, W, AD	Activity_Pre_HR	Avg fxn of two cells prior to stamp beginning activity, rounded to nearest whole number	For Sitting activity, use two epochs prior to transfer activity; same as pre-transfer values
C, J, Q, X, AE	Activity_Pre_Motion	Avg fxn of two cells prior to stamp beginning activity	
D, K, R, Y, AF	Activity_Max_HR	Max fxn of all HR cells of activity, including start and stop period, rounded to nearest whole number	For Sitting, epochs include 1 st one after Transfer Stop to Walking Start

E, L, S, Z, AG	Activity_Avg_HR	Avg fxn of all HR cells of activity, including start and stop marker HR, rounded to nearest whole number	
F, M, T, AA, AH	Activity_Tot_Motion	Sum fxn of all motion cells of activity	
G, N, U, AB, AI,	Activity_Min_Motion	Minimum motion value that is not zero for that activity	
H, O, V, AC, AJ	Activity_Max_Motion	Maximum motion value for that activity	
AK	NaN	Total of all HR cells with NaN from pre-turn rest period (1 st cell) to Walk Stop cell	In order to calculate percentage of subject's HR readings that were NaN
AL	Pre_Turn_Row	First row of pre-turn rest period (1 st cell)	Would allow calculation of total duration of activity period when subtracted from walk_stop_row and multiplied by 15 sec
AM	Walk_Stop_Row	Last row of activity period (last walk epoch)	
AN	Time_Shift	In seconds, shift of actiwatch markers to match actiheart data	Documented in seconds
AO	Avg_One	Activities for which the average reflects only one value (because others are NaN)	
AP	>1_NaN	Activities listed in which more than one NaN exists	
AQ	1_NaN	Activities listed with only 1 NaN value	
AR	Count_Turn_Mot	Count of cells for this activity	

AS	Count_Turn_HR	Count of cells for this activity	
AT	Count_Dangle_Mot	Count of cells for this activity	
AU	Count_Dangle_HR	Count of cells for this activity	
AV	Count_Trans_Mot	Count of cells for this activity	
AW	Count_Trans_HR	Count of cells for this activity	
AX	Count_Sit_Mot	Count of cells for this activity	
AY	Count_Sit_HR	Count of cells for this activity	
AZ	Count_Walk_Mot	Count of cells for this activity	
BA	Count_Walk_HR	Count of cells for this activity	
BB	Notes	Any pertinent notes documented	

General Tips:

NaN-Indicates Not A Number

Per Page 3-13, Actiheart manual

It is possible that due to device error, out-of-range activity or heart rate, or not enough data to compute an output, an output for an epoch may be given as NaN. A standard abbreviation for invalid data or incomplete computational data. Such an epoch will have a gray vertical line on the graph.

For example, computing Activity Intensity requires three minutes of data history so NaN will display for first and second minutes.

Can tell when Actiheart removed because Heart Rate becomes NaN.

Note any special issues/observations in the Decision Log file under the Observations Tab. Copy that observation and insert it in cell F13 after creating a NOTE cell in E13.

Additional Analyses (February 19, 2009)

In order to weight the data to reflect missing data for some of the HR values because of the NaN reading, 10 values had to be calculated that reflected the number of epochs for each activity for both motion and heart rate (5 for motion and 5 for heart rate).

To do this, the formula Count was used in Excel, along with the following names of cell ranges:

TurnHR, TurnMotion, DangleHR, DangleMotion, TransferHR, TransferMotion, SitHR, SitMotion, WalkHR, WalkMotion

For each file, the formulas for these 10 cells were inserted in the data sheet by position the cursor in the cell called Notes (Column AQ). After copying the 10 cell headers and formulas for the cell counts from the Header Row master file, right-click and click on Insert Copies Cells, Shift Cells to Right when prompted. Then click Yes 10 times before the cells appear population with numbers.

To verify the formula for accuracy, use the Split screen function and evaluate each of the five activities to determine if the cell counts accurately represent the number of cells.

Go to the Complete Study File, to the subject ID you have worked with. Go to column AQ (copy) and then paste the range from AR to BB. This will the linked formula for all 10 of the count cells plus the notes. Verify that the notes reads the same as it did in the AR column of the Complete Study File.

This analysis was performed for all 58 files with motion data.

To Plot the Data:

Use the template named plots.templateoriginaladjustedcolor.xls in C:\Documents and Settings\Staff\My Documents\MSN-OHSU\Dissertation-Post-Award\Data-Accelerometry\ActiHeart Data Adjusted\Plots.

Open that file and note the Plot and Data tabs. Rename immediately to the number of the subject (or if a deleted case, indicate this).

Also type in the subject # at the top of the Plots tab where it indicates ID#:XXX.

Pull up raw data file for that subject.

Under the Data Tab, copy and paste each activity from the raw data set into the corresponding area for each activity.

Delete any NaN readings from the HR column

Go to the Plots tab and make sure that all graphed activity looks appropriate on plots.

If HR > 160, change the value of the Y-axis to fit the data.

On the motion by HR plot, change the X axis (does not auto-fit for some reason) to whatever 5-increment level best fits the data (15, 20, 25, etc.) and change minor increment if necessary.

It is formatted to print on one page so view first to make sure you are not inadvertently clicked on a single plot and then print page.

Copy entire plot area of all 7 plots and paste into All Plot spreadsheets with border set around each one.